From:	Palmer, Lee Anne </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CF7C8BD53B6C45A39318A596ACEA7C53-LPALMER>
To:	Jones, Jennifer L
CC:	Carey, Lauren
Sent:	7/30/2019 12:28:35 AM
Subject:	Made one edit on one slide - could you please bring this one to AVMA?
Attachments:	FDA CVM_DCM presentation to AVMA meeting 8.2.2019.pptx

Thanks!

Lee Anne

Lee Anne M. Palmer, VMD, MPH
Acting Director, Division of Veterinary Product Safety

Center for Veterinary Medicine
Office of Surveillance and Compliance
U.S. Food and Drug Administration
Tel: 240-402-5767
Leeanne.palmer@fda.hhs.gov

From:	Carey, Lauren </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F0226BD682844FA2B71EA3750D4FCB82-LAUREN.CARE>
To:	Norris, Anne
CC:	Palmer, Lee Anne; Jones, Jennifer L
Sent:	12/6/2018 7:43:49 PM
Subject:	DCM Epi #'s
Attachments:	December 2018 DCM Update.doc

Anne,

Forwarding our numbers to you. Lee Anne and Jen have had a chance to look at it, so I think we're all on the same page on our side. Let me know what I can help with.

Thanks,
Lauren

Lauren Carey, DVM
Veterinary Medical Officer / Adverse Event Review Team

Center for Veterinary Medicine
Office of Surveillance and Compliance
U.S. Food and Drug Administration
Tel: 240-402-5732
Fax: 240-276-9993
Lauren.Carey@fda.hhs.gov

From: Freeman, Lisa <Lisa.Freeman@tufts.edu>
To: Jones, Jennifer L
Sent: 11/8/2018 11:25:35 AM
Subject: RE: reported cases

Hi Jen
You should have B6 now – I submitted him on 10/25/18 (report 246795).

I have about 8 more to report that I've gotten behind on – I'll catch up on those this weekend.

Darcy, Josh, Ryan, John, and I wrote an update on the DCM issue which will be published in JAVMA Dec 1. We've been hearing a lot of confusion and misinformation so hopefully this will remind people that it's not just taurine deficiency and it's not just grain-free diets. And that people should be reporting cases to you to help get this figured out quickly. So, you may start to get more cases reported.

Also, I was talking to Darcy yesterday and we were wondering if it would be worth another call to catch up.
Thanks!
Lisa

Lisa M. Freeman, DVM, PhD, DACVN
Board Certified Veterinary Nutritionist™
Professor
Cummings School of Veterinary Medicine
Friedman School of Nutrition Science and Policy
Tufts Clinical and Translational Science Institute
Tufts University
www.petfoodology.org

From: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Sent: Wednesday, November 07, 2018 10:11 AM
To: Freeman, Lisa <lisa.freeman@tufts.edu>
Subject: RE: reported cases

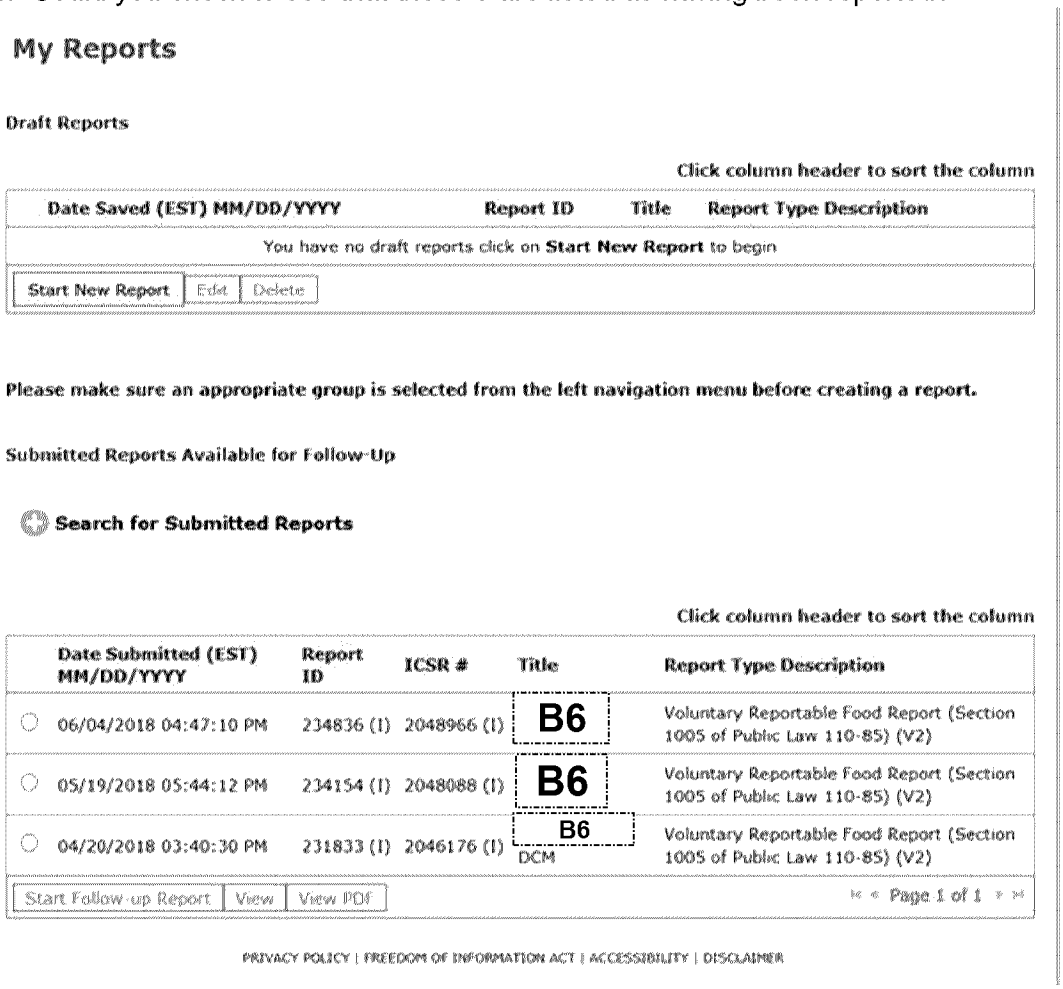
Hi Lisa,
We have all of the cases you listed below except B6 It's fine to send me the additional records for the cases ☺
Thank you for your tireless efforts at getting us the information.
It's greatly appreciated!!
Jen

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421
U.S. FOOD & DRUG ADMINISTRATION

From: Freeman, Lisa <Lisa.Freeman@tufts.edu>
Sent: Monday, October 01, 2018 3:51 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: reported cases

Hi Jen
I was looking through which cases I've submitted (have a bunch more to add) and saw that 3 were in a separate

account and there a few that are not showing up as having been reported.
1. Could you check to see that these 3 are listed as having been reported?



My Reports

Draft Reports

Click column header to sort the column

Date Saved (EST) MM/DD/YYYY	Report ID	Title	Report Type Description
You have no draft reports click on **Start New Report** to begin			

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Submitted Reports Available for Follow-Up

Search for Submitted Reports

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	Date Submitted (EST) MM/DD/YYYY	Report ID	ICSR #	Title	Report Type Description
○	06/04/2018 04:47:10 PM	234836 (I)	2048966 (I)	B6	Voluntary Reportable Food Report (Section 1005 of Public Law 110-85) (V2)
○	05/19/2018 05:44:12 PM	234154 (I)	2048088 (I)	B6	Voluntary Reportable Food Report (Section 1005 of Public Law 110-85) (V2)
○	04/20/2018 03:40:30 PM	231833 (I)	2046176 (I)	B6 DCM	Voluntary Reportable Food Report (Section 1005 of Public Law 110-85) (V2)

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Page 1 of 1

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2. Also, I have a 3 others that are not listed in my account but I'm pretty sure I reported. If not, I'll get them submitted:

3. I keep sending you the extra medical records that won't fit in the reporting portal. Is there someone else I should send these to so I don't keep clogging your inbox?

Many thanks
Lisa

Lisa M. Freeman, DVM, PhD, DACVN
Board Certified Veterinary Nutritionist™
Professor
Cummings School of Veterinary Medicine
Friedman School of Nutrition Science and Policy
Tufts Clinical and Translational Science Institute
Tufts University
www.petfoodology.org

FDA-CVM-FOIA-2019-1704-009942

Patient ID	Dog name	Owner name	Breed	Sex	Age	Diet	How long fed	Other foods offered	Gluten free	Chamber involvement	CHF (L, R,	Active patient	Outcome	Other relevant info	Other diagnostics	FDA
B6			Shih Tzu-poodle mix	MN	8 years	California Natural Kangaroo and Red Lentil	years		Y	LV- severe; LA- mod	N	N	alive	now symptoms which may be referable to heart/possible CHF	normal taurine	
			english bulldog	MN	8 years	no diet hx				LV,RV- mod; LA-mild	Y-L	N	deceased	right atrial mass		
			Labrador	FS	8 years	California Natural Kangaroo and Red Lentil	years	Changed to other grain free die: 9/17	Y	LV, LA - severe	Y	Y	alive	related to [B6]	Taurine [B6]	y
			Doberman	M	7 years	Hill's Science Diet adult maintanence	years		N	LV, LA-severe	Y	N	euthanized	no troponin or taurine		
			Saint Bernard	MN	9 years	Unknown Grain Free brand	years			LV, LA severe; RV,RA mod	N	N	deceased			
			German Shepherd	MN	8 years	Purina Proplan		unknown wet food	N	LV, LA- mod; RV, RA-mild	N	N-last visit 5/17	alive?	suspect EFI, elevated troponin; no taurine		
			Pitbull	FS	12 years	prescription diet for skin	years		N	LV,LA- mod	Y-L	N	deceased	no troponin or taurine		
			Great Dane	MN	7 years	Unknown diet				LV, LA-severe; RA, RV-mod	Y-R	N	alive?	O cx 3/2017- "going a different route", also dx w/PH		
			Papillon	FS	13 years	V-dog (commercial vegan diet)	years	changed to meat-based diet after diagnosis-w/d?	Y	LV, LA-severe	Y-L	Y	alive	Early gallbladder dz; elevated taurine [B6]; no troponin		
			Bullmastiff	M	8 years	Nutro Large Breed Chicken and Sweet Potato			Y	LV-mild; LA, RV, RA-mod	Y	Y	alive?	no troponin or taurine		
			Boxer	FS	2 years	Purina Proplan	years		N	LV,LA- severe	Y	N	deceased	no troponin or taurine		
			Doberman	FS	3 years	Blue Buffalo weight control			Y	LV-mild dec in contractility	N	N-last visit 4/17	alive	suspect occult DCM; no taurine or troponin		
			Cane Corso	M	10 years	Blue Buffalo		rotis chicken	Y	LV, RV, RA-mild; LA-mod	Y-L	N	deceased	no troponin or taurine		
			Golden Retriever	MN	6 years	Zignature Pork	years		Y	LV, LA, RV, RA-mod	Y-R	Y	alive	taurine deficient		
			Pitbull Mix	FS	16 years	Earthborn Holistic (Bison - Grass, Plains?)	years	pork & squash diet, Akana, duck & sweet potato	Y	Lv, LA-mod; RV, RA- mild	Maybe?	N	euthanized	no troponin or taurine		
			Labrador	FS	5 years	California Natural Kangaroo and Red Lentil	years	switched to venison & lentil diet	Y	L - severe, R - mod	Y - L	N	euthanized	related to [B6] niece)		Y
			Doberman	MN	9 years	Hill's I/D			N	LV-mod; LA-severe; RV,RA-mild	N	N-sees [B6]	alive			
			Cocker	MN	4 years	Zignature Kangaroo	years	switched to Origin	Y	LV,LA-mod; RV, RA-mild	Y-L	Y	alive	taurine deficient; no troponin		
			Golden Retriever	MN	13 years	Purina Proplan	years	owner home cooking now - meat and rice	N	LV, LA-mod	Y	Y	alive-CHF	normal taurine; no troponin		
			Great Dane	M	3 years	Nature's Domain Beef and Potato Grain Free		treats-popcorn; 4health	Y	LV, LA, RV, RA-mod	Y	Y	alive - CHF	also fed 4health		
			Boxer	FS	4 years	Hill's sensitive stomach	years		N	LV-mod; LA-severe; RV,RA-mild	Y	Y	alive-CHF			
			Great Dane	MN	8 years	Unknown Grain Free brand			Y	LV, LA-severe; RV-mild; RA-mod	N	N	deceased			
			Pitbull	MN	11 years	Unknown Grain Free brand			Y	LV-mild; LA-mod	Y-L	Y	alive-CHF			
			Labrador Mix	FS	7 years	California Natural Kangaroo and Red Lentil	years	Switched to j/d; offers canned pumpkin	Y	LV,LA-severe; RV, RA-mild	Y-L	Y	alive	Not taurine deficient		Y
			Doberman	MN	7 years	Origin Original	years		Y	LV-mod dec in contractility	N	Y	alive			
			Great Dane	FS	9 years	Unknown diet	years			LV-mild; LV-mod	Y-L	Y	alive			
			Doberman	MN	8 years	Unknown diet				LV, LA- mod; RV, RA-mild	N	Y, but overdue	alive	no troponin or taurine		
			Maltese	FS	11 yrs	Zignature Kangaroo and lentil	years	green beans				Y	alive			Y
			Blue Heeler Mix	FS	11 yrs	4Health Grain Free	years	Canine Carry Outs; Various ham, chix, beef scraps	Y	LV,RV,RA-mod; LA-mod-sev	N	Y	alive	no troponin; taurine [B6] (plasma); [B6] (whole blood)		Y
			Boxer Mix	MN	9 yrs	Zignature Kangaroo and lentil	years	Bland diet-ground beef & rice; Blue canned	Y	LV, LA-severe; RV, RA-mod	Y-L, R	Y	alive	no troponin; taurine [B6] (plasma); [B6] (whole blood)		Y

FDA-CVM-FOIA-2019-1704-009943

From:	Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>
To:	Palmer, Lee Anne
CC:	Carey, Lauren; Hartogensis, Martine
Sent:	6/26/2018 5:58:55 PM
Subject:	RE: If you can share the new file from the Cardiologists that mention Nutro, that would be great - thanks!
Attachments:	CVCA-Diet Breakdown by Brand.xlsx; CVCA-Diet Breakdown by Breed.xlsx

Absolutely! These are the two we received from CVCA. I've included them in my indexing. The really interesting brand is Natural Balance Grain Free-These are 3 labrador retrievers-no legumes but a ton of starch from potatoes.

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421

U.S. FOOD & DRUG ADMINISTRATION

From: Palmer, Lee Anne
Sent: Tuesday, June 26, 2018 1:31 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>
Subject: If you can share the new file from the Cardiologists that mention Nutro, that would be great - thanks!

Hi Jen – I apologize if I missed the email, but please send the new cases – thanks!

Lee Anne

Lee Anne M. Palmer, VMD, MPH
Team Leader HFV-242, Supervisory VMO

Center for Veterinary Medicine
OSC, Division of Veterinary Product Safety
U.S. Food and Drug Administration
Tel: 240-402-5767
Leeanne.palmer@fda.hhs.gov

U.S. FOOD & DRUG ADMINISTRATION

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From:	Reimschuessel, Renate </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4C00C47AE2794134B2906D6B9252FCF6-RREIMSCH>
To:	Norris, Anne; Jones, Jennifer L; Rotstein, David; Edwards, David; Hartogensis, Martine; Burkholder, William; Palmer, Lee Anne; DeLancey, Siobhan
CC:	Carey, Lauren; Lovell, Randall A; Ceric, Olgica; Nemser, Sarah; Conway, Charlotte; Atkinson, Krisztina Z; Hodges, April
Sent:	5/22/2018 12:36:06 PM
Subject:	RE: 800.267-DCM and meeting with Cardiac Care for Pets

That sounds like a reasonable approach

Renate Reimschuessel V.M.D. Ph.D. Vet-LIRN
Phone 1- 240-402-5404
Fax 301-210-4685
http://www.fda.gov/AnimalVeterinary/ScienceResearch/ucm247334.htm

From: Norris, Anne
Sent: Tuesday, May 22, 2018 8:34 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>
Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

B5

From: Jones, Jennifer L
Sent: Tuesday, May 22, 2018 8:31 AM
To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>
Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

B5

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421

U.S. FOOD & DRUG ADMINISTRATION

From: Rotstein, David
Sent: Tuesday, May 22, 2018 8:25 AM
To: Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>
Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

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B5

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
CVM OSC/DC/CERT
7519 Standish Place
240-506-6763 (BB)

U.S. FOOD & DRUG ADMINISTRATION

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From: Reimschuessel, Renate
Sent: Tuesday, May 22, 2018 8:18 AM
To: Edwards, David <David.Edwards@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>
Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

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Just some food for thought.... rr

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Phone 1- 240-402-5404
Fax 301-210-4685
http://www.fda.gov/AnimalVeterinary/ScienceResearch/ucm247334.htm

From: Edwards, David
Sent: Tuesday, May 22, 2018 7:54 AM
To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>
Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

Hi everyone,

B5

B5

B5

B5

Thanks,
Dave

From: Rotstein, David
Sent: Monday, May 21, 2018 7:49 AM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>
Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

B5

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
CVM OSC/DC/CERT
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240-506-6763 (BB)

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From: Hartogensis, Martine
Sent: Monday, May 21, 2018 7:47 AM
To: Burkholder, William <William.Burkholder@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>
Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>
Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

Thanks Bill and your concerns are noted!

B5

B5

Thank you all for your help and dedication to this fascinating issue!

Martine

From: Burkholder, William
Sent: Friday, May 18, 2018 5:04 PM
To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>
Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>
Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

B5

B5

Bill

What Socrates is really supposed to have said: *"The only true wisdom is in knowing that you know nothing."

From: Palmer, Lee Anne
Sent: Friday, May 18, 2018 2:09 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

Thanks, Jen, very interesting issue! B5

B5

I also cleaned up and B5 (added a few things). Thanks – hope we can figure this one out!

Lee Anne

From: Jones, Jennifer L
Sent: Friday, May 18, 2018 1:54 PM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

B5

Any other ideas or suggestions?

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421
U.S. FOOD & DRUG ADMINISTRATION

From: Hartogensis, Martine
Sent: Friday, May 18, 2018 11:58 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel,

Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

Thank you Jen! Sounds good and looking forward to the meeting.

Martine

From: Jones, Jennifer L
Sent: Friday, May 18, 2018 6:42 AM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

B5

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421
U.S. FOOD & DRUG ADMINISTRATION

From: Hartogensis, Martine
Sent: Thursday, May 17, 2018 7:52 PM
To: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

Yes, excellent work! One question though... **B5**

B5

Thanks in advance!

Martine

From: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Date: May 17, 2018 at 2:27:35 PM EDT
To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>, Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>, Rotstein, David <David.Rotstein@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>, Carey, Lauren <Lauren.Carey@fda.hhs.gov>, Norris, Anne <Anne.Norris@fda.hhs.gov>, Lovell, Randall A <Randall.Lovell@fda.hhs.gov>, Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>, Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>, Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

Indeed! Brands mentioned included California Naturals, Rachel Ray, Ellen DeGeneres' Halo brand - esp the vegan formulation - and a few other niche brands I didn't catch.

From: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Date: May 17, 2018 at 2:14:48 PM EDT
To: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>, Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>, Rotstein, David <David.Rotstein@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>, Carey, Lauren <Lauren.Carey@fda.hhs.gov>, Norris, Anne <Anne.Norris@fda.hhs.gov>, Lovell, Randall A <Randall.Lovell@fda.hhs.gov>, Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>, Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>, Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

Hah! Perfect timing! We're all heading down the same path…

From: DeLancey, Siobhan
Sent: Thursday, May 17, 2018 2:13 PM
To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

As luck would have it, I'm at CE today listening to B6 from B6 talk about nutrition and cardiomyopathies. See attached slide.

From: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Date: May 17, 2018 at 2:06:04 PM EDT
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>, Rotstein, David <David.Rotstein@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>, Carey, Lauren <Lauren.Carey@fda.hhs.gov>, Norris, Anne <Anne.Norris@fda.hhs.gov>, DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>, Lovell, Randall A <Randall.Lovell@fda.hhs.gov>, Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>, Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>, Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

B5

B5

B5

B5

From: Hartogensis, Martine
Sent: Thursday, May 17, 2018 11:59 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

Excellent work Jen!!

B5

Martine

From: Jones, Jennifer L
Sent: Thursday, May 17, 2018 11:29 AM
To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

B5

Please see the PPT for the rationale/summary

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421

From: Rotstein, David
Sent: Monday, May 14, 2018 10:22 AM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>
Subject: RE: DCM and meetign with Cardiac Care for Pets

I do not know B5 Once we get a better handle on a specific cause, we can work on that.

From: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>
Date: May 14, 2018 at 9:09:17 AM EDT
To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>, Rotstein, David <David.Rotstein@fda.hhs.gov>, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>, Carey, Lauren <Lauren.Carey@fda.hhs.gov>, Norris, Anne <Anne.Norris@fda.hhs.gov>, DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>, Lovell,

Randall A <Randall.Lovell@fda.hhs.gov>
Subject: RE: DCM and meetign with Cardiac Care for Pets

This is very interesting. B5 ..Dave, do you B5
B5

Martine

From: Palmer, Lee Anne
Sent: Friday, May 11, 2018 4:30 PM
To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>
Subject: RE: DCM and meetign with Cardiac Care for Pets

B5

From: Rotstein, David
Sent: Friday, May 11, 2018 4:14 PM
To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>
Subject: RE: DCM and meetign with Cardiac Care for Pets

Lee Anne,

This is fantastic. B5

B5

B5

B5 ????

From: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Date: May 11, 2018 at 4:06:05 PM EDT
To: Rotstein, David <David.Rotstein@fda.hhs.gov>, Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>, Carey, Lauren <Lauren.Carey@fda.hhs.gov>,

Norris, Anne <Anne.Norris@fda.hhs.gov>, DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>, Lovell, Randall A <Randall.Lovell@fda.hhs.gov>
Subject: RE: DCM and meetign with Cardiac Care for Pets

B5

B5

I'll final this up next week, have to get to other things yet today. Have a great weekend! J Lee Anne

B5

From: Rotstein, David
Sent: Wednesday, May 9, 2018 4:13 PM
To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Subject: RE: DCM and meetign with Cardiac Care for Pets

Sounds very intriguing!!!

From: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Date: May 9, 2018 at 4:09:18 PM EDT

To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>, Rotstein, David <David.Rotstein@fda.hhs.gov>, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>, Carey, Lauren <Lauren.Carey@fda.hhs.gov>, Norris, Anne <Anne.Norris@fda.hhs.gov>, DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Subject: RE: DCM and meetign with Cardiac Care for Pets

B5

From: Hartogensis, Martine
Sent: Wednesday, May 9, 2018 2:17 PM
To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Subject: RE: DCM and meetign with Cardiac Care for Pets

Awesome, thank you Dave!

Martine

From: Rotstein, David
Sent: Wednesday, May 09, 2018 2:06 PM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Subject: RE: DCM and meetign with Cardiac Care for Pets

Good Afternoon,

I spoke with **B6** @ Cardiac Care for Pets. He is going to look into times/dates with the cardiologists there and we can set the meeting up from that point.

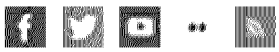
B5

As a side note, there is a facebook page dedicated to this issue:

https://www.facebook.com/groups/1952593284998859/about/

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
CVM OSC/DC/CERT
7519 Standish Place
240-506-6763 (BB)

U.S. FOOD & DRUG ADMINISTRATION



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From: Hartogensis, Martine
Sent: Tuesday, May 08, 2018 10:58 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Subject: RE: DCM

Thank you Jen and Dave! Very interesting and sounds like you all are on it! The resident I spoke to was Dr. **B6**

B6

Keep us posted!

Thanks again!

Martine

Hi Martine,

B5

B5

I'm happy to share more info as needed.
Jen

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421

From: Rotstein, David
Sent: Tuesday, May 08, 2018 9:45 AM

To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: RE: DCM

Martine,

Jen and I spoke with cardiologists from NCSU and a few other institutions. That's how we were able to get the information.

B5

B5

B5

Looping in Jen.

Thanks for the update!

dave

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
CVM OSC/DC/CERT
7519 Standish Place
240-506-6763 (BB)

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From: Hartogensis, Martine
Sent: Tuesday, May 08, 2018 9:00 AM
To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Subject: RE: DCM

Thank you Dave! We did not go around yesterday because the Vet-LIRN folks came in for their routine presentation.

B5

B5

Martine

From: Rotstein, David
Sent: Monday, May 07, 2018 1:13 PM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>
Subject: Re: DCM

Martine

B5

B5

B5

There's a way to go on this moving forward.

Dave

From: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>
Date: May 7, 2018 at 1:03:13 PM EDT
To: Rotstein, David <David.Rotstein@fda.hhs.gov>
Subject: DCM

Hi Dave!

Do you have any more details on the DCM and grain free diet issue?

Martine

From:	Palmer, Lee Anne </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CF7C8BD53B6C45A39318A596ACEA7C53-LPALMER>
To:	Norris, Anne; Rotstein, David; Jones, Jennifer L; Reimschuessel, Renate; Edwards, David; Hartogensis, Martine; Burkholder, William; DeLancey, Siobhan
CC:	Carey, Lauren; Lovell, Randall A; Ceric, Olgica; Nemser, Sarah; Conway, Charlotte; Atkinson, Krisztina Z; Hodges, April
Sent:	5/22/2018 1:12:50 PM
Subject:	RE: 800.267-DCM and meeting with Cardiac Care for Pets

B5

From: Norris, Anne
Sent: Tuesday, May 22, 2018 8:49 AM
To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>
Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

That should be fine. I apologize if we already discussed this, **B5**

B5

From: Palmer, Lee Anne
Sent: Tuesday, May 22, 2018 8:39 AM
To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte

<Charlotte.Conway@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>
Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

B5

B5

From: Rotstein, David
Sent: Tuesday, May 22, 2018 8:37 AM
To: Norris, Anne <Anne.Norris@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>
Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

Anne,

Agreed.

B5

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
CVM OSC/DC/CERT
7519 Standish Place
240-506-6763 (BB)

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From: Norris, Anne
Sent: Tuesday, May 22, 2018 8:34 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>

Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>
Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

B5

From: Jones, Jennifer L
Sent: Tuesday, May 22, 2018 8:31 AM
To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>
Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

B5

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421
U.S. FOOD & DRUG ADMINISTRATION

From: Rotstein, David
Sent: Tuesday, May 22, 2018 8:25 AM
To: Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>
Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

B5

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison

CVM OSC/DC/CERT
7519 Standish Place
240-506-6763 (BB)

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From: Reimschuessel, Renate
Sent: Tuesday, May 22, 2018 8:18 AM
To: Edwards, David <David.Edwards@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>
Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

B5

Just some food for thought.... rr

Renate Reimschuessel V.M.D. Ph.D. Vet-LIRN
Phone 1-240-402-5404
Fax 301-210-4685
http://www.fda.gov/AnimalVeterinary/ScienceResearch/ucm247334.htm

From: Edwards, David
Sent: Tuesday, May 22, 2018 7:54 AM
To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>
Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

Hi everyone,

B5

Thanks,
Dave

From: Rotstein, David
Sent: Monday, May 21, 2018 7:49 AM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>
Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

B5

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
CVM OSC/DC/CERT
7519 Standish Place
240-506-6763 (BB)

U.S. FOOD & DRUG ADMINISTRATION

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From: Hartogensis, Martine
Sent: Monday, May 21, 2018 7:47 AM
To: Burkholder, William <William.Burkholder@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>
Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>
Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

Thanks Bill and your concerns are noted!

B5

Jen, does CVCA know we need individual complaints for each case? We need to tell them and we may only reach a subset of the cases.

Thank you all for your help and dedication to this fascinating issue!

Martine

From: Burkholder, William
Sent: Friday, May 18, 2018 5:04 PM
To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>
Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>
Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

B5

B5

Bill

What Socrates is really supposed to have said: *"The only true wisdom is in knowing that you know nothing."

From: Palmer, Lee Anne
Sent: Friday, May 18, 2018 2:09 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

B5

I also cleaned up and B5 added a few things). Thanks – hope we can figure this one out!

Lee Anne

From: Jones, Jennifer L
Sent: Friday, May 18, 2018 1:54 PM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

B5

Any other ideas or suggestions?

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421
U.S. FOOD & DRUG ADMINISTRATION

From: Hartogensis, Martine
Sent: Friday, May 18, 2018 11:58 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

Thank you Jen! Sounds good and looking forward to the meeting.

Martine

From: Jones, Jennifer L
Sent: Friday, May 18, 2018 6:42 AM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

B5

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421
U.S. FOOD & DRUG ADMINISTRATION

From: Hartogensis, Martine
Sent: Thursday, May 17, 2018 7:52 PM
To: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

B5

Thanks in advance!

Martine

From: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Date: May 17, 2018 at 2:27:35 PM EDT
To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>, Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>, Rotstein, David <David.Rotstein@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>, Carey, Lauren <Lauren.Carey@fda.hhs.gov>, Norris, Anne <Anne.Norris@fda.hhs.gov>, Lovell, Randall A <Randall.Lovell@fda.hhs.gov>, Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>, Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>, Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

Indeed! Brands mentioned included California Naturals, Rachel Ray, Ellen DeGeneres' Halo brand - esp the vegan formulation - and a few other niche brands I didn't catch.

From: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Date: May 17, 2018 at 2:14:48 PM EDT
To: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>, Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>, Rotstein, David <David.Rotstein@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>, Carey, Lauren <Lauren.Carey@fda.hhs.gov>, Norris, Anne <Anne.Norris@fda.hhs.gov>, Lovell, Randall A <Randall.Lovell@fda.hhs.gov>, Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>, Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>, Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

Hah! Perfect timing! We're all heading down the same path…

From: DeLancey, Siobhan

Sent: Thursday, May 17, 2018 2:13 PM
To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

As luck would have it, I'm at CE today listening t[B6] talk about nutrition and cardiomyopathies. See attached slide.

From: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Date: May 17, 2018 at 2:06:04 PM EDT
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>, Rotstein, David <David.Rotstein@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>, Carey, Lauren <Lauren.Carey@fda.hhs.gov>, Norris, Anne <Anne.Norris@fda.hhs.gov>, DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>, Lovell, Randall A <Randall.Lovell@fda.hhs.gov>, Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>, Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>, Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

B5

From: Hartogensis, Martine
Sent: Thursday, May 17, 2018 11:59 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

Excellent work Jen!!

Just a few questions B5

B5

B5

Martine

From: Jones, Jennifer L
Sent: Thursday, May 17, 2018 11:29 AM
To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

B5

B5

Please see the PPT for the rationale/summary

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421

From: Rotstein, David
Sent: Monday, May 14, 2018 10:22 AM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>
Subject: RE: DCM and meetign with Cardiac Care for Pets

I do not know B5 Once we get a better handle on a specific cause, we can work on that.

From: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>
Date: May 14, 2018 at 9:09:17 AM EDT
To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>, Rotstein, David <David.Rotstein@fda.hhs.gov>, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>, Carey, Lauren <Lauren.Carey@fda.hhs.gov>, Norris, Anne <Anne.Norris@fda.hhs.gov>, DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>, Lovell, Randall A <Randall.Lovell@fda.hhs.gov>
Subject: RE: DCM and meetign with Cardiac Care for Pets

This is very interesting. B5 ...Dave, do you have any idea

B5

Martine

From: Palmer, Lee Anne
Sent: Friday, May 11, 2018 4:30 PM
To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>
Subject: RE: DCM and meetign with Cardiac Care for Pets

B5

B5

From: Rotstein, David
Sent: Friday, May 11, 2018 4:14 PM
To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>
Subject: RE: DCM and meetign with Cardiac Care for Pets

Lee Anne,

This is fantastic B5

B5

From: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Date: May 11, 2018 at 4:06:05 PM EDT
To: Rotstein, David <David.Rotstein@fda.hhs.gov>, Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>, Carey, Lauren <Lauren.Carey@fda.hhs.gov>, Norris, Anne <Anne.Norris@fda.hhs.gov>, DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>, Lovell, Randall A <Randall.Lovell@fda.hhs.gov>
Subject: RE: DCM and meetign with Cardiac Care for Pets

Hi there – it is still VERY ROUGH (will final it up next week sometime B5

B5

I'll final this up next week, have to get to other things yet today. Have a great weekend! J Lee Anne

B5

From: Rotstein, David
Sent: Wednesday, May 9, 2018 4:13 PM
To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Subject: RE: DCM and meetign with Cardiac Care for Pets

Sounds very intriguing!!!

From: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Date: May 9, 2018 at 4:09:18 PM EDT
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>, Rotstein, David <David.Rotstein@fda.hhs.gov>, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>, Carey, Lauren <Lauren.Carey@fda.hhs.gov>, Norris, Anne <Anne.Norris@fda.hhs.gov>, DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Subject: RE: DCM and meetign with Cardiac Care for Pets

B5

From: Hartogensis, Martine
Sent: Wednesday, May 9, 2018 2:17 PM
To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Subject: RE: DCM and meetign with Cardiac Care for Pets

Awesome, thank you Dave!

Martine

From: Rotstein, David
Sent: Wednesday, May 09, 2018 2:06 PM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Subject: RE: DCM and meetign with Cardiac Care for Pets

Good Afternoon,

I spoke with B6 @ Cardiac Care for Pets. He is going to look into times/dates with the cardiologists there and we can set the meeting up from that point.

B5

As a side note, there is a facebook page dedicated to this issue:

https://www.facebook.com/groups/1952593284998859/about/

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
CVM OSC/DC/CERT
7519 Standish Place
240-506-6763 (BB)

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From: Hartogensis, Martine
Sent: Tuesday, May 08, 2018 10:58 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Subject: RE: DCM

Thank you Jen and Dave! Very interesting and sounds like you all are on it! The resident I spoke to was Dr. B6

B6

Keep us posted!

Thanks again!

Martine

Hi Martine,

B5

I'm happy to share more info as needed.
Jen

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421

From: Rotstein, David
Sent: Tuesday, May 08, 2018 9:45 AM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: RE: DCM

Martine,

Jen and I spoke with cardiologists from NCSU and a few other institutions. That's how we were able to get the information.

B5

Looping in Jen.

Thanks for the update!

dave

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
CVM OSC/DC/CERT
7519 Standish Place
240-506-6763 (BB)

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From: Hartogensis, Martine
Sent: Tuesday, May 08, 2018 9:00 AM
To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Subject: RE: DCM

Thank you Dave! We did not go around yesterday because the Vet-LIRN folks came in for their routine presentation.

B5

Martine

From: Rotstein, David
Sent: Monday, May 07, 2018 1:13 PM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>
Subject: Re: DCM

Martine

B5

There's a way to go on this moving forward.

Dave

From: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>
Date: May 7, 2018 at 1:03:13 PM EDT
To: Rotstein, David <David.Rotstein@fda.hhs.gov>
Subject: DCM

Hi Dave!

Do you have any more details on the DCM and grain free diet issue?

Martine

DOCUMENT PRODUCED IN NATIVE

From: Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>
To: Schmidt, Rich
CC: Ceric, Olgica
Sent: 5/7/2018 10:41:29 AM
Subject: Vet-LIRN samples for testing (800.267)
Attachments: 800.267-Covance lab sub form-5.4.2018.xls

Good morning Rich,
We shipped another set of samples for testing. The tracking is:

Tracking Number: 1ZA442OT0193137321

It should arrive by close of business today.
Thank you,
Jen

Jennifer L. A. Jones, DVM
Veterinary Medical Officer
U.S. Food & Drug Administration
Center for Veterinary Medicine
Office of Research
Veterinary Laboratory Investigation and Response Network (Vet-LIRN)
8401 Muirkirk Road, G704
Laurel, Maryland 20708
new tel: 240-402-5421
fax: 301-210-4685
e-mail: *jennifer.jones@fda.hhs.gov*
Web: http://www.fda.gov/AnimalVeterinary/ScienceResearch/ucm247334.htm

U.S. FOOD & DRUG ADMINISTRATION

From:	Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>
To:	Rotstein, David; Hartogensis, Martine; Palmer, Lee Anne
CC:	Burkholder, William; Carey, Lauren; Norris, Anne; DeLancey, Siobhan; Lovell, Randall A; 'Reimschuessel, Renate (Renate.Reimschuessel@fda.hhs.gov)'; Ceric, Olgica; Nemser, Sarah
Sent:	5/17/2018 3:28:30 PM
Subject:	RE: 800.267-DCM and meetign with Cardiac Care for Pets
Attachments:	800.267-DCM-Grainfree analysis.pptx; DCM-Case Report Analysis-5.17.2018.xls

B5

Please see the PPT for the rationale/summary

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421
U.S. FOOD & DRUG ADMINISTRATION

From: Rotstein, David
Sent: Monday, May 14, 2018 10:22 AM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>
Subject: RE: DCM and meetign with Cardiac Care for Pets

B5

From: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>
Date: May 14, 2018 at 9:09:17 AM EDT
To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>, Rotstein, David <David.Rotstein@fda.hhs.gov>, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>, Carey, Lauren <Lauren.Carey@fda.hhs.gov>, Norris, Anne <Anne.Norris@fda.hhs.gov>, DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>, Lovell, Randall A <Randall.Lovell@fda.hhs.gov>
Subject: RE: DCM and meetign with Cardiac Care for Pets

This is very interesting. **B5**

B5

Martine

From: Palmer, Lee Anne

Sent: Friday, May 11, 2018 4:30 PM
To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>
Subject: RE: DCM and meetign with Cardiac Care for Pets

B5

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Sent: Friday, May 11, 2018 4:14 PM
To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>
Subject: RE: DCM and meetign with Cardiac Care for Pets

Lee Anne,

B5

From: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Date: May 11, 2018 at 4:06:05 PM EDT
To: Rotstein, David <David.Rotstein@fda.hhs.gov>, Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>, Carey, Lauren <Lauren.Carey@fda.hhs.gov>, Norris, Anne <Anne.Norris@fda.hhs.gov>, DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>, Lovell, Randall A <Randall.Lovell@fda.hhs.gov>
Subject: RE: DCM and meetign with Cardiac Care for Pets

Hi there – it is still VERY ROUGH (will final it up next week sometime B5

B5

B5

I'll final this up next week, have to get to other things yet today. Have a great weekend! J Lee Anne

B6

From: Rotstein, David
Sent: Wednesday, May 9, 2018 4:13 PM
To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
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Sounds very intriguing!!!

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Subject: RE: DCM and meetign with Cardiac Care for Pets

B5

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Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
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Awesome, thank you Dave!

Martine

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Sent: Wednesday, May 09, 2018 2:06 PM
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Subject: RE: DCM and meetign with Cardiac Care for Pets

Good Afternoon,

I spoke with **B6** Cardiac Care for Pets. He is going to look into times/dates with the cardiologists there and we can set the meeting up from that point.

B5

As a side note, there is a facebook page dedicated to this issue:

https://www.facebook.com/groups/1952593284998859/about/

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
CVM OSC/DC/CERT
7519 Standish Place
240-506-6763 (BB)

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From: Hartogensis, Martine

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To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Subject: RE: DCM

Thank you Jen and Dave! Very interesting and sounds like you all are on it! The resident I spoke to was Dr.

B6

B6

Keep us posted!

Thanks again!

Martine

Hi Martine,

B5

I'm happy to share more info as needed.
Jen

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421

U.S. FOOD & DRUG ADMINISTRATION

From: Rotstein, David
Sent: Tuesday, May 08, 2018 9:45 AM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: RE: DCM

Martine,

Jen and I spoke with cardiologists from NCSU and a few other institutions. That's how we were able to get the information.

B5

B5

Looping in Jen.

Thanks for the update!

dave

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
CVM OSC/DC/CERT
7519 Standish Place
240-506-6763 (BB)

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Subject: RE: DCM

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B5

Martine

From: Rotstein, David
Sent: Monday, May 07, 2018 1:13 PM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>
Subject: Re: DCM

Martine

B5

B5

There's a way to go on this moving forward.

Dave

From: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>
Date: May 7, 2018 at 1:03:13 PM EDT
To: Rotstein, David <David.Rotstein@fda.hhs.gov>
Subject: DCM

Hi Dave!

Do you have any more details on the DCM and grain free diet issue?

Martine

DOCUMENT PRODUCED IN NATIVE

Withheld in Full as B5

From:	Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>
To:	Hartogensis, Martine; DeLancey, Siobhan; Palmer, Lee Anne; Rotstein, David
CC:	Burkholder, William; Carey, Lauren; Norris, Anne; Lovell, Randall A; Reimschuessel, Renate; Ceric, Olgica; Nemser, Sarah
Sent:	5/18/2018 5:53:58 PM
Subject:	RE: 800.267-DCM and meetign with Cardiac Care for Pets
Attachments:	Diet Breakdown by Brand.xlsx; Diet Breakdown by Brand1.xlsx; Diet Breakdown by Breed.xlsx

Here are the spreadsheets CVCA sent.

B5

Any other ideas or suggestions?

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421

U.S. FOOD & DRUG ADMINISTRATION

From: Hartogensis, Martine
Sent: Friday, May 18, 2018 11:58 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

Thank you Jen! Sounds good and looking forward to the meeting.

Martine

From: Jones, Jennifer L
Sent: Friday, May 18, 2018 6:42 AM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

B5

B5

Jennifer Jones, DVM
Veterinary Medical Officer

Tel: 240-402-5421
U.S. FOOD & DRUG ADMINISTRATION

From: Hartogensis, Martine
Sent: Thursday, May 17, 2018 7:52 PM
To: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

Yes, excellent work! [B5] e

[B5]

Thanks in advance!

Martine

From: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Date: May 17, 2018 at 2:27:35 PM EDT
To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>, Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>, Rotstein, David <David.Rotstein@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>, Carey, Lauren <Lauren.Carey@fda.hhs.gov>, Norris, Anne <Anne.Norris@fda.hhs.gov>, Lovell, Randall A <Randall.Lovell@fda.hhs.gov>, Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>, Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>, Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

Indeed! Brands mentioned included California Naturals, Rachel Ray, Ellen DeGeneres' Halo brand - esp the vegan formulation - and a few other niche brands I didn't catch.

From: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Date: May 17, 2018 at 2:14:48 PM EDT
To: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>, Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>, Rotstein, David <David.Rotstein@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>, Carey, Lauren <Lauren.Carey@fda.hhs.gov>, Norris, Anne <Anne.Norris@fda.hhs.gov>, Lovell, Randall A <Randall.Lovell@fda.hhs.gov>, Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>, Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>, Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

Hah! Perfect timing! We're all heading down the same path…

From: DeLancey, Siobhan
Sent: Thursday, May 17, 2018 2:13 PM
To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

As luck would have it, I'm at CE today listening t[B6]alk about nutrition and cardiomyopathies. See attached slide.

From: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Date: May 17, 2018 at 2:06:04 PM EDT
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>, Rotstein, David <David.Rotstein@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>, Carey, Lauren <Lauren.Carey@fda.hhs.gov>, Norris, Anne <Anne.Norris@fda.hhs.gov>, DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>, Lovell, Randall A <Randall.Lovell@fda.hhs.gov>, Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>, Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>, Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

[B5]

B5

From: Hartogensis, Martine
Sent: Thursday, May 17, 2018 11:59 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

Excellent work Jen!!

Just a few questions. B5
DCM?

B5

Martine

From: Jones, Jennifer L
Sent: Thursday, May 17, 2018 11:29 AM
To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
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Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

B5

B5

Please see the PPT for the rationale/summary

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421
U.S. FOOD & DRUG ADMINISTRATION

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Subject: RE: DCM and meetign with Cardiac Care for Pets

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Lee Anne,

This is fantastic. B5

B5

From: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Date: May 11, 2018 at 4:06:05 PM EDT
To: Rotstein, David <David.Rotstein@fda.hhs.gov>, Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
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Hi there – it is still VERY ROUGH (will final it up next week sometime) - B5

B5

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B5

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Subject: RE: DCM and meetign with Cardiac Care for Pets

B6

From: Hartogensis, Martine
Sent: Wednesday, May 9, 2018 2:17 PM
To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
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Awesome, thank you Dave!

Martine

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Good Afternoon,

I spoke with B6 @ Cardiac Care for Pets. He is going to look into times/dates with the cardiologists there and we can set the meeting up from that point.

B5

As a side note, there is a facebook page dedicated to this issue:

https://www.facebook.com/groups/1952593284998859/about/

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
CVM OSC/DC/CERT
7519 Standish Place
240-506-6763 (BB)

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Subject: RE: DCM

Thank you Jen and Dave! Very interesting and sounds like you all are on it! The resident I spoke to was Dr.

B6

Keep us posted!

Thanks again!

Martine

Hi Martine,

B5

B5

B5

B5

I'm happy to share more info as needed.
Jen

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421

U.S. FOOD & DRUG ADMINISTRATION

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Subject: RE: DCM

Martine,

Jen and I spoke with cardiologists from NCSU and a few other institutions. That's how we were able to get the information.

B5

Looping in Jen.

Thanks for the update!

dave

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
CVM OSC/DC/CERT
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Subject: RE: DCM

Thank you Dave! We did not go around yesterday because the Vet-LIRN folks came in for their routine presentation.

B5

Martine

From: Rotstein, David
Sent: Monday, May 07, 2018 1:13 PM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>
Subject: Re: DCM

Martine

B5

There's a way to go on this moving forward.

Dave

From: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>
Date: May 7, 2018 at 1:03:13 PM EDT
To: Rotstein, David <David.Rotstein@fda.hhs.gov>
Subject: DCM

Hi Dave!

Do you have any more details on the DCM and grain free diet issue?

Martine

DOCUMENT PRODUCED IN NATIVE

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From: Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>
To: Burkholder, William
Sent: 5/18/2018 10:46:08 AM
Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets
Attachments: 800.218-Covance-Rd 2-Tau-Cys-Met.xlsx; 800.218-Covance-Taurine-Carnitine.pdf; 800.261-Covance-Tau-Cys-Met.PDF; 800.267-Covance-control Cys-Met-Tau.xlsx

B5

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421
U.S. FOOD & DRUG ADMINISTRATION

From: Burkholder, William
Sent: Thursday, May 17, 2018 12:42 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

B5

From: Jones, Jennifer L
Sent: Thursday, May 17, 2018 12:32 PM
To: Burkholder, William <William.Burkholder@fda.hhs.gov>
Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

I forgot to add

B5

B5

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421
U.S. FOOD & DRUG ADMINISTRATION

From: Burkholder, William
Sent: Thursday, May 17, 2018 12:30 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

B4, B5

From: Jones, Jennifer L

Sent: Thursday, May 17, 2018 12:22 PM
To: Burkholder, William <William.Burkholder@fda.hhs.gov>
Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

I was amazed myself. B5

B5

The Covance results are attached. Do you agree?

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421

U.S. FOOD & DRUG ADMINISTRATION

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B5

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B5

Please see the PPT for the rationale/summary

Jennifer Jones, DVM
Veterinary Medical Officer
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Good Afternoon,

I spoke with B5, B6 @ Cardiac Care for Pets. He is going to look into times/dates with the cardiologists there and we can set the meeting up from that point.

Just some basic information:

B5

As a side note, there is a facebook page dedicated to this issue:

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David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
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Thank you Jen and Dave! Very interesting and sounds like you all are on it! The resident I spoke to was Dr.

B5

B6

Keep us posted!

Thanks again!

Martine

Hi Martine,

B5

B5

I'm happy to share more info as needed.
Jen

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421

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Thanks for the update!

dave

David Rotstein, DVM, MPVM, Dipl. ACVP
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Martine

B5

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Dave

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To: Rotstein, David <David.Rotstein@fda.hhs.gov>
Subject: DCM

Hi Dave!

Do you have any more details on the DCM and grain free diet issue?

Martine

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COVANCE
SOLUTIONS MADE REAL®

Report Number:	**1894242-0**
Report Date:	**15-Aug-2017**
Report Status:	**Final**

Certificate of Analysis

Food and Drug Administration - CVM - Invoice Denise Durham

8401 Muirkirk Rd.
Laurel Maryland 20708 United States

Sample Name:	**800.218**	**Covance Sample:**	**6406524**
Project ID	FDA_CVM-20170804-0007	**Receipt Date**	04-Aug-2017
PO Number	HHSF223201610005I/HHSF22301002T	**Receipt Condition**	Ambient temperature
Sample Serving Size	100 g	**Login Date**	04-Aug-2017
		Online Order	20

Analysis	Result
L-Carnitine *	
L-Carnitine	69900 ppb
Taurine	
Taurine	231 mg/Serving Size

Method References	Testing Location
L-Carnitine (CARNITNE_S)	**Covance Laboratories - Madison**
STAREY ET AL.: JOURNAL OF AOAC INTERNATIONAL VOL. 91, NO.1, 2008. (Modified).	
Taurine (TAUR_LC_S)	**Covance Laboratories - Madison**
R. Schuster, "Determination of Amino Acids in Biological, Pharmaceutical, Plant and Food Samples by Automated Precolumn Deravitization and HPLC", Journal of Chromatography., 1988, 431, 271-284, Henderson, J.W., Ricker, R.D. Bidlingmeyer, B.A., Woodward, C., "Rapid, Accurate, Sensitive, and Reproducible HPLC Analysis of Amino Acids, Amino Acid Analysis Using Zorbax Eclipse-AAA columns and the Agilent 1100 HPLC," Agilent Publication, 2000, and Barkholt and Jensen, , "Amino Acid Analysis: Determination of Cysteine plus Half-Cystine in Proteins after Hydrochloric Acid Hydrolysis with a Disulfide Compound as Additive," Analytical Biochemistry, 177, 318-322 (1989).	

Testing Location(s)	Released on Behalf of Covance by
Covance Laboratories - Madison	**Edward Ladwig - Director**
Covance Laboratories Inc. 3301 Kinsman Blvd Madison WI 53704 800-675-8375	ilac-MRA A2LA ACCREDITED 2918.01

These results apply only to the items tested. This certificate of analysis shall not be reproduced, except in its entirety, without the written approval of Covance.

*** This analysis is not ISO accredited.**

FDA-CVM-FOIA-2019-1704-010016

COVANCE
SOLUTIONS MADE REAL®

Report Number:	**2119443-0**
Report Date:	**01-May-2018**
Report Status:	**Final**

Certificate of Analysis

Food and Drug Administration - CVM

8401 Muirkirk Rd.
Laurel Maryland 20708 United States

Sample Name:	**1-dog food**	**Covance Sample:**	**7192972**
Project ID	FDA_CVM-20180413-0004	**Receipt Date**	13-Apr-2018
PO Number	HHSF223201610005I HHSF22301003T	**Receipt Condition**	Ambient temperature
Sample Serving Size		**Login Date**	13-Apr-2018
Description	800.261-sub	**Online Order**	20

Analysis	Result
Cystine and Methionine *	
Cystine	293 mg/100g
Methionine	358 mg/100g
Taurine	
Taurine	45.5 mg/100g

Method References	Testing Location
Cystine and Methionine (AAAC_S)	**Covance Laboratories - Madison**
Official Methods of Analysis of AOAC INTERNATIONAL, Method 982.30 E(a/b)	
Taurine (TAUR_LC_S)	**Covance Laboratories - Madison**

Official Methods of Analysis of AOAC INTERNATIONAL, Method 999.12, AOAC International Gaithersburg, MD, USA, (Modified)

R. Schuster, "Determination of Amino Acids in Biological, Pharmaceutical, Plant and Food Samples by Automated Precolumn Derivatization and HPLC", *Journal of Chromatography, 431*:271-284, (1988) (Modified)

Henderson, J.W., Ricker, R.D. Bidlingmeyer, B.A., Woodward, C., "Rapid, Accurate, Sensitive, and Reproducible HPLC Analysis of Amino Acids, Amino Acid Analysis Using Zorbax Eclipse-AAA columns and the Agilent 1100 HPLC," Agilent Publication, 2000 (Modified)

Henderson, J.W., Books, A., "Improved Amino Acid Methods using Agilent Zorbax Eclipse Plus C18 Columns for a Variety of Agilent LC Instrumentation and Separation Goals," Agilent Application Note 5990-4547, (2010).

Testing Location(s)	Released on Behalf of Covance by
Covance Laboratories - Madison	**Edward Ladwig - Director**

Covance Laboratories Inc.
3301 Kinsman Blvd
Madison WI 53704
800-675-8375

ilac-MRA A2LA ACCREDITED
2918.01

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*** This analysis is not ISO accredited.**

FDA-CVM-FOIA-2019-1704-010017

DOCUMENT PRODUCED IN NATIVE

Grain-free as defined by absence of corn, wheat, soy.

Tufts 227185: **Blue Buffalo Basics** Salmon – is it Salmon & Potato? Both = LID. Grain-Free?

Pea and Pumpkin, no corn, wheat, soy, dairy or eggs (LID GF says same info as other Salmon Basics)

Blue Basics LID Salmon & Potato: (no lentil)

Deboned Salmon, Oatmeal, Brown Rice, Peas, Salmon Meal (source of Omega 3 Fatty Acids and Glucosamine), Potatoes, Pea Fiber, Canola Oil (source of Omega 6 Fatty Acids), Natural Flavor, Pea Protein, Calcium Carbonate, Dicalcium Phosphate, Fish Oil (source of Omega 3 Fatty Acids), Dehydrated Alfalfa Meal, Pumpkin, Dried Chicory Root, Flaxseed (source of Omega 3 and 6 Fatty Acids), Potato Starch, Choline Chloride, Natural Flavor, Caramel Color, Salt, Potassium Chloride, Vitamin E Supplement, L-Ascorbyl-2-Polyphosphate (source of Vitamin C), Mixed Tocopherols (a natural preservative), DL-Methionine, Ferrous Sulfate, Parsley, Dried Kelp, Blueberries, Cranberries, Barley Grass, Yucca Schidigera Extract, Iron Amino Acid Chelate, Turmeric, Zinc Amino Acid Chelate, Zinc Sulfate, Oil of Rosemary, L-Carnitine, L-Lysine, Copper Sulfate, Copper Amino Acid Chelate, Nicotinic Acid (Vitamin B3), Calcium Pantothenate (Vitamin B5), Taurine, Biotin (Vitamin B7), Manganese Sulfate, Vitamin A Supplement, Manganese Amino Acid Chelate, Dried Yeast, Dried Enterococcus faecium fermentation product, Dried Lactobacillus acidophilus fermentation product, Dried Aspergillus niger fermentation extract, Dried Trichoderma longibrachiatum fermentation extract, Dried Bacillus subtilis fermentation extract, Thiamine Mononitrate (Vitamin B1), Riboflavin (Vitamin B2), Vitamin D3 Supplement, Vitamin B12 Supplement, Pyridoxine Hydrochloride (Vitamin B6), Folic Acid (Vitamin B9), Calcium Iodate, Sodium Selenite.

Blue Basics LID Salmon & Potato – Grain-free formula: (no lentil)

Deboned Salmon, Potatoes, Peas, Pea Starch, Salmon Meal (source of Omega 3 Fatty Acids and Glucosamine), Tapioca Starch, Pea Fiber, Canola Oil (source of Omega 6 Fatty Acids), Pea Protein, Natural Flavor, Dicalcium Phosphate, Calcium Carbonate, Fish Oil (source of Omega 3 Fatty

Acids), Dehydrated Alfalfa Meal, Pumpkin, Dried Chicory Root, Choline Chloride, Flaxseed (source of Omega 3 and 6 Fatty Acids), Potato Starch, Caramel Color, Salt, Vitamin E Supplement, DL-Methionine, Mixed Tocopherols (a natural preservative), L-Ascorbyl-2-Polyphosphate (source of Vitamin C), Ferrous Sulfate, Parsley, Dried Kelp, Blueberries, Cranberries, Barley Grass, Yucca Schidigera Extract, Iron Amino Acid Chelate, Turmeric, Zinc Amino Acid Chelate, Zinc Sulfate, Oil of Rosemary, L-Carnitine, L-Lysine, Copper Sulfate, Copper Amino Acid Chelate, Nicotinic Acid (Vitamin B3), Calcium Pantothenate (Vitamin B5), Taurine, Biotin (Vitamin B7), Manganese Sulfate, Vitamin A Supplement, Manganese Amino Acid Chelate, Dried Yeast, Dried Enterococcus faecium fermentation product, Dried Lactobacillus acidophilus fermentation product, Dried Aspergillus niger fermentation extract, Dried Trichoderma longibrachiatum fermentation extract, Dried Bacillus subtilis fermentation extract, Thiamine Mononitrate (Vitamin B1), Riboflavin (Vitamin B2), Vitamin D3 Supplement, Vitamin B12 Supplement, Pyridoxine Hydrochloride (Vitamin B6), Folic Acid (Vitamin B9), Calcium Iodate, Sodium Selenite.

Tufts 233025, 316296, 345266, NCSU 323515, 323519, Ohio 345822, 345831, 345833

California Naturals Kangaroo and Lentil, Venison and Lentil – Grain free, Kangaroo, red and green lentils, Peas & pea fiber, sunflower oil, flaxseed (vit/min, rosemary extract). No Grains, white potatoes, corn, soy, dairy or eggs.

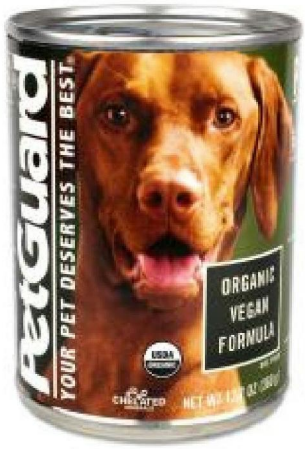
Ingredients: Kangaroo/Red Lentil:

Kangaroo, Red Lentils, Green Lentils, Peas, Sunflower Oil (Preserved with Mixed Tocopherols), Flaxseed, Pea Fiber, Dicalcium Phosphate, Natural Flavors, Calcium Carbonate, Salt, DL-Methionine, Minerals (Zinc Proteinate, Iron Proteinate, Copper Proteinate, Manganese Proteinate, Calcium Iodate, Vitamins (Betaine Hydrochloride, Vitamin A Supplement, Niacin Supplement, Calcium Pantothenate, Beta Carotene, Vitamin B12 Supplement, Vitamin D3 Supplement, Riboflavin Supplement, Pyridoxine Hydrochloride, Thiamine Mononitrate, Biotin, Folic Acid), Vitamin E Supplement, Rosemary Extract

Ingredients: Venison/Green Lentil:

Venison, Green Lentils, Red Lentils, Peas, Sunflower Oil (Preserved with Mixed Tocopherols), Flaxseed, Pea Fiber, Calcium Carbonate, Dicalcium Phosphate, Natural Flavors, Salt, Potassium Chloride, DL-Methionine, Taurine, Minerals (Zinc Proteinate, Iron Proteinate, Copper Proteinate, Manganese Proteinate, Calcium Iodate), Vitamin E Supplement, Vitamins (Betaine Hydrochloride, Vitamin A Supplement, Niacin Supplement, Calcium Pantothenate, Beta Carotene, Vitamin B12 Supplement, Vitamin D3 Supplement, Riboflavin Supplement, Pyridoxine Hydrochloride, Thiamine Mononitrate, Biotin, Folic Acid), Rosemary Extract

Tufts 331611 **PetGuard Organic Vegan** (only "Organic Vegan" is a canned food)



Organic Vegan Formula

INGREDIENTS:
Sufficient Water For Processing, Organic Pea Protein, Organic Oats, Organic Sunflower Oil, Organic Quinoa, Organic Barley, Organic Brown Rice, Deflourinated Tricalcium Phosphate, Organic Guar Gum, Organic Carrots, Organic Peas, Organic Potatoes, Organic Spinach, Potassium Chloride, Choline Chloride, Organic Flaxseed, Organic Apples, Organic Tomato Powder, Organic Dried Kelp, Zinc Amino Acid Chelate, Iron Amino Acid Chelate, Salt, Vitamin E Supplement, Copper Amino Acid Chelate, Manganese Amino Acid Chelate, Niacin, d-Calcium Pantothenate, Sodium Selenite, Vitamin A Supplement, Riboflavin Supplement (Vitamin B2), Biotin, Thiamine Monoritrate (Vitamin B1), Calcium Iodate, Pyridoxine Hydrochloride (Vitamin B6), Ergocalciferol (Source of Vitamin D2), Vitamin B12 Supplement, Cobalt Amino Acid Chelate, Folic Acid, Inositol.

Zignature Essentials:

Lamb (1), Salmon (3), Kangaroo (6)

Lamb: WHAT'S INSIDE (no lentils)

Lamb, Lamb Meal, Peas, Chickpeas, Pea Flour, Sunflower Oil (Preserved with Citric Acid), Pea Protein, Flaxseed, Natural Flavors, Dehydrated Alfalfa Meal, Dried Beet Pulp, Potassium Chloride, Salt, Minerals(Zinc Proteinate, Iron Proteinate, Copper Proteinate, Manganese Proteinate, Cobalt Proteinate, Selenium Yeast), Chorine Chloride, Vitamins (Vitamin A Acetate, Vitamin D3 Supplement, Vitamin E Supplement, Niacin, d-Calcium Pantothenate, Thiamine Mononitrate, Pyridoxine Hydrochloride, Riboflavin Supplement, Folic Acid, Biotin, Vitamin B12 Supplement), Blueberries, Carrots, Cranberries, Lactic Acid, DL Methionine, Calcium Iodate, Preserved with Mixed Tocopherols. Click here to explore what's inside our food.

Kangaroo WHAT'S INSIDE (lentils)

Kangaroo, Kangaroo Meal, Peas, Chickpeas, Pea Flour, Sunflower Oil (preserved with Citric Acid), Flaxseed, Red Lentils, Green Lentils, Dehydrated Alfalfa Meal, Pea Protein, Natural Flavors, Salt, Minerals (Zinc Proteinate, Iron Proteinate, Copper Proteinate, Manganese Proteinate, Cobalt Proteinate, Selenium Yeast), Choline Chloride, Potassium Chloride, Calcium Carbonate, Vitamins (Vitamin A, Acetate, Vitamin D3 Supplement, Vitamin E Supplement, Niacin, d-Calcium Pantothenate, Thiamine Mononitrate, Pyridoxine Hydrochloride, Riboflavin Supplement, Folic Acid, Biotin, Vitamin B12 Supplement), Lactic Acid, Calcium Iodate, Preserved With Mixed Tocopherols. Click here to explore what's inside our food.

Salmon WHAT'S INSIDE (no lentils)

Salmon, Salmon Meal, Pea Flour, Chickpeas, Peas, Sunflower Oil (Preserved With Mixed Tocopherols And Citric Acid), Flaxseed, Natural Flavors, Suncured Alfalfa Meal, Calcium Carbonate, Salt, Choline Chloride, Minerals (Zinc Proteinate, Iron Proteinate, Copper Proteinate, Manganese Proteinate, Cobalt Proteinate), Potassium Chloride, Vitamins (Vitamin A Acetate, Vitamin D3 Supplement, Vitamin E Supplement, Niacin, D-Calcium Pantothenate, Thiamine Mononitrate, Pyridoxine Hydrochloride, Riboflavin Supplement, Folic Acid, Biotin, Vitamin B12 Lactic Supplement), Lactic Acid, Calcium Iodate, Sodium Selenite. Click here to explore what's inside our food.

Physiologically Tuned™, limited ingredient premium food for dogs. Hypoallergenic meat first recipe, with no Corn, Wheat, Soy, Dairy, or Chicken, Chicken Eggs, or Chicken By-Products.

Nature's Recipe Salmon & Sweet Potato (2 separate cases): no lentils.

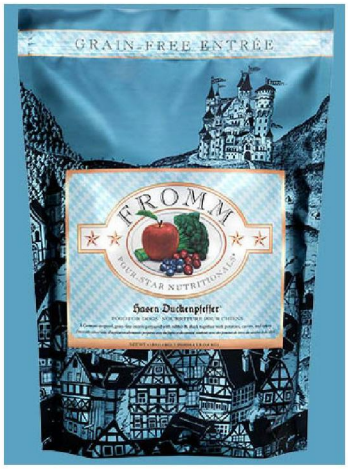
Ingredients

Salmon, garbanzo beans, peas, pea protein, salmon meal, poultry fat (preserved with mixed tocopherols), sweet potatoes, apples, pumpkin, natural flavor, dried tomato pomace, salt, potassium chloride, calcium carbonate, choline chloride, taurine, vitamins (vitamin E supplement, L-ascorbyl-2-polyphosphate (source of vitamin C), Inositol, niacin, d-calcium pantothenate, vitamin A supplement, riboflavin supplement, thiamine mononitrate, beta-carotene, pyridoxine hydrochloride, vitamin B12 supplement, menadione sodium bisulfite complex, vitamin D3 supplement, folic acid, biotin), minerals (ferrous sulfate, iron proteinate, zinc proteinate, zinc oxide, copper sulfate, manganese proteinate, copper proteinate, manganous oxide, calcium iodate, sodium selenite), lactic acid, citric acid (used as a preservative), yucca schidigera extract, rosemary extract.

Kirkland Nature's Domain Turkey and Sweet Potato: (no lentils) 1 case, had a low blood taurine

Ingredients:
Turkey meal, sweet potatoes, peas, potatoes, canola oil, tomato pomace, flaxseed, natural flavor, salmon oil (a source of DHA), salt, choline chloride, dried chicory root, tomatoes, blueberries, raspberries, yucca schidigera extract, dried Lactobacillus acidophilus fermentation product, dried Bifidobacterium animalis fermentation product, dried Lactobacillus reuteri fermentation product, vitamin E supplement, iron proteinate, zinc proteinate, copper proteinate, ferrous sulfate, zinc sulfate, copper sulfate, potassium iodide, thiamine mononitrate (vitamin B1), manganese proteinate, manganous oxide, ascorbic acid, vitamin A supplement, biotin, niacin, calcium pantothenate, manganese sulfate, sodium selenite, pyridoxine hydrochloride (vitamin B6), vitamin B12 supplement, riboflavin (vitamin B2), vitamin D supplement, folic acid.

Fromm Hasen Duckenpfeffer; Gamebird; Lamb/Lentil: 2 cases, 2 had duck, 1 had the duck, gamebird, lamb



INGREDIENTS:

Hasen Duckenpfeffer, Gamebird and Lamb/Lentil:

Rabbit, Duck, Pork Meat Meal, Peas, Potatoes, Lentils, Chickpeas, Pea Flour, Dried Tomato Pomace, Dried Whole Egg, Pork Fat, Rabbit Meal, Pork Liver, Pea Protein, Salmon Oil, Cheese, Flaxseed, Alfalfa Meal, Carrots, Celery, Lettuce, Watercress, Spinach, Potassium Chloride, Salt, Chicory Root Extract, Yucca Schidigera Extract, Sodium Selenite, Folic Acid, Taurine, Parsley, Sorbic Acid (Preservative), Vitamins, Minerals, Probiotics.

Lamb, Lamb Meal, Lentils, chickpeas, Dried Whole Egg, Peas, Dried Tomato Pomace, Pork Fat, Pea Flour, Pork Liver, Salmon oil, cheese, olive oil, yellow squash, zucchini, apples, flaxseed, pea fiber, tomatoes, carrots, broccoli, KCl, salt, chicory root extract, yucca schidigera extract, sodium selenite, folic acid, taurine, sorbic acid, vitamins, minerals, probiotics.

Duck, Duck meal, peas, turkey, potatoes, pea protein, dried tomato pomace, pea flour, dried whole egg, quail, chicken meal, chicken fat, salmon oil, sweet potatoes, chicken, pheasant, cheese, flaxseed, carrots, broccoli, cauliflower, apples, celery, parsley, lettuce, spinach, chicken cartilage, KCl, blueberries,

cranberries, salt, chicory root extract, yucca schidigera extract, alfalfa sprouts, sodium selenite, folic acid, taurine, sorbic acid, vitamins, minerals, probiotics.

Earthborn Holistic Meadow Feast/Primitive Natural:

Meadow Feast:

Lamb Meal, Peas, Tapioca, Canola Oil (preserved with Mixed Tocopherols), Pea Protein, Pea Fiber, Flaxseed, Natural Flavors, Blueberries, Cranberries, Apples, Carrots, Spinach, Salt, Potassium Chloride, Choline Chloride, DL-Methionine, L-Lysine, Taurine, L-Carnitine, Beta-Carotene, Vitamin A Supplement, Vitamin D_3 Supplement, Vitamin E Supplement, Zinc Sulfate, L-Ascorbyl-2-Polyphosphate (source of Vitamin C), Ferrous Sulfate, Niacin, Calcium Pantothenate, Riboflavin Supplement, Copper Sulfate, Pyridoxine Hydrochloride, Thiamine Mononitrate, Beta-Carotene, Manganese Sulfate, Zinc Proteinate, Manganese Proteinate, Copper Proteinate, Calcium Iodate, Cobalt Carbonate, Folic Acid, Sodium Selenite, Biotin, Vitamin B12 Supplement, Yucca Schidigera Extract, Rosemary Extract, Dried Enterococcus Faecium Fermentation Product, Dried Lactobacillus Casei Fermentation Product, Dried Lactobacillus Acidophilus Fermentation Product.

Primitive Natural:

Turkey Meal, Chicken Meal, Peas, Dried Egg, Pea Starch, Chicken Fat (preserved with Mixed Tocopherols), Whitefish Meal, Flaxeed, Natural Flavors, Pea Fiber, Blueberries, Cranberries, Apples, Carrots, Spinach, Salt, Potassium Chloride, Choline Chloride, DL-Methionine, L-Lysine, Taurine, L-Carnitine, Beta-Carotene, Vitamin A Supplement, Vitamin D3 Supplement, Vitamin E Supplement, Zinc Sulfate, Ferrous Sulfate, Niacin, Folic Aid, Biotin, Manganese Sulfate, Copper Sulfate, Calcium Pantothenate, Thiamine Mononitrate, Pyridoxine Hydrochloride, Riboflavin Supplement, L-Ascorbyl-2-Polyphosphate (source of Vitamin C), Zinc Proteinate, Manganese Proteinate, Copper Proteinate, Calcium Iodate, Sodium Selenite, Cobalt Carbonate, Vitamin B12 Supplement, Yucca Schidigera Extract, Rosemary Extract, Dried Enterococcus Faecium Fermentation Product, Dried Lactobacillus Casei Fermentation Product, Dried Lactobacillus Acidophilus Fermentation Product.

4Health Grain-free:

Free of grain, wheat, soy and corn; added omega fatty acids.

Flavor unknown, but a check of the 4Health Grain-Free Chicken & Vegetable dry shows:

Ingredients:
Chicken, Chicken Meal, Garbanzo Beans, Lentils, Peas, Potatoes, Chicken Fat (Preserved with Mixed Tocopherols), Tapioca, Egg Product, Tomato Pomace, Natural Flavor, Flaxseed, Ocean Fish Meal, Salt, Choline Chloride, Dried Chicory Root, Tomatoes, Blueberries, Raspberries, Glucosamine Hydrochloride, Yucca Schidigera Extract, Chondroitin Sulfate, Dried Lactobacillus Acidophilus Fermentation Product, Dried Bifidobacterium Animalis Fermentation Product, Dried Lactobacillus Reuteri Fermentation Product, Vitamin E Supplement, Beta Carotene, Iron Proteinate, Zinc Proteinate, Copper Proteinate, Ferrous Sulfate, Zinc Sulfate, Copper Sulfate, Potassium Iodide, Thiamine Mononitrate (Vitamin B1), Manganese Proteinate, Manganous Oxide, Ascorbic Acid, Vitamin A Supplement, Biotin, Niacin, Calcium Pantothenate, Manganese Sulfate, Sodium Selenite, Pyridoxine Hydrochloride (Vitamin B6), Vitamin B12 Supplement, Riboflavin (Vitamin B2), Vitamin D Supplement, Folic Acid.

4Health Grain-Free Large Breed:

Ingredients:
Turkey, Turkey Meal, Garbanzo Beans, Lentils, Peas, Potatoes, Tapioca, Chicken Fat (Preserved with Mixed Tocopherols), Egg Product, Tomato Pomace, Natural Flavor, Flaxseed, Ocean Fish Meal, Salt, Choline Chloride, Glucosamine Hydrochloride, Dried Chicory Root, Tomatoes, Blueberries, Raspberries, Chondroitin Sulfate, Yucca Schidigera Extract, Dried Lactobacillus Acidophilus Fermentation Product, Dried Bifidobacterium Animalis Fermentation Product, Dried Lactobacillus Reuteri Fermentation Product, Vitamin E Supplement, Beta Carotene, Iron Proteinate, Zinc Proteinate, Copper Proteinate, Ferrous Sulfate, Zinc Sulfate, Copper Sulfate, Potassium Iodide, Thiamine Mononitrate (Vitamin B1), Manganese Proteinate, Manganous Oxide, Ascorbic Acid, Vitamin A Supplement, Biotin, Niacin, Calcium Pantothenate, Manganese Sulfate, Sodium Selenite, Pyridoxine Hydrochloride (Vitamin B6), Vitamin B12 Supplement, Riboflavin (Vitamin B2), Vitamin D Supplement, Folic Acid.

Petcurean Now Fresh; LID unknown; Raw patties:

Example only: Petcurean Now Fresh Grain Free Adult dog food recipe

De-boned turkey, potato flour, peas, apples, whole dried egg, pea fibre, tomato, potatoes, flaxseed, canola oil (preserved with mixed tocopherols), natural flavour, salmon, de-boned duck, sundried alfalfa, coconut oil (preserved with mixed tocopherols), carrots, pumpkin, bananas, blueberries, cranberries, raspberries, blackberries, papayas, pineapple, grapefruit, lentil beans, broccoli, spinach, cottage cheese, alfalfa sprouts, calcium carbonate, dicalcium phosphate, lecithin, sodium chloride, potassium chloride, vitamins (vitamin E supplement, L-ascorbyl-2-polyphosphate (a source of vitamin C), **B4** vitamin A supplement, thiamine mononitrate, d-calcium pantothenate, pyridoxine hydrochloride, riboflavin, beta-carotene, vitamin D3 supplement, folic acid, biotin, vitamin B12 supplement), minerals (zinc proteinate, ferrous sulphate, zinc oxide, iron proteinate, copper sulphate, copper proteinate,

manganese proteinate, manganous oxide, calcium iodate, selenium yeast), taurine, DL-methionine, L-lysine, dried chicory root, dried Lactobacillus acidophilus fermentation product, dried Enterococcus faecium fermentation product, yucca schidigera extract, dried rosemary.

Example 2: Petcurean Now Fresh Fish Recipe for Adult Dogs

De-boned trout, whole dried egg, potatoes, potato flour, peas, pea flour, apples, flaxseed, canola oil (preserved with mixed tocopherols), natural flavour, de-boned salmon, de-boned herring, calcium carbonate, dicalcium phosphate, coconut oil (preserved with mixed tocopherols), tomato, alfalfa, carrots, pumpkin, sweet potatoes, squash, bananas, blueberries, cranberries, blackberries, pomegranate, papayas, lentils, broccoli, dried chicory root, sodium chloride, potassium chloride, choline chloride, vitamins (vitamin A supplement, vitamin D3 supplement, vitamin E supplement, B4 niacin, L-ascorbyl-2-polyphosphate (a source of vitamin C), d-calcium pantothenate, thiamine mononitrate, beta-carotene, riboflavin, pyridoxine hydrochloride, folic acid, biotin, vitamin B12 supplement), minerals (zinc proteinate, iron proteinate, copper proteinate, zinc oxide, manganese proteinate, copper sulphate, ferrous sulphate, calcium iodate, manganous oxide, selenium yeast), taurine, DL-methionine, L-lysine, dried Lactobacillus acidophilus fermentation product, dried Enterococcus faecium fermentation product, dried rosemary.

Example 3: LID version with venison:

De-boned venison, venison meal, tapioca, peas, pea flour, lentils, chickpeas, canola oil (preserved with mixed tocopherols), dried chicory root, sodium chloride, algae extract, potassium chloride, choline chloride, vitamins (vitamin A supplement, vitamin D3 supplement, vitamin E supplement, B4 niacin, L-ascorbyl-2-polyphosphate (a source of vitamin C), d-calcium pantothenate, thiamine mononitrate, beta-carotene, riboflavin, pyridoxine hydrochloride, folic acid, biotin, vitamin B12 supplement), minerals (zinc proteinate, iron proteinate, copper proteinate, zinc oxide, manganese proteinate, copper sulphate, ferrous sulphate, calcium iodate, manganous oxide, selenium yeast), DL-methionine, L-lysine, dried rosemary.

Ingredient definitions:

Pea Fiber: An insoluble fibre source that helps to regulate glucose levels, and promotes digestive health

Pea Flour: A source of complex carbohydrates, soluble and insoluble fiber

Peas: A good source of beta-carotene, niacin, Vitamin B6, folate, phosphorus and copper, and a very good source of dietary fibre, Vitamin C, Vitamin K, thiamin and manganese

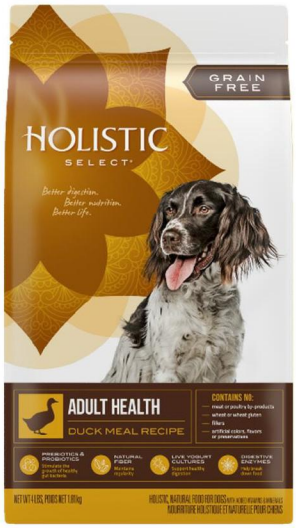
Lentils: A low glycemic carbohydrate that is also a good source of protein, iron, phosphorus and copper, and a very good source of dietary fibre, folate and manganese

Flaxseed: A source of Omega 3 and 6, naturally preserved, as well as fibre

Supreme Source Salmon Meal and Sweet Potato:

Salmon Meal, Peas, Lentils, Faba Beans, Sweet Potatoes, Poultry Fat (Preserved with Mixed Tocopherols), Chickpeas, Tomato Pomace, Dicalcium Phosphate, Natural Flavor, Salmon Oil (Preserved with Mixed Tocopherols), Salt, Dried Seaweed Meal (Ascophyllum nodosum), Calcium Carbonate, Betaine, Choline Chloride, Carrots, Blueberries, Cranberries, Spinach, Parsley, Pomegranates, Vitamin E Supplement, Zinc Oxide, Zinc Proteinate, Ferrous Sulfate, Vitamin A Supplement, d-Calcium Pantothenate, Manganous Oxide, Niacin Supplement, Riboflavin Supplement, Thiamine Mononitrate, Copper Sulfate, Pyridoxine Hydrochloride, Manganese Proteinate, Vitamin D3 Supplement, Calcium Iodate, Copper Proteinate, Folic Acid, Biotin, Sodium Selenite, Vitamin B12 Supplement, Cobalt Carbonate, Rosemary Extract.

Holistic Select GF Adult Health Duck Meal Recipe:



Duck Meal, Chickpeas, Peas, Lentils, Chicken Fat (preserved with Mixed Tocopherols), Dried Plain Beet Pulp, Flaxseed, Pumpkin, Cranberries, Apples, Brewers Dried Yeast, Papayas, Choline Chloride, Blueberries, Pomegranates, Vitamin E Supplement, Inulin, Dried Kelp, Zinc Proteinate, Mixed Tocopherols added to preserve freshness, Zinc Sulfate, Niacin, Ferrous Sulfate, Iron Proteinate, Vitamin A Supplement, Yucca Schidigera Extract, Glucosamine Hydrochloride, Ascorbic Acid (Vitamin C), Ground Cinnamon, Ground Fennel, Ground Peppermint, Copper Sulfate, Thiamine Mononitrate, Copper Proteinate, Manganese Proteinate, Manganese Sulfate, d-Calcium Pantothenate, Sodium Selenite, Dried Enterococcus faecium Fermentation Product, Pyridoxine Hydrochloride, Riboflavin, Vitamin D3 Supplement, Biotin, Dried Lactobacillus bulgaricus Fermentation Product, Dried Enterococcus thermophilus Fermentation Product, Calcium Iodate, Vitamin B12 Supplement, Folic Acid, Dried Bacillus licheniformis Fermentation Product, Dried Bacillus subtilis Fermentation Product, Dried Aspergillus oryzae Fermentation Product, Dried Trichoderma reesei Fermentation Product, Dried Rhizopus oryzae Fermentation Product, Dried Lactobacillus acidophilus Fermentation Product, Dried Lactobacillus casei Fermentation Product, Rosemary Extract, Green Tea Extract, Spearmint Extract.

Canidae LID Duck, Bison, Boar flavors:

Duck, duck meal, turkey meal, sweet potatoes, peas, chicken fat (preserved with mixed tocopherols), potatoes, suncured alfalfa, natural flavor, minerals (iron proteinate, zinc proteinate, copper proteinate,

ferrous sulfate, zinc sulfate, copper sulfate, potassium iodide, manganese proteinate, manganous oxide, manganese sulfate, sodium selenite), vitamins (vitamin E supplement, thiamine mononitrate, ascorbic acid, vitamin A supplement, biotin, niacin, calcium pantothenate, pyridoxine hydrochloride, vitamin B12 supplement, riboflavin, vitamin D3 supplement, folic acid), choline chloride, mixed tocopherols (a preservative), dried enterococcus faecium fermentation product, dried lactobacillus acidophilus fermentation product, dried lactobacillus casei fermentation product, dried lactobacillus plantarum fermentation product, dried trichoderma longibrachiatum fermentation extract

Bison, lamb meal, sweet potatoes, peas, chickpeas, canola oil, suncured alfalfa, natural flavor, minerals (iron proteinate, zinc proteinate, copper proteinate, ferrous sulfate, zinc sulfate, copper sulfate, potassium iodide, manganese proteinate, manganous oxide, manganese sulfate, sodium selenite), vitamins (vitamin E supplement, thiamine mononitrate, ascorbic acid, vitamin A supplement, biotin, niacin, calcium pantothenate, pyridoxine hydrochloride, vitamin B12 supplement, riboflavin, vitamin D3 supplement, folic acid), choline chloride, mixed tocopherols (a preservative), dried enterococcus faecium fermentation product, dried lactobacillus acidophilus fermentation product, dried lactobacillus casei fermentation product, dried lactobacillus plantarum fermentation product, dried trichoderma longibrachiatum fermentation extract

Wild boar, pork meal, sweet potatoes, peas, chickpeas, canola oil, suncured alfalfa, natural flavor, minerals (iron proteinate, zinc proteinate, copper proteinate, ferrous sulfate, zinc sulfate, copper sulfate, potassium iodide, manganese proteinate, manganous oxide, manganese sulfate, sodium selenite), vitamins (vitamin E supplement, thiamine mononitrate, ascorbic acid, vitamin A supplement, biotin, niacin, calcium pantothenate, pyridoxine hydrochloride, vitamin B12 supplement, riboflavin, vitamin D3 supplement, folic acid), choline chloride, mixed tocopherols (a preservative), dried enterococcus faecium fermentation product, dried lactobacillus acidophilus fermentation product, dried lactobacillus casei fermentation product, dried lactobacillus plantarum fermentation product, dried trichoderma longibrachiatum fermentation extract

Merrick GF Buffalo Sw P (same case as above):

Deboned Buffalo, Chicken Meal, Sweet Potatoes, Turkey Meal, Salmon Meal, Potatoes, Peas, Chicken Fat (preserved with mixed tocopherols), Natural Pork Flavor, Lamb Meal, Pea Protein, Deboned Beef, Natural Chicken Flavor, Deboned Salmon, Deboned Turkey, Deboned Chicken, Flaxseed Oil, Apples,

Blueberries, Organic Alfalfa, Salmon Oil, Salt, Minerals (Zinc Amino Acid Complex, Zinc Sulfate, Iron Amino Acid Complex, Manganese Amino Acid Complex, Copper Amino Acid Complex, Potassium Iodide, Cobalt Amino Acid Complex, Sodium Selenite), Vitamins (Vitamin E Supplement, Vitamin A Supplement, Vitamin B12 Supplement, d-Calcium Pantothenate, Vitamin D3 Supplement, Niacin, Riboflavin Supplement, Biotin, Pyridoxine Hydrochloride, Folic Acid, Thiamine Mononitrate), Choline Chloride, Yucca Schidigera Extract, Dried Lactobacillus plantarum Fermentation Product, Dried Lactobacillus casei Fermentation Product, Dried Enterococcus faecium Fermentation Product, Dried Lactobacillus acidophilus Fermentation Product, Rosemary Extract.

Purina ONE Lamb and Rice: 1 case, has corn, soy and wheat, NOT GF. No peas, but Lamb/Rice known in past as issue.

Lamb (source of glucosamine), brewer's rice, whole grain corn, whole grain wheat, poultry by-product meal (source of glucosamine), corn gluten meal, soybean meal, animal fat preserved with mixed-tocopherols, calcium phosphate, glycerin, animal digest, calcium carbonate, potassium chloride, salt, caramel color, Vitamin E supplement, choline chloride, zinc sulfate, L-Lysine monohydrochloride, ferrous sulfate, sulfur, manganese sulfate, niacin, Vitamin A supplement, calcium pantothenate, thiamine mononitrate, copper sulfate, riboflavin supplement, Vitamin B-12 supplement, pyridoxine hydrochloride, garlic oil, folic acid, Vitamin D-3 supplement, calcium iodate, biotin, menadione sodium bisulfite complex (source of Vitamin K activity), sodium selenite.

Taste of the Wild Pacific Stream Canine Formula:

Salmon, ocean fish meal, sweet potatoes, potatoes, peas, canola oil, lentils, salmon meal, smoked salmon, potato fiber, natural flavor, salt, choline chloride, dried chicory root, tomatoes, blueberries, raspberries, yucca schidigera extract, dried Lactobacillus plantarum fermentation product, dried Bacillus subtilis fermentation product, dried Lactobacillus acidophilus fermentation product, dried Enterococcus faecium fermentation product, dried Bifidobacterium animalis fermentation product, vitamin E supplement, iron proteinate, zinc proteinate, copper proteinate, ferrous sulfate, zinc sulfate, copper sulfate, potassium iodide, thiamine mononitrate (vitamin B1), manganese proteinate, manganous oxide, ascorbic acid, vitamin A supplement, biotin, niacin, calcium pantothenate, manganese sulfate, sodium selenite, pyridoxine hydrochloride (vitamin B6), vitamin B12 supplement, riboflavin (vitamin B2), vitamin D supplement, folic acid.

Acana Lamb & Apple Limited Ingredient:

Deboned lamb*, lamb meal, whole green peas, red lentils, lamb liver*, lamb fat, pinto beans, chickpeas, herring oil, green lentils, whole yellow peas, lentil fiber, apples*, natural lamb flavor, lamb tripe*, lamb kidney*, lamb cartilage*, dried kelp, whole pumpkin*, whole butternut squash*, kale,* spinach*, mustard greens*, collard greens*, turnip greens*, carrots*, pears*, freeze-dried lamb liver, freeze-dried lamb tripe, pumpkin seeds, sunflower seeds, zinc proteinate, mixed tocopherols (preservative), chicory root, turmeric, sarsaparilla root, althea root, rosehips, juniper berries, dried lactobacillus acidophilus fermentation product, dried bifidobacterium animalis fermentation product, dried lactobacillus casei fermentation product.

Nature's Variety Instinct Limited Ingredient Diet Lamb Meal and Peas:

Only Lamb LID now sold is Instinct LID GF Lamb.

Lamb Meal, Peas, Tapioca, Pea Protein, Canola Oil (preserved with Mixed Tocopherols and Citric Acid), Lamb, Natural Flavor, Montmorillonite Clay, Coconut Oil, Salt, Vitamins (Vitamin E Supplement, L-Ascorbyl-2-Polyphosphate, Niacin Supplement, Thiamine Mononitrate, d-Calcium Pantothenate, Vitamin A Supplement, Riboflavin Supplement, Pyridoxine Hydrochloride, Vitamin B12 Supplement, Folic Acid, Vitamin D3 Supplement, Biotin), Potassium Chloride, Choline Chloride, DL-Methionine, Minerals (Zinc Proteinate, Iron Proteinate, Copper Proteinate, Manganese Proteinate, Sodium Selenite, Ethylenediamine Dihydriodide), Freeze Dried Lamb, Pumpkinseeds, Freeze Dried Lamb Liver, Freeze Dried Lamb Spleen, Freeze Dried Lamb Heart, Freeze Dried Lamb Kidney, Rosemary Extract.

Roll over image to zoom in

Hill's U/D Urinary Care:

Ingredients - Dry

Brewers Rice, Corn Starch, Pork Fat, Egg Product, Powdered Cellulose, Chicken Liver Flavor, Flaxseed,

Lactic Acid, Potassium Citrate, Soybean Oil, Calcium Carbonate, L-Lysine, Iodized Salt, Choline Chloride, vitamins (Vitamin E Supplement, Niacin Supplement, Thiamine Mononitrate, Vitamin A Supplement, Calcium Pantothenate, Biotin, Vitamin B12 Supplement, Pyridoxine Hydrochloride, Riboflavin Supplement, Folic Acid , Vitamin D3 Supplement), Dried Beet Pulp, L-Threonine, Taurine, minerals (Ferrous Sulfate, Zinc Oxide, Manganous Oxide, Copper Sulfate, Calcium Iodate, Sodium Selenite), L-Carnitine, L-Tryptophan, Mixed Tocopherols for freshness, Natural Flavors, Beta-Carotene

Ingredients – Canned

Water, Corn Starch, Egg Product, Chicken Fat, Pork Liver, Sugar, Rice, Powdered Cellulose, Flaxseed, Potassium Citrate, Calcium Carbonate, Choline Chloride, Monosodium Phosphate, vitamins (Vitamin E Supplement, Thiamine Mononitrate, Niacin Supplement, Calcium Pantothenate, Vitamin B12 Supplement, Pyridoxine Hydrochloride, Biotin, Riboflavin Supplement, Vitamin D3 Supplement, Folic Acid), L-Lysine, Iodized Salt, Magnesium Oxide, minerals (Manganese Sulfate, Zinc Oxide, Ferrous Sulfate, Copper Sulfate, Calcium Iodate), Taurine, L-Carnitine, Beta-Carotene.

EVO Grain-Free Turkey and Chicken Formula Cat food:

Turkey, Chicken, Chicken Meal, Tapioca Starch, Chicken Fat (Preserved with Mixed Tocopherols, a Source of Vitamin E), Herring, Pea Fiber, Salmon Meal, Natural Flavors, Potassium Chloride, Apples, Eggs, Carrots, Menhaden Oil, Peas, Cranberries, Alfalfa Sprouts, Pumpkin, Tomatoes, Cottage Cheese, Dried Chicory Root Extract, Minerals (Zinc Proteinate, Iron Proteinate, Copper Proteinate, Manganese Proteinate, Calcium Iodate), DL-Methionine, Vitamins (Betaine Hydrochloride, Niacin Supplement, Vitamin A Supplement, Thiamine Mononitrate, Calcium Pantothenate, Riboflavin Supplement, Beta Carotene, Vitamin B12 Supplement, Vitamin D3 Supplement, Biotin, Pyridoxine Hydrochloride, Folic Acid), Taurine, Ascorbic Acid, Vitamin E Supplement Direct Fed Microbials (Dried Enterococcus faecium, Dried Lactobacillus acidophilus, Dried Lactobacillus casei) Rosemary Extract

Merrick Purrfect Bistro Grain-free Real Chicken Recipe:

Deboned Chicken, Chicken Meal, Turkey Meal, Dried Potatoes, Peas, Natural Pork Flavor, Potato Protein, Powdered Cellulose, Chicken Fat (preserved with mixed tocopherols), Natural Chicken Flavor, Sweet Potatoes, Ground Flaxseed, Dried Egg Product, Chicken Liver, Dried Whey Protein Concentrate, Organic Alfalfa, Cranberries, Phosphoric Acid, Flaxseed Oil (source of Omega 3 fatty acids), Salt, Minerals (Zinc

Sulfate, Iron Amino Acid Complex, Zinc Amino Acid Complex, Manganese Amino Acid Complex, Copper Amino Acid Complex, Potassium Iodide, Cobalt Amino Acid Complex, Sodium Selenite), Vitamins (Vitamin E Supplement, Vitamin A Acetate, Vitamin B12 Supplement, d-Calcium Pantothenate, Vitamin D3 Supplement, Niacin, Riboflavin Supplement, Biotin, Pyridoxine Hydrochloride, Folic Acid, Thiamine Mononitrate), Choline Chloride, Taurine, Yucca Schidigera Extract, Dried Bacillus coagulans Fermentation Product, Rosemary Extract, Dried Lactobacillus plantarum Fermentation Product, Dried Lactobacillus casei Fermentation Product, Dried Enterococcus faecium Fermentation Product, Dried Lactobacillus acidophilus Fermentation Product.

Rachael Ray Nutrish: no flavor variety given, so try several. All qualify as GF – in that no corn, wheat or soy.

Ingredients – chicken and brown rice (Salmon & Brown Rice; Chicken w/ Lentils & Salmon; Chicken w/ chickpeas & Salmon; Turkey w Chickpeas & Salmon)

Nutrish Chicken & Brown Rice

Chicken, Chicken Meal, Corn Gluten Meal, Ground Rice, Brown Rice, Poultry Fat (Preserved with Mixed Tocopherols), Brewer's Dried Yeast, Natural Flavor, Dried Plain Beet Pulp, Potassium Chloride, Choline Chloride, Iron Oxide (color), Dried Ground Peas, Dried Carrots, Olive Oil, Taurine, Vitamin E Supplement, Zinc Sulfate, Salt, Ferrous Sulfate, Calcium Carbonate, Niacin, L-Ascorbyl-2-Polyphosphate (Source of Vitamin C), Manganese Sulfate, Copper Sulfate, Vitamin A Supplement, Thiamine Mononitrate, d-Calcium Pantothenate, Sodium Selenite, Riboflavin Supplement, Pyridoxine Hydrochloride (Source of Vitamin B6), Biotin, Menadione Sodium Bisulfite Complex (Source of Vitamin K Activity), Vitamin B12 Supplement, Folic Acid, Vitamin D3 Supplement, Cobalt Sulfate, Potassium Iodide.

Nutrish Salmon & Brown Rice:

Salmon, Ground Rice, Corn Gluten Meal, Fish Meal, Brown Rice, Poultry Fat (Preserved with Mixed Tocopherols), Brewer's Dried Yeast, Dried Ground Peas, Pea Protein, Natural Flavor, Salmon Meal, Dried Plain Beet Pulp, Calcium Carbonate, Choline Chloride, Iron Oxide (color), Dried Carrots, Olive Oil,

Taurine, Salt, Vitamin E Supplement, Zinc Sulfate, Ferrous Sulfate, Niacin, L-Ascorbyl-2-Polyphosphate (Source of Vitamin C), Manganese Sulfate, Copper Sulfate, Vitamin A Supplement, Thiamine Mononitrate, d-Calcium Pantothenate, Sodium Selenite, Riboflavin Supplement, Pyridoxine Hydrochloride (Source of Vitamin B6), Biotin, Menadione Sodium Bisulfite Complex (Source of Vitamin K Activity), Vitamin B12 Supplement, Folic Acid, Vitamin D3 Supplement, Cobalt Sulfate, Potassium Iodide.

Nutrish Chicken w/ Chickpeas & Salmon

Chicken, Chicken Meal, Dried Peas, Brewer's Rice, Corn Protein Concentrate, Dried Chickpeas, Chicken Fat (Preserved with Mixed Tocopherols), Salmon, Dried Plain Beet Pulp, Natural Flavor, Dicalcium Phosphate, Menhaden Fish Meal, Dried Cranberries, Salt, Menhaden Fish Oil (Preserved with Mixed Tocopherols), Potassium Chloride, Choline Chloride, Taurine, Iron Oxide (Color), Dried Blueberry, Dried Pumpkin, Vitamin E Supplement, L-Ascorbyl-2-Polyphosphate (Source of Vitamin C), Zinc Sulfate, Ferrous Sulfate, Calcium Carbonate, Niacin, Dried Dandelion, Manganese Sulfate, Copper Sulfate, Vitamin A Supplement, Thiamine Mononitrate, d-Calcium Pantothenate, Biotin, Sodium Selenite, Riboflavin Supplement, Pyridoxine Hydrochloride (Source of Vitamin B6), Menadione Sodium Bisulfite Complex (Source of Vitamin K Activity), Vitamin B12 Supplement, Folic Acid, Vitamin D3 Supplement, Potassium Iodide.

Nutrish Lentils and Salmon:

Chicken, Chicken Meal, Corn Gluten Meal, Dried Ground Peas, Lentils, Pea Protein, Poultry Fat (Preserved with Mixed Tocopherols), Dried Plain Beet Pulp, Powdered Cellulose, Salmon, Ground Rice, Natural Flavor, Salt, Choline Chloride, Iron Oxide (color), Taurine, Dried Cranberry, Dried Blueberry, Dried Pumpkin, Vitamin E Supplement, Zinc Sulfate, Ferrous Sulfate, Calcium Carbonate, Niacin, L-Ascorbyl-2-Polyphosphate (Source of Vitamin C), Dandelion, Manganese Sulfate, Copper Sulfate, Vitamin A Supplement, Thiamine Mononitrate, d-Calcium Pantothenate, Sodium Selenite, Riboflavin Supplement, Pyridoxine Hydrochloride (Source of Vitamin B6), Biotin, Menadione Sodium Bisulfite Complex (Source of Vitamin K Activity), Vitamin B12 Supplement, Folic Acid, Vitamin D3 Supplement, Cobalt Sulfate, Potassium Iodide.

Nutrish Zero Grain Chicken:

Chicken, Chicken Meal, Dried Ground Peas, Whole Dried Potato, Pea Protein, Chicken Fat (Preserved with Mixed Tocopherols), Tapioca, Natural Flavor, Dried Egg Product, Cranberries, Whole Flaxseed, Dried Plain Beet Pulp, Salt, Choline Chloride, Taurine, DL-Methionine, Vitamin E Supplement, Zinc Sulfate, Ferrous Sulfate, Calcium Carbonate, Niacin, L-Ascorbyl-2-Polyphosphate (Source of Vitamin C), Manganese Sulfate, Copper Sulfate, Vitamin A Supplement, Thiamine Mononitrate, d-Calcium Pantothenate, Sodium Selenite, Riboflavin Supplement, Pyridoxine Hydrochloride (Source of Vitamin B6), Biotin, Menadione Sodium Bisulfite Complex (Source of Vitamin K Activity), Vitamin B12 Supplement, Folic Acid, Vitamin D3 Supplement, Cobalt Sulfate, Potassium Iodide.

Nutrish Zero Grain Whitefish:

Whitefish, Salmon Meal, Fish Meal, Turkey Meal, Dried Peas, Tapioca, Poultry Fat (Preserved with Mixed Tocopherols), Whole Dried Potatoes, Dried Egg Product, Pea Protein, Turkey, Natural Fish Flavor, Salt, Dried Plain Beet Pulp, Whole Flaxseed, Dried Carrots, Choline Chloride, Potassium Chloride, Dried Cranberry, Taurine, Vitamin E Supplement, Zinc Sulfate, Ferrous Sulfate, Niacin, L-Ascorbyl-2-

Polyphosphate (Source of Vitamin C), Manganese Sulfate, Copper Sulfate, Vitamin A Supplement, Thiamine Mononitrate, d-Calcium Pantothenate, Sodium Selenite, Riboflavin Supplement, Pyridoxine Hydrochloride (Source of Vitamin B6), Biotin, Menadione Sodium Bisulfite Complex (Source of Vitamin K activity), Vitamin B12 Supplement, Folic Acid, Vitamin D3 Supplement, Cobalt Sulfate, Potassium Iodide.

Nutrish Woodland Recipe:

Chicken, Chicken Meal, Menhaden Fish Meal, Dried Peas, Pea Protein, Salmon Meal, Chicken Fat (Preserved with Mixed Tocopherols), Tapioca, Turkey Meal, Dried Egg Product, Dried Sweet Potato, Salmon, Trout, Natural Flavor, Salt, Dried Plain Beet Pulp, Choline Chloride, Vitamin E Supplement, Zinc Sulfate, Taurine, Calcium Carbonate, Ferrous Sulfate, Niacin, Dried Dandelion, L-Ascorbyl-2-Polyphosphate (Source of Vitamin C), Manganese Sulfate, Copper Sulfate, Vitamin A Supplement, Thiamine Mononitrate, d-Calcium Pantothenate, Biotin, Sodium Selenite, Riboflavin Supplement, Pyridoxine Hydrochloride (Source of Vitamin B6), Menadione Sodium Bisulfate Complex (Source of Vitamin K Activity), Vitamin B12 Supplement, Folic Acid, Potassium Iodide, Vitamin D3 Supplement.

FOR COMPARISON ONLY:

IAMS Proactive Health dry dog food:

Chicken, Chicken By-Product Meal, Ground Whole Grain Corn, Ground Whole Grain Sorghum, Chicken Fat (preserved with mixed Tocopherols), Dried Beet Pulp, Natural Flavor, Dried Egg Product, Potassium Chloride, Flaxseed, Caramel Color, L-Lysine Monohydrochloride, Salt, Sodium Hexametaphosphate, Choline Chloride, Carrots, Tomatoes, Fructooligosaccharides, Spinach, Green Peas, Minerals (Ferrous Sulfate, Zinc Oxide, Sodium Selenite, Manganese Sulfate, Copper Sulfate, Manganous Oxide, Potassium Iodide), Calcium Carbonate, Vitamins (Vitamin E Supplement, Ascorbic Acid, Calcium Pantothenate, Vitamin A Supplement, Biotin, Thiamine Mononitrate (source of Vitamin B1), Vitamin B12 supplement, Niacin, Riboflavin Supplement (source of Vitamin B2), Inositol, Pyridoxine Hydrochloride (source of Vitamin B6), Vitamin D3 Supplement, Folic Acid), Dried Brewers Yeast, DL-Methionine, Dried Apple Pomace, L-Carnitine , Dried Blueberry Pomace, Mixed Tocopherols, Rosemary Extract.

Purina Dog Chow Little Bites w/ Chicken and Beef:

Whole grain corn, corn gluten meal, meat and bone meal, soybean meal, beef fat naturally preserved with mixed-tocopherols, poultry by-product meal, whole grain wheat, chicken, beef, poultry and pork digest, ground rice, salt, calcium carbonate, potassium chloride, L-Lysine monohydrochloride, choline chloride, mono and dicalcium phosphate, **MINERALS** [zinc sulfate, ferrous sulfate, manganese sulfate, copper sulfate, calcium iodate, sodium selenite], **VITAMINS** [Vitamin E supplement, niacin (Vitamin B-3), Vitamin A supplement, calcium pantothenate (Vitamin B-5), pyridoxine hydrochloride (Vitamin B-6), Vitamin B-12 supplement, thiamine mononitrate (Vitamin B-1), Vitamin D-3 supplement, riboflavin supplement (Vitamin B-2), menadione sodium bisulfite complex (Vitamin K), folic acid (Vitamin B-9), biotin (Vitamin B-7)], Yellow 6, Yellow 5, Red 40, Blue 2, garlic oil. K-4120

Pedigree Adult Roasted Chicken, Rice and Vegetable Flavor:

Ground Whole Grain Corn, Meat And Bone Meal (Source Of Calcium), Corn Gluten Meal, Animal Fat (Source Of Omega 6 [Preserved With Bha & Citric Acid]), Soybean Meal, Natural Flavor, Chicken By-Product Meal, Dried Plain Beet Pulp, Ground Whole Grain Wheat, Salt, Potassium Chloride, Brewers Rice, Choline Chloride, Dried Peas, Calcium Carbonate, Zinc Sulfate, Dl-Methionine, Vitamin E Supplement, Niacin [Vitamin B3], Biotin, Dried Carrots, L-Tryptophan, Bha & Citric Acid (A Preservative), Blue 2, Yellow 5, Yellow 6, D-Calcium Pantothenate [Source Of Vitamin B5], Riboflavin Supplement [Vitamin B2], Red 40, Pyridoxine Hydrochloride [Vitamin B6], Copper Sulfate, Sodium Selenite, Potassium Iodide, Vitamin A Supplement, Thiamine Mononitrate [Vitamin B1], Vitamin B12 Supplement, Vitamin D3 Supplement, Folic Acid

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Document properties

Author: Palmer, Lee Anne
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FDA-CVM-FOIA-2019-1704-010040

From: Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>
To: Burkholder, William
Sent: 5/17/2018 4:22:14 PM
Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets
Attachments: 800.267-Covance-control Cys-Met-Tau.xlsx; DCM-Case Report Analysis-5.17.2018.xls

I was amazed myself. B5

B5

The Covance results are attached. Do you agree?

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421
U.S. FOOD & DRUG ADMINISTRATION

From: Burkholder, William
Sent: Thursday, May 17, 2018 12:13 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

B5

From: Jones, Jennifer L
Sent: Thursday, May 17, 2018 11:29 AM
To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

B5

Please see the PPT for the rationale/summary

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421
U.S. FOOD & DRUG ADMINISTRATION

From: Rotstein, David
Sent: Monday, May 14, 2018 10:22 AM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>
Subject: RE: DCM and meetign with Cardiac Care for Pets

B5 Once we get a better handle on a specific cause, we can work on that.

From: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>
Date: May 14, 2018 at 9:09:17 AM EDT
To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>, Rotstein, David <David.Rotstein@fda.hhs.gov>, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>, Carey, Lauren <Lauren.Carey@fda.hhs.gov>, Norris, Anne <Anne.Norris@fda.hhs.gov>, DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>, Lovell, Randall A <Randall.Lovell@fda.hhs.gov>
Subject: RE: DCM and meetign with Cardiac Care for Pets

This is very interesting. B5

B5

Martine

From: Palmer, Lee Anne
Sent: Friday, May 11, 2018 4:30 PM
To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>
Subject: RE: DCM and meetign with Cardiac Care for Pets

B5

From: Rotstein, David
Sent: Friday, May 11, 2018 4:14 PM
To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>
Subject: RE: DCM and meetign with Cardiac Care for Pets

Lee Anne,

This is fantastic. B5

B5

From: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Date: May 11, 2018 at 4:06:05 PM EDT
To: Rotstein, David <David.Rotstein@fda.hhs.gov>, Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>, Carey, Lauren <Lauren.Carey@fda.hhs.gov>, Norris, Anne <Anne.Norris@fda.hhs.gov>, DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>, Lovell, Randall A <Randall.Lovell@fda.hhs.gov>
Subject: RE: DCM and meetign with Cardiac Care for Pets

Hi there – it is still VERY ROUGH (will final it up next week sometime) – B5

B5

I'll final this up next week, have to get to other things yet today. Have a great weekend! J Lee Anne

B5

From: Rotstein, David
Sent: Wednesday, May 9, 2018 4:13 PM
To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Subject: RE: DCM and meetign with Cardiac Care for Pets

Sounds very intriguing!!!

From: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Date: May 9, 2018 at 4:09:18 PM EDT
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>, Rotstein, David <David.Rotstein@fda.hhs.gov>, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>, Carey, Lauren <Lauren.Carey@fda.hhs.gov>, Norris, Anne <Anne.Norris@fda.hhs.gov>, DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Subject: RE: DCM and meetign with Cardiac Care for Pets

B5

From: Hartogensis, Martine
Sent: Wednesday, May 9, 2018 2:17 PM
To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Subject: RE: DCM and meetign with Cardiac Care for Pets

Awesome, thank you Dave!

Martine

From: Rotstein, David
Sent: Wednesday, May 09, 2018 2:06 PM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Subject: RE: DCM and meetign with Cardiac Care for Pets

Good Afternoon,

I spoke with B6 @ Cardiac Care for Pets. He is going to look into times/dates with the cardiologists there and we can set the meeting up from that point.

B5

As a side note, there is a facebook page dedicated to this issue:

https://www.facebook.com/groups/1952593284998859/about/

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
CVM OSC/DC/CERT
7519 Standish Place
240-506-6763 (BB)

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From: Hartogensis, Martine
Sent: Tuesday, May 08, 2018 10:58 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Subject: RE: DCM

Thank you Jen and Dave! Very interesting and sounds like you all are on it! The resident I spoke to was Dr. B6

B6

Keep us posted!

Thanks again!

Martine

Hi Martine,

B5

I'm happy to share more info as needed.
Jen

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421

From: Rotstein, David
Sent: Tuesday, May 08, 2018 9:45 AM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: RE: DCM

Martine,

Jen and I spoke with cardiologists from NCSU and a few other institutions. That's how we were able to get the information.

B5

Looping in Jen.

Thanks for the update!

dave

David Rotstein, DVM, MPVM, Dipl. ACVP

CVM Vet-LIRN Liaison
CVM OSC/DC/CERT
7519 Standish Place
240-506-6763 (BB)

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From: Hartogensis, Martine
Sent: Tuesday, May 08, 2018 9:00 AM
To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Subject: RE: DCM

Thank you Dave! We did not go around yesterday because the Vet-LIRN folks came in for their routine presentation.

B5

B5

Martine

From: Rotstein, David
Sent: Monday, May 07, 2018 1:13 PM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>
Subject: Re: DCM

Martine

B5

There's a way to go on this moving forward.

Dave

From: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>

Date: May 7, 2018 at 1:03:13 PM EDT
To: Rotstein, David <David.Rotstein@fda.hhs.gov>
Subject: DCM

Hi Dave!

Do you have any more details on the DCM and grain free diet issue?

Martine

DOCUMENT PRODUCED IN NATIVE

DOCUMENT PRODUCED IN NATIVE

From: Andrea Fascetti <ajfascetti@ucdavis.edu>
To: B6
CC: Guag, Jake; Jones, Jennifer L
Sent: 3/23/2019 5:30:04 PM
Subject: Re: Heads up: Vet-LIRN (FDA) shipped 800.267 samples
Attachments: 14Cases__FDA_BL_PL_Urine.xlsx

Hello Jen and Jake- Please see attached file with your results. Thanks for the heads-up on the species. We have to know in case someone in the lab comes in contact with the blood (especially through a cut). Our occupational health and safety folks then have us file a report and follow up on those cases to ensure vaccination status etc.

We will bill according to your comments below.

Have a nice weekend.

Andrea

On Mar 21, 2019, at 10:51 AM, B6 wrote:

Hi Jake,

May you help to confirm the samples are for dogs or cats? I could not find the information

Thanks,
B6

From: Guag, Jake <Jake.Guag@fda.hhs.gov>
Sent: Tuesday, March 12, 2019 8:53 AM
To: B6
Cc: Jones, Jennifer L
Subject: Heads up: Vet-LIRN (FDA) shipped 800.267 samples

Hi B6
Hope you are well. We shipped 800.267 samples on dry ice to you.
Box#1 has urine samples its tracking number is 1ZA4420T0194520315 with UPS.
Box#2 has whole blood and serum samples and its tracking number is 1ZA4420T0192121929 with UPS. Both boxes are expected to arrive your location tomorrow (Mar. 13th, 2019)

Please charge the urine sample analysis under AA contract.
Please provide invoice for the blood and serum analysis.

Thank you
Jake

Jake Guag, MPH, CPH
Biologist (FDA/CVM/OR/Vet-LIRN)
8401 Muirkirk Road
Laurel, Maryland 20708
Email: jake.guag@fda.hhs.gov
Tel: 240-402-0917

Number	EON#	CC	Date Died	Owner	Dog Name	Age	Sex	Breed	Necro Location	Full tissues	Kogia?	Necropsy Results	Read	Dog kg	Frs heart kg	Fix heart kg	Special Stains	IHC
1	362724	020				2 yr	MI	Cane Corso		No	No	ty; subjectively enlarged heart; r	No	73.6				
2	362570	155				5 yr	FS	Retriever		Recuts?	No	d grossly, RV and LV dilated and	No	26.8				
3	361131	125				3 yr	FS	Great Dane		Recuts?	No	consistent with DCM. Moderate	No	59.4				
4	359970	142				4 yr	MI	Golden retriever		Recuts, some	No	ocal jet lesion; LV and RV eccentr	Slides	36.0				
5	360887	085				4 yr	FI	Samoyed		Yes	1-Nov	ed on gross examination; heart r	x	18.2			none	
6	362158	128				5 yr	MC	Pug		Yes	30-Nov	ity, roughened liver capsule, sof	x	7.4			none	
7	364330	104				8 yr	FS	Mixed breed hound		Yes	1-Nov	e, enlarged heart esp RV free wa	x	17.2			none	
8	364393	004				6 yr	F	German shepherd		Yes	1-Nov	initial abdominal incision of skin	x	~45			none	
9	361694	092				6 yr	MC	Pit bull		Yes	1-Nov	lungs. Enlarged, thin walled char	x	33.0			none	
10	359942	122				13 yr	MC	Rat terrier		Yes	30-Nov	attachment. Colon partially strict	x	9.2			none	
11	365660	110				6 yr	MC	Rottweiler		Yes	1-Nov	firm and pink, heart appeared e	x	~46.3			Alcian Blue	cytokeratin, vimentin, Factor VIII, insulin-like growth factor II mRNA-binding protein 3 and glucose transporter 1
12	367073	cv06				3 yr	MC	Labrador retriever		Yes	30-Nov	lungs pink and mottled; other o	x	32.7			PAS, Giemsa, / Toxo, Neospora, Sarcocystis, Lyme	
13	361685	002				3 yr	FS	Mixed breed		Yes	30-Nov	No report submitted	x	~18			none	
14	370801	cv03				6 yr	MC	German shepherd		No	12-Apr	Heart only-no report	x	~32.3				
15	323515	136				3 yr	MC	Schnauzer		No	No	mod-marked pulm edema; mild	No	8.2				
16	373371	264				6 yr	MC	Mixed breed husky		No	No	severe lung expansion w/ red-p	No	42.6				
17	375111	210				5 yr	MI	Golden retriever		No	12-Apr	Heart only-no report	x	29.2				
18	364014	191				12 yr	MC	Labrador retriever		No	12-Apr	Heart only-no report	x	~44.4			oil red O, sudan Black, Alcian blue	
19	374145	183				9 yr	MN	Terrier mix		Yes	12-Apr	Serosanguinous pleural/abd flui	x	8.4			Trichrome	
20	364610	295				4 yr	FS	Golden retriever		Yes	25-Jun	ic congestion, R lung normal; en	x	28				
21	386113	296				3 yr	MN	Great Dane		No	No	Heart slide recuts only	x	81				
22	380743	297				8 yr	MN	Bulldog		No	19-Jun	Heart only-no report	x					
23	CC-157454	298				1.5 yr	MN	Hound mix		Yes	25-Jun	Samples only-no report	x					
24	388261	299				4 yr	MN	Boxer mix		No	19-Jun	Heart only-no report	x					
25	380742	297				8.5 yr	FS	Bulldog		Yes	19-Jun	No report submitted	x					
26	389861	300				2 yr	MN	DSH		No	Partial	Heart only-no report	x					
27		301						Mixed breed		No	No	Sample archive only						

B6

B6

Not Kogia

Final premortem dx
Echo dx...DCM etc
Tau def, yes no
Cut-in necropsy remarks

FDA-CVM-FOIA-2019-1704-010053

Report Details - EON-358519

ICSR:	2051555	
Type Of Submission:	Initial	
Report Version:	FPSR.FDA.PETF.V.V1	
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)	
Reporting Type:	Voluntary	
Report Submission Date:	2018-07-09 08:43:16 EDT	
Reported Problem:	**Problem Description:**	Diagnosed with LV cavity dilation and reduced contractile function
	Date Problem Started:	06/20/2018
	Concurrent Medical Problem:	Yes
	Pre Existing Conditions:	B6
	Outcome to Date:	Unknown
Product Information:	**Product Name:**	Earthborn Coastal Catch dry
	Product Type:	Pet Food
	Lot Number:	
	Package Type:	BAG
	Product Use Information:	
	Manufacturer /Distributor Information:	
	Purchase Location Information:	
Animal Information:	**Name:**	B6
	Type Of Species:	Dog
	Type Of Breed:	Boxer (German Boxer)
	Gender:	Female
	Reproductive Status:	Neutered
	Weight:	33.2 Kilogram
	Age:	7.6 Years
	Number of Animals Reacted:	1
	Owner Information:	**Owner Information provided:** Yes
		Contact: **Name:** B6
		Phone:
		Address: B6 United States
	Healthcare Professional Information:	**Practice Name:** Tufts Cummings School of Veterinary Medicine
		Contact: **Name:** Lisa Freeman
		Phone: (508) 887-4523
		Email: lisa.freeman@tufts.edu
		Address: 200 Westboro Rd North Grafton Massachusetts 01536 United States
Sender Information:	**Name:**	Lisa Freeman

FDA-CVM-FOIA-2019-1704-010054

	Address:	200 Westboro Rd North Grafton Massachusetts 01536 United States
	Contact:	**Phone:** 5088874523 **Email:** lisa.freeman@tufts.edu
	Permission To Contact Sender:	Yes
	Preferred Method Of Contact:	Email
	Reported to Other Parties:	None
Additional Documents:		

From: Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>
To: Carey, Lauren
Sent: 7/12/2018 12:11:43 PM
Subject: RE: Earthborn Coastal Catch dry: Lisa Freeman - EON-358519

Thanks!

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421
U.S. FOOD & DRUG ADMINISTRATION

From: Carey, Lauren
Sent: Thursday, July 12, 2018 8:00 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: FW: Earthborn Coastal Catch dry: Lisa Freeman - EON-358519

"Missing" DCM report from the most recent group.

From: PFR Event [mailto:pfreventcreation@fda.hhs.gov]
Sent: Monday, July 09, 2018 8:52 AM
To: Cleary, Michael * <Michael.Cleary@fda.hhs.gov>; HQ Pet Food Report Notification <HQPetFoodReportNotification@fda.hhs.gov>; B6
Subject: Earthborn Coastal Catch dry: Lisa Freeman - EON-358519

A PFR Report has been received and PFR Event [EON-358519] has been created in the EON System.

A "PDF" report by name "2051555-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report:

EON Key: EON-358519
ICSR #: 2051555
EON Title: PFR Event created for Earthborn Coastal Catch dry; 2051555

AE Date	06/20/2018	**Number Fed/Exposed**	
Best By Date		**Number Reacted**	1
Animal Species	Dog	**Outcome to Date**	Unknown
Breed	Boxer (German Boxer)		
Age	7.6 Years		
District Involved	PFR-New England DO		

Product information
Individual Case Safety Report Number: 2051555
Product Group: Pet Food
Product Name: Earthborn Coastal Catch dry
Description: Diagnosed with LV cavity dilation and reduced contractile function
Submission Type: Initial
Report Type: Adverse Event (a symptom, reaction or disease associated with the product)
Outcome of reaction/event at the time of last observation: Unknown
Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Earthborn Coastal Catch dry		

Sender information
Lisa Freeman
200 Westboro Rd
North Grafton, MA 01536
USA

Owner information
B6
USA

To view this PFR Event, please click the link below:
https://eon.fda.gov/eon//browse/EON-358519

To view the PFR Event Report, please click the link below:
https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jspa?decorator=none&e=0&issueType=12&issueId=375143

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From: Freeman, Lisa <Lisa.Freeman@tufts.edu>
To: Jones, Jennifer L
Sent: B6 8:12:33 PM
Subject: B6

Hi Jen
Wanted to let you know that B6 died unexpectedly due to B6 yesterday while eating. Owner said he had been doing well and we were going to do a recheck in Feb.
So sad ☹
Lisa

Lisa M. Freeman, DVM, PhD, DACVN
Board Certified Veterinary Nutritionist™
Professor
Cummings School of Veterinary Medicine
Friedman School of Nutrition Science and Policy
Tufts Clinical and Translational Science Institute
Tufts University
www.petfoodology.org

From: Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>
To: 'Freeman, Lisa'
Sent: 1/28/2019 3:02:04 PM
Subject: RE: B6

Thank you for the update, Lisa. I'm sorry to hear that he passed away. Can you please forward the records for his case?

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421
U.S. FOOD & DRUG ADMINISTRATION

From: Freeman, Lisa <Lisa.Freeman@tufts.edu>
Sent: Sunday, B6 3:13 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: B6

Hi Jen
Wanted to let you know that B6 died unexpectedly due to B6 yesterday while eating. Owner said he had been doing well and we were going to do a recheck in Feb.
So sad ☹
Lisa

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From: Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>
To: 'Freeman, Lisa'
Sent: 8/22/2018 4:53:34 PM
Subject: RE: updates

Hi Lisa,
I don't have the report in our records from B6. If she submitted one and has an ICSR number, we can track it down.

Also, I had our team check for reports for B6 and B6 but there weren't any. Are you also able to send those along with records?

Thank you again for all of your efforts gathing the records, getting permission for interviews with owners, and submitting these complaints. You've been a great help to the investigation!!
Jen

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421
U.S. FOOD & DRUG ADMINISTRATION

From: Freeman, Lisa [mailto:Lisa.Freeman@tufts.edu]
Sent: Tuesday, August 21, 2018 10:56 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: RE: updates

Hi Jen
Actually, B6 from B6 submitted B6 If you don't have that one, let me know and I can submit
Owner would be very happy to talk to you
Thanks
Lisa

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Tufts Clinical and Translational Science Institute
Tufts University
www.petfoodology.org

From: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Sent: Tuesday, August 21, 2018 10:46 AM
To: Freeman, Lisa <lisa.freeman@tufts.edu>
Subject: RE: updates

Thank you, Lisa.
We're going to send you the box this week with 7 whirl-pak bags. Each bag will be labelled for the dog and our internal identifier number (EON-XXXXXX). Please fill the bags with the respective food. I've calculated the return weight based on filling 7 bags full.

Also, I have the medical records for B6, but did you submit a pet food report for him? I'm wondering if I didn't see it on our end.

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421

U.S. FOOD & DRUG ADMINISTRATION

From: Freeman, Lisa [mailto:Lisa.Freeman@tufts.edu]
Sent: Monday, August 20, 2018 6:18 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: updates

Hi Jen
I forgot to note on the report I submitted today that I have a food sample and UPC code for the Acana food that the 2 Dobies were eating.

Also, for B6, whose heart has improved significantly, I just got a sample from the owner who found some food remaining at her summer house – it is not fresh but I'm saving for you in case you want
Thanks
Lisa

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From: Freeman, Lisa <Lisa.Freeman@tufts.edu>
To: Jones, Jennifer L
Sent: 8/23/2018 10:42:57 AM
Subject: B6
Attachments: B6 cardio report 2-9-18.pdf; B6 cardio report 2-21-18.pdf; B6 cardio report 8-17-18.pdf; B6 compiled hx.pdf; B6 discharge 2-9-18.pdf; B6 discharge 2-21-18.pdf; B6 discharge 4-9-18.pdf; B6 discharge 8-17-18.pdf; B6 radiology 2-9-18.pdf

Note that this owner did not change to the recommended diet. Just rechecked and heart is much worse. I'm going to try again to get her to switch!
B6 email is: B6
Lisa

Lisa M. Freeman, DVM, PhD, DACVN
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Tufts Clinical and Translational Science Institute
Tufts University
www.petfoodology.org

From: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Sent: Wednesday, August 22, 2018 12:54 PM
To: Freeman, Lisa <lisa.freeman@tufts.edu>
Subject: RE: updates

Hi Lisa,
I don't have the report in our records from B6. If she submitted one and has an ICSR number, we can track it down.

Also, I had our team check for reports for B6 and B6 but there weren't any. Are you also able to send those along with records?

Thank you again for all of your efforts gathing the records, getting permission for interviews with owners, and submitting these complaints. You've been a great help to the investigation!!
Jen

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421
U.S. FOOD & DRUG ADMINISTRATION

From: Freeman, Lisa [mailto:Lisa.Freeman@tufts.edu]
Sent: Tuesday, August 21, 2018 10:56 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: RE: updates

Hi Jen
Actually, B6 from B6 submitted B6. If you don't have that one, let me know and I can submit
Owner would be very happy to talk to you

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Tufts Clinical and Translational Science Institute
Tufts University
www.petfoodology.org

From: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Sent: Tuesday, August 21, 2018 10:46 AM
To: Freeman, Lisa <lisa.freeman@tufts.edu>
Subject: RE: updates

Thank you, Lisa.
We're going to send you the box this week with 7 whirl-pak bags. Each bag will be labelled for the dog and our internal identifier number (EON-XXXXXX). Please fill the bags with the respective food. I've calculated the return weight based on filling 7 bags full.

Also, I have the medical records for B6 , but did you submit a pet food report for him? I'm wondering if I didn't see it on our end.

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421

From: Freeman, Lisa [mailto:Lisa.Freeman@tufts.edu]
Sent: Monday, August 20, 2018 6:18 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: updates

Hi Jen
I forgot to note on the report I submitted today that I have a food sample and UPC code for the Acana food that the 2 Dobies were eating.

Also, for B6 whose heart has improved significantly, I just got a sample from the owner who found some food remaining at her summer house – it is not fresh but I'm saving for you in case you want
Thanks
Lisa

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Cummings
Veterinary Medical Center
AT TUFTS UNIVERSITY
Cardiology Liaison: 508-887-4696

B6

Patient ID: 412374
B6 Canine
Years Old Male (Neutered) Labrador Retriever
Black BW: Weight(lbs) 0.00

Cardiology Consultation

Date: 2/9/2018
Weight: Weight(lbs) 98
Patient location: ICU
Requesting Clinician: B6 (Resident, Emergency & Critical Care)

Attending Cardiologist:
☐ John E. Rush DVM, MS, DACVIM (Cardiology), DACVECC

B6

Cardiology Resident:

B6

Thoracic radiographs available for review?
☐ Yes - in SS
☑ Yes - in PACS
☐ No

Presenting complaint and important concurrent diseases:
Difficulty breathing, increased heart rate and lethargy since last night after running in the afternoon. Diagnosed with

Current medications and doses:

B6

Key indication for consultation: (murmur, arrhythmia, needs fluids, etc.):
In CHF - has arrhythmia, pulmonary edema, increased size of left ventricle and right atrium.
EKG: VPCs, Afib, tachycardia

Questions to be answered from the Consult:
Reasonable expectations for future and quality of life? Dog is very high energy and o has difficulty restraining.

Is your consult time-sensitive? (e.g., anesthesia today, owner waiting, trying to get biopsy today)
☐ Yes (explain)
☑ No

STOP - remainder of form to be filled out by Cardiology

Physical Examination

B6

Muscle condition:

- ☑ Normal
- ☐ Mild muscle loss
- ☐ Moderate cachexia
- ☐ Marked cachexia

Cardiovascular Physical Exam

Murmur Grade: difficult to ascult due to panting

- ☐ None
- ☐ I/VI
- ☐ II/VI
- ☐ III/VI
- ☐ IV/VI
- ☐ V/VI
- ☐ VI/VI

Murmur location/description:

Jugular vein: difficult to assess due to panting

- ☐ Bottom 1/3 of neck
- ☐ Middle 1/3 of neck
- ☐ Top 2/3 of neck

Arterial pulses:

- ☐ Weak
- ☑ Fair
- ☐ Good
- ☐ Strong
- ☐ Bounding
- ☐ Pulse deficits
- ☐ Pulsus paradoxus
- ☐ Other (describe):

Arrhythmia:

- ☑ None
- ☐ Sinus arrhythmia
- ☐ Premature beats
- ☐ Bradycardia
- ☐ Tachycardia

Gallop:

- ☐ Yes
- ☑ No
- ☐ Intermittent
- ☐ Pronounced
- ☐ Other:

Pulmonary assessments:

- ☐ Eupneic
- ☑ Mild dyspnea
- ☐ Marked dyspnea
- ☐ Normal BV sounds
- ☐ Pulmonary Crackles
- ☐ Wheezes
- ☐ Upper airway stridor
- ☐ Other auscultatory findings:

Abdominal exam:

- ☑ Normal
- ☐ Hepatomegaly
- ☐ Abdominal distension
- ☐ Mild ascites

Echocardiogram Findings:

General/2-D findings:

B6

Doppler findings:

1+ MR

ECG findings:

B6

Radiographic findings:

B6

Assessment and recommendations:

DCM with clinical signs consistent with CHF. We recommend continuing with B6 increasing B6 (if he is actually on a higher dose) given the concern of the renal values. We will recheck his arrhythmia on his 2 week recheck to decide at that time if an anti-arrhythmic medication is indicated when his heart failure is under control. We will also recheck his renal values at that time.

Final Diagnosis:

DCM with CHF and ventricular arrhythmia

Heart Failure Classification Score:

ISACHC Classification:

- ☐ Ia
- ☐ Ib
- ☐ II
- ☑ IIIa
- ☐ IIIb

ACVIM CHF Classification:

- ☐ A
- ☐ B1
- ☐ B2
- ☑ C
- ☐ D

M-Mode		
IVSd	B6	cm
LVIDd		cm
LVPWd		cm
IVSs		cm
LVIDs		cm
LVPWs		cm
%FS		%
Ao Diam		cm
LA Diam		cm
LA/Ao		
Max LA		cm

EPSS		cm
M-Mode Normalized		
IVSdN		(0.29 - 0.52) !
LVIDdN		(1.35 - 1.73) !
LVPWdN		(0.33 - 0.53)
IVSsN		(0.43 - 0.71) !
LVIDsN		(0.79 - 1.14) !
LVPWsN		(0.53 - 0.78)
Ao Diam N		(0.68 - 0.89)
LA Diam N		(0.64 - 0.90) !
2D		
SA LA		cm
Ao Diam		cm
SA LA / Ao Diam		
Doppler		
AV Vmax		m/s
AV maxPG		mmHg

B6

Cummings
Veterinary Medical Center
AT TUFTS UNIVERSITY
Cardiology Liaison: 508-887-4696

B6

Patient ID: 412374
B6 Canine
Years Old Male (Neutered) Labrador Retriever
Black

Cardiology Appointment Report

Date: 2/21/2018

Attending Cardiologist:
John E. Rush DVM, MS, DACVIM (Cardiology), DACVECC

B6

Cardiology Resident:
B6

Cardiology Technician:
B6

Student:
B6 V18

Presenting Complaint:
Recheck DCM with CHF

Concurrent Diseases:
None

General Medical History:
O thinks he is doing better. No more gagging like he was doing prior to ER visit. RR was 30-35 first few days after ER visit and now has been 20-25/min. More hesitant to go up stairs. No coughing or collapses. Appetite is good and normal eliminations. O thinks there is a secondary process happening in the neck. Has a mass on neck that has never been aspirated. Has a history of positional snorting/snoring. O interested in carnitine and CoQu-10. O interested in immuno-booster.

Diet and Supplements:
Feeding kibbles (Canidae with duck or bison) with chicken breast and yams

B6

Cardiovascular History:
Prior CHF diagnosis? Yes

Prior ATE? No
Prior arrhythmia? Yes, episodes of VPCs, ventricular bigeminy
Cough? No
Shortness of breath or difficulty breathing? Increased RR/RE and gagging episodes
Syncope or collapse? No
Sudden onset lameness? No
Exercise intolerance? More hesitant to go upstairs
Prior heart murmur? Difficult to assess

Current Medications Pertinent to CV System:

B6

Need refills?

Cardiac Physical Examination:

B6

Muscle condition:

- ☐ Normal
- ☑ Mild muscle loss
- ☐ Moderate cachexia
- ☐ Marked cachexia

Cardiovascular Physical Exam:

Murmur Grade: difficult to assess due to breathing and temperament

- ☐ None
- ☐ I/VI
- ☐ II/VI
- ☐ III/VI
- ☐ IV/VI
- ☐ V/VI
- ☐ VI/VI

Murmur location/description:

Jugular vein: difficult to assess due to breathing and temperament

- ☐ Bottom 1/3 of neck
- ☐ Middle 1/3 of neck
- ☐ Top 2/3rd of neck

Arterial pulses:

- ☐ Weak
- ☐ Fair
- ☐ Bounding
- ☐ Pulse deficits

- [x] Good
- [ ] Strong
- [ ] Pulsus paradoxus
- [ ] Other:

Arrhythmia:
- [ ] None
- [ ] Sinus arrhythmia
- [ ] Premature beats
- [ ] Bradycardia
- [x] Tachycardia

Gallop:
- [ ] Yes
- [x] No
- [ ] Intermittent
- [ ] Pronounced
- [ ] Other:

Pulmonary assessments:
- [x] Eupneic
- [ ] Mild dyspnea
- [ ] Marked dyspnea
- [ ] Normal BV sounds
- [ ] Pulmonary crackles
- [ ] Wheezes
- [ ] Upper airway stridor

Abdominal exam:
- [x] Normal
- [ ] Hepatomegaly
- [ ] Abdominal distension
- [ ] Mild ascites
- [ ] Marked ascites

Problems:
DCM with no active CHF
Upper airway noise: r/o nasal (neoplasia vs FB) vs laryngeal (lar par) vs tracheal mass

Diagnostic plan:
- [ ] Echocardiogram
- [ ] Chemistry profile
- [ ] ECG
- [x] Renal profile
- [ ] Blood pressure
- [ ] Dialysis profile
- [ ] Thoracic radiographs
- [ ] NT-proBNP
- [ ] Troponin I
- [ ] Other tests:

Echocardiogram Findings:
General/2-D findings:
not performed today

Assessment and recommendations:
Patient appears to be breathing comfortably. We will be rechecking his renal values today. The upper airway noise does not appear to be associated with the heart disease (RR remains in the 20s at home, and the video that the owner recorded showed him breathing comfortably and resting while making the snorting sound). This is likely an upper airway noise, which is also not related to the lipoma at the sternum. Continue with the current medication doses. Nutrition consultation is scheduled for tomorrow. Recheck echocardiogram, ECG, and renal values in 3-4 months.

Final Diagnosis:
DCM with history of LCHF

Heart Failure Classification Score:
ISACHC Classification:
- [ ] Ia
- [ ] IIIa

- [ ] Ib
- [x] II
- [ ] IIIb

ACVIM Classification:

- [ ] A
- [ ] B1
- [ ] B2
- [x] C
- [ ] D

From: Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>
To: 'Freeman, Lisa'
Sent: 8/23/2018 1:18:30 PM
Subject: RE: B6

Thank you, Lisa. If the owner has questions about submitting a pet food report, I can answer them.

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421

U.S. FOOD & DRUG ADMINISTRATION

From: Freeman, Lisa [mailto:Lisa.Freeman@tufts.edu]
Sent: Thursday, August 23, 2018 6:43 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: B6

Note that this owner did not change to the recommended diet. Just rechecked and heart is much worse. I'm going to try again to get her to switch!
B6
Lisa

Lisa M. Freeman, DVM, PhD, DACVN
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Cummings School of Veterinary Medicine
Friedman School of Nutrition Science and Policy
Tufts Clinical and Translational Science Institute
Tufts University
www.petfoodology.org

From: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Sent: Wednesday, August 22, 2018 12:54 PM
To: Freeman, Lisa <lisa.freeman@tufts.edu>
Subject: RE: updates

Hi Lisa,
I don't have the report in our records from B6 If she submitted one and has an ICSR number, we can track it down.

Also, I had our team check for reports for B6 and B6 but there weren't any. Are you also able to send those along with records?

Thank you again for all of your efforts gathing the records, getting permission for interviews with owners, and submitting these complaints. You've been a great help to the investigation!!
Jen

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421

U.S. FOOD & DRUG ADMINISTRATION

From: Freeman, Lisa [mailto:Lisa.Freeman@tufts.edu]
Sent: Tuesday, August 21, 2018 10:56 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: RE: updates

Hi Jen
Actually, B6 from B6 submitted B6. If you don't have that one, let me know and I can submit
Owner would be very happy to talk to you
Thanks
Lisa

Lisa M. Freeman, DVM, PhD, DACVN
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From: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Sent: Tuesday, August 21, 2018 10:46 AM
To: Freeman, Lisa <lisa.freeman@tufts.edu>
Subject: RE: updates

Thank you, Lisa.
We're going to send you the box this week with 7 whirl-pak bags. Each bag will be labelled for the dog and our internal identifier number (EON-XXXXXX). Please fill the bags with the respective food. I've calculated the return weight based on filling 7 bags full.

Also, I have the medical records for B6, but did you submit a pet food report for him? I'm wondering if I didn't see it on our end.

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421

U.S. FOOD & DRUG ADMINISTRATION

From: Freeman, Lisa [mailto:Lisa.Freeman@tufts.edu]
Sent: Monday, August 20, 2018 6:18 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: updates

Hi Jen
I forgot to note on the report I submitted today that I have a food sample and UPC code for the Acana food that the 2 Dobies were eating.

Also, for B6, whose heart has improved significantly, I just got a sample from the owner who found some food remaining at her summer house – it is not fresh but I'm saving for you in case you want
Thanks

Lisa

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From: Freeman, Lisa <Lisa.Freeman@tufts.edu>
To: Peloquin, Sarah
Sent: 10/21/2018 10:40:14 PM
Subject: question on fda pet food reports re dcm

Dear Sarah
I'm trying to confirm whether the following cases were received by the FDA. I'm nearly positive I reported them but don't see them in my list of submitted cases on the FDA reporting portal. Could you confirm?

- B6

Many thanks
Lisa

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From: Freeman, Lisa
Sent: Saturday, September 15, 2018 10:28 AM
To: Peloquin, Sarah <Sarah.Peloquin@fda.hhs.gov>
Subject: RE: 800.267 FDA Case Investigation for B6 (EON-364568) and B6 (EON-365002)

Hi Sarah,
B6 is fine with you contacting her. Email is best for initial contact
B6
Please let me know if you need more info on this case
Thanks
Lisa

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From: Peloquin, Sarah <Sarah.Peloquin@fda.hhs.gov>
Sent: Friday, September 14, 2018 9:51 AM
To: Freeman, Lisa <lisa.freeman@tufts.edu>
Cc: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: RE: 800.267 FDA Case Investigation for B6 (EON-364568) and B6 (EON-365002)

Hi Lisa, thanks so much for passing those along. Sorry for the multiple emails—it looks like we've received everything we need for these two.

Please let me know when you confirm permission to contact B6 owner.

Thanks!
Sarah

From: Freeman, Lisa <Lisa.Freeman@tufts.edu>
Sent: Friday, September 14, 2018 9:44 AM
To: Peloquin, Sarah <Sarah.Peloquin@fda.hhs.gov>
Subject: RE: 800.267 FDA Case Investigation for B6 (EON-364568) and B6 (EON-365002)

Hi Sarah
I sent additional records on B6 directly to Dr. Jones since there were too many to upload individually. I think that should have everything you need on him but if not, please let me know
The owner is happy to talk to you.

Attached are RDVM records on B6 I also have a food sample for her. I'll need to confirm it's ok to contact
Thanks
Lisa

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From: Peloquin, Sarah <Sarah.Peloquin@fda.hhs.gov>
Sent: Friday, September 14, 2018 9:36 AM
To: Freeman, Lisa <lisa.freeman@tufts.edu>
Subject: 800.267 FDA Case Investigation for B6 (EON-364568) and B6 (EON-365002)

Good morning Dr. Freeman,

Thank you for submitting a few more consumer complaints to FDA!

As part of our investigation, we'd like to request:

- **Full Medical Records**
  - Please email (preferred) or fax (301-210-4685) copies of B6 **entire** medical history (not just this event), including any referral diagnostics/records.
    - If you do not have primary vet records, do you mind sending us the primary vets' contact info?
    - We have received the cardio records you attached to the reports.
- **Owner phone interview** about B6 diet and environmental exposures
  - Please confirm permission to contact the owners.
  - The interview generally lasts 30 minutes.

I have attached a copy of our Vet-LIRN network procedures. The procedures describe how Vet-LIRN operates and how veterinarians help with our case investigations. I have also attached an owner-friendly version.

Please respond to this email so that we can initiate our investigation.

Thank you kindly,

Dr. Peloquin

Sarah K. Peloquin, DVM
Veterinary Medical Officer

U.S. Food & Drug Administration
Center for Veterinary Medicine
Veterinary Laboratory Investigation and Response Network
tel: 240-402-1218
fax: 301-210-4685
e-mail: sarah.peloquin@fda.hhs.gov

From: Peloquin, Sarah </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8607f880df2b494aa639e6d9a3874132-Sarah.Peloq>
To: 'Freeman, Lisa'
CC: Jones, Jennifer L
Sent: 10/24/2018 11:45:31 AM
Subject: RE: question on fda pet food reports re dcm

Hi Lisa,

I see that we have records for B6 and B6 from this August, but no reports. I don't see anything for B6 I'll double check with my team and get back to you.

Thanks for all of your help!
Sarah

From: Freeman, Lisa <Lisa.Freeman@tufts.edu>
Sent: Sunday, October 21, 2018 6:40 PM
To: Peloquin, Sarah <Sarah.Peloquin@fda.hhs.gov>
Subject: question on fda pet food reports re dcm

Dear Sarah
I'm trying to confirm whether the following cases were received by the FDA. I'm nearly positive I reported them but don't see them in my list of submitted cases on the FDA reporting portal. Could you confirm?

- B6

Many thanks
Lisa

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Hi Sarah,
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From: Peloquin, Sarah <Sarah.Peloquin@fda.hhs.gov>
Sent: Friday, September 14, 2018 9:51 AM
To: Freeman, Lisa <lisa.freeman@tufts.edu>
Cc: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: RE: 800.267 FDA Case Investigation for B6 (EON-364568) and B6 (EON-365002)

Hi Lisa, thanks so much for passing those along. Sorry for the multiple emails—it looks like we've received everything we need for these two.

Please let me know when you confirm permission to contact B6 owner.

Thanks!
Sarah

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Subject: RE: 800.267 FDA Case Investigation for B6 (EON-364568) and B6 (EON-365002)

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Thanks
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From: Peloquin, Sarah <Sarah.Peloquin@fda.hhs.gov>
Sent: Friday, September 14, 2018 9:36 AM
To: Freeman, Lisa <lisa.freeman@tufts.edu>
Subject: 800.267 FDA Case Investigation for B6 EON-364568) and B6 (EON-365002)

Good morning Dr. Freeman,

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- **Full Medical Records**
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    - If you do not have primary vet records, do you mind sending us the primary vets' contact info?
    - We have received the cardio records you attached to the reports.
- **Owner phone interview** about B6 diet and environmental exposures
  - Please confirm permission to contact the owners.
  - The interview generally lasts 30 minutes.

I have attached a copy of our Vet-LIRN network procedures. The procedures describe how Vet-LIRN operates and how veterinarians help with our case investigations. I have also attached an owner-friendly version.

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Thank you kindly,

Dr. Peloquin

Sarah K. Peloquin, DVM
Veterinary Medical Officer

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tel: 240-402-1218
fax: 301-210-4685
e-mail: sarah.peloquin@fda.hhs.gov

From: Peloquin, Sarah </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8607f880df2b494aa639e6d9a3874132-Sarah.Peloq>
To: Palmer, Lee Anne; Rotstein, David; Carey, Lauren
Sent: 10/24/2018 11:49:25 AM
Subject: 800.267 DCM -- did we get reports from these cases?

Did we receive PER reports from any of the following cases from Tufts?

- B6

Let me know. Thanks!!

Sarah K. Peloquin, DVM
Veterinary Medical Officer

U.S. Food & Drug Administration
Center for Veterinary Medicine
Veterinary Laboratory Investigation and Response Network
tel: 240-402-1218
fax: 301-210-4685
e-mail: sarah.peloquin@fda.hhs.gov

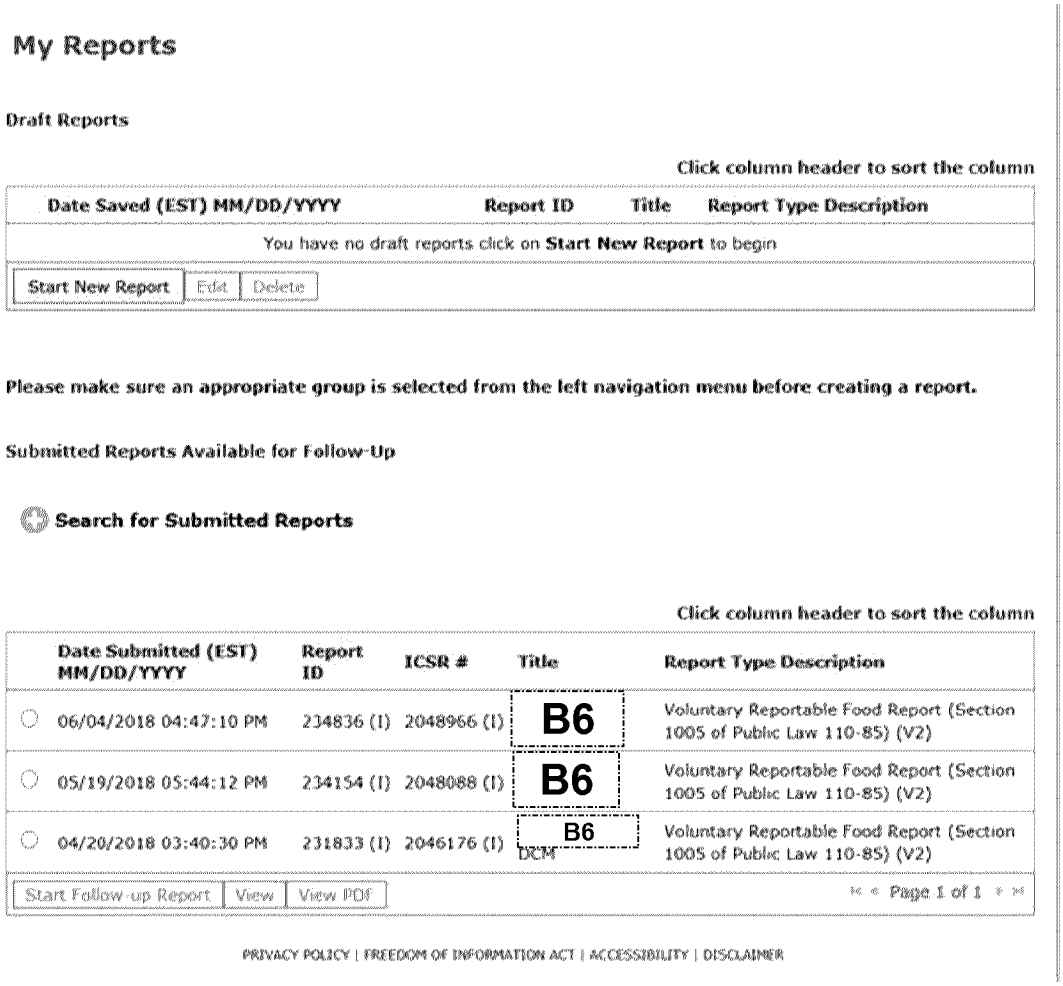
From: Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>
To: 'Freeman, Lisa'
Sent: 11/7/2018 3:11:20 PM
Subject: RE: reported cases

Hi Lisa,
We have all of the cases you listed below except B6 It's fine to send me the additional records for the cases
Thank you for your tireless efforts at getting us the information.
It's greatly appreciated!!
Jen

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421
U.S. FOOD & DRUG ADMINISTRATION

From: Freeman, Lisa <Lisa.Freeman@tufts.edu>
Sent: Monday, October 01, 2018 3:51 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: reported cases

Hi Jen
I was looking through which cases I've submitted (have a bunch more to add) and saw that 3 were in a separate account and there a few that are not showing up as having been reported.
1. Could you check to see that these 3 are listed as having been reported?



My Reports

Draft Reports

Click column header to sort the column

Date Saved (EST) MM/DD/YYYY	Report ID	Title	Report Type Description
You have no draft reports click on **Start New Report** to begin			

Start New Report | Edit | Delete

Please make sure an appropriate group is selected from the left navigation menu before creating a report.

Submitted Reports Available for Follow-Up

Search for Submitted Reports

Click column header to sort the column

	Date Submitted (EST) MM/DD/YYYY	Report ID	ICSR #	Title	Report Type Description
○	06/04/2018 04:47:10 PM	234836 (I)	2048966 (I)	B6	Voluntary Reportable Food Report (Section 1005 of Public Law 110-85) (V2)
○	05/19/2018 05:44:12 PM	234154 (I)	2048088 (I)	B6	Voluntary Reportable Food Report (Section 1005 of Public Law 110-85) (V2)
○	04/20/2018 03:40:30 PM	231833 (I)	2046176 (I)	B6 DCM	Voluntary Reportable Food Report (Section 1005 of Public Law 110-85) (V2)

Start Follow-up Report | View | View PDF

« Page 1 of 1 »

PRIVACY POLICY | FREEDOM OF INFORMATION ACT | ACCESSIBILITY | DISCLAIMER

2. Also, I have a 3 others that are not listed in my account but I'm pretty sure I reported. If not, I'll get them submitted:

3. I keep sending you the extra medical records that won't fit in the reporting portal. Is there someone else I should send these to so I don't keep clogging your inbox?

Many thanks
Lisa

Lisa M. Freeman, DVM, PhD, DACVN
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Report Details - EON-372606

ICSR:	2059540	
Type Of Submission:	Initial	
Report Version:	FPSR.FDA.PETF.V.V1	
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)	
Reporting Type:	Voluntary	
Report Submission Date:	2018-12-03 09:27:13 EST	
Reported Problem:	**Problem Description:**	Littermate diagnosed with DCM. Initial taurine level (plasma only) was B6 WB taurine submitted = B6 Eats BEG diet Mildly reduced contractile function on echo NT-proBNP = B6 troponin mildly elevated at B6 (istat) and B6 at B6 B6 Will recheck in 3-4 months
	Date Problem Started:	11/08/2018
	Concurrent Medical Problem:	Yes
	Pre Existing Conditions:	Chronic diarrhea Hx of anaplasmosis
	Outcome to Date:	Stable
Product Information:	**Product Name:**	Acana Lamb and Apple singles
	Product Type:	Pet Food
	Lot Number:	
	Package Type:	BAG
	Product Use Information:	**Description:** Fed since 2016
	Manufacturer /Distributor Information:	
	Purchase Location Information:	
Animal Information:	**Name:**	B6
	Type Of Species:	Dog
	Type Of Breed:	Irish Wolfhound
	Gender:	Male
	Reproductive Status:	Intact
	Weight:	82.7 Kilogram
	Age:	3 Years
	Assessment of Prior Health:	Good
	Number of Animals Given the Product:	1
	Number of Animals Reacted:	1
	Owner Information:	**Owner Information provided:** Yes
		Contact: **Name:** B6
		Phone: B6
		Email: B6
		Address: B6 United States
	Healthcare Professional Information:	**Practice Name:** Tufts Cummings School of Veterinary Medicine
		Contact: **Name:** Lisa Freeman
		Phone: (508) 887-4523

FDA-CVM-FOIA-2019-1704-010086

		Email:	lisa.freeman@tufts.edu
		Address:	200 Westboro Rd North Grafton Massachusetts 01536 United States

Sender Information:	**Name:**	Lisa Freeman	
	Address:	200 Westboro Rd North Grafton Massachusetts 01536 United States	
	Contact:	**Phone:**	5088874523
		Email:	lisa.freeman@tufts.edu
	Permission To Contact Sender:	Yes	
	Preferred Method Of Contact:	Email	

Additional Documents:	**Attachment:**	**B6**	compiled records.pdf
	Description:	Medical records	
	Type:	Medical Records	

FDA-CVM-FOIA-2019-1704-010087

Client: B6
Patient:

IDEXX BNP - 3/5/2019

IDEXX Reference Laboratories

Client: B6 Patient: B6

IDEXX VetConnect 1-888-433-9987

Client: B6
Patient:
Species: CANINE
Breed:
Gender: MALE
Age: 3Y

Date: B6
Requisition #: 337144
Accession #: B6
Ordered by: FREEMAN

TUFTS UNIVERSITY
200 WESTBORO RD
NORTH GRAFTON, Massachusetts 01536
508-839-5395

Account #88933

CARDIOPET proBNP - CANINE

Test	Result	Reference Range	Low	Normal	High
CARDIOPET proBNP - CANINE	B6	0 - 900 pmol/L	HIGH	B6	

Comments:
1

B6

Please note: Complete interpretive comments for all concentrations of Cardiopet proBNP are available in the online directory of services. Serum specimens received at room temperature may have decreased NT-proBNP concentrations.

Page 1 of 1

FDA-CVM-FOIA-2019-1704-010088

Client:
Patient: B6

Texas A and M Troponin

Gastrointestinal Laboratory
Dr. J.M. Steiner
Department of Small Animal Clinical Sciences
Texas A&M University
4474 TAMU
College Station, TX 77843-4474

Website User ID: clinpath@tufts.edu

GI Lab Assigned Clinic ID: 11405

Dr. Freeman
Tufts University-Clinical Pathology Lab
Attn: B6
200 Westboro Road
North Grafton, MA 01536
USA

Phone: 508 887 4669
Fax: 9 508 839 7936
Animal Name: B6
Owner Name:
Species: Canine
Date Received: Mar 06, 2019

Tufts University-Clinical Pathology Lab
Tracking Number: 337144

GI Lab Accession: B6

Test	Result	Reference Interval	Assay Date
Ultra-Sensitive Troponin I Fasting	B6 ng/mL	≤0.06	B6

B6

Comments:

GI Lab Contact Information

Phone: (979) 862-2861
Fax: (979) 862-2864
Email: gilab@cvm.tamu.edu
vetmed.tamu.edu/gilab

FDA-CVM-FOIA-2019-1704-010089

Client:
Patient: **B6**

Diet Hx 3/5/19

CARDIOLOGY DIET HISTORY FORM

Please answer the following questions about your pet

Pet's name: B6 Owner's name B6 Today's date: 3/5/19

1. How would you assess your pet's appetite? (mark the point on the line below that best represents your pet's appetite)
   Example: ***Poor*** _____|_____ ***Excellent***

   Poor _____|_____ **Excellent**

2. Have you noticed a change in your pet's appetite over the last 1-2 weeks? (check all that apply)
   ☒ Eats about the same amount as usual ☐ Eats less than usual ☐ Eats more than usual
   ☐ Seems to prefer different foods than usual ☐ Other_____

3. Over the last few weeks, has your pet (check one)
   ☐ Lost weight ☐ Gained weight ☒ Stayed about the same weight ☐ Don't know

1. Please list below ALL pet foods, people food, treats, snack, dental chews, rawhides, and any other food item that your pet currently eats and that you have fed in the last 2 years.

   Please provide enough detail that we could go to the store and buy the exact same food - examples are shown in the table

Food (include specific product and flavor)	Form	Amount	How often?	Dates fed
Nutro Grain Free Chicken, Lentil, & Sweet Potato Adult	*dry*	*1 ½ cup*	*2x/day*	*Jan 2016-present*
85% lean hamburger	*microwaved*	*3 oz*	*1x/week*	*June -Aug 2016*
Pupperoni original beef flavor	*treat*	*½*	*1x/day*	*Sept 2016-present*
Rawhide	*treat*	*6 inch twist*	*1x/week*	*Dec 2018-present*
Hills Prescription Diet i/d digestive Care chicken & vegetable Stew Canned		½ can	2X day	Since 11/18
Hills Presc. diet i/d Chicken flavor dry dog food		3 cups	2X day	Since 11/18
2 months prior to above I was trying him on several types of food due to diarrhea (raw diet Chicken or beef) but continued with diarrhea so went to Hills				

**Any additional diet information can be listed on the back of this sheet*

2. Do you give any dietary supplements to your pet (for example: vitamins, glucosamine, fatty acids, or any other supplements)? ☐ Yes ☒ No If yes, please list which ones and give brands and amounts:

		Brand/Concentration	Amount per day
Taurine	☒ Yes ☐ No	Stopped 2 months ago	1000 2X daily x 4 months
Carnitine	☐ Yes ☐ No		
Antioxidants	☐ Yes ☐ No		
Multivitamin	☐ Yes ☐ No		
Fish oil	☐ Yes ☐ No		
Coenzyme Q10	☐ Yes ☐ No		
Other (please list):			
Example: Vitamin C		*Nature's Bounty*	*500 mg tablets – 1 per day*

3. How do you administer pills to your pet?
   ☐ I do not give any medications
   ☐ I put them directly in my pet's mouth without food
   ☒ I put them in my pet's dog/cat food when needed
   ☐ I put them in a Pill Pocket or similar product
   ☐ I put them in foods (list foods):_____

FDA-CVM-FOIA-2019-1704-010090

Client: B6
Patient:

Vitals Results

B6	3:47:44 PM	Nursing note	B6
	4:41:36 PM	Heart Rate (/min)	
	4:41:37 PM	Respiratory Rate	
	4:41:38 PM	Temperature (F)	
B6	10:04:53 AM	Weight (kg)	
	0:04:41 AM	Weight (kg)	

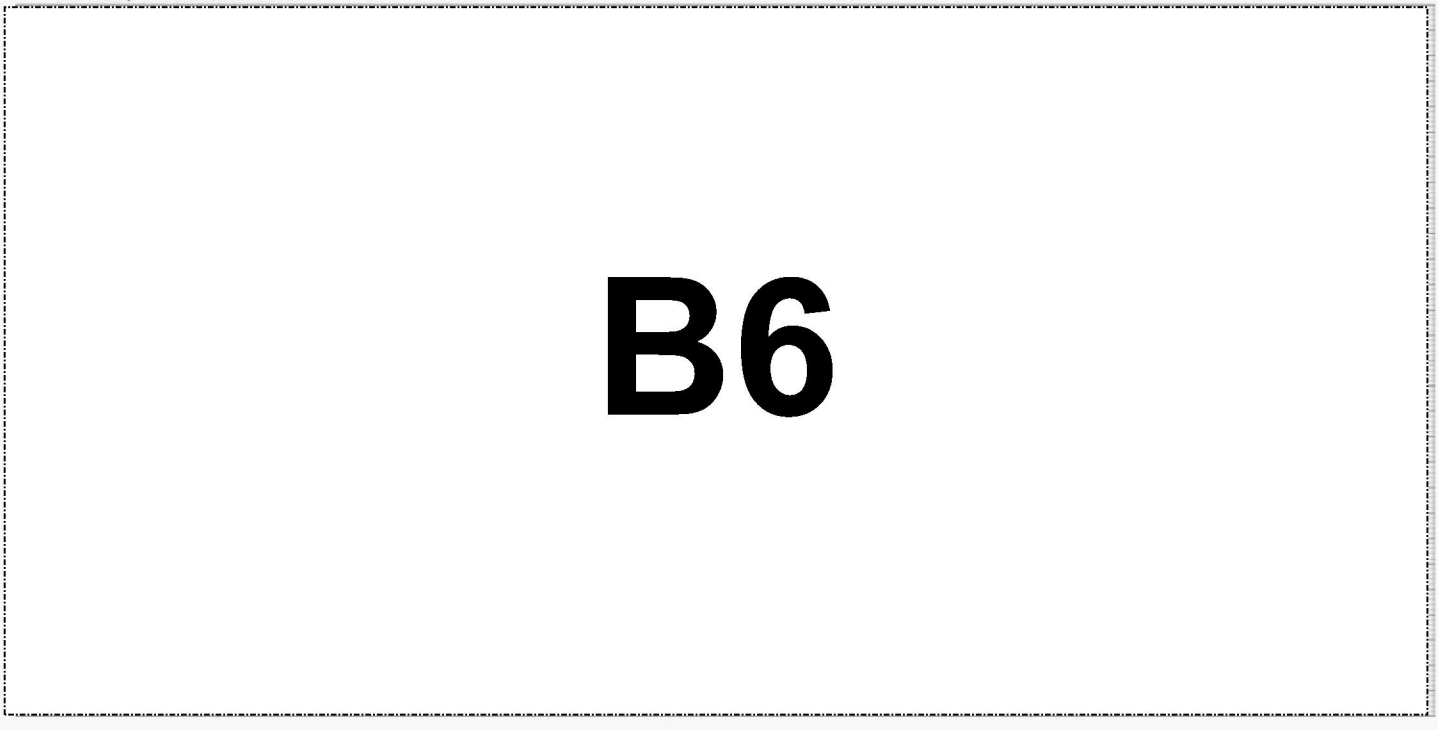
FDA-CVM-FOIA-2019-1704-010091

Client: B6
Patient:

ECG from Cardio

B6 B6 12:00:47 PM Page 1 of 2
Tufts University
Tufts Cummings School of Vet Med
Cardiology

12 Lead; Standard Placement



FDA-CVM-FOIA-2019-1704-010092

Client: B6
Patient:

ECG from Cardio

B6 B6 12:00:47 PM
Tufts University
Tufts Cummings School of Vet Med
Cardiology

FDA-CVM-FOIA-2019-1704-010093

Client: B6
Patient:

ECG from Cardio

B6 B6 12:00:59 PM
Tufts University
Tufts Cummings School of Vet Med
Cardiology

FDA-CVM-FOIA-2019-1704-010094

Patient History

	08:35 PM	UserForm
	08:36 PM	Purchase
	10:53 PM	Treatment
	10:55 PM	Prescription
	11:03 PM	UserForm
	11:04 PM	Purchase
	10:45 PM	Prescription
	10:48 PM	Purchase
	10:48 PM	Purchase
	06:01 AM	UserForm
	06:01 AM	Email
	01:12 PM	Purchase
	02:15 PM	UserForm
	03:18 PM	Purchase
	03:18 PM	Treatment
	03:30 PM	UserForm
	03:45 PM	Treatment
	03:45 PM	Deleted Reason
B6	03:47 PM	Treatment
	03:47 PM	Vitals
	04:41 PM	Vitals
	04:41 PM	Vitals
	04:41 PM	Vitals
	02:38 AM	UserForm
	02:38 AM	Email
	10:40 AM	Appointment
	10:04 AM	UserForm
	10:04 AM	Vitals
	11:07 AM	Treatment
	11:14 AM	UserForm
	11:30 AM	Purchase
	03:31 PM	Labwork
	03:34 PM	Purchase
	03:34 PM	Purchase
	03:34 PM	Purchase
	01:04 PM	Appointment
	06:07 PM	Appointment

B6

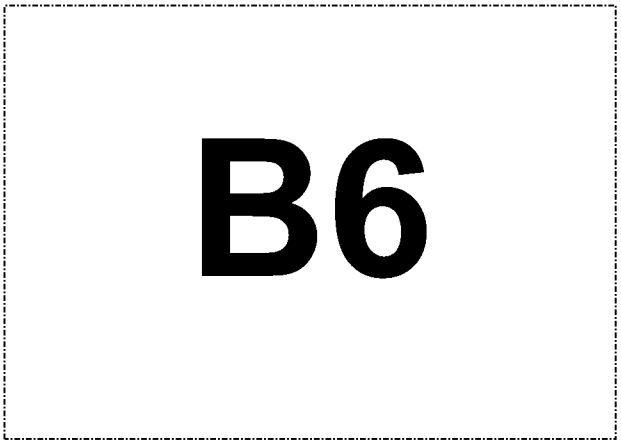
FDA-CVM-FOIA-2019-1704-010095

Client:
Patient: B6

Patient History

B6

	09:51 AM	Purchase
	09:55 AM	UserForm
	09:59 AM	Treatment
	10:04 AM	Vitals
	10:28 AM	UserForm
	11:12 AM	Appointment
	11:12 AM	Email
	03:03 PM	Purchase



Patient Account History	Description	Qty	price	Extended	Disc	Pmt

FDA-CVM-FOIA-2019-1704-010096

{

Report Details - EON-382951

ICSR:	2064360
Type Of Submission:	Followup
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)
Reporting Type:	Voluntary
Report Submission Date:	2019-03-21 11:55:12 EDT
Initial Report Date:	12/03/2018
Parent ICSR:	2059540
Follow-up Report to FDA Request:	Yes

Reported Problem:

Problem Description:	Littermate diagnosed with DCM. Initial taurine level (plasma only) was B6 WB taurine submitted = B6 Eats BEG diet Mildly reduced contractile function on echo NT-proBNP = B6 troponin mildly elevated at B6 (istat) and B6 at B6 B6 Will recheck in 3-4 months Follow-up - NT-proBNP, troponin, echo and ECG
Date Problem Started:	11/08/2018
Concurrent Medical Problem:	Yes
Pre Existing Conditions:	B6
Outcome to Date:	Stable

Product Information:

Product Name:	Acana Lamb and Apple singles
Product Type:	Pet Food
Lot Number:	
Package Type:	BAG
Product Use Information:	**Description:** Fed since 2016
Manufacturer /Distributor Information:	
Purchase Location Information:	

Animal Information:

Name:	B6
Type Of Species:	Dog
Type Of Breed:	Irish Wolfhound
Gender:	Male
Reproductive Status:	Intact
Weight:	82.7 Kilogram
Age:	3 Years
Assessment of Prior Health:	Good
Number of Animals Given the Product:	1
Number of Animals Reacted:	1

Owner Information:

Owner Information provided:	Yes
Contact:	**Name:** B6
	Phone: B6
	Email: B6
Address:	B6

FDA-CVM-FOIA-2019-1704-010097

			B6 United States
	Healthcare Professional Information:	Practice Name:	Tufts Cummings School of Veterinary Medicine
		Contact:	Name: Lisa Freeman Phone: (508) 887-4523 Email: lisa.freeman@tufts.edu
		Address:	200 Westboro Rd North Grafton Massachusetts 01536 United States
Sender Information:	Name:		Lisa Freeman
	Address:		200 Westboro Rd North Grafton Massachusetts 01536 United States
	Contact:	Phone:	5088874523
		Email:	lisa.freeman@tufts.edu
	Permission To Contact Sender:		Yes
	Preferred Method Of Contact:		Email
Additional Documents:	Attachment:		Medical Record 2.pdf
	Description:		Follow-up medical records
	Type:		Medical Records
	Attachment:		Medical Record 1.pdf
	Description:		Follow-up medical records
	Type:		Medical Records

FDA-CVM-FOIA-2019-1704-010098

Client: B6
Patient:

IDEXX BNP - 3/5/2019

IDEXX Reference Laboratories

Client: B6 Patient: B6

IDEXX VetConnect 1-888-433-9987

Client: B6
Patient: B6
Species: CANINE
Breed:
Gender: MALE
Age: 3Y

Date: 03/05/2019
Requisition #: 337144
Accession #: B6
Ordered by: FREEMAN

TUFTS UNIVERSITY
200 WESTBORO RD
NORTH GRAFTON, Massachusetts 01536
508-839-5395

Account #88933

CARDIOPET proBNP - CANINE

Test	Result	Reference Range	Low	Normal	High
CARDIOPET proBNP - CANINE	B6	0 - 900 pmol/L	HIGH		B6

Comments:

B6

Please note: Complete interpretive comments for all concentrations of Cardiopet proBNP are available in the online directory of services. Serum specimens received at room temperature may have decreased NT-proBNP concentrations.

Page 1 of 1

FDA-CVM-FOIA-2019-1704-010099

Client:
Patient: B6

Texas A and M Troponin

Gastrointestinal Laboratory
Dr. J.M. Steiner
Department of Small Animal Clinical Sciences
Texas A&M University
4474 TAMU
College Station, TX 77843-4474

Website User ID: clinpath@tufts.edu

GI Lab Assigned Clinic ID: 11405

Dr. Freeman
Tufts University-Clinical Pathology Lab
Attn: B6
200 Westboro Road
North Grafton, MA 01536
USA

Phone: 508 887 4669
Fax: 9 508 839 7936
Animal Name: B6
Owner Name: B6
Species: Canine
Date Received: Mar 06, 2019

Tufts University-Clinical Pathology Lab
Tracking Number: 337144

GI Lab Accession: B6

Test	Result	Reference Interval	Assay Date
Ultra-Sensitive Troponin I Fasting	B6 ng/mL	≤0.06	03/06/19

B6

Comments:

GI Lab Contact Information

Phone: (979) 862-2861
Fax: (979) 862-2864
Email: gilab@cvm.tamu.edu
vetmed.tamu.edu/gilab

FDA-CVM-FOIA-2019-1704-010100

Client: B6
Patient:

Diet Hx 3/5/19

CARDIOLOGY DIET HISTORY FORM
Please answer the following questions about your pet

Pet's name: B6 Owner's name B6 Today's date: 3/5/19

1. How would you assess your pet's appetite? (mark the point on the line below that best represents your pet's appetite)
   Example: ***Poor*** _____|_____ ***Excellent***

   Poor _____|_____ **Excellent**

2. Have you noticed a change in your pet's appetite over the last 1-2 weeks? (check all that apply)
   ☒ Eats about the same amount as usual ☐ Eats less than usual ☐ Eats more than usual
   ☐ Seems to prefer different foods than usual ☐ Other_____

3. Over the last few weeks, has your pet (check one)
   ☐ Lost weight ☐ Gained weight ☒ Stayed about the same weight ☐ Don't know

1. Please list below ALL pet foods, people food, treats, snack, dental chews, rawhides, and any other food item that your pet currently eats and that you have fed in the last 2 years.

   Please provide enough detail that we could go to the store and buy the exact same food - examples are shown in the table

Food (include specific product and flavor)	Form	Amount	How often?	Dates fed
Nutro Grain Free Chicken, Lentil, & Sweet Potato Adult	*dry*	*1 ½ cup*	*2x/day*	*Jan 2016-present*
85% lean hamburger	*microwaved*	*3 oz*	*1x/week*	*June -Aug 2016*
Pupperoni original beef flavor	*treat*	*½*	*1x/day*	*Sept 2016-present*
Rawhide	*treat*	*6 inch twist*	*1x/week*	*Dec 2018-present*
Hills Prescription Diet i/d digestive Care chicken Vegetable Stew Canned		½ can	2X day	Since 11/18
Hills Presc. diet i/d Chicken flavor dry dog food		3 cups	2X day	Since 11/18
2 months prior to above I was trying him on several types of food due to diarrhea (raw diet Chicken or beef) but continued with diarrhea so went to Hills				

**Any additional diet information can be listed on the back of this sheet*

2. Do you give any dietary supplements to your pet (for example: vitamins, glucosamine, fatty acids, or any other supplements)? ☐ Yes ☒ No If yes, please list which ones and give brands and amounts:

		Brand/Concentration	Amount per day
Taurine	☒ Yes ☐ No	Stopped 2 months ago	1000 2X daily x 4 months
Carnitine	☐ Yes ☐ No		
Antioxidants	☐ Yes ☐ No		
Multivitamin	☐ Yes ☐ No		
Fish oil	☐ Yes ☐ No		
Coenzyme Q10	☐ Yes ☐ No		
Other (please list):			
Example: Vitamin C		*Nature's Bounty*	*500 mg tablets – 1 per day*

3. How do you administer pills to your pet?
   ☐ I do not give any medications
   ☐ I put them directly in my pet's mouth without food
   ☒ I put them in my pet's dog/cat food when needed
   ☐ I put them in a Pill Pocket or similar product
   ☐ I put them in foods (list foods):_____

FDA-CVM-FOIA-2019-1704-010101

Client:
Patient: B6

Vitals Results

B6	3:47:44 PM	Nursing note	B6
	4:41:36 PM	Heart Rate (/min)	
	4:41:37 PM	Respiratory Rate	
	4:41:38 PM	Temperature (F)	
B6	10:04:53 AM	Weight (kg)	
B6	10:04:41 AM	Weight (kg)	

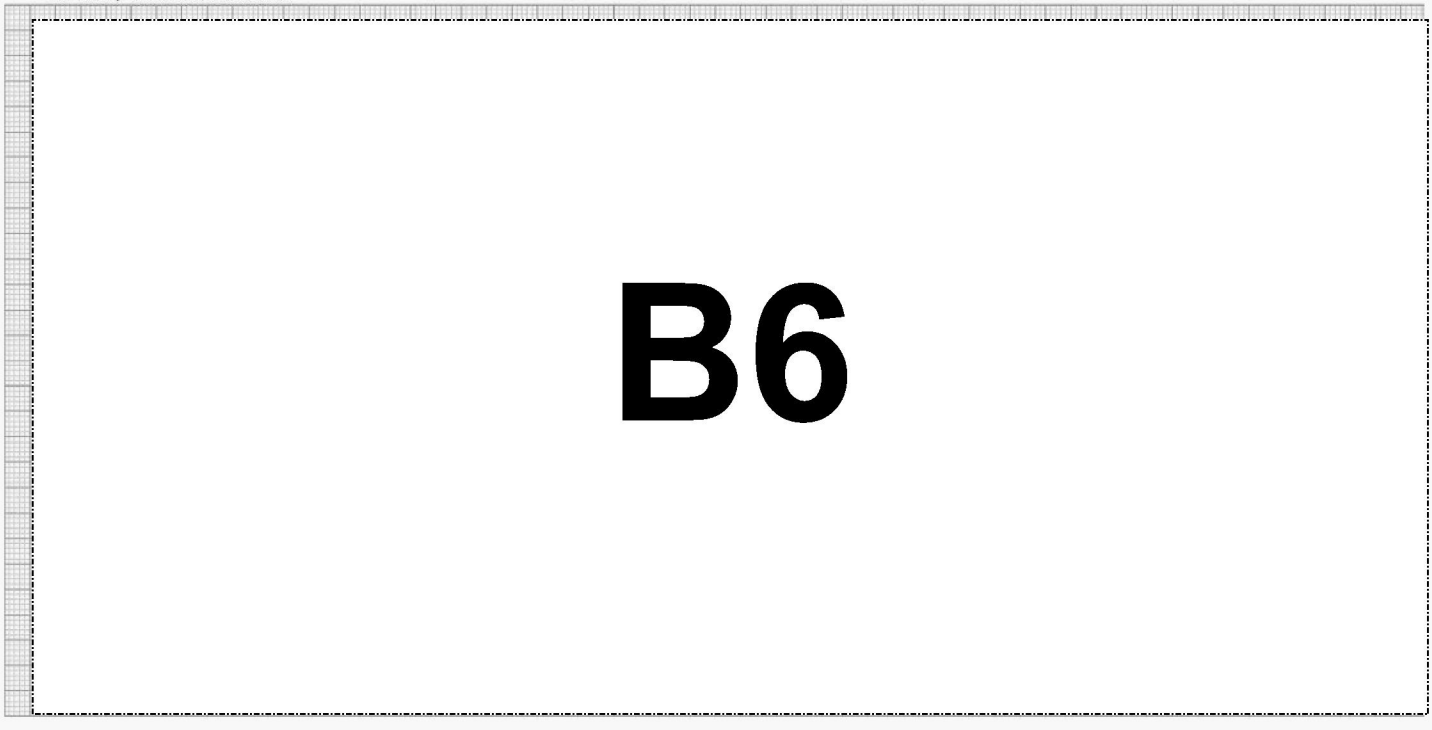
FDA-CVM-FOIA-2019-1704-010102

Client: B6
Patient:

ECG from Cardio

B6 B6 12:00:47 PM Page 1 of 2
Tufts University
Tufts Cummings School of Vet Med
Cardiology

12 Lead; Standard Placement



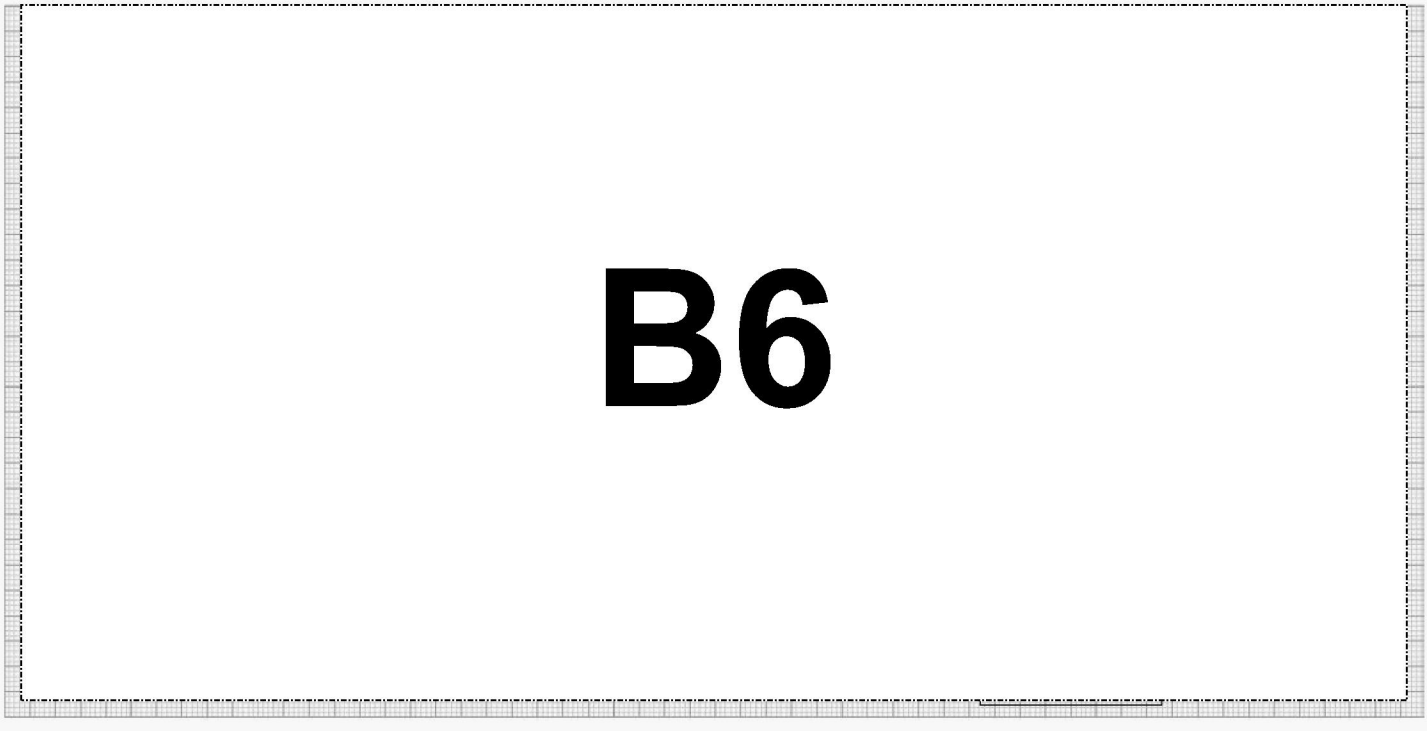
FDA-CVM-FOIA-2019-1704-010103

Client: B6
Patient:

ECG from Cardio

B6 B6 12:00:47 PM

Tufts University
Tufts Cummings School of Vet Med
Cardiology



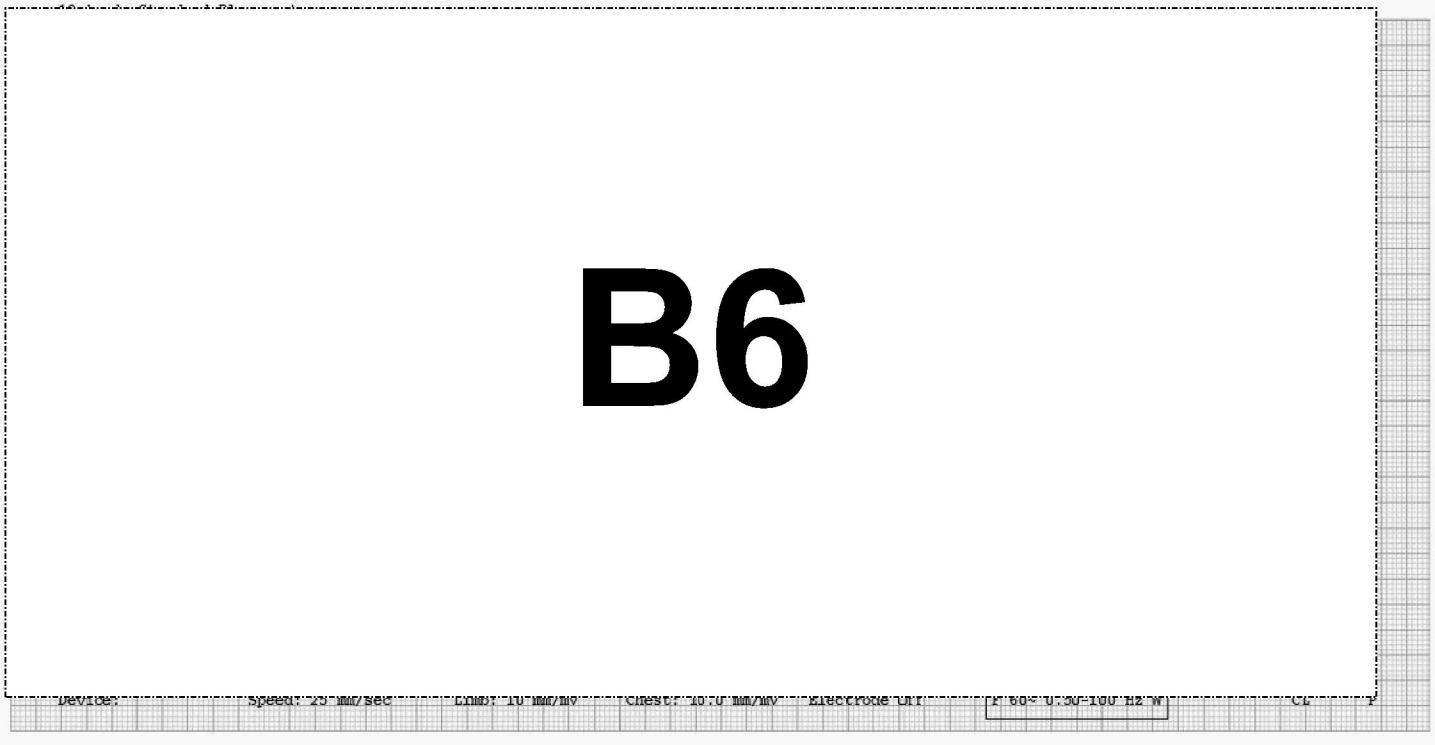
FDA-CVM-FOIA-2019-1704-010104

Client: B6
Patient:

ECG from Cardio

B6

B6 12:00:59 PM
Tufts University
Tufts Cummings School of Vet Med
Cardiology



FDA-CVM-FOIA-2019-1704-010105

Patient History

	08:35 PM	UserForm
	08:36 PM	Purchase
	10:53 PM	Treatment
	10:55 PM	Prescription
	11:03 PM	UserForm
	11:04 PM	Purchase
	10:45 PM	Prescription
	10:48 PM	Purchase
	10:48 PM	Purchase
	06:01 AM	UserForm
	06:01 AM	Email
	01:12 PM	Purchase
	02:15 PM	UserForm
	03:18 PM	Purchase
	03:18 PM	Treatment
	03:30 PM	UserForm
	03:45 PM	Treatment
	03:45 PM	Deleted Reason
B6	03:47 PM	Treatment
	03:47 PM	Vitals
	04:41 PM	Vitals
	04:41 PM	Vitals
	04:41 PM	Vitals
	02:38 AM	UserForm
	02:38 AM	Email
	10:40 AM	Appointment
	10:04 AM	UserForm
	10:04 AM	Vitals
	11:07 AM	Treatment
	11:14 AM	UserForm
	11:30 AM	Purchase
	03:31 PM	Labwork
	03:34 PM	Purchase
	03:34 PM	Purchase
	03:34 PM	Purchase
	01:04 PM	Appointment
	06:07 PM	Appointment

B6

FDA-CVM-FOIA-2019-1704-010106

Client: B6
Patient:

Patient History

B6

09:51 AM	Purchase
09:55 AM	UserForm
09:59 AM	Treatment
10:04 AM	Vitals
10:28 AM	UserForm
11:12 AM	Appointment
11:12 AM	Email
03:03 PM	Purchase

B6

Patient Account History	Description	Qty	price	Extended	Disc	Pmt

FDA-CVM-FOIA-2019-1704-010107

Cummings Veterinary Medical Center AT TUFTS UNIVERSITY

Foster Hospital for Small Animals
55 Willard Street
North Grafton, MA 01536
(508) 839-5395

All Medical Records

Client:
Address: B6

Patient: B6
Breed: Boxer
DOB: B6

Species: Canine
Sex: Female

Home Phone: B6
Work Phone: ( ) -
Cell Phone: B6

B6

Referring Information

B6

Client:
Patient: B6

Initial Complaint:
Scanned Record

Initial Complaint:
New, boxer 2-3 murmur. ok per B6

Initial Complaint:
Recheck B6

FDA-CVM-FOIA-2019-1704-010108

Client: B6
Patient:

Initial Complaint:
Recheck - B6 - B6 to oversee

SOAP Text B6 **4:07PM -** B6

B6 4:30:12 PM
Prescribed - B6 80mg Tablets - FHSA (30)
Instructions - Give 1/2 tab by mouth every 12 hours. - Expires: B6 11 Refills
Initial Complaint:
Recheck B6

SOAP Text B6 **11:20AM -** B6

Initial Complaint:
Recheck B6

Initial Complaint:
Recheck - B6

SOAP Text B6 **2:01PM -** B6

Disposition/Recommendations

FDA-CVM-FOIA-2019-1704-010109

FDA-CVM-FOIA-2019-1704-010110

Cummings Veterinary Medical Center
AT TUFTS UNIVERSITY

Foster Hospital for Small Animals
55 Willard Street
North Grafton, MA 01536
(508) 839-5395

Client:	B6
Veterinarian:	
Patient ID:	B6
Visit ID:	

Patient:	B6
Species:	Canine
Breed:	Boxer
Sex:	Female
Age:	B6 Years Old

Lab Results Report

B6 3:35:43 PM Accession ID: B6

Test	Results	Reference Range	Units
Troponin I Research - FHSA	B6	0 - 0.08	mg/dl

4/111 B6

stringsoft

Printed Tuesday, December 04, 2018

FDA-CVM-FOIA-2019-1704-010111

Client: B6
Patient:

Referral and records- B6

B6

REFERRAL FORM

TUFTS NEW ENGLAND VETERINARY MEDICAL CENTER
Henry and Lois Foster Hospital for Small Animals
Hospital for Large Animals
200 Westboro Road, Route 30
North Grafton, MA 01536
508-839-5395

Service to Which Referred: _____ Appointment Date: B6 Time: _____

OWNER INFORMATION

Name: B6 Daytime Phone: B6 Evening Phone(____): _____

Address: B6 City: B6 State: B6 Zip Code: B6

PATIENT INFORMATION

Registered Name (if any): B6

Species: CANINE Breed: B6 Sex: Female Age: 20mo

CASE HISTORY

Chief Current Presenting Signs: heart murmur

Current Status: 2VHS 2.9 kg, BAP 2/5 /4

Other History: _____

Diagnostic Test Results (if possible, please attach results):

Are Radiographs enclosed? NO

Current Therapy & Medications (include dosages): _____

Special Concerns or Requests: _____

REFERRING VETERINARIAN INFORMATION

Name: B6 Clinic/Hospital: B6

Phone: Fax: B6

Address: City: B6 State: B6 Zip Code: B6

If an animal is being referred which has had lab work done at TVDL, please include copies of the lab results & the TVDL accession number. If you are faxing us information about a clinical case which has been referred, please use fax number (508) 839-7911.

FDA-CVM-FOIA-2019-1704-010112

Client: B6
Patient:

Referral and records- B6

B6

B6

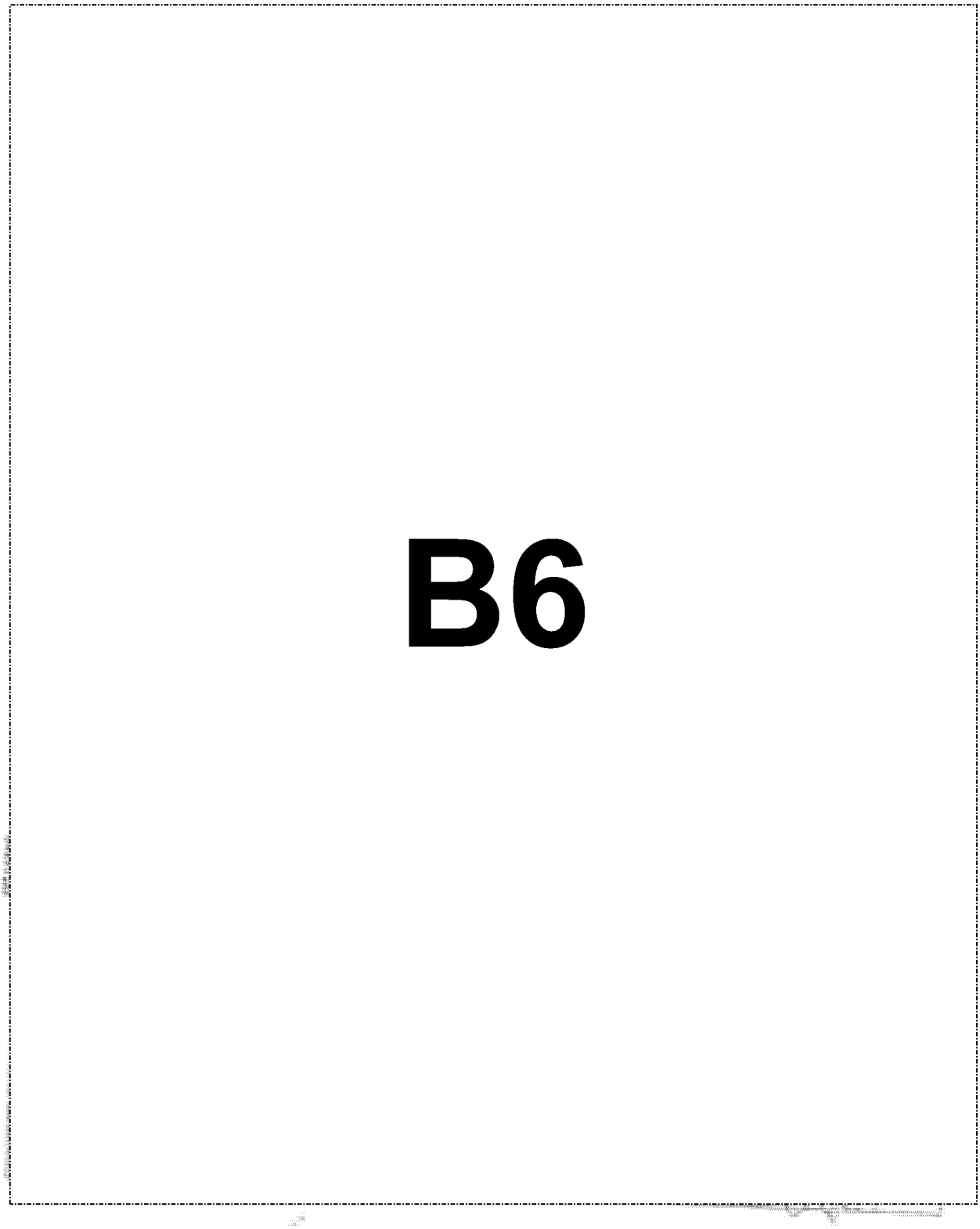
B6

B6

B6

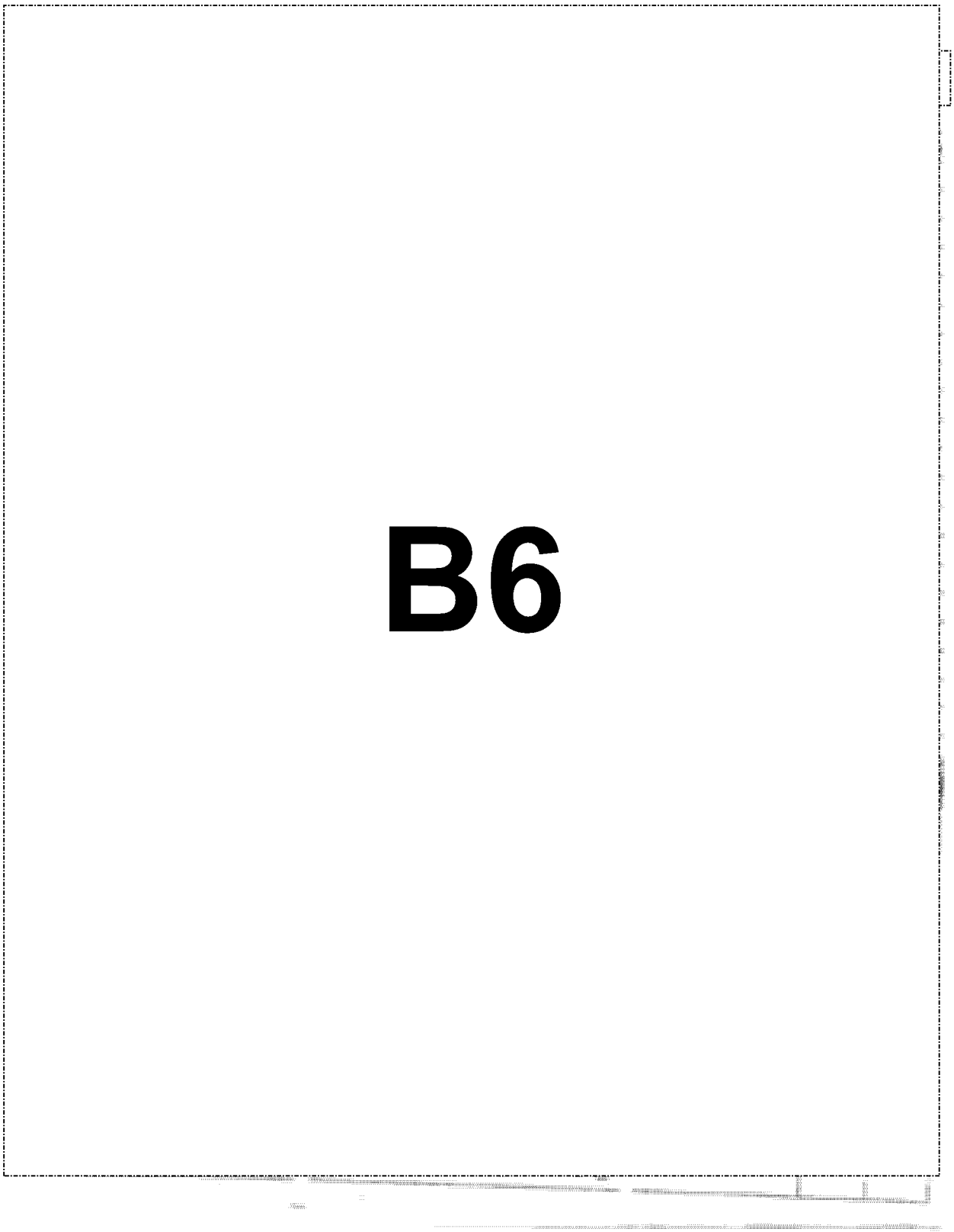
FDA-CVM-FOIA-2019-1704-010113

B6



FDA-CVM-FOIA-2019-1704-010114

B6



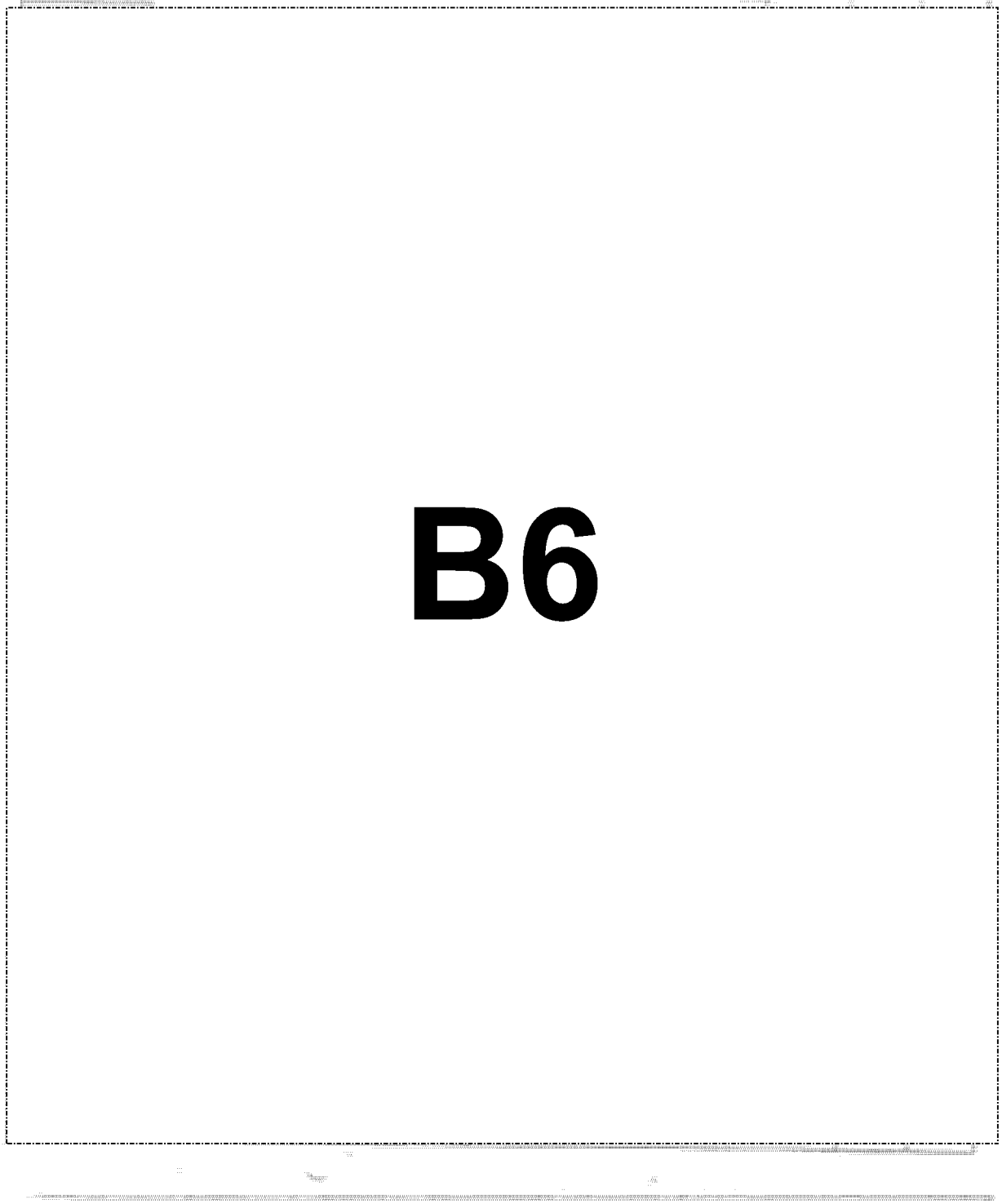
FDA-CVM-FOIA-2019-1704-010115

B6

B6

B6

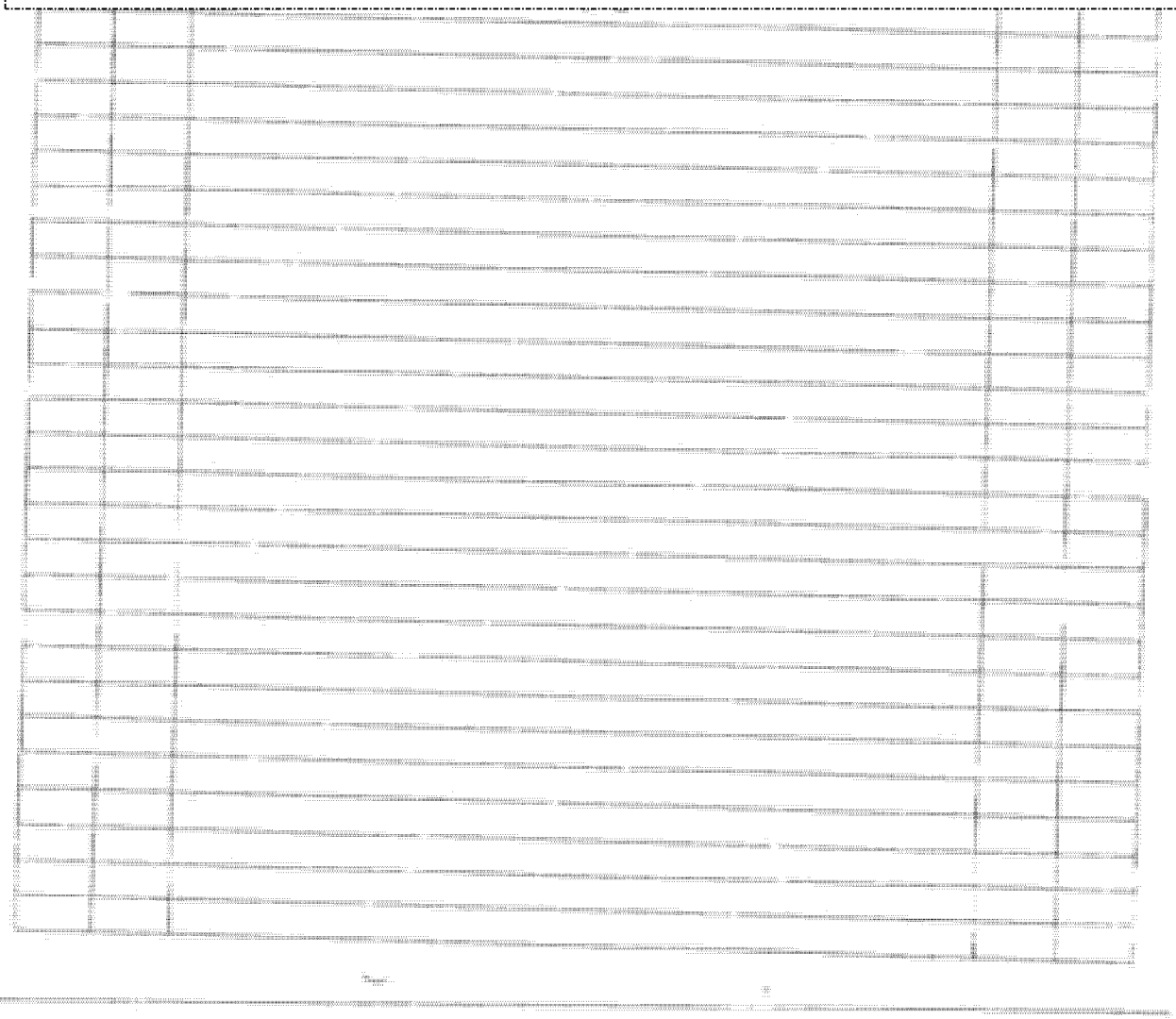
B6



FDA-CVM-FOIA-2019-1704-010116

B6

B6



FDA-CVM-FOIA-2019-1704-010117

Signed consent

Tufts Cummings School of Veterinary Medicine

B6

B6 Female
Canine Boxer Cross 1 year
Patient ID: B6

STANDARD CONSENT FORM

I am the owner, or agent for the owner, of the above described animal and have the authority to execute consent. I hereby authorize the Cummings School of Veterinary Medicine at Tufts University (herein after Cummings School) to provide for treatment of said animal according to the following terms and conditions.

Cummings School and its officers, agents and employees will provide such veterinary medical care as they deem reasonable and appropriate under the circumstances.

Cummings School and its officers, agents, and employees will use all reasonable care in the treatment of the above mentioned animal, but will not be liable for any loss or accident that may occur or any disease that may develop as a result of the care and treatment provided.

I understand that the above described animal may be treated by Cummings School students under the supervision and assistance of Cummings School staff members.

In executing this form, I hereby expressly acknowledge that risks, benefits and alternative forms of treatment have been explained to me. I understand said explanation, and I consent to treatment. Should any additional treatments or diagnostics be required during the continued care of my animal, I understand that I will be given the opportunity to discuss and consent to these additional procedures. I understand that further or additional treatment may be required without an opportunity for discussion and consideration by me, in the case of the development of any life threatening emergency during the continued care of my animal and I expressly consent to all such reasonable treatment as required. I realize and understand that results cannot be guaranteed.

If any equipment is left with the animal, it will be accepted with the understanding that Cummings School assumes no responsibility for any loss of equipment that may occur.

I agree to pick up the animal when notified that it is ready for release.

In the event the animal is not picked up, and if ten (10) days have expired since a registered letter was sent to the address given above, notifying me to call for the animal, the animal may be sold or otherwise disposed of in a humane manner and the proceeds applied to the charges incurred in caring and treating the animal. Failure to remove said animal will not and does not relieve me from obligation for the costs of services rendered.

I hereby grant to the Cummings School of Veterinary Medicine at Tufts University, its officers and employees (collectively referred to herein as Cummings School), and its agents and assigns (the Grantees) the irrevocable right to photograph / videotape the operation or procedure to be performed, including appropriate and otherwise use such photographs and images for, and in connection with, a Grantee's medical, scientific, educational, and publicity purposes, by any means, methods and media (print and electronic) now known or, in the future, developed that the Grantee deems appropriate (provided that such photographs and images may not be used in for profit commercial, except such commercials are publicizing educational programs at Cummings School). As medical and surgical treatment may necessitate the removal of tissue, cells, fluids or body parts of my animal, I authorize the Grantees to dispose of or use these tissues, cells, fluids or body parts for scientific and educational purposes.

FDA-CVM-FOIA-2019-1704-010118

Client: B6
Patient:

Signed consent

I understand that a FINANCE CHARGE will be applied to all accounts unpaid after 30 days. The FINANCE CHARGE is computed on a monthly rate of 1.33% per month, which is an annual percentage rate of 16% applied to the average daily balance outstanding, with a minimum fee of $ 50.

I do further agree that should any payment, or the full amount of the sum stated above, become overdue more than 30 days from the above agreed upon time of payment or payments, the entire balance shall be considered in default and become due and payable. **I further agree to be responsible for any or all collection agency and/or attorney fees necessary to collect the full amount.**

I do further agree to comply with hours of visitation in conjunction with our Hospital's policy.

I have read, understand, and agree to accept the terms and conditions herein.

Owner's name: B6 Date: B6

Owner's Address: B6

B6

B6

If the individual admitting the animal is someone other than the legal owner, please complete the portion below:

The owner of the animal B6 ed me authority to obtain medical treatment and to bind the owner to pay the veterinary medical services provided at Cummings School pursuant to the terms and conditions described above.

Authorized Agent - Please Print

Agent's Signature

Street Address

Date

Town/City State Zip

FDA-CVM-FOIA-2019-1704-010119

B6

Patient Chart

B6

B6

B6

B6

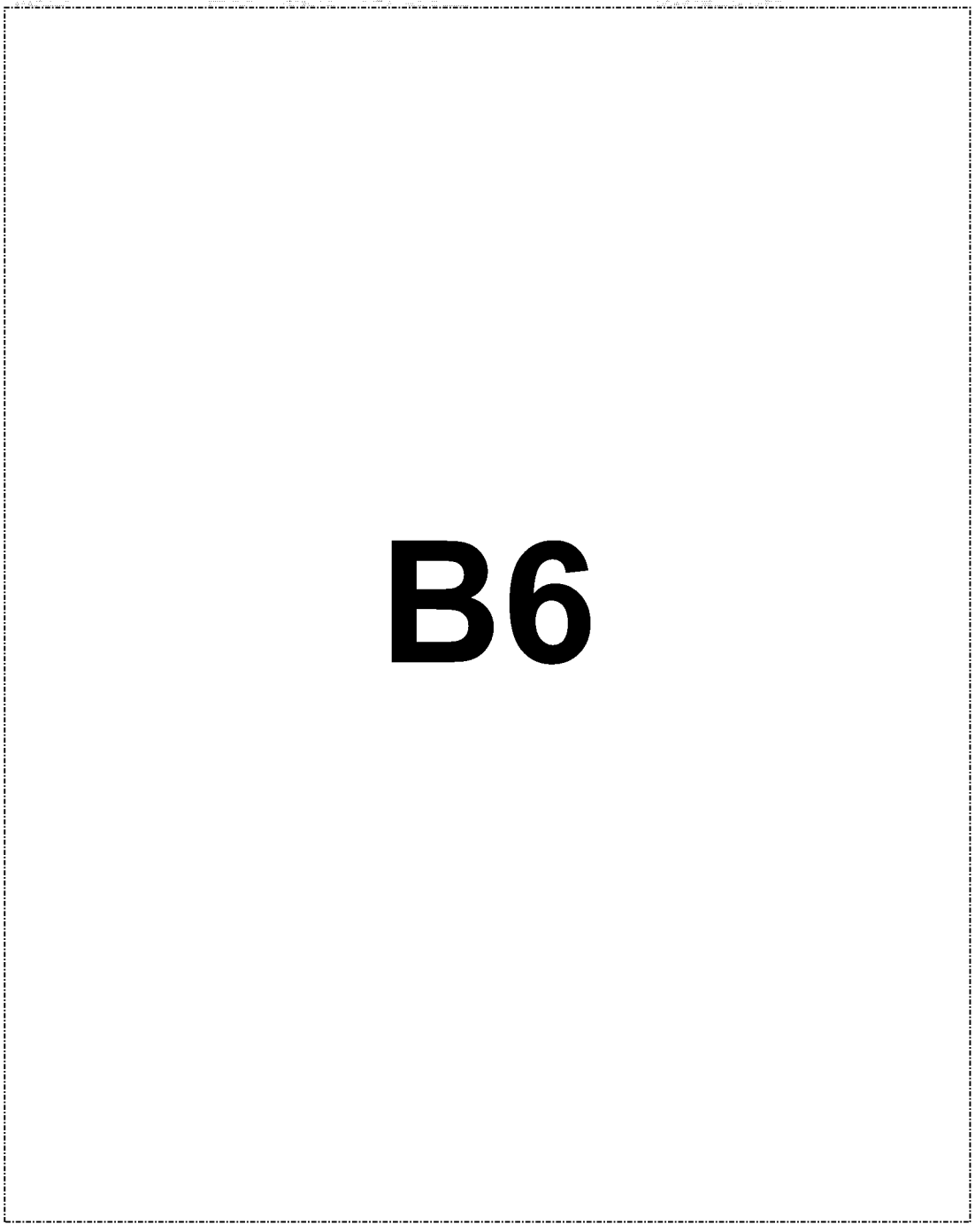
B6

B6

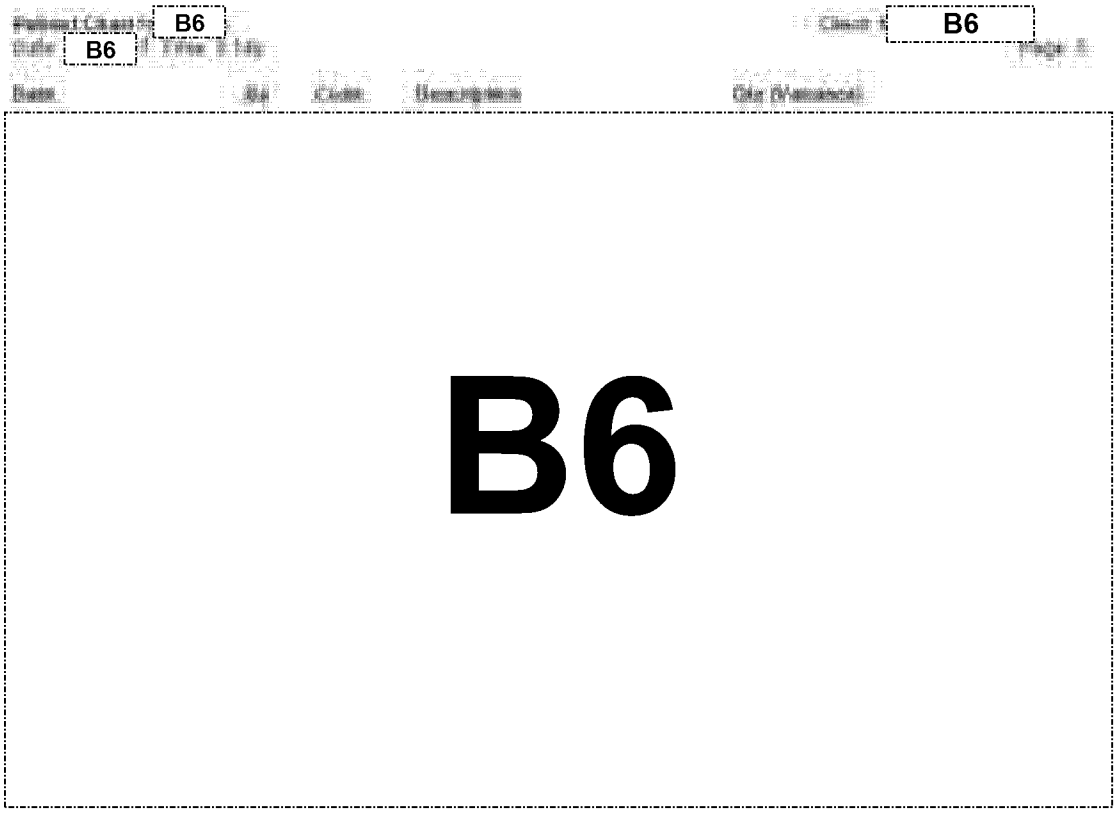
B6

B6

FDA-CVM-FOIA-2019-1704-010120



FDA-CVM-FOIA-2019-1704-010121



FDA-CVM-FOIA-2019-1704-010122

Client: B6 a
Patient:

rDVM B6 Chem 25 w/SDMA, CBC, T4 B6

B6 B6 B4

B4 B6

B6

B6

B6

B6

HEALTHCHECK PLUS CHEM 25 W/ SDMA

Test	Result		
ALP	(5 - 160) U/L		
ALT	(18 - 121) U/L	H	
AST	(16 - 55) U/L		
CREATINE KINASE	(10 - 200) U/L		
GGT	(0 - 10) U/L		
ALBUMIN	(2.7 - 3.9) g/dL		
TOTAL PROTEIN	(5.5 - 7.5) g/dL		
GLOBULIN	(2.4 - 4.0) g/dL		
TOTAL BILIRUBIN	(0.0 - 0.2) mg/dL		
BILIRUBIN CONJUGATED	(0.0 - 0.1) mg/dL		
BUN	(9 - 31) mg/dL		
CREATININE	(0.5 - 1.5) mg/dL		
CHOLESTEROL	(101 - 340) mg/dL		
GLUCOSE	(60 - 114) mg/dL		
CALCIUM	(9.4 - 11.3) mg/dL		
PHOSPHORUS	(2.6 - 8.1) mg/dL		
TCO2 (BICARBONATE)	(13 - 27) mmol/L		
CHLORIDE	(108 - 118) mmol/L		
POTASSIUM	(4.0 - 5.4) mmol/L		
SODIUM	(142 - 152) mmol/L		
ALB/GLOB RATIO	(0.7 - 1.5)		
BUN/CREATININE RATIO			
BILIRUBIN UNCONJUGATED	(0.0 - 0.2) mg/dL		
BUN RATIO	(09 - 37)		
HEMOLYSIS INDEX			
Index of H, 1+, 2+ exhibits no significant effect on chemistry values.			
LIPEMIA INDEX	0		
Index of L, 1+, 2+ exhibits no significant effect on chemistry values.			

B6

B6

B6

FDA-CVM-FOIA-2019-1704-010123

Client: B6
Patient:

rDVM B6 25 w/SDMA, CBC, T4 B6

B6 B4

ANION GAP	B6		(11 - 28) mmol/L	B6
SDMA			(0 - 14) µg/dL	

BOTH SDMA AND CREATININE ARE WITHIN THE REFERENCE INTERVAL which indicates kidney function is likely good. Evaluate a complete urinalysis and confirm there is no other evidence of kidney disease.

HEALTHCHECK PLUS CBC COMPREHENSIVE

Test		Result		
WBC	B6		(4.9 - 17.6) K/uL	B6
RBC			(5.39 - 8.70) M/uL	
HGB			(13.4 - 22.0) g/dL	
HCT			(39.3 - 58.5) %	
MCV			(69 - 76) fL	
MCH			(21.9 - 26.1) pg	
MCHC			(32.6 - 36.2) g/dL	
% RETICULOCYTE			%	
RETICULOCYTE			(10 - 110) K/uL	
% NEUTROPHIL			%	
% LYMPHOCYTE			%	
% MONOCYTE			%	
% EOSINOPHIL			%	
% BASOPHIL			%	
PLATELET			(143 - 448) K/uL	
REMARKS				

SLIDE REVIEWED MICROSCOPICALLY.
NO PARASITES SEEN

NEUTROPHIL	B6		(2445 - 13672) /uL	B6
LYMPHOCYTE			(1088 - 4896) /uL	
MONOCYTE			(130 - 1150) /uL	
EOSINOPHIL			(70 - 1490) /uL	
BASOPHIL			(0 - 100) /uL	

HEALTHCHECK PLUS T4

Test		Result			
T4	2.9	(1.0 - 4.0) ug/dL	L	B	

Interpretive ranges:
<1.0 Low
1.0-4.0 Normal
>4.0 High
2.1-3.4 Therapeutic

Dogs with no clinical signs of hypothyroidism and results within the

B6

FINAL REPORT - CONTINUED ON NEXT PAGE
PAGE 2

B6 B6

FDA-CVM-FOIA-2019-1704-010124

Client: B6
Patient:

rDVM B6 Chem 25 w/SDMA, CBC, T4 B6

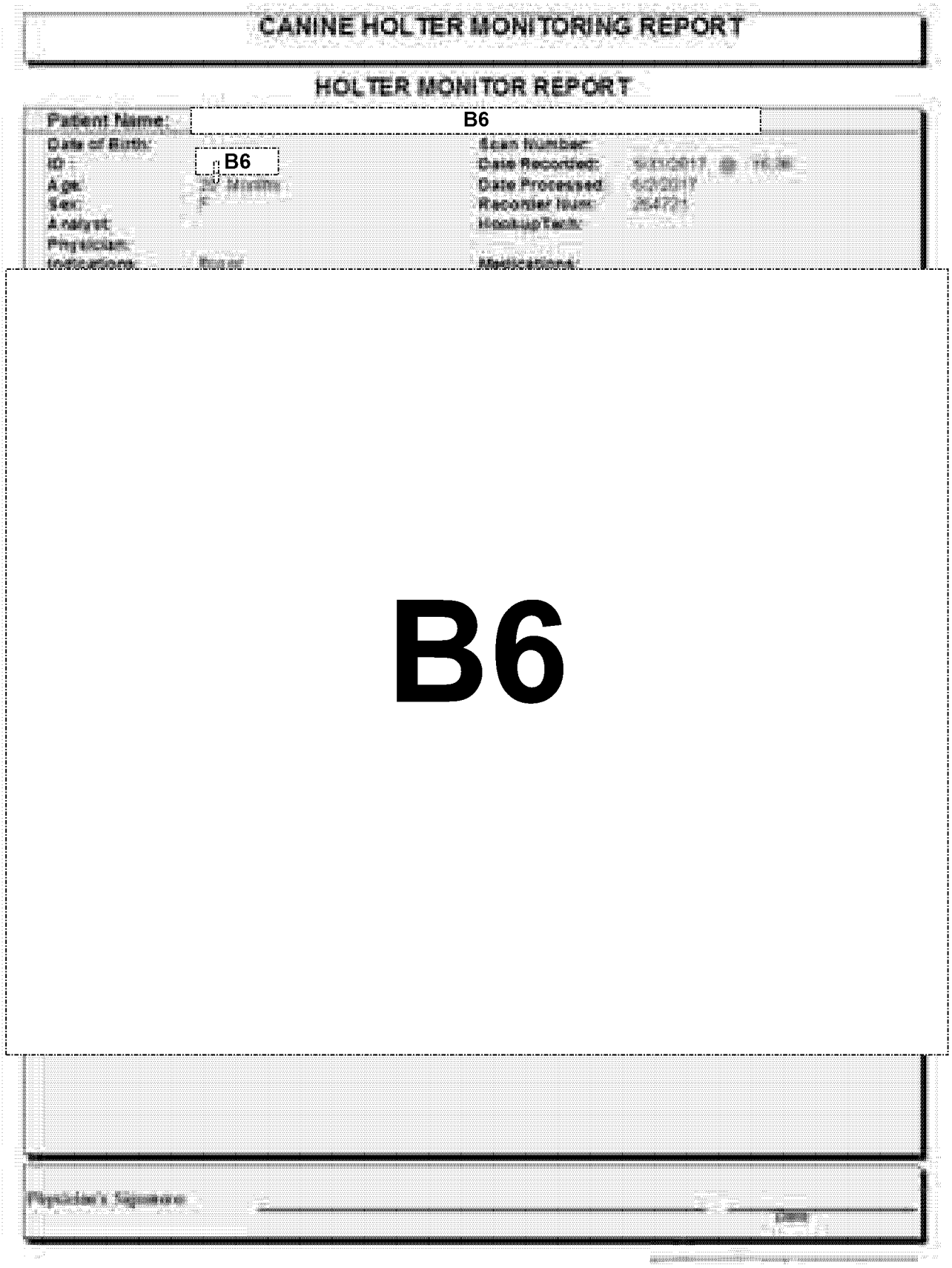
B6 B4

B6

B6

B6 B6

FDA-CVM-FOIA-2019-1704-010125



FDA-CVM-FOIA-2019-1704-010126

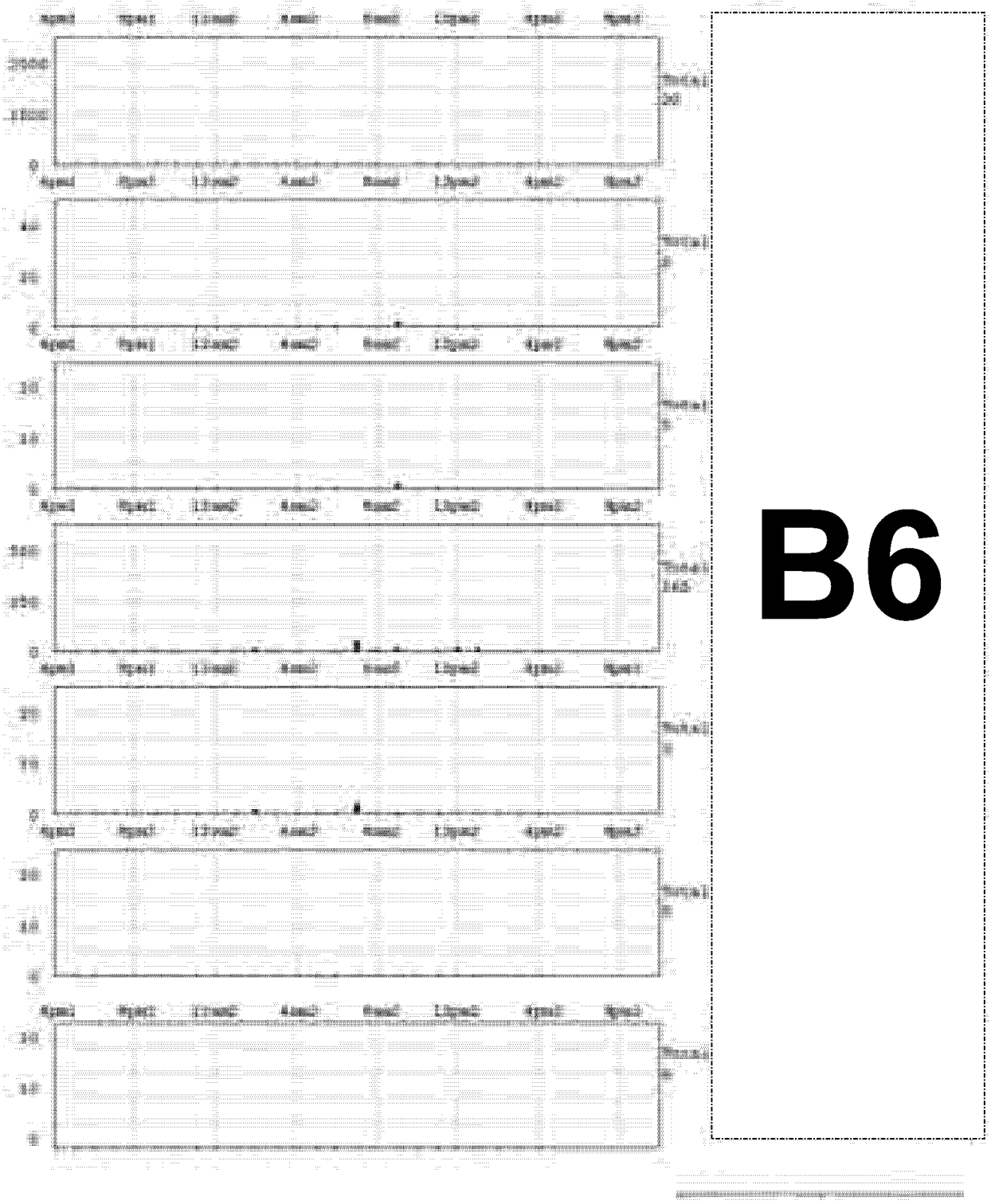
GENERAL PROFILE

B6

FDA-CVM-FOIA-2019-1704-010127

B6 B6 B6 B6

CRITICAL EVENTS



FDA-CVM-FOIA-2019-1704-010128

FULL SIZED STRIPS

(Gain 0.50 cm/mV 15 G 25 mm/sec (ALL)

B6

FDA-CVM-FOIA-2019-1704-010129

Holter Monitor report 5/31/17

FULL SIZED STRIPS

Gain 0.50 mm/mV ECG 25 mm/sec (ALL)

B6

FDA-CVM-FOIA-2019-1704-010130

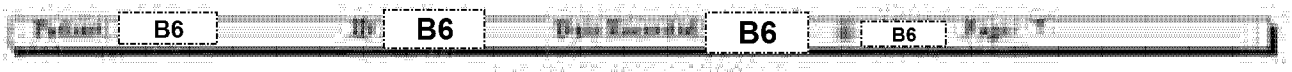
FULL SIZED STRIPS

(Gain 0.50 cm/mV ECG 25 mm/sec (ALL)

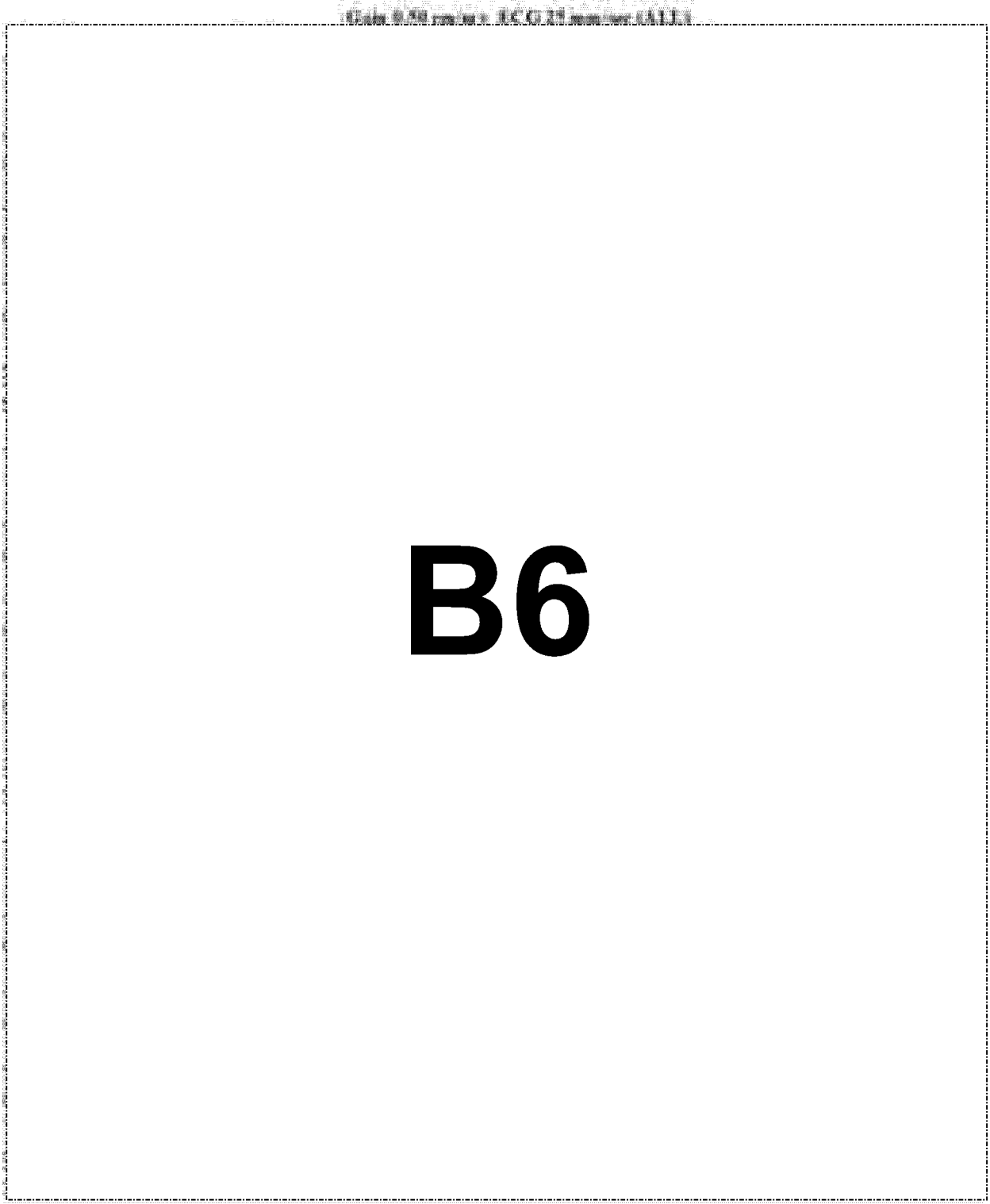
B6

FDA-CVM-FOIA-2019-1704-010131

Holter Monitor report 5/31/17



FULL SIZED STRIPS



FDA-CVM-FOIA-2019-1704-010132

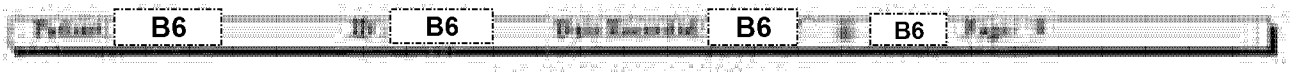
Holter Monitor report 5/31/17

FULL SIZED STRIPS

Gain 0.50 cm/mV ECG 25 mm/sec (ALL)

B6

FDA-CVM-FOIA-2019-1704-010133



FULL SIZED STRIPS

B6

FDA-CVM-FOIA-2019-1704-010134

FULL SIZED STRIPS

(Gain 0.50 cm/mV ECG 25 mm/sec (ALL)

B6

FDA-CVM-FOIA-2019-1704-010135

Holter Monitor report 5/31/17

FULL SIZED STRIPS

(Gain 0.50 mm/mV ECG 25 mm/sec (ALL)

B6

FDA-CVM-FOIA-2019-1704-010136

B6

B6

Client: B6 | B6 | Neuter | Female, Spayed | 7y | B6 | 28 kg
Referred by: B6 | Provider: B6 | Date seen: B6

Date: B6
B6 (Vet)

History: B6 B6 month female intact boxer, presented for a collapse episode at home. She came in from outside wildly and disoriented then fell over rigidly. She was unable to stand briefly and defecated. She quickly recovered from the episode. She has a diagnosed aortic hypoplasia that was declared well compensated with no restrictions by a cardiologist. She is not on any medications currently.

B6

Plan:
Owners to monitor at home and follow up with cardiologist at Tufts.
If you have questions regarding this case and I am not available, please contact B6

B6

If your patient had diagnostic imaging while at B6 please follow this link and enter the PATIENT ID
B6
B6

FDA-CVM-FOIA-2019-1704-010137

B6

B6

Client: B6 (B6)

Discharge Instructions for B6
B6

Final Diagnosis: Aortic Hypoplasia, Suspect Syncopal Episode

B6 came in tonight for an episode of collapse that she rapidly recovered from. Due to her history of aortic hypoplasia, we checked an ECG and her blood pressure which were within normal limits.

Please schedule an appointment with your cardiologist for reevaluation. If at any time B6 has exercise intolerance, more collapse episodes, change in behavior, or change in mucous membrane color please have her evaluated by a veterinarian.

Thank you for entrusting us with B6 care. She is such a sweet girl and we wish her the best! If you have any questions or concerns please do not hesitate to call.

B6 DVM

FDA-CVM-FOIA-2019-1704-010138

Client: B6
Patient: B6

B6 visit B6

B6

B6

B6 B6 B6

1½ yo FSF

DATE B6
TIME ER 9:30 pm
DR. B6

CHIEF COMPLAINT collapsed; now unable to walk
APPETITE GOOD DECREASED NONE DIET Southern Meadow Fast
VOMITING YES NO STOOL NORMAL DIARRHEA CONSTIPATION PUPD YES NO
VACCINES UTD
HISTORY

- aortic hypoplasia - Tufts
- born in mom outside - wobbly, fell over, couldn't get up
  second, defecated
  disoriented/slow, fell over-rigid

no restrictions/
medications

DIFFERENTIAL LIST

HOME INSTRUCTIONS

FINAL DIAGNOSIS

B6

IP

FDA-CVM-FOIA-2019-1704-010139

Client: B6
Patient:

B6 visit B6

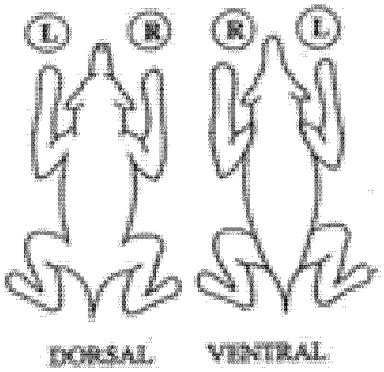
1 General Appearance	N A	4 Mucous Membranes	N A	7 Lymph Nodes	N A	10 Musculoskeletal	N A
2 Eyes	N A	5 Circulatory	N A	8 Digestive	N A	11 Genitourinary	N A
3 Ears	N A	6 Respiratory	N A	9 Neurologic	N A	12 Integumentary	N A
						13 Endocrine	N A

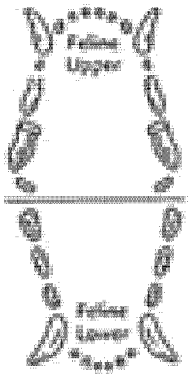
T 97.8	P 100	WT 38 Kg	Body Condition (1-5) 1=Emaciated 5=Obese
R 20	Last WT		
Pain (0-10)		Date:	
Localized to:			
Chronic or Acute			
Last Pain Score:	Date:		

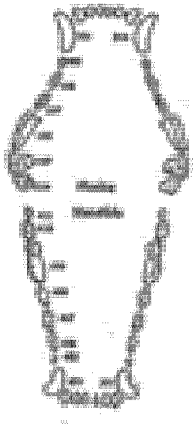
DESCRIPTION OF PE ABNORMALITIES:

Initial PE:

B6







B6

B6

A. ☐ Plaque
B. ☐ Bad Breath
C. ☐ Tartar
D. ☐ Gingivitis
E. ☐ Loose Teeth
F. ☐ Broken Teeth
G. ☐ Missing Teeth
H. ☐ Feline Resorptive Lesion
I. ☐ Other

**Please highlight corresponding recommendation code on travel sheet

FDA-CVM-FOIA-2019-1704-010140

CANINE HOLTER MONITORING REPORT

HOLTER MONITOR REPORT

Patient Name:	B6	Interp. Physician:	
Date of Birth:		Scan Number:	B6
ID:		Date Received:	B6
Age:		Date Processed:	B6
Sex:		Recorder Type:	
Analyst:		HookupTech:	
Physician:			
Indications:		Medications:	

B6

Physician's Signature: _____ Date: _____

FDA-CVM-FOIA-2019-1704-010141

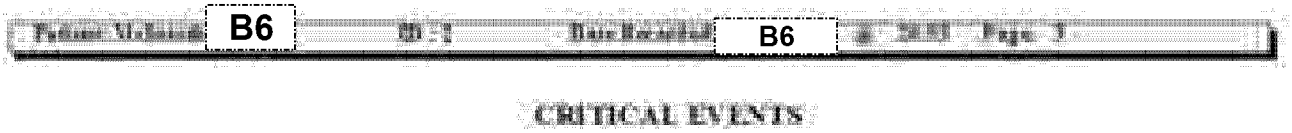
Client: B6
Patient:

Holter Monitor Report B6

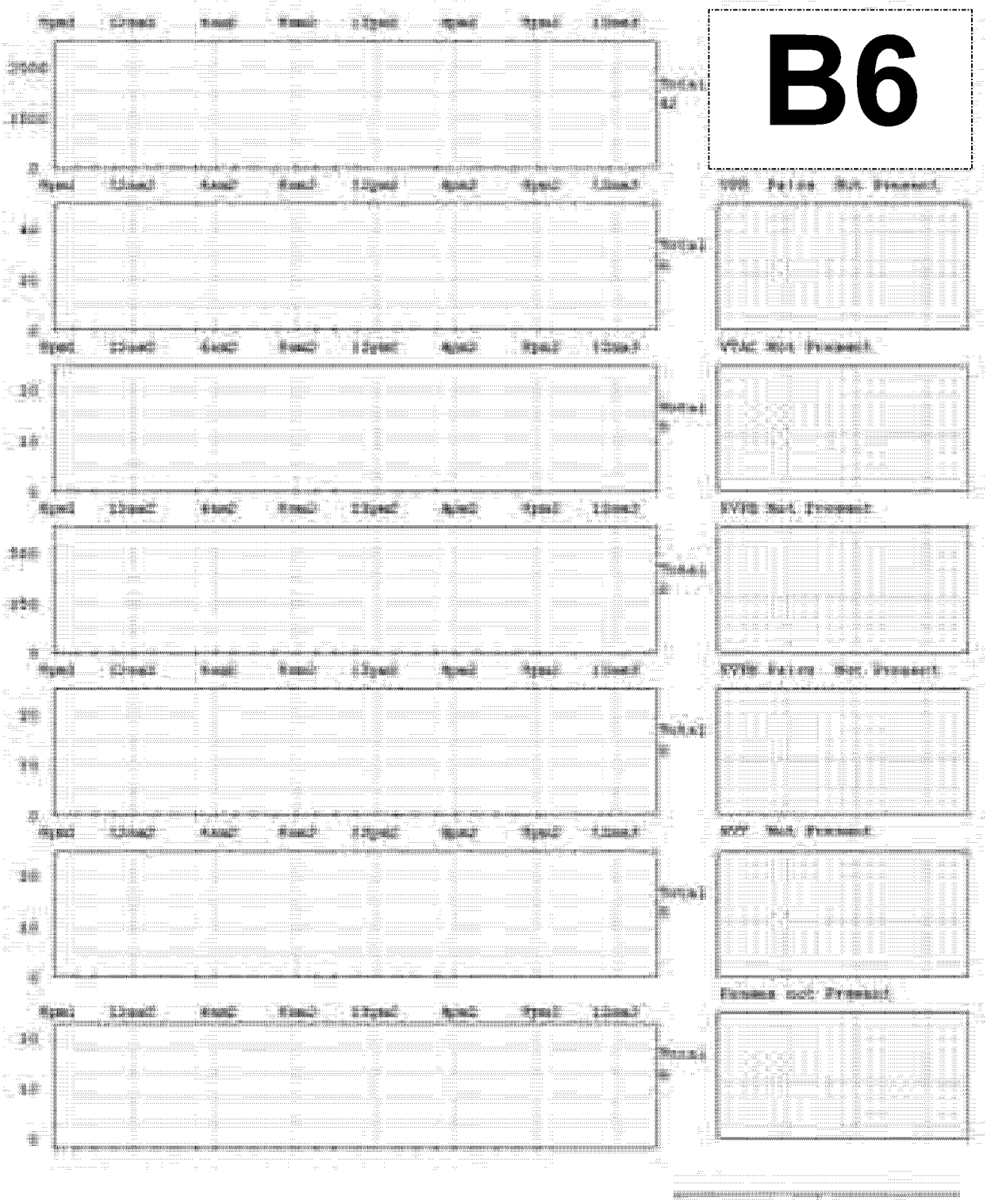
GENERAL PROFILE

B6

FDA-CVM-FOIA-2019-1704-010142



CRITICAL EVENTS



FDA-CVM-FOIA-2019-1704-010143

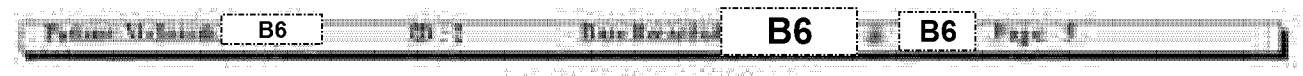
B6 B6 B6

FULL SIZED STRIPS

B6

FDA-CVM-FOIA-2019-1704-010144

Holter Monitor Report 11/16/17



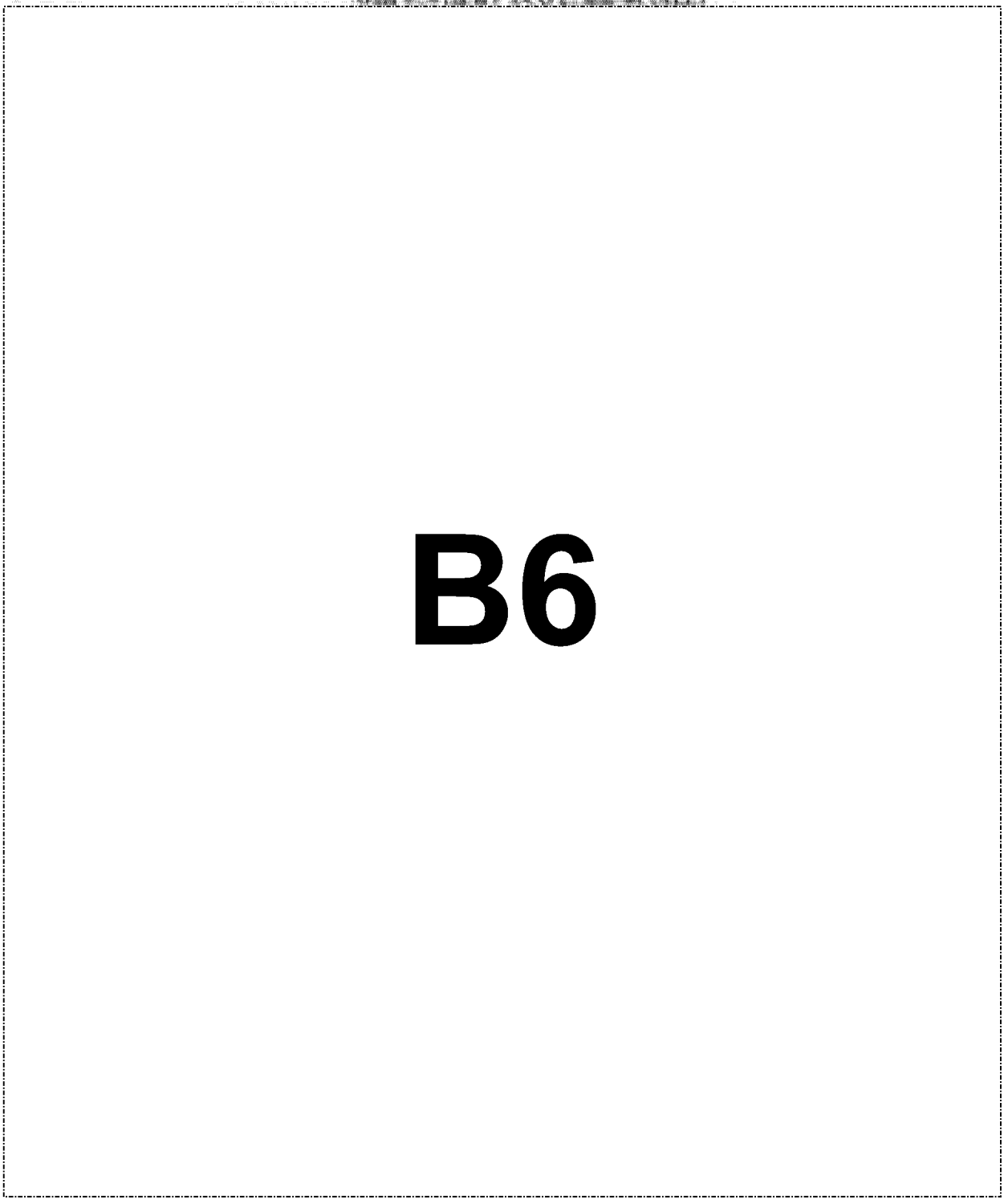
FULL SIZED STRIPS

B6

FDA-CVM-FOIA-2019-1704-010145

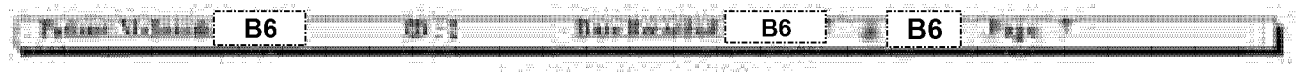
Holter Monitor Report 11/16/17

FULL SIZED STRIPS



FDA-CVM-FOIA-2019-1704-010146

Holter Monitor Report 11/16/17



FULL SIZED STRIPS

B6

FDA-CVM-FOIA-2019-1704-010147

Holter Monitor Report 11/16/17

FULL SIZED STRIPS

B6

FDA-CVM-FOIA-2019-1704-010148

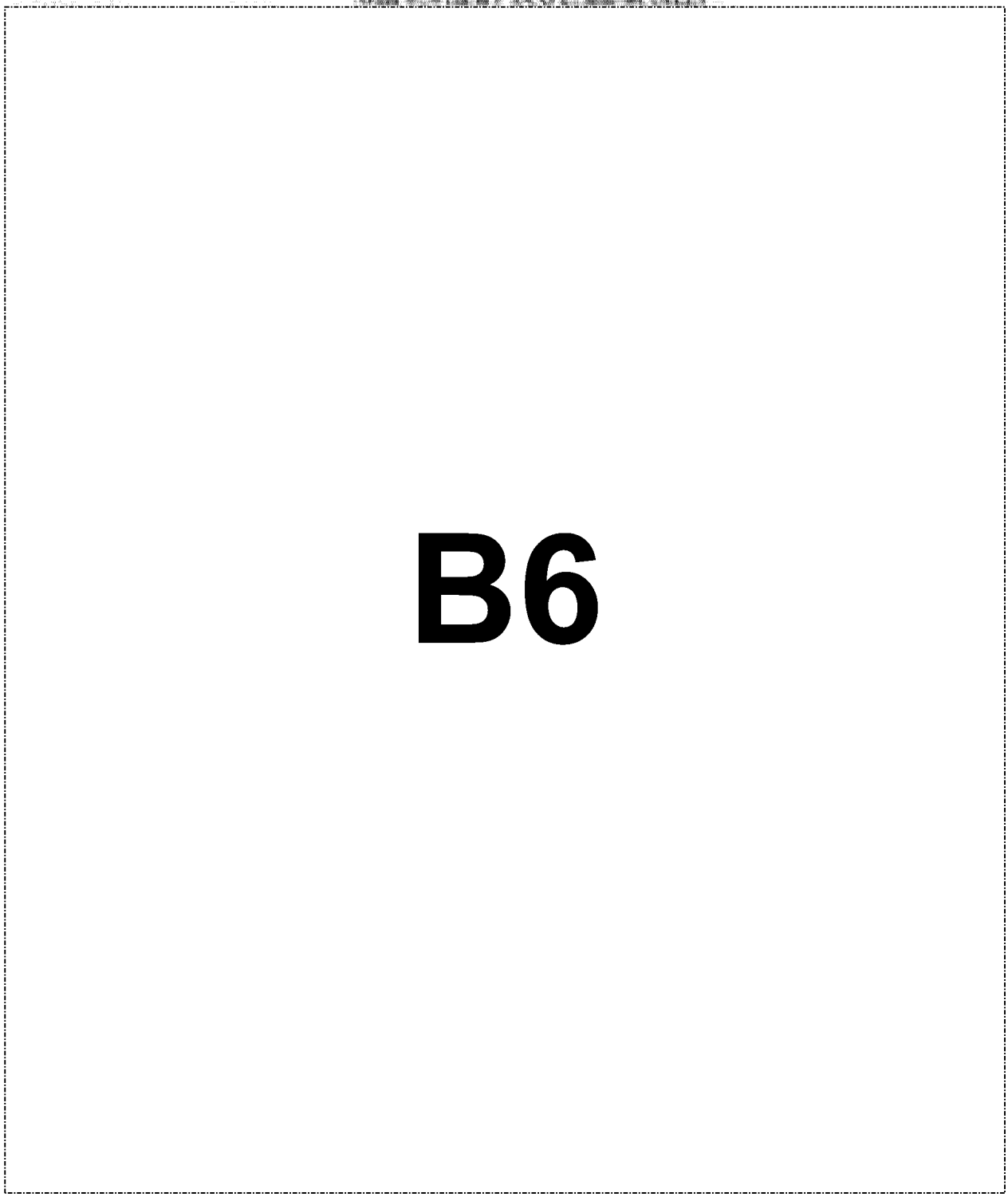
FULL SIZED STRIPS

B6

FDA-CVM-FOIA-2019-1704-010149

Holter Monitor Report 11/16/17

FULL SIZED STRIPS



FDA-CVM-FOIA-2019-1704-010150

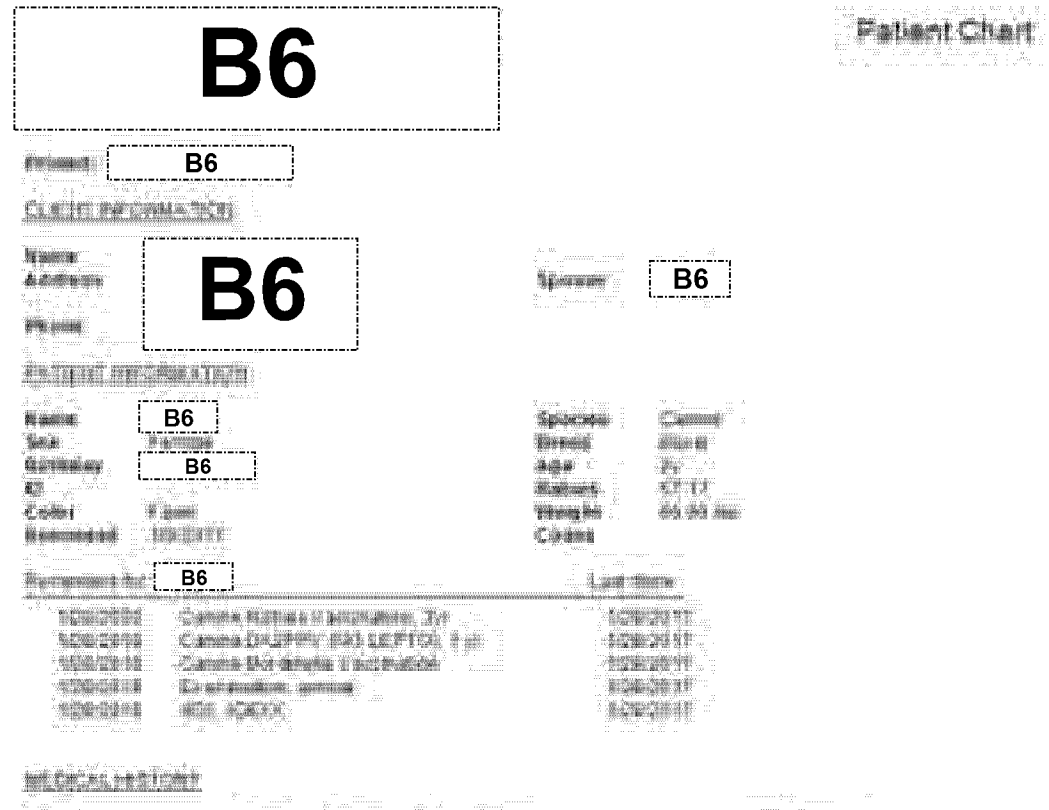
Holter Monitor Report 11/16/17

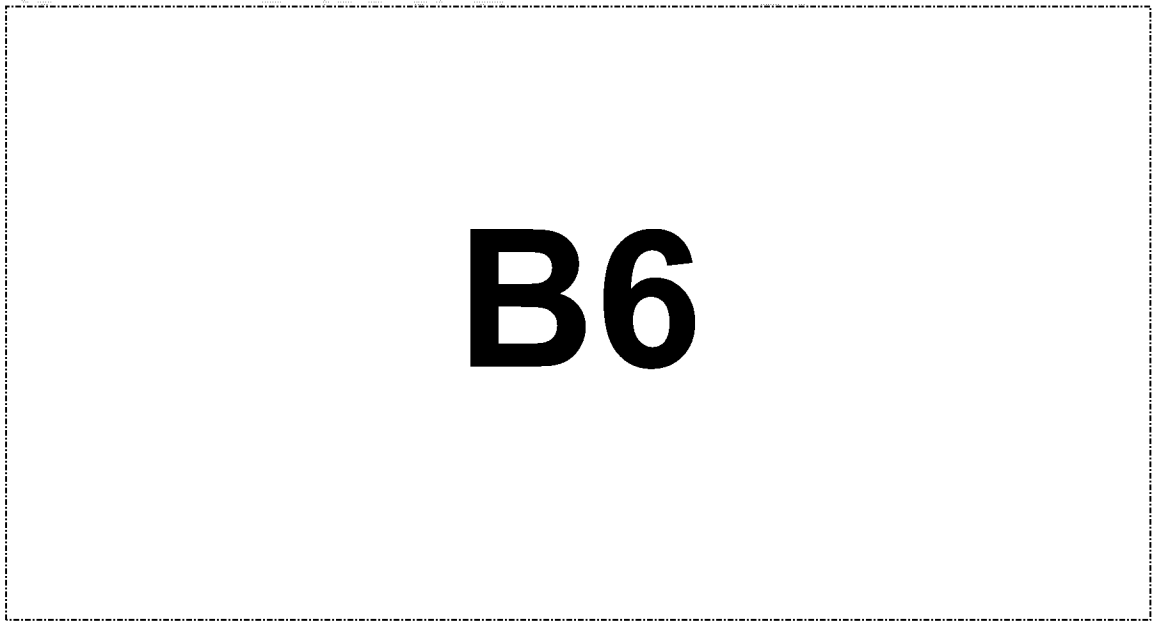
B6 B6 B6

FULL SIZED STRIPS

B6

FDA-CVM-FOIA-2019-1704-010151





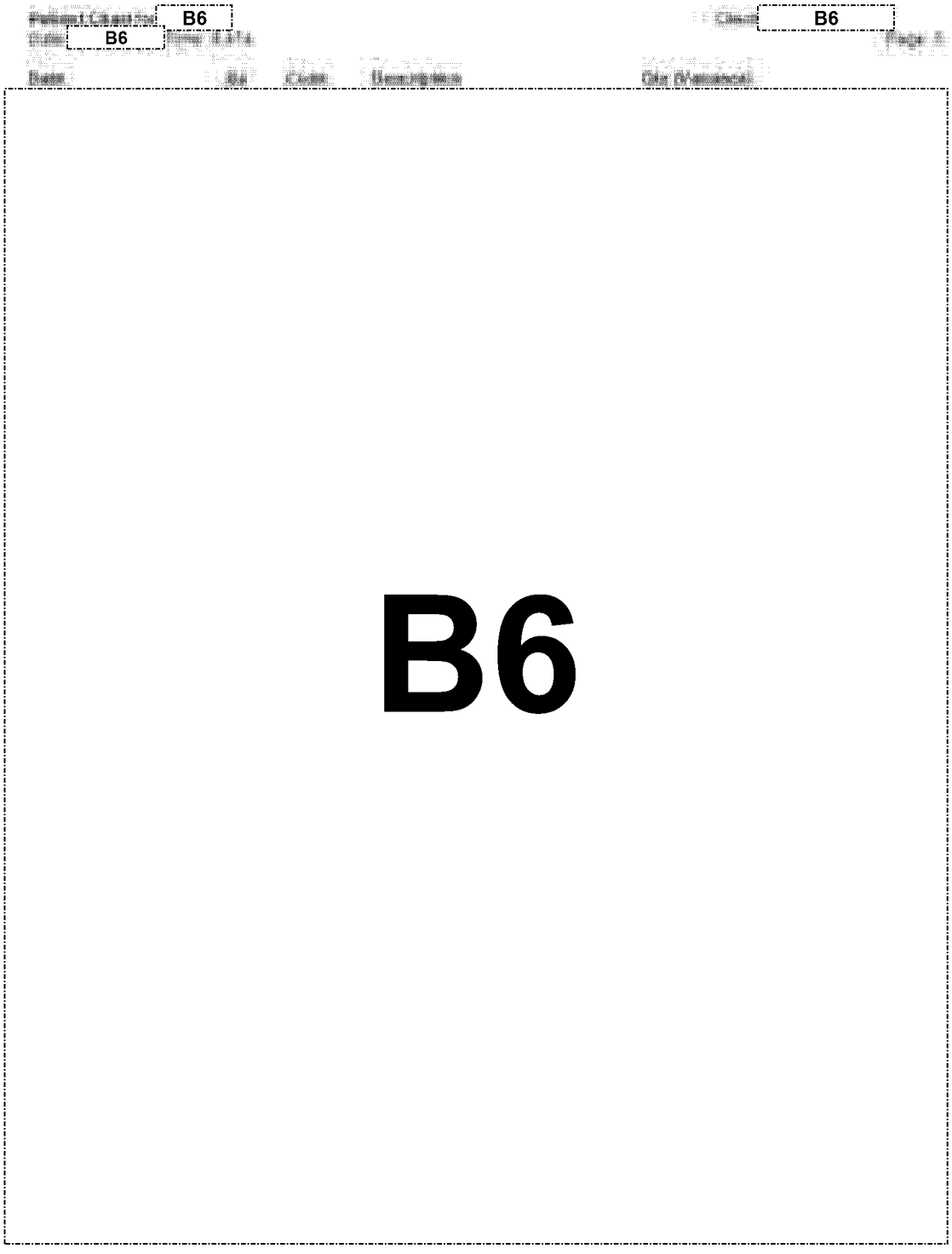
FDA-CVM-FOIA-2019-1704-010152

B6 B6

B6 B6

B6

FDA-CVM-FOIA-2019-1704-010153



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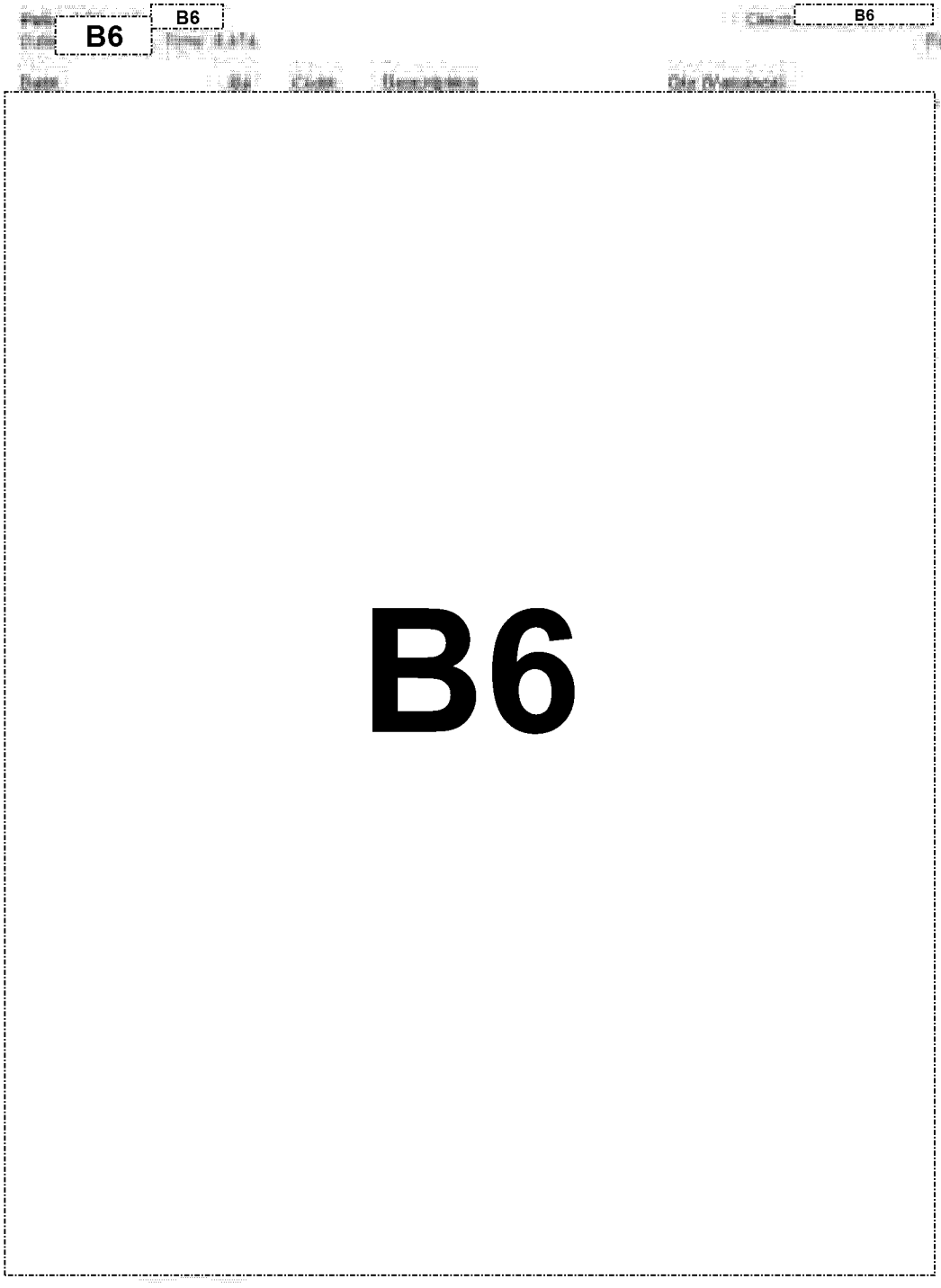
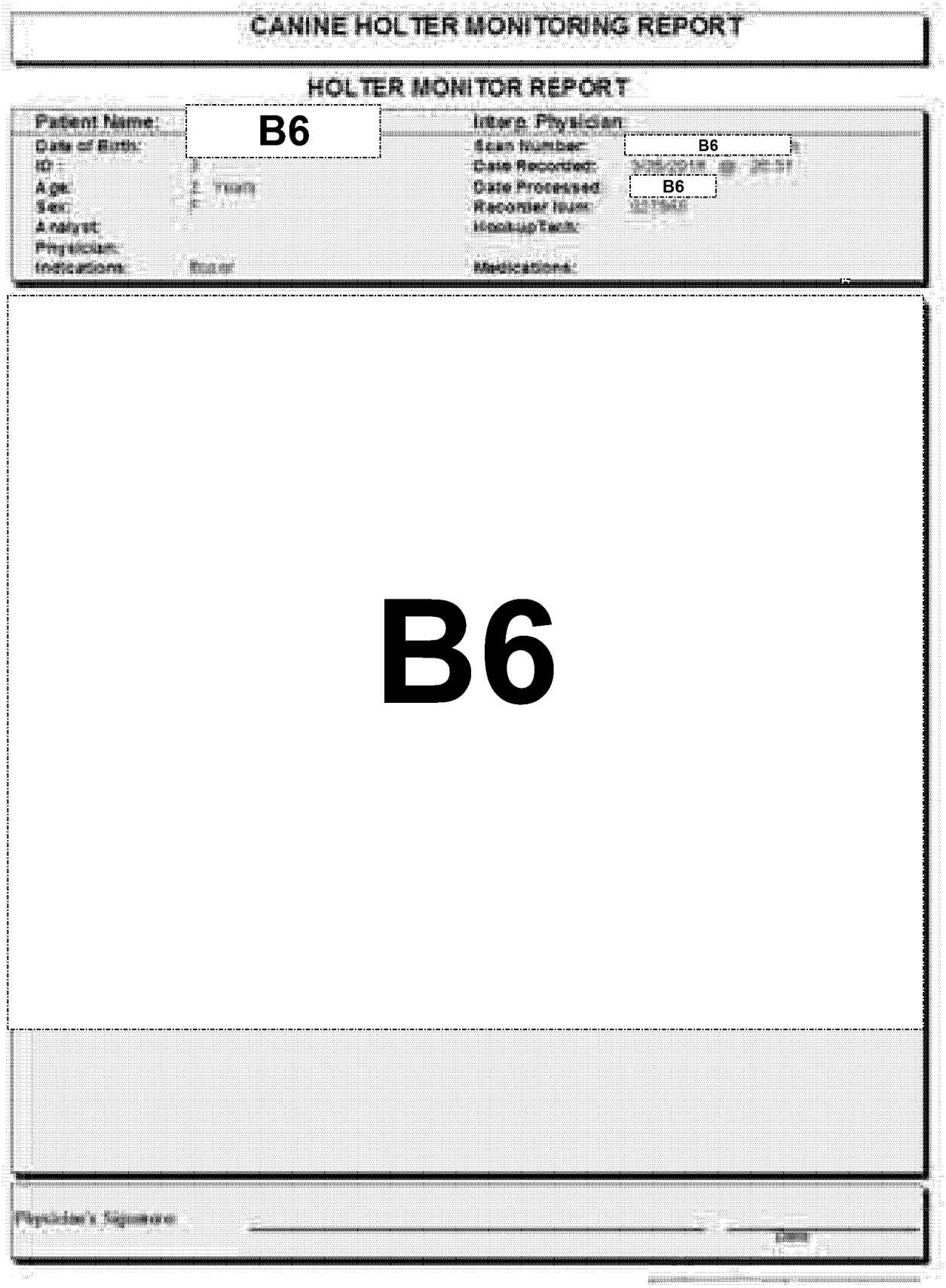


FDA-CVM-FOIA-2019-1704-010155

B6

FDA-CVM-FOIA-2019-1704-010156



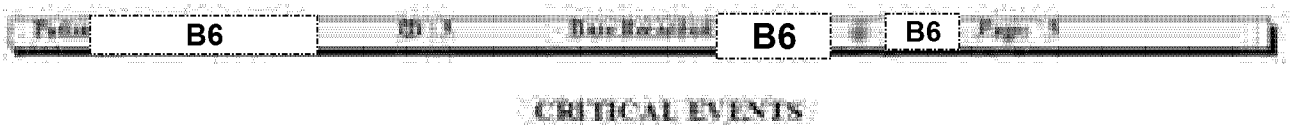
FDA-CVM-FOIA-2019-1704-010157

GENERAL PROFILE

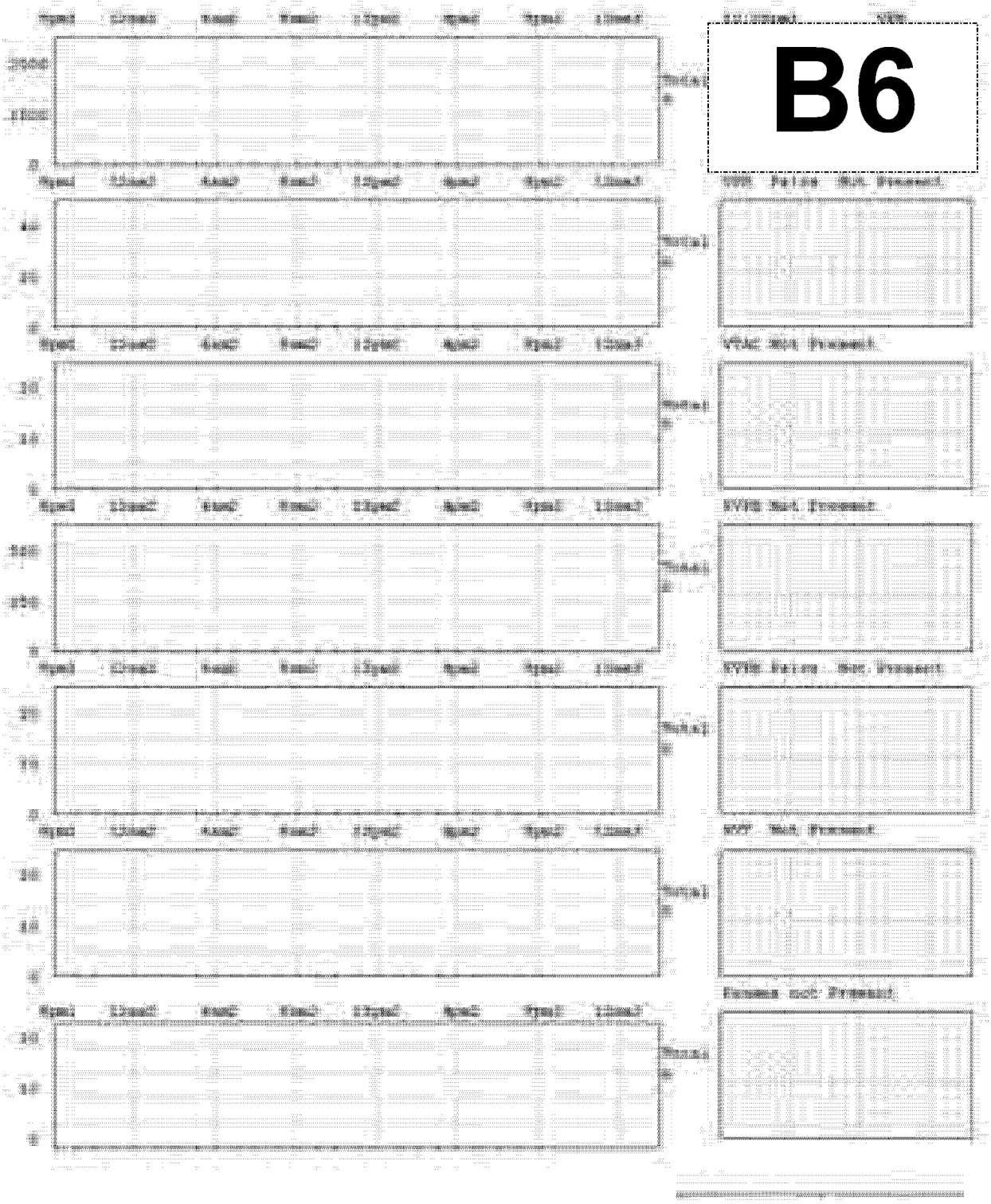
FDA-CVM-FOIA-2019-1704-010158

Client: B6
Patient:

Holter report 3/30/18

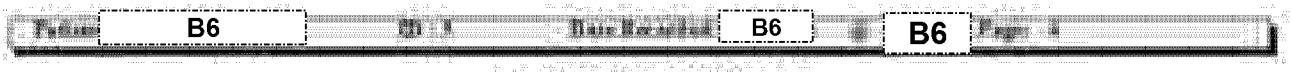


CRITICAL EVENTS

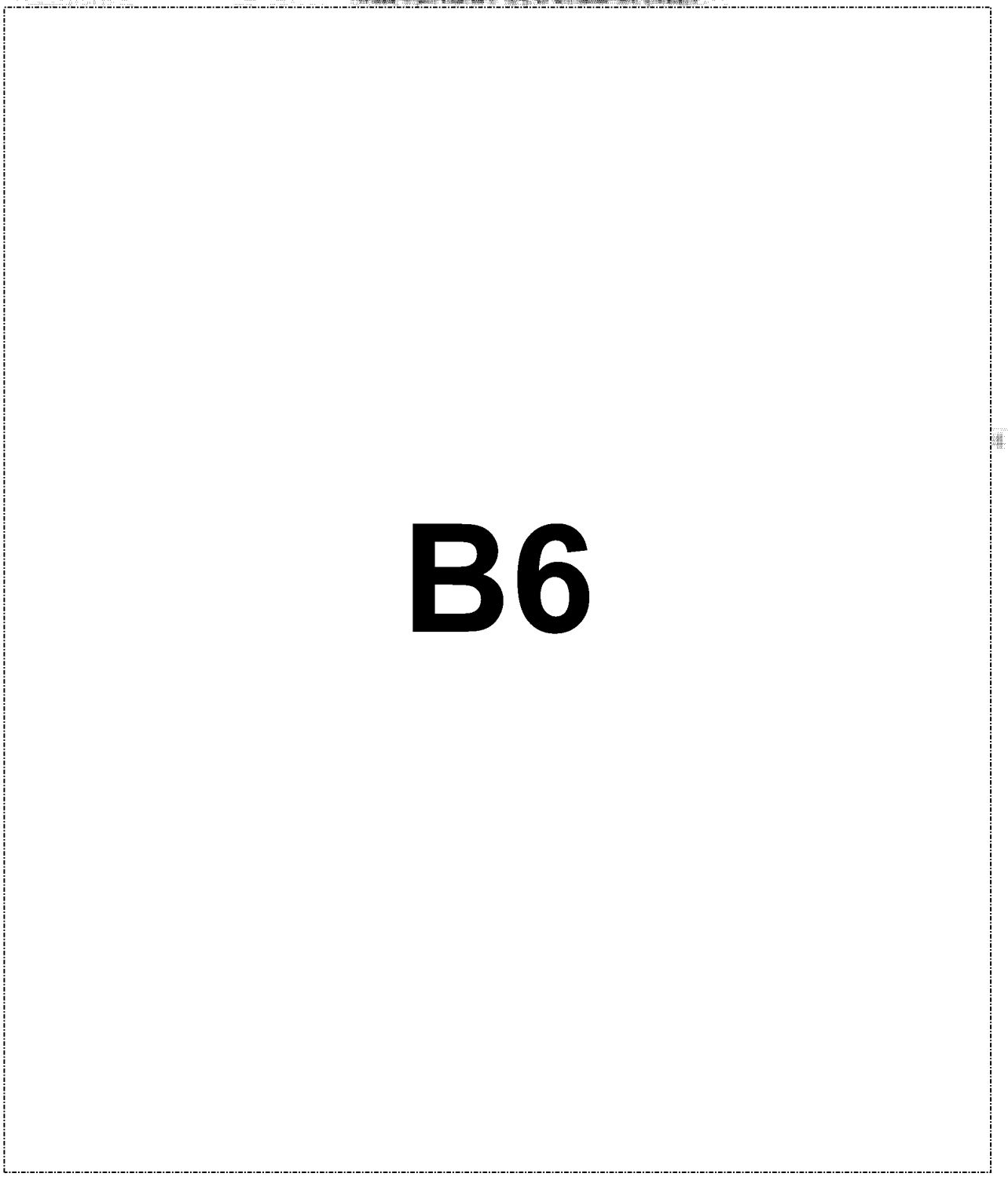


FDA-CVM-FOIA-2019-1704-010159

Holter report 3/30/18



FULL SIZED STRIPS



FDA-CVM-FOIA-2019-1704-010160

FULL SIZED STRIPS

Gain 0.25 cm/mV 12 CG 25 mm/sec (ALL)

B6

FDA-CVM-FOIA-2019-1704-010161

B6 B6 B6

FULL SIZED STRIPS

B6

FDA-CVM-FOIA-2019-1704-010162

FULL SIZED STRIPS

(Gain 0.25 cm/mV ECG 25 mm/sec (ALL)

B6

FDA-CVM-FOIA-2019-1704-010163

Holter report 3/30/18

FULL SIZED STRIPS

Gain 0.25 cm/mV ECG 25 mm/sec (ALL)

B6

FDA-CVM-FOIA-2019-1704-010164

Holter report 3/30/18

FULL SIZED STRIPS

B6

FDA-CVM-FOIA-2019-1704-010165

FULL SIZED STRIPS

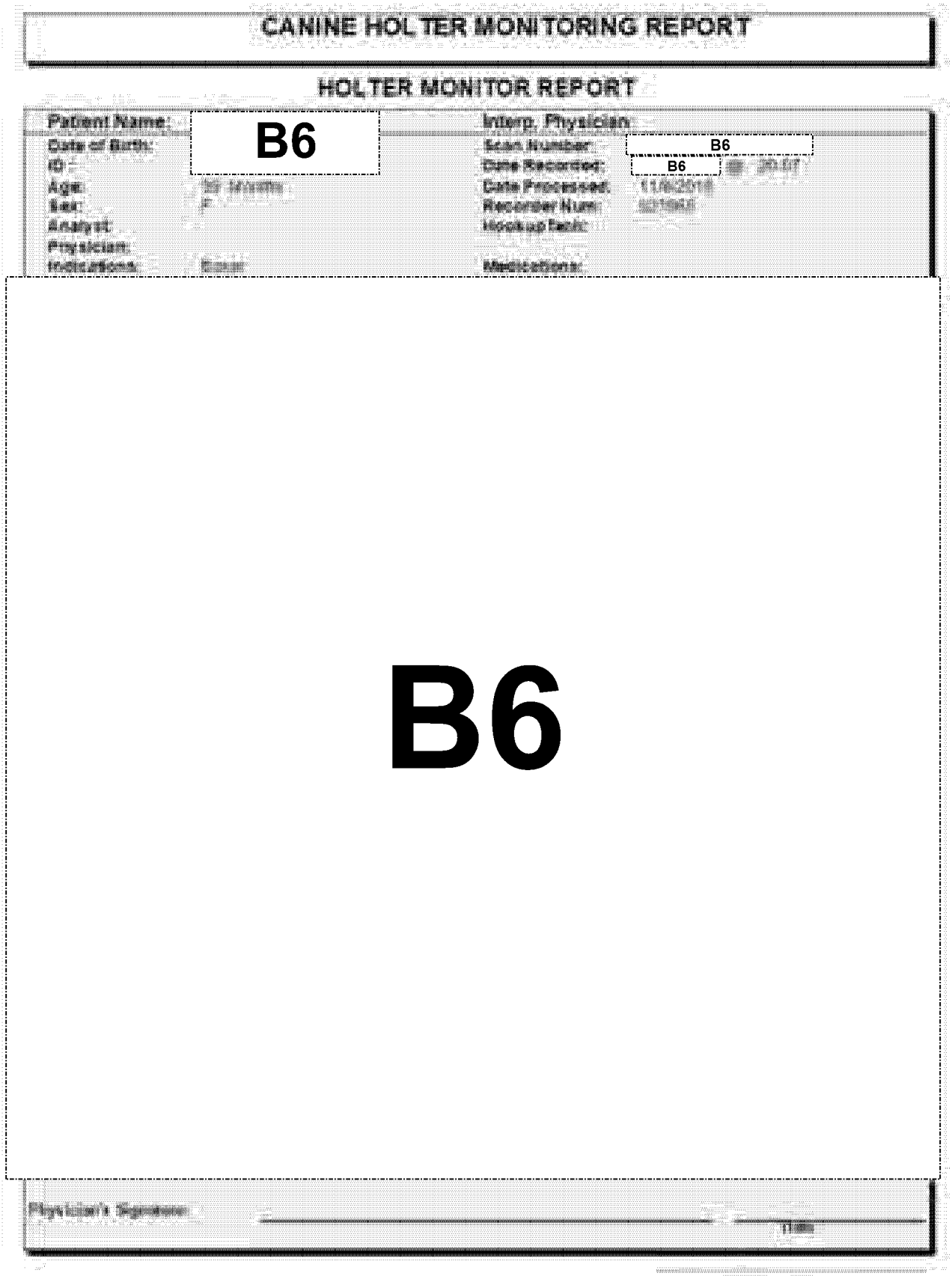
(Gain 0.25 mm/mV ECG 25 mm/sec (ALL))

B6

FDA-CVM-FOIA-2019-1704-010166

Client: B6
Patient:

Holter Monitior report 11/7/19



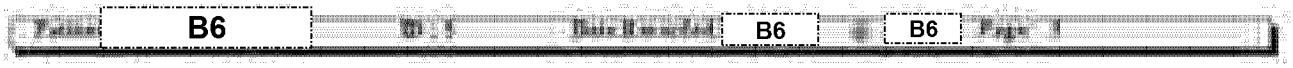
FDA-CVM-FOIA-2019-1704-010167

Holter Monitior report 11/7/19

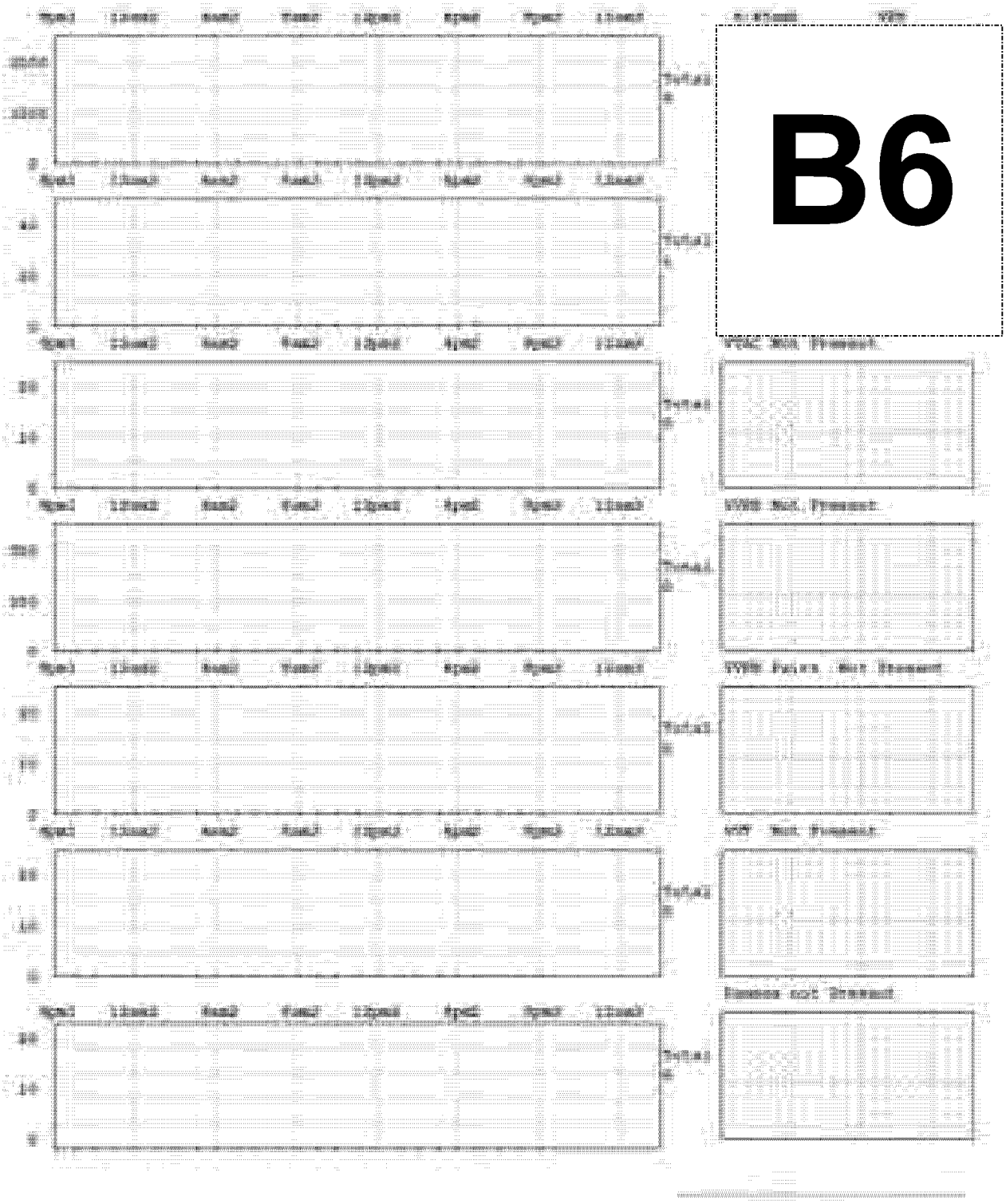
GENERAL PROFILE

FDA-CVM-FOIA-2019-1704-010168

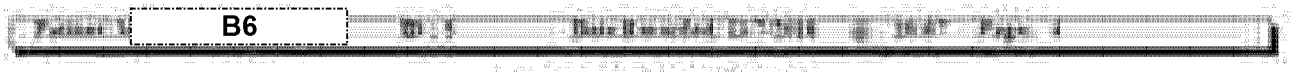
Holter Monitior report 11/7/19



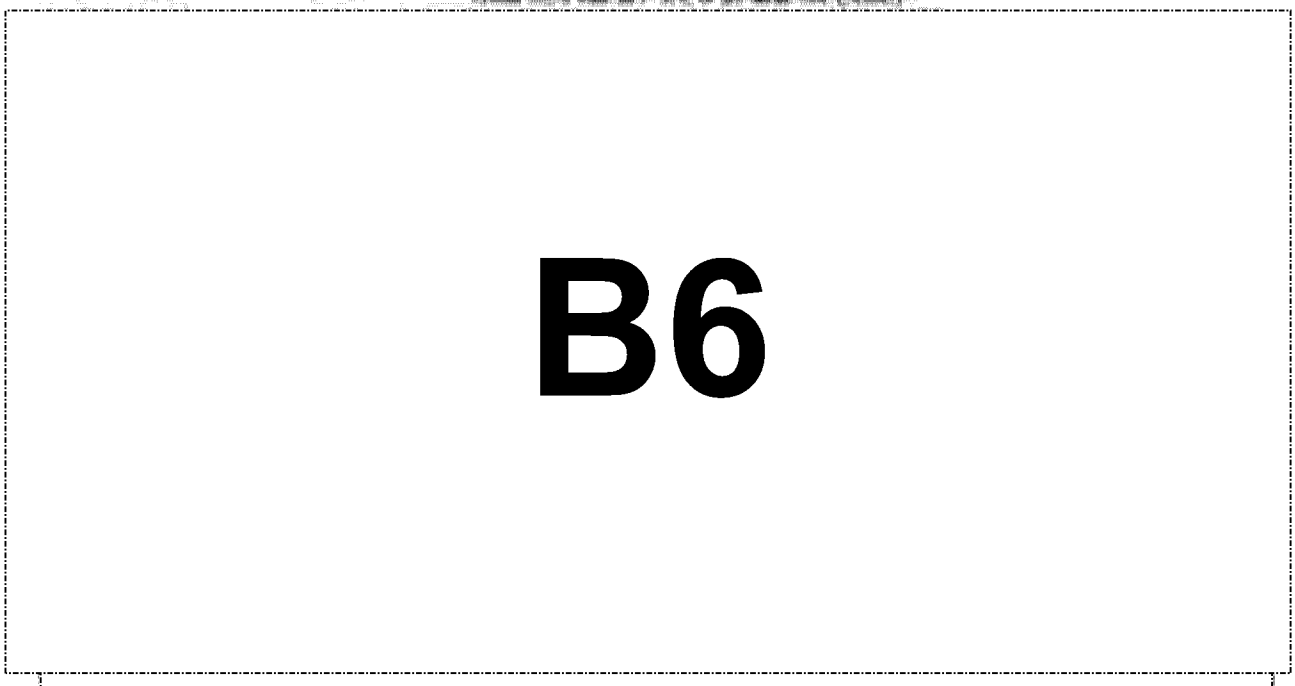
CRITICAL EVENTS

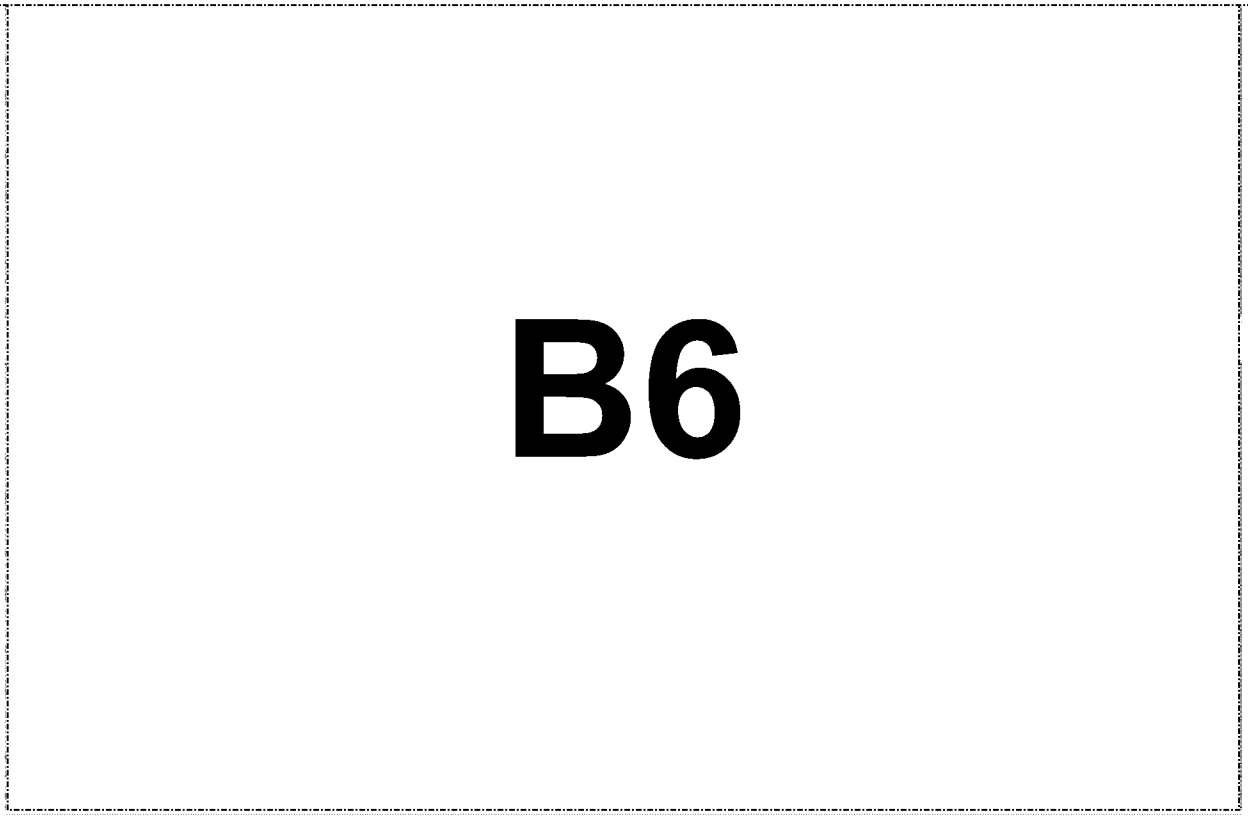


FDA-CVM-FOIA-2019-1704-010169



FULL-SIZED STRIPS



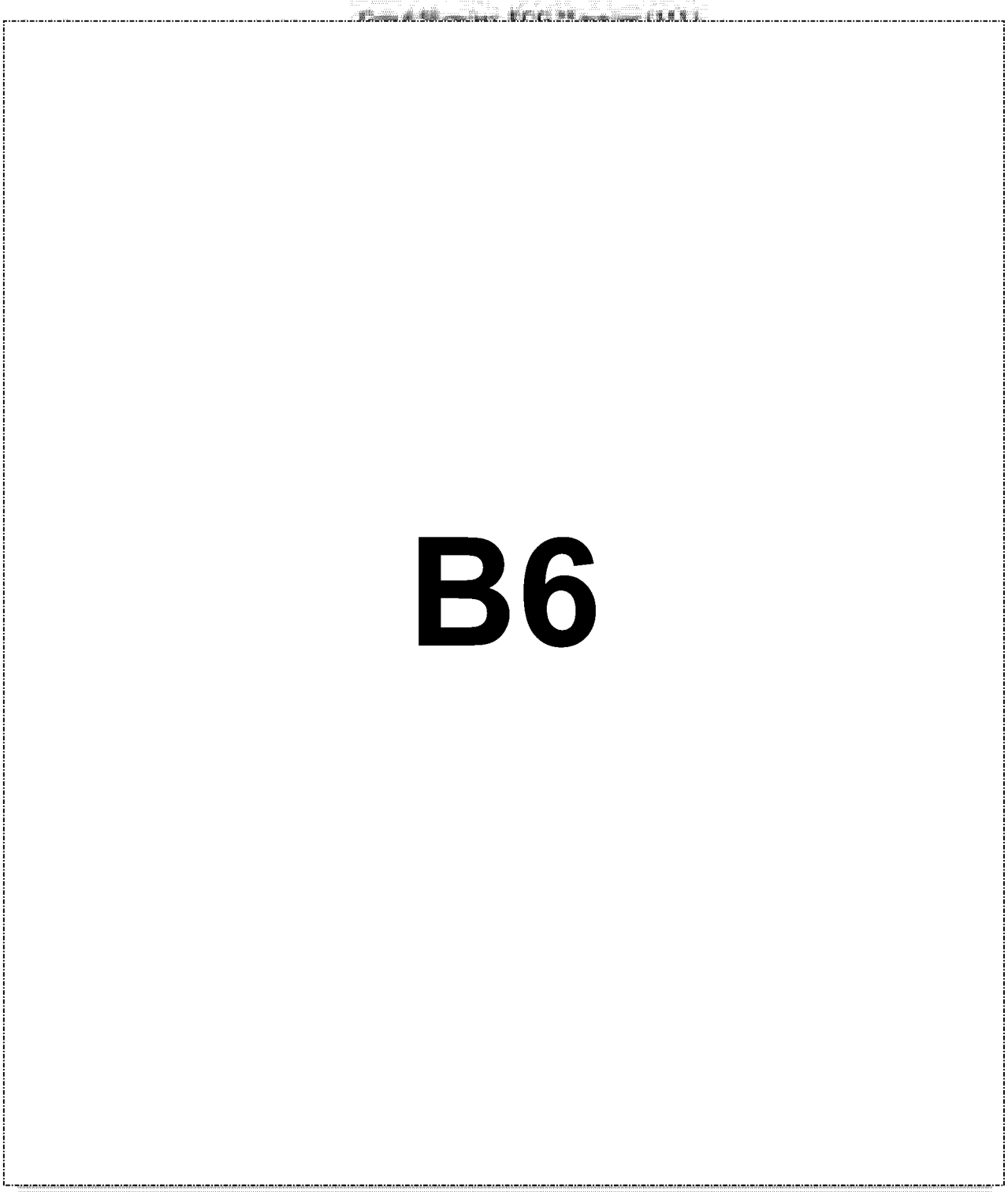


FDA-CVM-FOIA-2019-1704-010170

Client: B6
Patient:

Holter Monitior report 11/7/19

FULL-SIZED STRIPS



FDA-CVM-FOIA-2019-1704-010171

Holter Monitior report 11/7/19

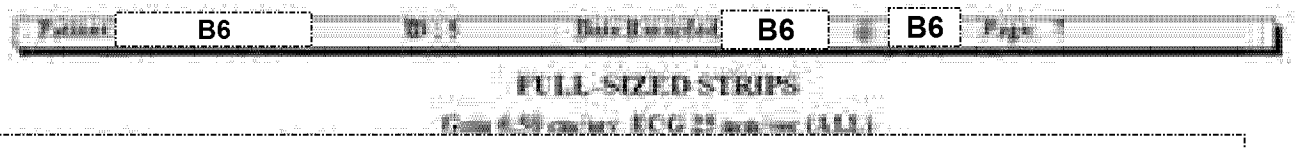
FULL-SIZED STRIPS

From 4:59 pm on 10/6/19 to 4:59 pm on 10/7/19

B6

FDA-CVM-FOIA-2019-1704-010172

Holter Monitior report 11/7/19



B6

FDA-CVM-FOIA-2019-1704-010173

Holter Monitior report 11/7/19

FULL-SIZED STRIPS

B6

FDA-CVM-FOIA-2019-1704-010174

Holter Monitior report 11/7/19

FULL-SIZED STRIPS

Gain 4.50 mm/mV ECG 25 mm/sec (ALL)

B6

FDA-CVM-FOIA-2019-1704-010175

Holter Monitior report 11/7/19

FULL-SIZED STRIPS

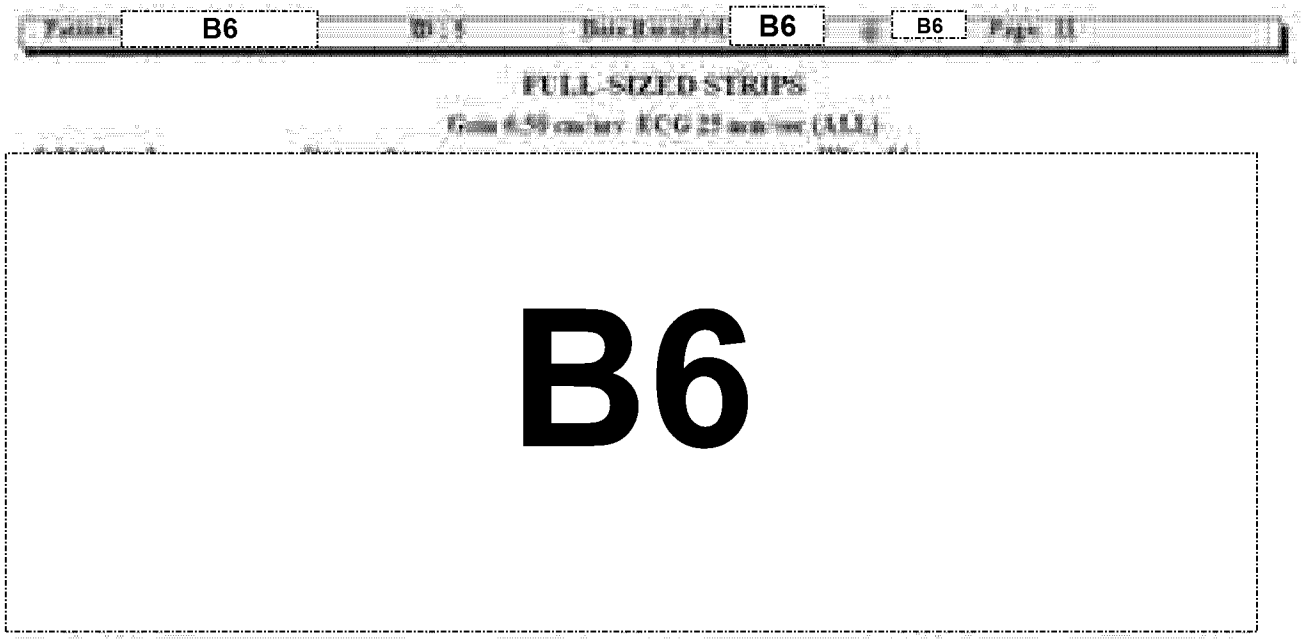
6 mm/mV ECG 25 mm/sec (ALL)

B6

FDA-CVM-FOIA-2019-1704-010176

Client: B6
Patient:

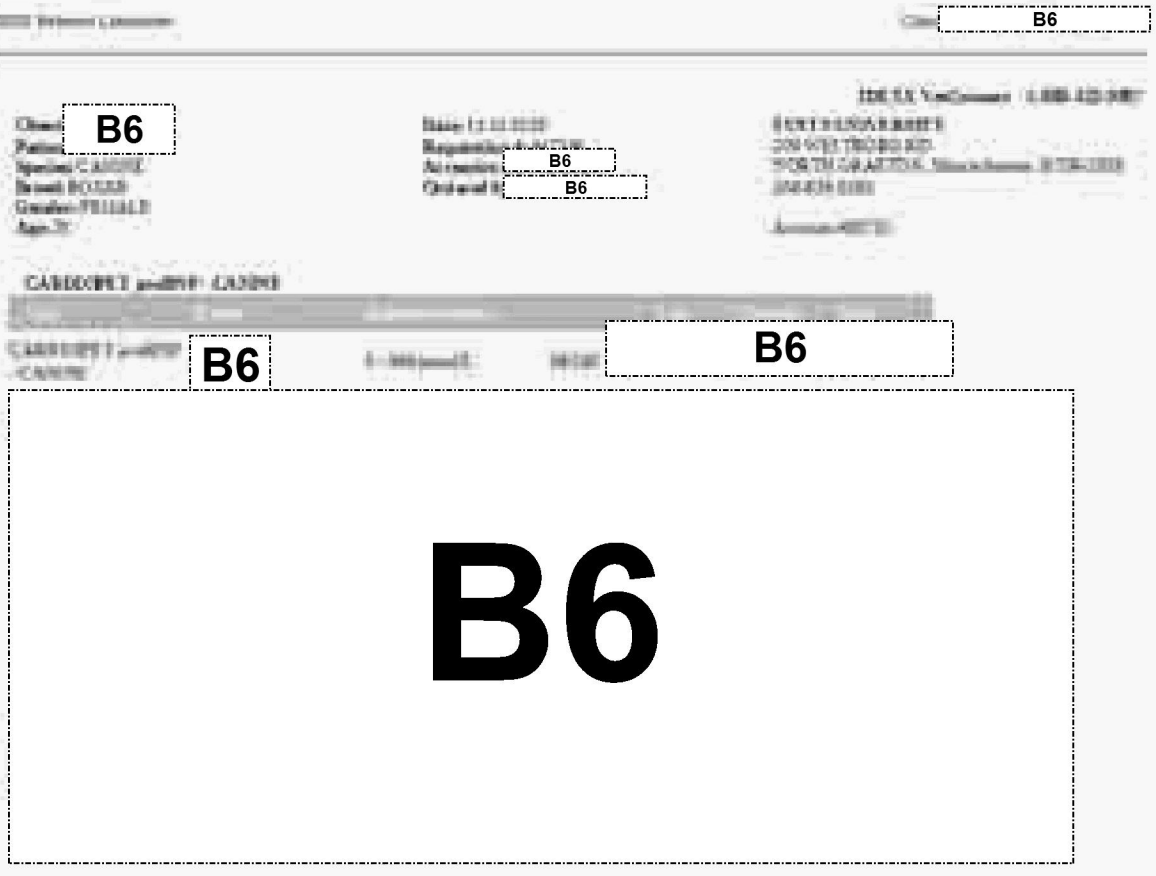
Holter Monitior report 11/7/19



FDA-CVM-FOIA-2019-1704-010177

Client: B6
Patient:

Lab Results IDEXX CARDIOPET proBNP 11/15/18



FDA-CVM-FOIA-2019-1704-010178

Client: B6
Patient:

Cardiac Troponin/Texgi SST 11/15/18

Gastrointestinal Laboratory
Dr. J.M. Steiner
Department of Small Animal Clinical Sciences
Texas A&M University
4474 TAMU
College Station, TX 77843-4474

Website User ID: cfingath@tufts.edu

GI Lab Assigned Clinic ID: 11488

B6
Tufts University Clinical Pathology Lab
Attn: B6
200 Westboro Road
North Grafton, MA 01536
USA

Phone: 508 887 4660
Fax: 1 508 839 7936
Animal Name: B6
Owner Name:
Species: Canine
Date Received: Nov 20, 2018

Tufts University Clinical Pathology Lab
Tracking Number B6

GI Lab Accession: B6

Test	Result	Reference Interval	Assay Date

B6

Comments:

B6
Canine
11/15/2018 3:51 PM
CARDIAC TROPONIN-TEXGI SST

GI Lab Contact Information

Phone: (979) 862-2661
Fax: (979) 862-2864

Email: glab@cvm.tamu.edu
vetmed.tamu.edu/glab

FDA-CVM-FOIA-2019-1704-010179

Client:
Patient: **B6**

Cardiac Troponin/Texgi SST 11/15/18

Gastrointestinal Laboratory
Dr. J.M. Steiner
Department of Small Animal Clinical Sciences
Texas A&M University
4474 TAMU
College Station, TX 77843-4474

Important Notices:

Ongoing studies

Cobalamin Supplementation Study- Dogs and cats with cobalamin deficiency with normal fPLI and either normal or low(consistent with EPI) TLI to compare the efficacy of oral vs parenteral cobalamin supplementation. Contact Dr. Chang at chchang@cvm.tamu.edu for further information.

Chronic Pancreatitis with Uncontrolled Diabetes Mellitus- Seeking dogs with chronic pancreatitis and uncontrolled diabetes mellitus for enrollment into a drug trial(medication provided at no cost). Contact Dr. Sue Yee Lim at slim@cvm.tamu.edu or Dr. Sina Marsilio at smarsilio@cvm.tamu.edu

Dogs with Primary Hyperlipidemia- Prescription diet naive dogs newly diagnosed with primary hyperlipidemia are eligible to be enrolled in a dietary trial. Contact Dr. Lawrence at ylawrence@cvm.tamu.edu for more information.

Dogs with Chronic Pancreatitis-Dogs with chronic pancreatitis (cPLI >400µg/L) and hypertriglyceridemia (>300 mg/dl) are eligible to be enrolled in a dietary trial. Contact Dr. Lawrence at ylawrence@cvm.tamu.edu

Chronic enteropathies in dogs-Please fill out this brief form http://tinyurl.com/lbd-enroll to see if your patient qualifies.

Feline Chronic Pancreatitis- Cats with chronic pancreatitis for more than 2 weeks and fPLI >10 µg/L are eligible for enrollment into a treatment trial investigating the efficacy of prednisolone or cyclosporine. Please contact Dr. Yamkate for further information at pyamkate@cvm.tamu.edu.

We can not accept packages that are marked "Bill Receiver"

Use our preprinted shipping labels to save on shipping. Call 979-862-2861 for assistance. The GI Lab is not here to accept packages on the weekend. Samples may be compromised if you ship for arrival on Saturday or Sunday or if shipped via US Mail.

GI Lab Contact Information

Phone: (979) 862-2861
Fax: (979) 862-2864
Email: gilab@cvm.tamu.edu
vetmed.tamu.edu/gilab

FDA-CVM-FOIA-2019-1704-010180

Client: B6
Patient:

TAURINE Panel 11/15/18

Veterinarian Contact: B6

Clinic/Company Name: Tufts Cummings School of Vet. Med. - Clinical Pathology Laboratory

Address: 200 Westboro Road, North Grafton, MA, 01536

Email: Clinpath@tufts.edu

Telephone: 508-887-4662 Fax: 508-839-7928

Billing Contact: B6 Email: B6

Billing Contact Phone: B6 Tax ID:

Patient Name: B6 Species: Cat

Breed: Owner's Name: B6

Current Diet:

Sample type: Plasma Whole Blood Urine Feces

Test: Taurine Complete Amino Acids Other: B6 Canine Taurine Panel, Lithium Heparin

Taurine Results (lab use only)

Plasma: B6 Whole Blood: B6 Urine: Feces:

	Plasma (nMol/ml)		Whole Blood (nMol/ml)	
	Normal Range	No known risk for deficiency	Normal Range	No known risk for deficiency
Cat	80-120	>40	300-600	>200
Dog	60-120	>40	200-350	>150

* Please note with the recent increase in the number of dogs screened for taurine deficiency, we are seeing dogs with values within the reference ranges (or above the "no known risk for deficiency range") yet are still exhibiting signs of cardiac disease. Veterinarians are welcome to contact our laboratory for assistance in evaluating your patient's results.

FDA-CVM-FOIA-2019-1704-010181

Client:
Patient: **B6**

TAURINE Panel 11/15/18

UC DAVIS
VETERINARY MEDICINE

CARDIOLOGY SERVICE UPDATES: DOG FOOD & DILATED CARDIOMYOPATHY

The Cardiology Service has developed this document in response to the alerts from the FDA. These alerts identify an associated risk for some grain-free diets containing certain ingredients (legumes like peas, pea components, lentils, white potatoes, sweet potatoes) and a diagnosis of dilated cardiomyopathy (DCM). The links provided throughout this document can be copied and pasted to obtain additional information.

FDA Alerts found here:
https://www.fda.gov/AnimalVeterinary/NewsEvents/CVMUpdates/ucm611000.htm
https://www.fda.gov/AnimalVeterinary/ResourcesforYouAnimalHealth/ucm611379.htm

What is Dilated Cardiomyopathy (DCM)?
DCM is a heart muscle disorder that results in a weak pump function and heart chamber enlargement. In the early stages of this disease pets may appear totally healthy with no apparent clinical signs. Later in the course of this disease, dogs may have a heart murmur, an arrhythmia (irregular heart beat), collapse episodes, weakness or tiredness with exercise, and even trouble breathing from congestive heart failure. While there are some breeds of dogs (like Dobermans) that have a genetic predisposition to development of DCM, there are also nutritional factors that may result in this disease.

What should I do?
If you are feeding a diet of concern based upon the FDA alert we recommend that you consult with your veterinarian or veterinary cardiologist. We provide 4 general points for guidance below:

1. An initial step is to **consider whether you are willing or interested in performing additional testing** to assess whether your pet is affected with DCM. If you believe your dog is at risk, showing any of the aforementioned clinical signs or would prefer to simply rule out any heart disease, we recommend that you first have your pet's taurine levels tested (both whole blood and plasma levels) as well as seek an echocardiogram by a board-certified veterinary cardiologist. Low taurine levels are associated with development of DCM in dogs and are sometimes a component of this current issue.

Information on taurine testing can be found here: https://www.vetmed.ucdavis.edu/labs/amino-acid-laboratory

2. At this time, **diet change is recommended when possible** and should be considered regardless of the results obtained from any testing. You can consult with your veterinarian in selecting a new diet that avoids the ingredients of concern listed by the FDA. When selecting this diet, we recommend that you choose a diet that is manufactured with rigorous quality control measures and research behind the formulation. A way to ensure that your diet meets these recommendations is to follow the following guidelines that were generated by a large number of the world's leading experts in veterinary nutrition.

Food selection guidelines found here:
https://www.wsava.org/WSAVA/media/Arpita-and-E-mma-editorial/Selecting-the-Best-Food-for-your-Pet.pdf

3. If your pet is identified through testing to have a low blood taurine level or evidence of DCM by echocardiogram, we urge you to **report this information to the FDA.**

FDA reporting guidelines found here: https://www.fda.gov/AnimalVeterinary/SafetyHealth/ReportaProblem/ucm383412.htm

4. **Work with your veterinarian(s)** to determine the best course of action and medical treatments if indicated. In the case of a DCM diagnosis, diet change alone may not be sufficient and additional medications may be prescribed.

Please continue to monitor the FDA website and the UC Davis School of Veterinary Medicine Newsfeeds for updates and recommendations regarding this issue.

FDA-CVM-FOIA-2019-1704-010182

Client: B6
Patient:

Diet hx

CARDIOLOGY DIET HISTORY FORM

Please answer the following questions about your pet

Pet's name: B6 Owner's name: B6 today's date: 1/11/2019

1. How would you describe your pet's appetite? (mark the point on the line below that best represents your pet's appetite)
   Example: Poor _____ Excellent
   Poor _____ Excellent

2. Have you noticed a change in your pet's appetite over the last 1-2 weeks? (check all that apply)
   ☒Eats about the same amount as usual ☐Eats less than usual ☐Eats more than usual
   ☐Seems to prefer different foods than usual ☐Other: _____

3. Over the last few weeks, has your pet (check one)
   ☐Lost weight ☐Gained weight ☒Stayed about the same weight ☐Don't know

4. Please list below ALL pet foods, people food, treats, snack, dental chews, rawhides, and any other food item that your pet currently eats. Please include the brand, specific product, and flavor so we know exactly what you pet is eating.

   Examples are shown in the table – please provide enough detail that we could go to the store and buy the exact same food.

Food (include specific product and flavor)	Form	Amount	How often?	Fed since
Nutro Grain Free Chicken, Lentil, & Sweet Potato Adult	dry	1 ¾ cup	2x/day	Jan 2018
85% lean hamburger	microwaved	3 oz	1x/week	Jan 2018
Pupperoni original beef flavor	treat	4	1x/day	Aug 2018
Rawhide	treat	6 inch twist	1x/week	Dec 2018
Fish Pattern – Mature Cream Variety	dry	1 ¾	2x/day	Sept 2018
Scratch – Fractured Corn	canned	1 tbsp	3 x/week	2018
Purina Beneful Chicken (Discontinued)		½ cup	1x/week	~2017
Canned – mixed (Discontinued)		½ cup	1x/week	~2017
Purina – Medallion (Discontinued)		½ cup	2-3 days	~2017 (Puppy)
(DO NOT SCRATCH, DO NOT USE!!)				

*Any additional diet information can be listed on the back of this sheet

5. Do you give any dietary supplements to your pet (for example: vitamins, glucosamine, fatty acids, or any other supplements)? ☒Yes ☐No If yes, please list which ones and give brands and amounts:

		Brand/Concentration	Amount per day
Taurine	☐Yes ☐No		
Carnitine	☐Yes ☐No		
Antioxidants	☐Yes ☐No		
Multivitamin	☐Yes ☐No		
Fish oil	☐Yes ☐No		
Coenzyme Q10	☐Yes ☐No		
Other (please list)			
Example: vitamin C		Nature's Bounty	500 mg tablets – 1 per day
[illegible]		[illegible]	[illegible]

6. How do you administer pills to your pet?
   ☐I do not give any medications
   ☐I put them directly in my pet's mouth without food
   ☐I put them in my pet's dog/cat food
   ☐I put them in a Pill Pocket or similar product
   ☒I put them in foods pet foodies small piece (w/ cream) cheese

FDA-CVM-FOIA-2019-1704-010183

Client: B6
Patient:

Vitals Results

B6	5 3:29:53 PM	Weight (kg)	B6
	16 2:23:42 PM	Weight (kg)	
	17 10:41:26 AM	Weight (kg)	
	2:45:48 PM	Weight (kg)	
B6	2:01:47 PM	Weight (kg)	

FDA-CVM-FOIA-2019-1704-010184

Client: B6
Patient:

ECG from Cardio

B6

B6

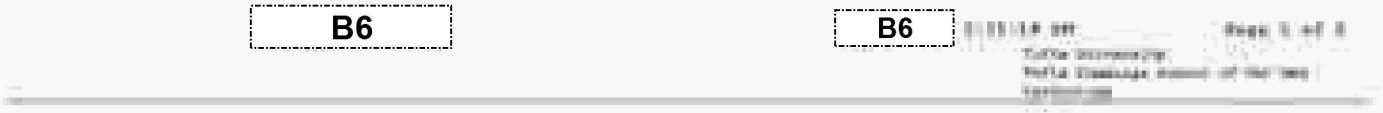
B6

FDA-CVM-FOIA-2019-1704-010185

Client: B6
Patient:

ECG from Cardio

B6 B6



B6

FDA-CVM-FOIA-2019-1704-010186

Client: B6
Patient:

ECG from Cardio

B6 B6

B6

FDA-CVM-FOIA-2019-1704-010187

Client: B6
Patient:

ECG from Cardio

B6 B6

B6

FDA-CVM-FOIA-2019-1704-010188

Client: B6
Patient:

ECG from Cardio

B6

B6

B6

FDA-CVM-FOIA-2019-1704-010189

Client: B6
Patient:

ECG from Cardio

B6

B6

B6

FDA-CVM-FOIA-2019-1704-010190

Client: B6
Patient:

ECG from Cardio

B6 B6

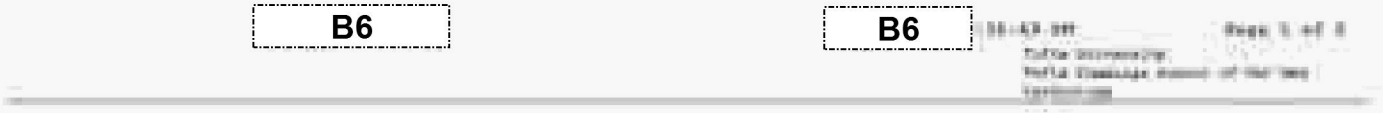
B6

FDA-CVM-FOIA-2019-1704-010191

Client: B6
Patient:

ECG from Cardio

B6 B6



B6

FDA-CVM-FOIA-2019-1704-010192

Client: B6
Patient:

ECG from Cardio

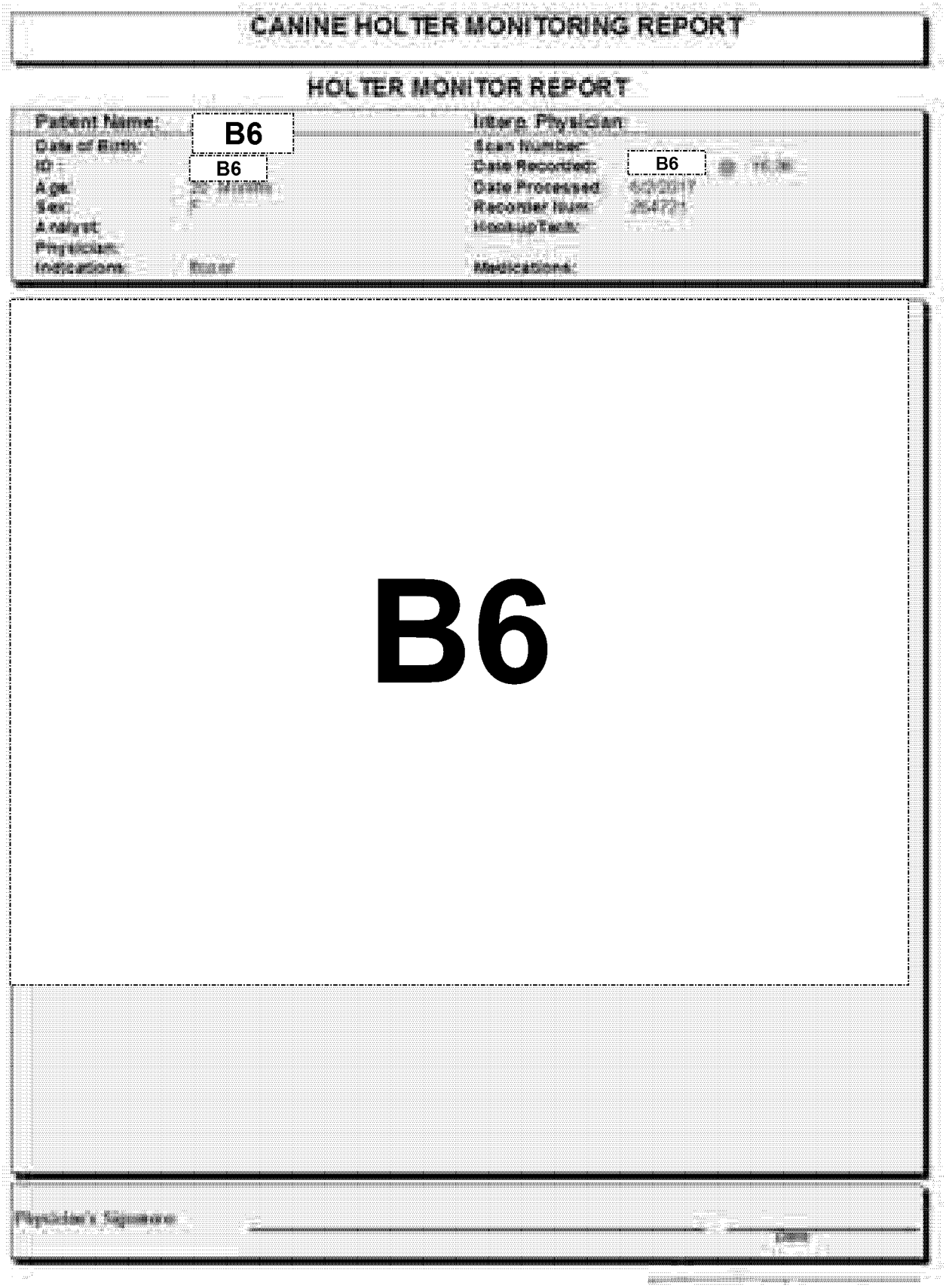
B6 B6

B6

FDA-CVM-FOIA-2019-1704-010193

Client: B6
Patient:

Alba Hotler



FDA-CVM-FOIA-2019-1704-010194

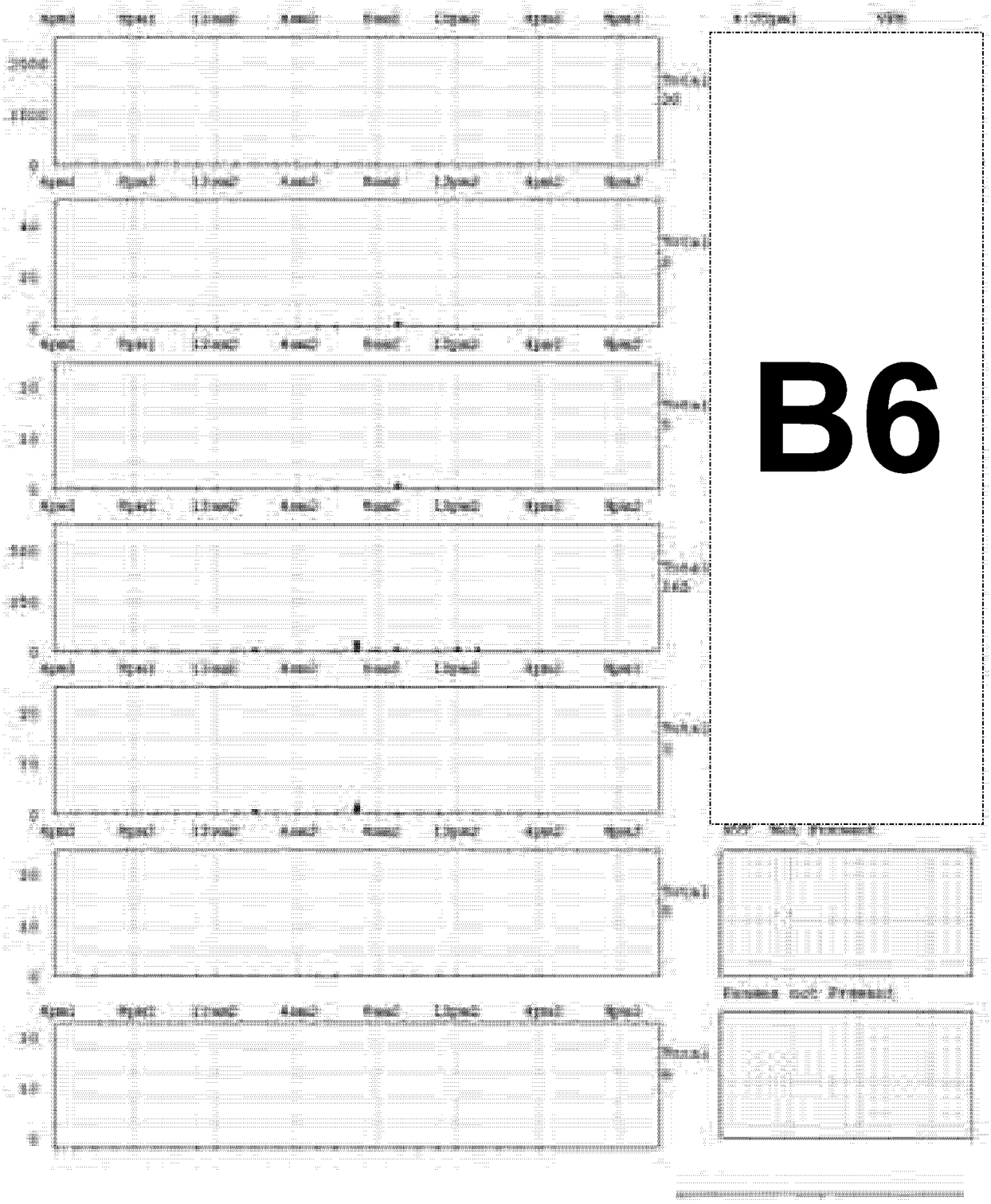
Alba Hotler

GENERAL PROFILE

B6

FDA-CVM-FOIA-2019-1704-010195

CRITICAL EVENTS



FDA-CVM-FOIA-2019-1704-010196

B6 B6 B6 B6

FULL SIZED STRIPS

B6

FDA-CVM-FOIA-2019-1704-010197

FULL SIZED STRIPS

B6

FDA-CVM-FOIA-2019-1704-010198

FULL SIZED STRIPS

Gain 0.50 cm/mV ECG 25 mm/sec (ALL)

B6

FDA-CVM-FOIA-2019-1704-010199

B6 B6 B6 B6

FULL SIZED STRIPS

B6

FDA-CVM-FOIA-2019-1704-010200

FULL SIZED STRIPS

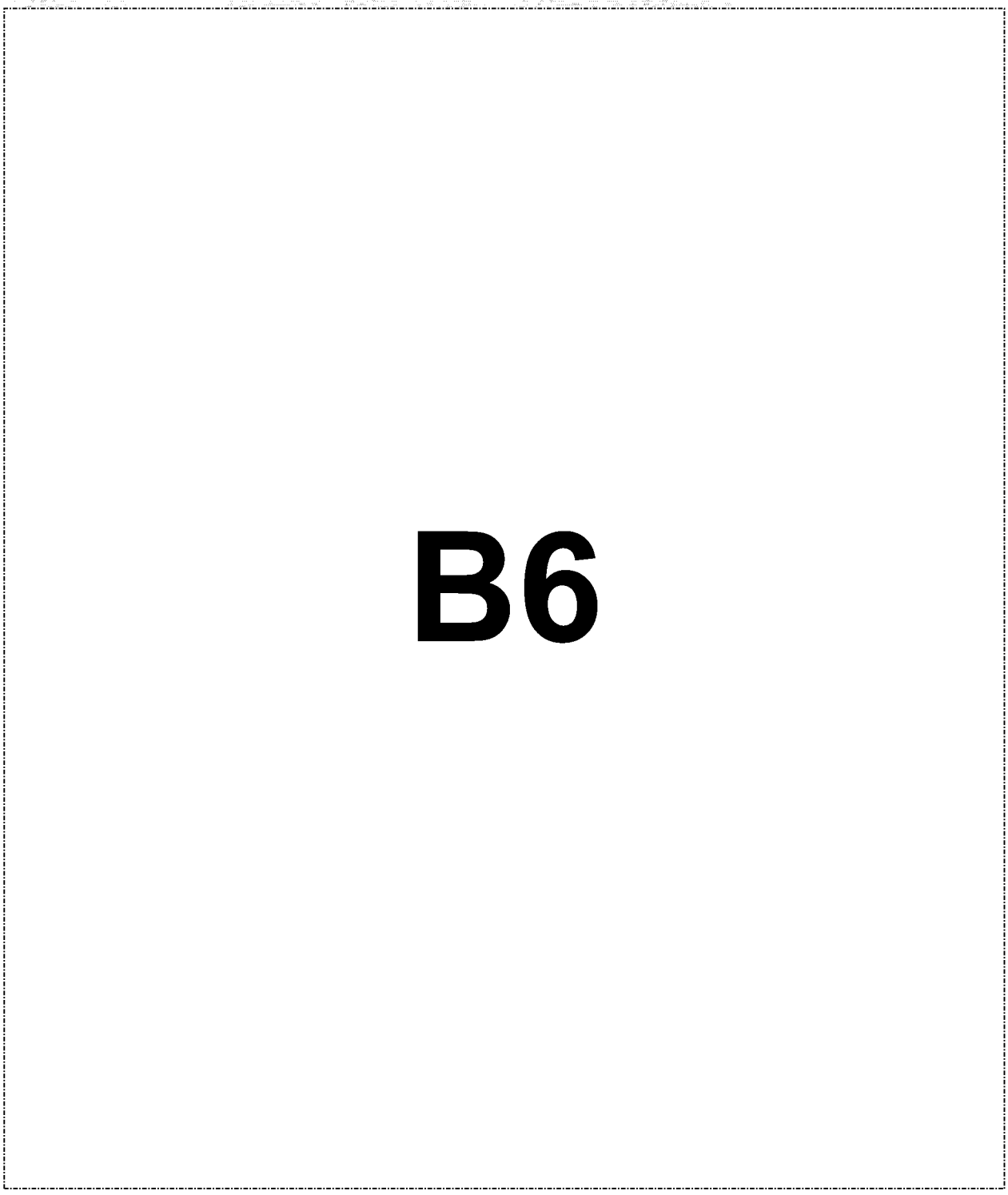
Gain 0.50 cm/mV 12SL 25 mm/sec (ALL)

B6

FDA-CVM-FOIA-2019-1704-010201

B6 B6 B6 B6

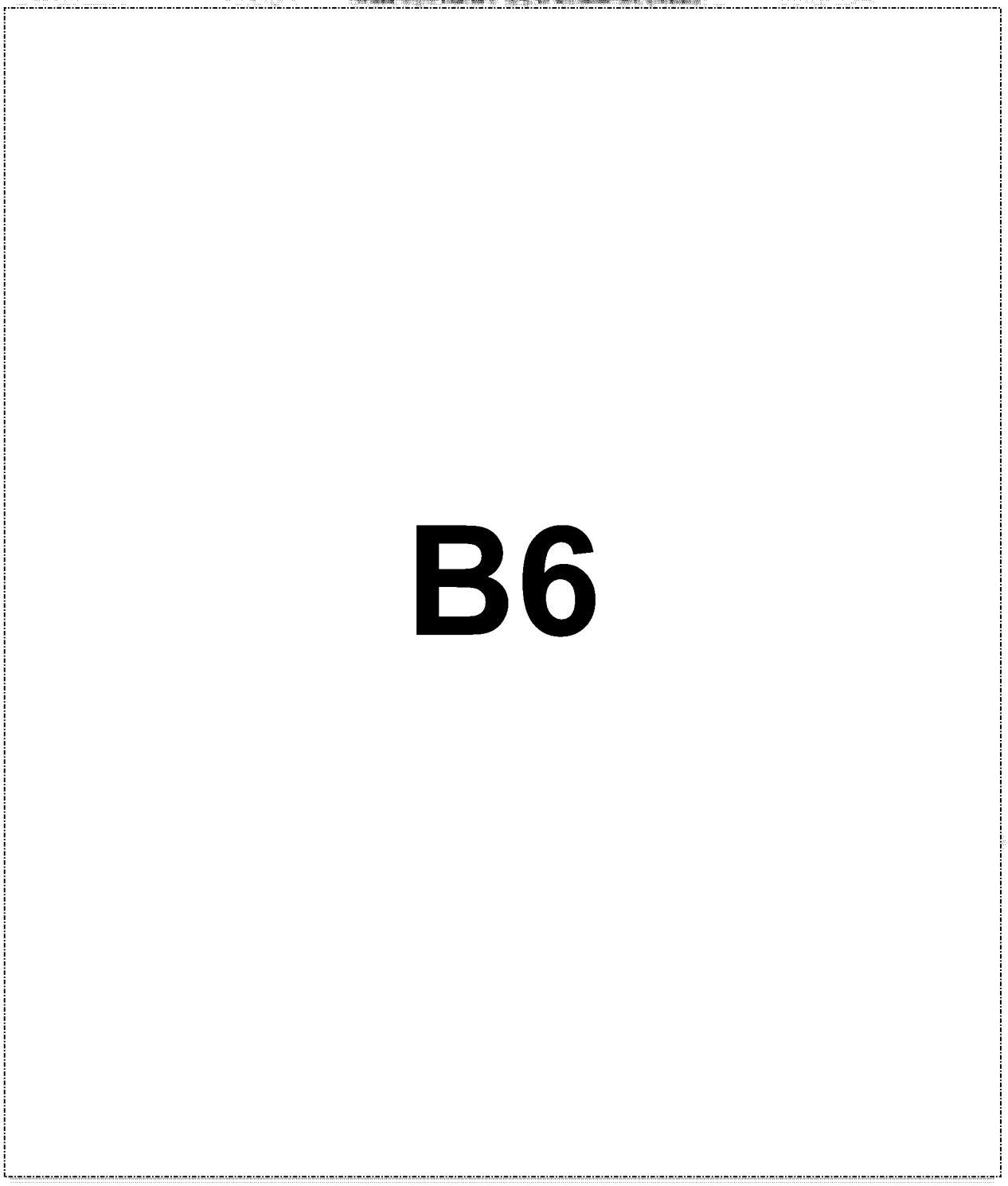
FULL SIZED STRIPS



FDA-CVM-FOIA-2019-1704-010202

FULL SIZED STRIPS

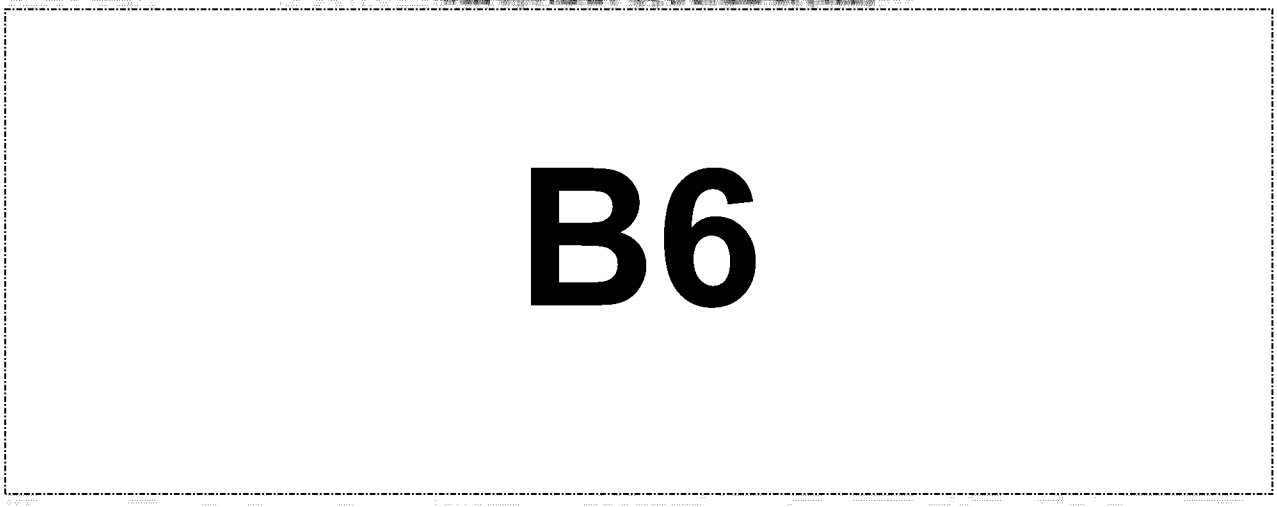
Gain 0.50 cm/mV ECG 25 mm/sec (ALL)



FDA-CVM-FOIA-2019-1704-010203

FULL SIZED STRIPS

(Gain 0.50 cm/mV ECG 25 mm/sec (ALL)



FDA-CVM-FOIA-2019-1704-010204

Client: B6
Patient:

ECG from Cardio

B6

B6

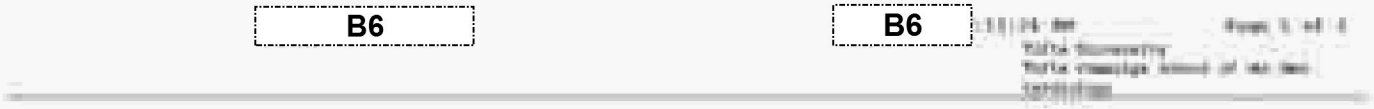
B6

FDA-CVM-FOIA-2019-1704-010205

Client: B6
Patient:

ECG from Cardio

B6 B6



B6

FDA-CVM-FOIA-2019-1704-010206

Client: B6
Patient:

ECG from Cardio

B6 B6

B6

FDA-CVM-FOIA-2019-1704-010207

Client: B6
Patient:

ECG from Cardio

B6 B6

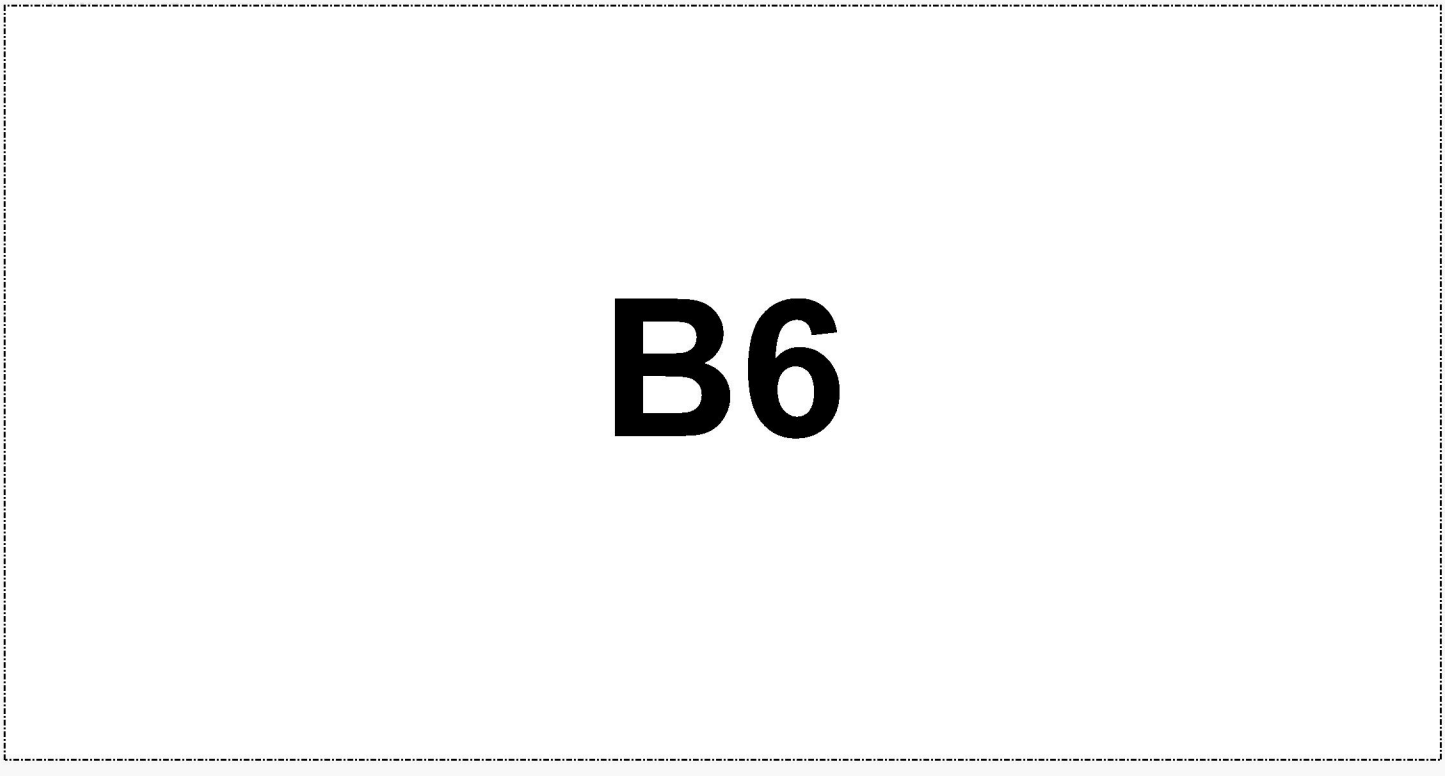
B6

FDA-CVM-FOIA-2019-1704-010208

Client: B6
Patient:

ECG from Cardio

B6 B6



FDA-CVM-FOIA-2019-1704-010209

Client: B6
Patient:

Patient History

B6	03:28 PM	Appointment
	04:51 PM	Appointment
	04:52 PM	Appointment
	04:53 PM	Appointment
	04:58 PM	Appointment
	04:58 PM	Appointment
	04:59 PM	Appointment
B6	05:19 PM	Purchase
	02:33 PM	UserForm
	02:45 PM	Purchase
	03:29 PM	Vitals
	03:30 PM	Purchase
	03:40 PM	Treatment
	04:02 PM	UserForm
	05:47 PM	Email
	05:47 PM	Email
	12:15 PM	Appointment
B6	02:10 PM	UserForm
	02:23 PM	UserForm
	02:23 PM	Vitals
	03:10 PM	Treatment
	03:10 PM	Purchase
	03:22 PM	Purchase
	04:46 PM	UserForm
	03:24 PM	Email
	02:20 PM	Appointment
	02:20 PM	Appointment
	02:22 PM	Appointment

B6

FDA-CVM-FOIA-2019-1704-010210

Client: B6
Patient:

Patient History

	02:18 PM	UserForm
	02:22 PM	UserForm
	03:07 PM	Treatment
	03:39 PM	Purchase
	03:52 PM	Purchase
	04:15 PM	Purchase
	04:36 PM	Prescription
	04:38 PM	Purchase
	09:56 AM	Appointment
	10:46 AM	Appointment
	09:50 AM	Appointment
	09:57 AM	UserForm
	10:17 AM	Purchase
	10:26 AM	Treatment
	10:41 AM	Vitals
	11:08 AM	Purchase
B6	11:20 AM	Purchase
	11:51 AM	UserForm
	05:22 PM	Email
	08:51 AM	Appointment
	02:19 PM	UserForm
	02:43 PM	UserForm
	02:45 PM	Treatment
	02:45 PM	Vitals
	02:46 PM	Purchase
	03:26 PM	Purchase
	12:57 PM	Email
	10:35 AM	UserForm
	05:14 PM	Appointment
	06:58 PM	Appointment
	01:02 PM	UserForm
	01:04 PM	Treatment
	02:01 PM	Vitals
	02:22 PM	Prescription

B6

FDA-CVM-FOIA-2019-1704-010211

Client: B6
Patient:

Patient History

B6	03:00 PM	Deleted Reason
	03:00 PM	Deleted Reason
	03:00 PM	Deleted Reason
	03:22 PM	Purchase
	03:25 PM	Purchase
	03:25 PM	Purchase
	03:36 PM	Labwork
	03:36 PM	Purchase
	04:48 PM	UserForm
	06:08 PM	Email

B6

FDA-CVM-FOIA-2019-1704-010212

Tufts University | Cummings School of Veterinary Medicine

Healing Animals. Helping Humans. Transforming Global Health

Foster Hospital for Small Animals
25 Willard Street
North Grafton, MA 01536
Telephone: (508) 839-5395
Fax: (508) 839-8739
http://vetmed.tufts.edu/

B6

B6 Female
Canine Boxer Fawn
B6

B6

B6

Dear B6

Thank you for referring B6 with their pet B6

If you have any questions, or concerns, please contact us at 508-887-4988.

Thank you,

B6 DVM, DACVIM (Cardiology)

Tufts University | Cummings School of Veterinary Medicine

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North Grafton, MA 01536
Telephone: (508) 839-5395
Fax: (508) 839-8739
http://vetmed.tufts.edu/

B6

B6 Female
Canine Boxer Fawn
B6

B6

Date B6

Thank you for referring B6 with their pet B6

If you have any questions, or concerns, please contact us at 508-887-4988.

Thank you,

B6 DVM, DACVIM (Cardiology)

Cummings
Veterinary Medical Center
AT TUFTS UNIVERSITY

Foster Hospital for Small Animals
35 Willard Street
North Grafton, MA 01536
Telephone: (508) 839-5395
Fax: (508) 839-8739
http://vetmed.tufts.edu/

B6

B6

B6, Female
Canine Boxer Fawn
B6

B6

Dear B6

Thank you for referring B6 with their pet B6

If you have any questions, or concerns, please contact us at 508-887-4988.

Thank you,

B6 DVM (Resident, Cardiology)

Cummings
Veterinary Medical Center
AT TUFTS UNIVERSITY

Foster Hospital for Small Animals
25 Willard Street
North Grafton, MA 01536
Telephone: (508) 839-5395
Fax: (508) 839-7951
http://vetmed.tufts.edu/

B6

B6 Female
Canine Boxer Fawn
B6

B6

B6

Dear B6

Thank you for referring B6 with their pet B6

If you have any questions, or concerns, please contact us at 508-887-4988.

Thank you,

B6 DVM, DACVIM (Cardiology)

Cummings
Veterinary Medical Center
AT TUFTS UNIVERSITY

Foster Hospital for Small Animals
35 Willard Street
North Grafton, MA 01536
Telephone: (508) 839-5395
Fax: (508) 839-7951
http://vetmed.tufts.edu/

B6

B6 Female
Canine Boxer Patient
B6

B6

Dear B6

Thank you for referring B6 with their pet B6.

If you have any questions, or concerns, please contact us at 508-887-4988.

Thank you,

B6 DVM, DACVIM (Cardiology)

Cummings
Veterinary Medical Center
AT TUFTS UNIVERSITY

Foster Hospital for Small Animals
25 Willard Street
North Grafton, MA 01536
Telephone: (508) 839-5395
Fax: (508) 839-7951
http://vetmed.tufts.edu/

B6

B6 Female
Canine Boxer Fawn
B6

11/26/2018

Dear B6

Thank you for referring B6 with their pet B6

If you have any questions, or concerns, please contact us at 508-887-4988.

Thank you,

B6 DVM, DACVIM (Cardiology)

From: PFR Event <pfreventcreation@fda.hhs.gov>

To: Cleary, Michael *; HQ Pet Food Report Notification; B6

Sent: 12/27/2018 3:56:41 PM

Subject: Homecooked diet - see diet history in medical record: Lisa Freeman - EON-374789

Attachments: 2060600-report.pdf; 2060600-attachments.zip

A PFR Report has been received and PFR Event [EON-374789] has been created in the EON System.

A "PDF" report by name "2060600-report.pdf" is attached to this email notification for your reference. Please note that all documents received in the report are compressed into a zip file by name "2060600-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-374789
ICSR #: 2060600
EON Title: PFR Event created for Homecooked diet - see diet history in medical record; 2060600

AE Date	11/15/2018	**Number Fed/Exposed**	1
Best By Date		**Number Reacted**	1
Animal Species	Dog	**Outcome to Date**	Stable
Breed	Doberman Pinscher		
Age	B6 Years		
District Involved	PFR-New England DO		

Product information
Individual Case Safety Report Number: 2060600
Product Group: Other
Product Name: Homecooked diet - see diet history in medical record
Description: Arrhythmia identified at primary care vet on 11/15/18. Evaluated at Tufts B6 and diagnosed DCM with VPCs and APCs. Eating unbalanced homecooked diet. WB taurine B6 (plasma not measured because owner had started taurine supplementation). Owner was recommended to change diet and we will recheck in 3 months
Submission Type: Initial

Report Type: Adverse Event (a symptom, reaction or disease associated with the product)
Outcome of reaction/event at the time of last observation: Stable
Number of Animals Treated With Product: 1
Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Homecooked diet - see diet history in medical record		

Sender information
Lisa Freeman
200 Westboro Rd
North Grafton, MA 01536
USA

Owner information
B6
USA

To view this PFR Event, please click the link below:
https://eon.fda.gov/eon//browse/EON-374789

To view the PFR Event Report, please click the link below:
https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jspa?decorator=none&e=0&issueType=12&issueId=391798

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This email and attached document are being provided to you in your capacity as a Commissioned Official with the U.S. Department of Health and Human Services as authorized by law. You are being provided with this information pursuant to your signed Acceptance of Commission.

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Report Details - EON-374789

ICSR:	2060600	
Type Of Submission:	Initial	
Report Version:	FPSR.FDA.PETF.V.V1	
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)	
Reporting Type:	Voluntary	
Report Submission Date:	2018-12-27 10:47:28 EST	
Reported Problem:	**Problem Description:**	Arrhythmia identified at primary care vet on 11/15/18. Evaluated at Tufts B6 and diagnosed DCM with VPCs and APCs. Eating unbalanced homecooked diet. WB taurine B6 plasma not measured because owner had started taurine supplementation). Owner was recommended to change diet and we will recheck in 3 months
	Date Problem Started:	11/15/2018
	Concurrent Medical Problem:	Yes
	Pre Existing Conditions	B6
	Outcome to Date:	Stable
Product Information:	**Product Name:**	Homecooked diet - see diet history in medical record
	Product Type:	Other
	Lot Number:	
	Product Use Information:	
	Manufacturer /Distributor Information:	
	Purchase Location Information:	
Animal Information:	**Name:**	B6
	Type Of Species:	Dog
	Type Of Breed:	Doberman Pinscher
	Gender:	Male
	Reproductive Status:	Neutered
	Weight:	40.9 Kilogram
	Age:	B6 Years
	Assessment of Prior Health:	Good
	Number of Animals Given the Product:	1
	Number of Animals Reacted:	1
	Owner Information:	**Owner Information provided:** Yes
		Contact: **Name:** B6
		Phone: B6
		Email: B6
		Address: B6 United States
	Healthcare Professional Information:	**Practice Name:** Tufts Cummings School of Veterinary Medicine
		Contact: **Name:** Lisa Freeman
		Phone: (508) 887-4523

FDA-CVM-FOIA-2019-1704-010221

		Email:	lisa.freeman@tufts.edu
		Address:	200 Westboro Rd North Grafton Massachusetts 01536 United States

Sender Information:	**Name:**	Lisa Freeman	
	Address:	200 Westboro Rd North Grafton Massachusetts 01536 United States	
	Contact:	**Phone:**	5088874523
		Email:	lisa.freeman@tufts.edu
	Permission To Contact Sender:	Yes	
	Preferred Method Of Contact:	Email	

Additional Documents:		
	Attachment:	rpt_medical_record_preview.pdf
	Description:	**B6** medical records
	Type:	Medical Records

FDA-CVM-FOIA-2019-1704-010222

Cummings
Veterinary Medical Center
AT TUFTS UNIVERSITY

B6

Patient: B6
B6 Male (Neutered)
Canine Doberman Pinscher
Patient ID: B6

SURGERY REPORT

Date of report: B6
Attending Clinician: B6
Date of procedure: B6
Primary Surgeon: B6 BVSc
Secondary Surgeon: B6 DVM DACVS
Procedure(s) performed: B6

Report:

B6

Specimens obtained:
Right B6 mass for histopathology

Cummings Veterinary Medical Center
AT TUFTS UNIVERSITY

Oncology Liaison: 508-887-4682

Foster Hospital for Small Animals
55 Willard Street
North Grafton, MA 01536
Telephone (508) 839-5395
Fax (508) 839-7951
http://vetmed.tufts.edu/

Patient
Name: B6
Signalment: Years Old Black/Tan Male (Neutered) Doberman Pinscher

Owner
Name:
Address: B6

Patient ID: B6

Contact Clinician: B6 DVM (Medical Oncology Resident)
Alternate Clinician: B6 DVM DACVIM
Student: B6 V'19

Discharge Instructions

Appointment Date: B6

Diagnosis:
1. B6

Procedures:
1. Physical examination
2. Complete blood count
3. Blood chemistry profile
4. Urinalysis

Medications:
Dispense:

B6

Continue:

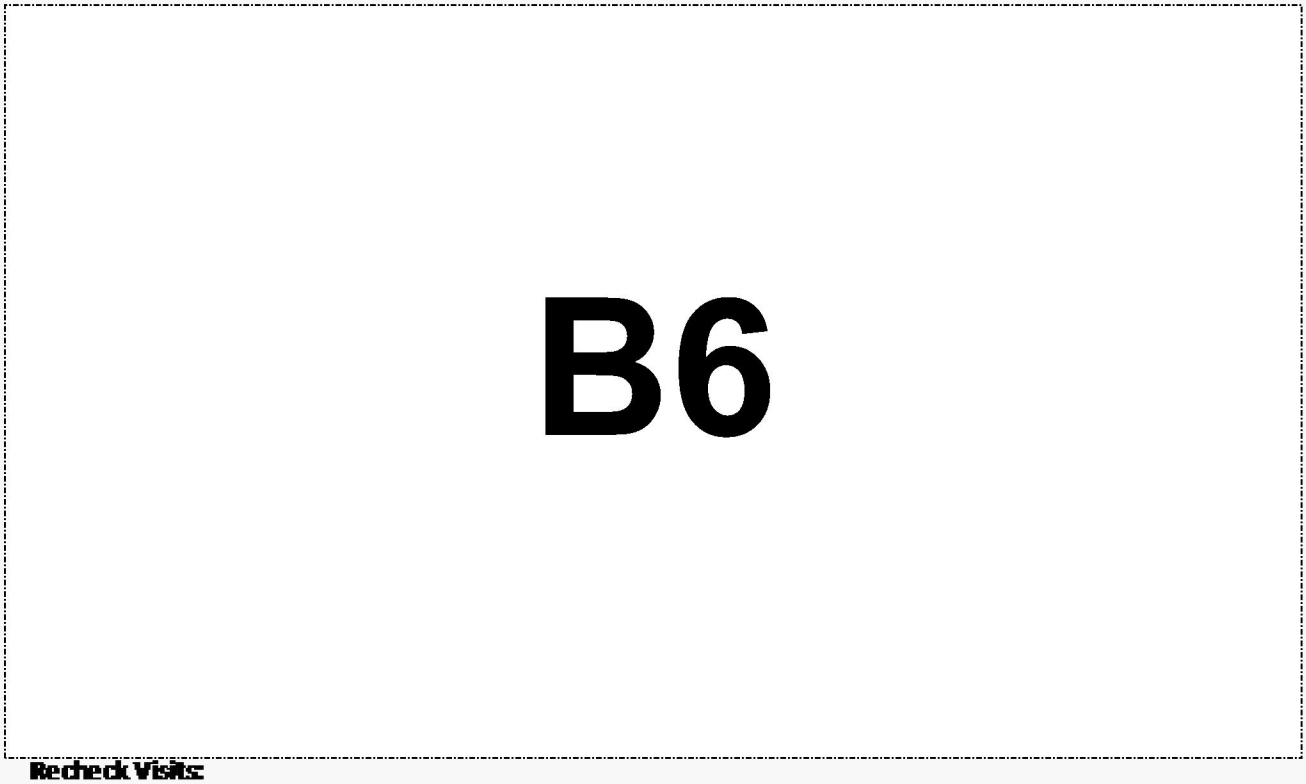
Diet:
Please continue feeding B6 the diet you have discussed with the Cardiology department.

CASE SUMMARY

Thank you for bringing B6 to the Tufts Oncology Service for evaluation of his B6 The bulk of his B6 by Tufts Surgery department on B6 and you report he has recovered well from

surgery with minimal pain. On physical exam, B6 is bright and alert, but nervous to be here. His B6

B6



Recheck Visits:

1. B6 **should have a complete blood count checked in 2 weeks – this can be done at your primary care veterinarian and faxed to us, or can be done here as a technician appointment.**

2. **I'd like to see** B6 **back in one month for a physical examination, complete blood count, chemistry panel, and urinalysis in one month. You can schedule this by calling our liaison at 508-887-4682.**

3. **After that visit, we can then plan to see him back every 2-3 months.**

Thank you for entrusting us with B6 **care! He is the sweetest boy and the best patient.**

***Cummings Veterinary Medical Center offers a free support group for caregivers of companion animals with cancer. For more information please visit our website http://vetmed.tufts.edu/oncology**

Prescription Refill Disclaimer:

For the safety and well-being of our patients, your pet must have had an examination by one of our veterinarians within the past year in order to obtain prescription medications.

Ordering Food:

Please check with your primary veterinarian to purchase the recommended diet(s). If you wish to purchase your food from us, please call 7-10 days in advance (508-887-4629) to ensure the food is in stock. Alternatively, veterinary diets can be ordered from online retailers with a prescription/veterinary approval

Clinical Trials:

Clinical trials are studies in which our veterinary doctors work with you and your pet to investigate a specific disease process or a promising new test or treatment. Please see our website: vet.tufts.edu/cvmc/clinical-studies

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FDA-CVM-FOIA-2019-1704-010226

Cummings
Veterinary Medical Center
AT TUFTS UNIVERSITY

B6

B6 Male (Neutered)
Canine Doberman Pinscher Black/Tan
Patient ID: B6

Outside Prescription Log

1. Date: B6
   Clinician: B6
   Prescription: B6 B6
   Pharmacy sent to: B6 fill online
   Completed by:
   Origin of request:

2. Date: B6
   Clinician: B6
   Prescription: B6
   Pharmacy sent to: B6
   Completed by: B6
   Origin of request:

3. Date:
   Clinician:
   Prescription:
   Pharmacy sent to:
   Completed by:
   Origin of request:

4. Date:
   Clinician:
   Prescription:
   Pharmacy sent to:
   Completed by:
   Origin of request:

5. Date:
   Clinician:
   Prescription:
   Pharmacy sent to:
   Completed by:
   Origin of request:

6. Date:
   Clinician:
   Prescription:
   Pharmacy sent to:
   Completed by:
   Origin of request:

7. Date:

Clinician:
Prescription:
Pharmacy sent to:
Completed by:
Origin of request:

8. Date:
Clinician:
Prescription:
Pharmacy sent to:
Completed by:
Origin of request:

9. Date:
Clinician:
Prescription:
Pharmacy sent to:
Completed by:
Origin of request:

10. Date:
Clinician:
Prescription:
Pharmacy sent to:
Completed by:
Origin of request:

Cummings
Veterinary Medical Center
AT TUFTS UNIVERSITY

Foster Hospital for Small Animals
55 Willard Street
North Grafton, MA 01536
Telephone (508) 839-5395
Fax (508) 839-7951
http://vetmed.tufts.edu/

Patient
Name: B6
Signalment: B6 Years Old Black/Tan Male (Neutered) Doberman Pinscher

Owner
Name: B6
Address: B6

Patient ID: B6

Contact Clinician: B6 DVM, DACVS
Student: B6 V19

Discharge Instructions

Appointment date: B6 0:04:21 AM

Medications: Continue all of B6 medications as previously prescribed by our cardiology and oncology departments.

History: B6 presented today for a consultation regarding his B6 mass B6 It was debulked with our department and sent for histopathology on B6 . Based on its composition, B6 was evaluated by our oncology department and metronomic chemotherapy B6 was initiated on B6 Since the surgery, you report that the mass has returned and growing larger.

Follow Up: Please email B6 when you are ready to schedule B6 surgery.
B6

Please contact the Surgery Liaison @ (508) 887-4794 to arrange your next appointment.

If you have any problems or questions, please contact B6 DVM, DACVS as soon as possible. If it is an emergency, contact the emergency service @ (508) 887-4623.

Prescription Refill Disclaimer:
For the safety and well-being of our patients, your pet must have had an examination by one of our veterinarians within the past year in order to obtain prescription medications.

Ordering Food:
Please check with your primary veterinarian to purchase the recommended diet(s). If you wish to purchase your food from us, please call 7-10 days in advance (508-887-4629) to ensure the food is in stock. Alternatively, veterinary diets can be ordered from online retailers with a prescription/veterinary approval.

Clinical Trials:
Clinical trials are studies in which our veterinary doctors work with you and your pet to investigate a specific disease process or a promising new test or treatment. Please see our website: vet.tufts.edu/cvmc/clinical-studies

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FDA-CVM-FOIA-2019-1704-010229

Cummings
Veterinary Medical Center
AT TUFTS UNIVERSITY
Cardiology Liaison: 508-887-4696

B6

Patient ID: B6

B6 Canine
Years Old Male (Neutered)
Doberman Pinscher
Black/Tan BW: Weight (kg) 40.00

Canceled

Cummings
Veterinary Medical Center
AT TUFTS UNIVERSITY

Foster Hospital for Small Animals
55 Willard Street
North Grafton, MA 01536
Telephone (508) 839-5395
Fax (508) 839-7951
http://vetmed.tufts.edu/

Patient
Name: B6
Signalment: Years Old Black/Tan Male (Neutered) Doberman Pinscher

Owner
Name:
Address: B6

Patient ID: B6

Contact Clinician: B6 DVM, DACVS
Alternate Clinician: B6 DVM
Student: B6 V19

Discharge Instructions

Admit Date: B6 7:46:58 AM
Discharge Date: B6

Diagnosis:
1. B6

Procedures:

B6

4. Chest radiographs (x-rays)
5. Cardiology Consult

Medications:
Continue: B6 can continue to receive his medications as prescribed by the cardiology service. You may give them to him tonight with a small amount of soft food.

Diet: Please feed B6 soft food.

CASE SUMMARY

General summary:
Thank you for bringing B6 to Tufts to B6 This B6 s was initially observed around mid-May of B6 It was debulked on B6 but has continued to grow since this procedure and despite receiving metronomic chemotherapy through the Oncology Department. B6 also has a history of B6 isease, dilated cardiomyopathy, and atrial fibrillation. He is on medications to help manage his heart condition. Today, his baseline bloodwork was normal and h B6 actor was 78%, or high enough to procede with surgery.

Chest radiographs did not show any metastasis to the lungs. His heart is enlarged, which is consistent with his dilated cardiomyopathy. His lungs showed mild signs of pneumonia or chronic lower airway disease. B6 was considered a stable candidate for surgery and had hi B6 debulked. B6
B6
B6 B6 recovered well and is ready

to go home with you.

Patient care instructions:
Please monitor B6 for bleeding from his mouth. If bleeding continues and does not stop, please contact the ER.

Please also monitor B6 respiratory rate and effort at home. If you notice that his respiratory effort is increased or that he is experiencing respiratory distress, please bring him to an emergency veterinary as soon as possible for evaluation.

Please monitor B6 for any evidence of inappetence, lethargy, vomiting or diarrhea. If you notice these signs, please have him re-evaluated as soon as possible.

B6 also may not defecate for the next few days, which is normal for any pet undergoing anesthesia. As long as Brom is not straining to defecate, we are not concerned.

Recheck Visits:
Please schedule a recheck appointment for 2 weeks to see how B6 is healing from his procedure. Please contact the Surgery Liaison @ (508) 887-4794 to arrange your recheck appointment.

If it is an emergency, contact the emergency service @ (508) 887-4623.

Prescription Refill Disclaimer:
For the safety and well-being of our patients, your pet must have had an examination by one of our veterinarians within the past year in order to obtain prescription medications.

Ordering Food:
Please check with your primary veterinarian to purchase the recommended diet(s). If you wish to purchase your food from us, please call 7-10 days in advance (508-887-4629) to ensure the food is in stock. Alternatively, veterinary diets can be ordered from online retailers with a prescription/veterinary approval.

Clinical Trials:
Clinical trials are studies in which our veterinary doctors work with you and your pet to investigate a specific disease process or a promising new test or treatment. Please see our website: vet.tufts.edu/cvmc/clinical-studies

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FDA-CVM-FOIA-2019-1704-010232

Cummings
Veterinary Medical Center
AT TUFTS UNIVERSITY

Foster Hospital for Small Animals
55 Willard Street
North Grafton, MA 01536
Telephone (508) 839-5395
Fax (508) 839-7951
http://vetmed.tufts.edu/

Radiology Request & Report

Patient
Name: B6
Species: Canine
Black/Tan Male (Neutered)
Doberman Pinscher
Birthdate: B6

Owner
Name: B6
Address: B6

Patient ID: B6
Date of request: B6

Attending Clinician: B6 DVM, DACVS **Student:** B6 , V19

Date of exam: B6

Patient Location: Ward/Cage: B ward Run 4 **Weight (kg)** 40.00

- [x] Inpatient
- [ ] Outpatient Time:
- [ ] Waiting
- [ ] Emergency

Sedation
- [ ] BAG
- [ ] OBAG
- [ ] 1/2 dose OBAG
- [ ] DexDomitor/Butorphanol
- [x] Anesthesia to sedate/anesthetize

Examination Desired: Met check under pre-med before surgery

Presenting Complaint and Clinical Questions you wish to answer:
Admit to B Ward, Collect Drposit

Pertinent History:
B6 debulked or B6 , second debulking surgery today
History of DCM and B6

Findings:

B6

B6

Conclusions:

- Faint right middle lung lobe interstitial to alveolar pattern. This may represent a focus of pneumonia. Correlate to thoracic auscultation. Follow-up radiographs are recommended to monitor.
- Mild generalized cardiomegaly with moderate left-sided enlargment without evidence of cardiac decompensation. This is consistent with reported DCM. Echocardiography can be considered for further evaluation as clinically indicated prior to anesthesia.
- Mild diffuse bronchial pattern may represent chronic lower airway disease (allergic, infectious or parasitic etiologies) or age related changes. Correlate with clinical history.
- No evidence of thoracic neoplasia.

Radiologists

Primary: B6, DVM

Reviewing: B6 BVSc, DACVR

Dates

Reported: B6

Finalized: 2/28/2019

Cummings
Veterinary Medical Center
AT TUFTS UNIVERSITY

B6

Patient: B6
B6 Male (Neutered)
Canine Doberman Pinscher
Patient ID: B6

SURGERY REPORT

Date of report: B6

Attending Clinician: B6

Date of procedure: B6

Primary Surgeon: B6
Student: B6, V19

Procedure(s) performed: Right B6

Report:

B6

Specimens obtained:
Right B6 for histopathology

Concerns:
-aspiration

Cummings
Veterinary Medical Center
AT TUFTS UNIVERSITY

Foster Hospital for Small Animals
55 Willard Street
North Grafton, MA 01536
Telephone (508) 839-5395
Fax (508) 839-7951
http://vetmed.tufts.edu/

Discharge Instructions

Patient
Name: B6
Species: Canine
Black/Tan Male (Neutered) Doberman Pinscher
Birthdate: B6

Owner
Name: B6
Address: B6

Patient ID: B6

Attending Cardiologist:
B6

Cardiology Resident:
B6

Cardiology Technician:
B6

Student: B6 **V'19**

Date: B6

Diagnoses:
Dilated cardiomyopathy (DCM), asymptomatic
B6

Case summary:
Thank you for bringing B6 to Tufts for evaluation of his heart. Upon echocardiogram (ultrasound of the heart) today, his DCM is stable. There were no significant differences in comparison to findings from B6 previous echocardiogram. Electrocardiogram was also similar but showed slightly less frequent arrhythmia (abnormal heart rhythm), more specifically some atrial and fewer ventricular premature contractions, and slower heart rate so we will continue his B6 medication. Since B6 is enrolled in the study on DCM, and we submitted some blood work for that study which will give us other markers of heart health. We will plan to call you with those results.

We are sorry to hear that his mouth is causing him discomfort and decreased appetite. We are sending you home with an appetite stimulant and some anti-diarrheal medication to help improve his comfort at home. It is ok to dissolve his medication to give in a liquid slurry if that works better for him. We recommend avoiding putting his pills in his food.

Monitoring at home:

- We would like you to occasionally monitor your dog's breathing rate and effort at home, ideally during sleep or at a time of rest. The doses of drugs will be adjusted based on the breathing rate and effort.
- ***In general, most dogs with heart failure that is well controlled have a breathing rate at rest of less than 35 to 40 breaths per minute.*** Given that B6 is a large breed dog, his respiratory rate should be no more than 35 breaths

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per minute at rest, and it may be much lower. In addition, the breathing effort, noted by the amount of belly wall motion used for each breath, is fairly minimal if heart failure is controlled.

- An increase in breathing rate or effort will usually mean that you should give a dose of furosemide (Lasix). If difficulty breathing is not improved by within 30-60 minutes after giving extra furosemide then we recommend that a recheck exam be scheduled and/or that your dog be evaluated by an emergency clinic.
- There are instructions for monitoring breathing, and a form to help keep track of breathing rate and drug doses, on the Tufts HeartSmart web site (http://vet.tufts.edu/heartsmart/at-home-monitoring/).
- We also want you to watch for weakness or collapse, a reduction in appetite, worsening cough, or distention of the belly as these findings indicate that we should do a recheck examination.
- If you have any concerns, please call or have your dog evaluated by a veterinarian. Our emergency clinic is open 24 hours/day.

Recommended Medications:

We discussed tips for getting medications into B6 You can crush or dissolve his tablets right before you give the medications if you find it easier to give them this way. You can use small amounts of appetizing foods like low-sodium peanut butter, cream cheese, cake frosting, and marshmellows to hide pills in. *If you are unable to get all of his oral medications in to him, we want you to prioritize his Pimobendan and Amiodarone medications.*

B6

AS NEEDED:

B6

Diet Suggestions

Diet and supplement suggestions:

Dogs with heart failure accumulate more fluid in their body if they eat large amounts of sodium (salt). Sodium can be found in all foods, but some foods are lower in sodium than others. Many pet treats, people foods, and supplements used to give pills often have more sodium than is desirable – a sheet that has suggestions for low sodium treats can be found on the HeartSmart web site (http://vet.tufts.edu/heartsmart/diet/)

- The FDA is currently investigating an apparent association between diet and a type of heart disease called dilated cardiomyopathy. The exact cause is still unclear, but it appears to be associated with boutique diets and those

containing exotic ingredient or are grain-free. Therefore, we are currently recommending that dogs do not eat these types of diets.

- We recommend switching B6 to commercial diet made by a well-established company that is not grain-free and does not contain any exotic ingredients, such as kangaroo, duck, lamb, venison, lentils, peas, beans, buffalo, tapioca, barley, and chickpeas.
- The FDA issued a statement regarding this issue (https://www.fda.gov/AnimalVeterinary/NewsEvents/CVMUpdates/ucm613305.htm) and a recent article published by Dr. Lisa Freeman on the Cummings School's Petfoodology blog can further explain these findings (http://vetnutrition.tufts.edu/2018/06/a-broken-heart-risk-of-heart-disease-in-boutique-or-grain-free-diets-and-exotic-ingredients/).
- Our nutritionists have compiled a list of dog foods that are good options for dogs with heart disease.

Dry Food Options:
Royal Canin Early Cardiac (veterinary diet)
Royal Canin Boxer
Purina Pro Plan Adult Weight Management
Purina Pro Plan Bright Mind Adult Small Breed Formula
Canned Food Options:
Hill's Science Diet Adult Beef and Barley Entree
Hill's Science Diet Adult 1-6 Healthy Cuisine Roasted Chicken, Carrot, and Spinach Stew
Royal Canin Mature 8+

Exercise Recommendations
Limited activity is recommended, but B6 can still be allowed to play. Short leash walks are ideal. If you find that B6 is lagging behind or needs to stop on a walk then this was too long a walk and shorter walks are advised in the future. Repetitive or strenuous high energy activities (repetitive ball chasing, running fast off-leash, etc.) are generally not advised at this stage of heart disease. Please be aware that dog's with significant arrhythmia, as B6 case, are at risk of sudden death as a result of fatal arrhythmia, and we worry that high intensity activity can increase this risk.

Recheck Visits: A recheck visit is scheduled for Monday B6 at 4PM. At this visit we will want to check breathing effort and heart function with an echocardiogram, ECG and a blood test as part of the DCM study.

Thank you for entrusting us with B6 care. He is such a good boy and we hope that the entyce helps his appetite. Please contact our Cardiology liaison at (508)-887-4696 or email us at cardiovet@tufts.edu for scheduling and non-emergent questions or concerns.

Please visit our HeartSmart website for more information
http://vet.tufts.edu/heartsmart/

Prescription Refill Disclaimer:
For the safety and well-being of our patients, your pet must have had an examination by one of our veterinarians within the past year in order to obtain prescription medications.

Ordering Food:
Please check with your primary veterinarian to purchase the recommended diet(s). If you wish to purchase your food from us, please call 7-10 days in advance (508-887-4629) to ensure the food is in stock. Alternatively, veterinary diets can be ordered from online retailers with a prescription/veterinary approval.

Clinical Trials:
Clinical trials are studies in which our veterinary doctors work with you and your pet to investigate a specific disease process or a promising new test or treatment. Please see our website: vet.tufts.edu/cvmc/clinical-studies

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FDA-CVM-FOIA-2019-1704-010238

Cummings
Veterinary Medical Center
AT TUFTS UNIVERSITY

Foster Hospital for Small Animals
55 Willard Street
North Grafton, MA 01536
Telephone (508) 839-5395
Fax (508) 839-7951
http://vetmed.tufts.edu/

Nutritional Tips for Pets with Heart Disease

Low sodium, high quality pet treats

Notes:

1. Most other dog treats are high in sodium.
2. If your pet has other medical conditions, these treats may not be appropriate. Talk to your veterinarian if you have questions or make an appointment with the Nutrition Service.

Product	Calories per treat
Dogs	
Hill's Science Diet Baked Light Biscuits with Real Chicken Small Dog Treat	8
Hill's Science Diet Baked Light Biscuits with Real Chicken Medium Dog Treat	34
Hill's Science Diet Soft Savories Peanut Butter & Banana, Beef & Cheddar, or Chicken & Yogurt Dog Treat	25-27, depending on flavor
Hill's Ideal Balance Soft-Baked Naturals with Chicken & Carrots, Duck & Pumpkin, or Beef & Sweet Potato Dog Treat	12-13, depending on flavor
Purina Beyond Natural Salmon Dog Biscuit Treat with Oats or Chicken & Barley	27-29, depending on flavor
Purina Alpo Variety Snaps Little Bites (beef, chicken, liver, lamb or beef, bacon, cheese, peanut butter)	16
Purina Alpo Variety Snaps Big Bites (beef, chicken, liver, lamb)	58
Royal Canin Original Canine treat	5
Cats	
Royal Canin Original Feline treat	2
Fancy Feast Duos Natural Rotisserie Chicken Cat treat	2
Fancy Feast Duos Tuna with Accents of Parsley Cat treat	2

Taste enhancers to can make your pet's food tastier to increase food intake

Safe and effective appetite stimulants are now available for dogs and cats. Please talk to your veterinarian if your pet is not eating well, not eating ideal foods, or is losing weight.

Notes:

1. All foods in this list should be prepared without salt
2. These taste enhancers should be added in small amounts. If your pet eats too much of them, they will unbalance the diet and increase your pet's risk for nutritional deficiencies

Dogs

- Honey or maple syrup
- Homemade chicken, beef, or fish broth (made without salt; avoid all deli meats and rotisserie chicken). Avoid store bought broths because even the low sodium brands are too high in sodium.
- Sugar (brown or white) – Domino pourable light brown sugar is a good option
- Vanilla or fruit yogurt – One option that dogs seem to like is Yoplait Custard Yogurt (caramel or vanilla flavors). If you try other brands, just be sure the sodium is less than 100 mg per 100 calories (the Yoplait is 95 mg per 170 calories which comes out to 56 mg sodium per 100 calories). Also avoid yogurts with artificial sweeteners.
- Maple syrup. Low salt brands include Log Cabin All Natural, Maple Grove Farm 100% pure maple syrup, or Stop and Shop Original Syrup
- Applesauce (be sure they have less than 50 mg sodium per serving)
- Ketchup (no salt added). Examples include Hunts or Heinz no salt added
- Pasta sauce (no salt added). Examples: Francesco Rinaldi no salt added or Enrico's no salt added)
- Frosted Mini Wheats Original – these can be crumbled on his food
- Lean meats, cooked (chicken, turkey, beef, or fish) – not deli/sandwich meats/cold cuts, rotisserie chicken, and any canned fish or meat
- Eggs, cooked

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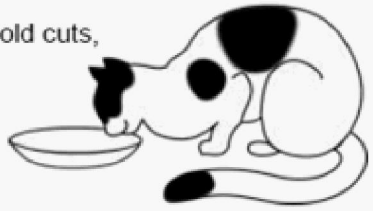
Dogs (continued)

- Homemade chicken, beef, or fish broth (even low sodium store-bought broths are too high in sodium). Avoid all canned soups unless labeled as no salt added
- Low-salt breakfast cereal - the label should read, "very low sodium food" or contain less than 20 mg sodium per serving. A good option is Frosted Mini Wheats Original or Little Bites Original
- Fresh vegetables/fruit. Examples include carrots, green beans, apple, orange, banana (avoid grapes, raisins, onions, garlic)
- Low sodium canned dog foods

Cats

- Lean meats, cooked (chicken, turkey, beef, or fish) – not sandwich meats/cold cuts, canned tuna, or rotisserie chicken
- Eggs, cooked
- Homemade chicken, beef, or fish broth (even low sodium store-bought broths are too high in sodium)
- Low sodium canned cat foods



Foods to avoid

- Fatty foods (meat trimmings, cream, ice cream)
- Baby food
- Pickled foods
- Bread
- Pizza
- Condiments (ketchup, soy sauce, barbecue sauce, etc – unless they are unsalted or no salt added)
- Sandwich meats/cold cuts (ham, corned beef, salami, sausages, bacon, hot dogs)
- Rotisserie chicken
- Most cheeses, including "squirtable" cheeses
- Processed foods (such as, potato mixes, rice mixes, macaroni and cheese)
- Canned vegetables (unless "no salt added")
- Potato chips, packaged popcorn, crackers, and other snack foods
- Soups (unless homemade without salt)
- Most commercial pet treats

Tips for administering medications

Foods commonly used to administer your pet's pills can provide a large amount of additional salt to your pet's diet. Preferable ways to give medications include:

- Have one of our staff show you how to give medications without using food
- Insert medications into one of the following foods:

Dogs or cats

- Low-sodium canned pet food
- Home-cooked meat such as chicken or hamburger (made without salt); not lunch meats
- Whipped cream (Reddi Wip)
- Marshmallows
- Greenies Pill Pockets
  - Dog chicken, hickory smoke, or peanut butter flavors; cat chicken or salmon flavor
  - Avoid grain-free duck and pea which is high in sodium
  - Try to use the smallest size possible (ideally, the cat sized Pill Pockets, even for dogs) and as few as possible to avoid excessive salt.
    - Caution: Not all similar products from other companies are low in sodium .

Dogs

- Soft fruit, such as banana, orange, melon, or strawberries (avoid grapes)
- Peanut butter (only if labeled as "no salt added") – examples include Smucker's Natural Creamy Peanut Butter with No Salt Added or Teddie All Natural Smooth Unsalted Butter
- Frosting (should be less than 75 mg/serving and contain no artificial sweeteners or xylitol). Examples include Duncan Hines whipped vanilla frosting, Betty Crocker whipped vanilla frosting)

You may find our Petfoodology post called, "Pill-popping pets" helpful for additional ideas:
http://vetnutrition.tufts.edu/2018/09/foods_for_giving_pills/

Cummings
Veterinary Medical Center
AT TUFTS UNIVERSITY
Cardiology Liaison: 508-887-4696

B6

Patient ID: B6
B6 Canine
Years Old Male (Neutered) Doberman Pinscher
Black/Tan

Cardiology Appointment Report

Date: B6

Attending Cardiologist:
John E. Rush DVM, MS, DACVIM (Cardiology), DACVECC

B6

Cardiology Resident:
B6

Cardiology Technician:
B6

Student: B6 V'19

Presenting Complaint: Recheck DCM/arrhythmia; DCM study

Concurrent Diseases:
B6

History of
History of
History of B6
History of elevated ALT

General Medical History:
Has been doing okay on and off; owner thinks that he is painful and has been picking out pills. Owner is getting B6 from vet. Owner has not been able to get heart medication in for 2 days except 1 B6 yesterday. Owner wants to know if possible to do compounding into a liquid for medications. Still wants to go for walks twice a day. Appetite has decreased but owner suspects it is because of pain related to oral mass. Diarrhea/soft stool for the past week and seems to be improving. Owner thinks the oral mass is infected based on smell. Owner asks about compounding liquid metronidazole. Couple weeks ago vomited a couple of times right after eating but resolved on its own.
Owner wants to know about appetite stimulants.

Diet and Supplements:
Only willing to eat pure beef/lamb, not interested in vegetables. Owner is trying to incorporate regular

dog food (one of the recommend low sodium diets we recommend but can't remember which one).
No supplements

Cardiovascular History:
Prior CHF diagnosis? No
Prior heart murmur? No
Prior ATE? no
Prior arrhythmia? Yes
Monitoring respiratory rate and effort at home? Not daily, always below 17/min
Cough? 2 coughs yesterday for the first time but none since then
Shortness of breath or difficulty breathing? No
Syncope or collapse? No
Sudden onset lameness? No
Exercise intolerance? No

Current Medications Pertinent to CV System:

B6

Has been off B6 for couple of weeks, owner wants to restart a compounded version

Heartworm preventative April-November

B6 starting yesterday for mouth pain

Cardiac Physical Examination:

B6

Muscle condition:
☐ Normal ☐ Moderate cachexia

- [x] Mild muscle loss
- [ ] Marked cachexia

Cardiovascular Physical Exam:

Murmur Grade:

- [x] None
- [ ] I/VI
- [ ] II/VI
- [ ] III/VI
- [ ] IV/VI
- [ ] V/VI
- [ ] VI/VI

Jugular vein:

- [x] Bottom 1/3 of the neck
- [ ] Middle 1/3 of the neck
- [ ] 1/2 way up the neck
- [ ] Top 2/3 of the neck

Arterial pulses:

- [ ] Weak
- [x] Fair
- [ ] Good
- [ ] Strong
- [ ] Bounding
- [ ] Pulse deficits
- [ ] Pulsus paradoxus
- [ ] Other:

Arrhythmia:

- [ ] None
- [ ] Sinus arrhythmia
- [x] Premature beats
- [ ] Bradycardia
- [ ] Tachycardia

Gallop:

- [ ] Yes
- [x] No
- [ ] Intermittent
- [ ] Pronounced
- [ ] Other:

Pulmonary assessments:

- [x] Eupneic
- [ ] Mild dyspnea
- [ ] Marked dyspnea
- [x] Normal BV sounds
- [ ] Pulmonary crackles
- [ ] Wheezes
- [ ] Upper airway stridor

Abdominal exam:

- [x] Normal
- [ ] Hepatomegaly
- [ ] Abdominal distension
- [ ] Mild ascites
- [ ] Marked ascites

Problems & Differential Diagnoses:

History of DCM and APCs/VPCs

B6

Diagnostics plan:

- [x] Echocardiogram
- [x] Chemistry profile
- [x] ECG-during echo
- [ ] Renal profile
- [ ] Blood pressure
- [ ] Dialysis profile
- [ ] Thoracic radiographs
- [x] NT-proBNP
- [x] Troponin I
- [x] Other tests: DCM study

Echocardiogram Findings:

General/2-D findings:

B6

Doppler findings:
Trace MR and TR

Mitral inflow:

- ☐ Summated
- ☐ Normal
- ☑ Delayed relaxation
- ☐ Pseudonormal
- ☐ Restrictive

ECG findings:

B6

Assessment and recommendations:
Echocardiogram reveals similar advanced DCM compared too previous exam. Patient is not eating well lately; suspect related to oral mass, but chemistry panel submitted to assess renal and liver values. Recommend prioritizing B6 until taking meds better. Sent home with a sample of Entyce. If appetite improves, strongly recommend feeding one of the recommended dog food diets rather than home cooked, just in case this could be playing a role in his heart disease. Continue to have B6 on hand in case of increased RR/RE. BNP and troponin submitted for study. Recheck echo and blood work in another 3 months for the study.

Final Diagnosis:
DCM
Ventricular and supraventricular ectopy

B6

Heart Failure Classification Score:
ISACHC Classification:

- ☐ Ia
- ☑ Ib
- ☐ II
- ☐ IIIa
- ☐ IIb

ACVIM Classification:

- ☐ A
- ☐ B1
- ☑ B2
- ☐ C
- ☐ D

M-Mode		
IVSd	B6	cm
LVIDd		cm
LVPWd		cm
IVSs		cm
LVIDs		cm
LVPWs		cm
EDV(Teich)		ml
ESV(Teich)		ml

EF(Teich)	B6	%
%FS		%
SV(Teich)		ml
Ao Diam		cm
LA Diam		cm
LA/Ao		
Max LA		cm
Ao Diam		cm
LA Diam		cm
LA/Ao		
TAPSE		cm
EPSS		cm

M-Mode Normalized		
IVSdN	B6	(0.290 - 0.520)
LVIDdN		(1.350 - 1.730) !
LVPWdN		(0.330 - 0.530) !
IVSsN		(0.430 - 0.710)
LVIDsN		(0.790 - 1.140) !
LVPWsN		(0.530 - 0.780) !
Ao Diam N		(0.680 - 0.890)
LA Diam N		(0.640 - 0.900) !

2D		
SA LA	B6	cm
Ao Diam		cm
SA LA / Ao Diam		
IVSd		cm
LVIDd		cm
LVPWd		cm
EDV(Teich)		ml
IVSs		cm
LVIDs		cm
LVPWs		cm
ESV(Teich)		ml
EF(Teich)		%
%FS		%
SV(Teich)		ml
LV Major		cm
LV Minor		cm
Sphericity Index		
LVLd LAX		cm
LVAd LAX		cm
LVEDV A-L LAX		ml
LVEDV MOD LAX		ml
LVLs LAX		cm
LVAs LAX		cm
LVESV A-L LAX		ml
LVESV MOD LAX		ml

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HR	B6	BPM
EF A-L LAX		%
LVEF MOD LAX		%
SV A-L LAX		ml
SV MOD LAX		ml
CO A-L LAX		l/min
CO MOD LAX		l/min

Doppler

MR Vmax	B6	m/s
MR maxPG		mmHg
MV E Vel		m/s
MV DecT		ms
MV Dec Slope		m/s
MV A Vel		m/s
MV E/A Ratio		
E'		m/s
E/E'		
A'		m/s
S'		m/s
AV Vmax		m/s
AV maxPG		mmHg
PV Vmax		m/s
PV maxPG		mmHg

FDA-CVM-FOIA-2019-1704-010246

B6

B6

Client and Pet Registration Form

Client Name: B6

Spouse/Partner: B6

Address: B6

City, State, Zip: B6

Home Phone: B6
Work Phone: (___) _-
Cell Phone: B6
Email: B6
Pager: (___) _-____

Pet Name:
Patient ID: B6
Date of Birth
Age: B6 Years Old
Species: Canine
Breed: Doberman Pinscher
Color: Black/Tan
Sex: Male (Neutered)
Weight: Weight (kg) 38.10 kg
Rabies Date:

Referring Veterinarian: B6

B6 Agreement and Consent:

- I agree to pay for all services rendered to my pet at the end of today's examination.
- I understand that payment is required at the time of service.
- I understand that the cost of the initial exam does not cover any further diagnostics, treatments, or medications that may be necessary for my pet.
- I understand that if further diagnostics or treatments are recommended by the doctor I may request an estimate of those charges first.
- I understand that I have the right to refuse any treatments, diagnostics, or medications that have been recommended to me by the doctor.

Signature: _____ Date: B6

You and your doctor will be provided with a report from the doctor for every examination performed on your pet at B6. Thank you for trusting us to care for your pet!

B6

B6

Patient
Discharge Summary

Client Name: B6

Referring Veterinarian: B6

Patient Name: B6
Patient ID:
Species: Canine
Breed: Doberman Pinscher
Age: B6 Years Old
Weight: Weight (kg) 38.10 kg
Check in date: B6 1:49:45 PM

Veterinary Medical Team: B6 DVM, DACVAA

Diagnosis: B6

Case Summary:

B6

Patient Care Instructions:

B6

B6

Medications:

Dispense: B6 **mg/ml suspension: Give 2.5 ml (3.75 mg) once a day.**

Continue: B6 **as prescribed. All heart medications as prescribed.**

Follow-up Instructions:
I can make additional recommendations going forward. I will send you the comfort diary to use if you choose.

Please do not hesitate to email me with questions or concerns and we can set up a time to talk by phone.
B6

You are truly honoring his well being above all and it was a pleasure to meet both of you.

B6 **DVM, DACVAA** **Discharge Date:** B6

Cummings Veterinary Medical Center
AT TUFTS UNIVERSITY

Treatment Plan

Foster Hospital for Small Animals
55 Willard Street
North Grafton MA 01536
(508) 839-5395
http://vetmed.tufts.edu/

Estimated Charges

B6

B6

This estimate is based upon our preliminary examination. This is an estimate and is not the final bill. Every effort will be made to keep you informed of the current status of your bill throughout your animal's hospitalization. The final fee may vary considerably from this estimated cost.

Patient	Description	Low Qty	Low Extended	High Qty	High Extended
B6	B6	1.00	B6	1.00	B6
	Anesthesia Work-Up	1.00		1.00	
	B6	1.00		1.00	
	Daily Professional Care: General Ward	.50		.50	
	Anesthesia Disposables/agents	1.00		1.00	
	Medication (General Estimate) - FHSA	.50		.50	
	Hospitalization: Day Board (Dog)	1.00		1.00	
	B6	1.00		1.00	
	General Supplies: Surgery	2.00		2.00	
	B6	1.00		1.00	
		1.00		1.00	
	Anesthesia 1 Hr/30 M	1.00		1.00	

B6

Doctor of Record: B6

Client Signature

I understand that no guarantee of successful treatment is made. I certify that I have read and fully understand the authorization for medical and/or surgical treatment, the reason for why such medical and/or surgical treatment is considered necessary, as well as its advantages and possible complications, if any. I also assume financial responsibility for all charges incurred to this patient(s). I agree to pay 75% of the estimated cost at the time of admission. Additional deposits will be required if additional care or procedures are required. I further agree to pay the balance of the charges when this patient(s) is released.
Procedural billing is inclusive up to and including the estimated duration of hospitalization. There will be additional expenses if hospitalization extends beyond the specified duration.
I have read, understand, and agree to accept the conditions of this treatment plan.

Thank you for entrusting us with your pet's care.

High Total	B6
Low Total	
75% Deposit	

Printed Thursday, March 21, 2019

FDA-CVM-FOIA-2019-1704-010251

Report Details - EON-372653

ICSR:	2059567	
Type Of Submission:	Initial	
Report Version:	FPSR.FDA.PETF.V.V1	
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)	
Reporting Type:	Voluntary	
Report Submission Date:	2018-12-03 14:40:53 EST	
Reported Problem:	**Problem Description:**	Collapsing episodes began soon before diagnosis DCM and CHF diagnosed. Taurine pending One other dog in household that we will evaluate soon (asymptomatic)
	Date Problem Started:	11/20/2018
	Concurrent Medical Problem:	No
	Outcome to Date:	Stable
Product Information:	**Product Name:**	Loyall Professional All Life Stages dry
	Product Type:	Pet Food
	Lot Number:	
	Package Type:	BAG
	Product Use Information:	**Description:** Fed since May 2018 Before that, fed Native Food Performance dry for many years
	Manufacturer /Distributor Information:	
	Purchase Location Information:	
Animal Information:	**Name:**	B6
	Type Of Species:	Dog
	Type Of Breed:	Pointing Dog - German Short-haired
	Gender:	Male
	Reproductive Status:	Intact
	Weight:	26.7 Kilogram
	Age:	B6 Years
	Assessment of Prior Health:	Excellent
	Number of Animals Given the Product:	2
	Number of Animals Reacted:	1
	Owner Information:	**Owner Information provided:** Yes
		Contact: **Name:** B6 **Phone:** **Email:**
		Address: B6
	Healthcare Professional Information:	**Practice Name:** Tufts Cummings School of Veterinary Medicine
		Contact: **Name:** Lisa Freeman **Phone:** (508) 887-4523 **Email:** lisa.freeman@tufts.edu

FDA-CVM-FOIA-2019-1704-010252

		Address:	200 Westboro Rd North Grafton Massachusetts 01536 United States
Sender Information:	**Name:**	Lisa Freeman	
	Address:	200 Westboro Rd North Grafton Massachusetts 01536 United States	
	Contact:	**Phone:**	5088874523
		Email:	lisa.freeman@tufts.edu
	Permission To Contact Sender:	Yes	
	Preferred Method Of Contact:	Email	
Additional Documents:			
	Attachment:	compiled medical record **B6** pdf	
	Description:	Medical records	
	Type:	Medical Records	

FDA-CVM-FOIA-2019-1704-010253

Cummings Veterinary Medical Center AT TUFTS UNIVERSITY

Foster Hospital for Small Animals
55 Willard Street
North Grafton, MA 01536
(508) 839-5395

All Medical Records

Client: B6
Address:

Patient: B6
Breed: German Shorthair Pointer
DOB: B6

Species: Canine
Sex: Male

Home Phone:
Work Phone:
Cell Phone: (B6

Referring Information

B6

Initial Complaint:

Initial Complaint:
B6

SOAP Text B6 1:23PM - B6

11-3-14

B6

FDA-CVM-FOIA-2019-1704-010254

Client: B6
Patient:

B6 on medial B6
Neuro - mentally appropriate, normal gait

A1 B6 days ago

P1:
P2: B6
P3:

Initial Complaint:
Emergency

SOAP Text B6 **8:35AM - Clinician, Unassigned FHSA**

Subjective
NEW VISIT (ER)

Doctor: B6
Student: B6
Presenting complaint: Collapsing episodes
Referral visit? N
Diagnostics completed prior to visit

HISTORY:

Signalment: 10 yo Intact German Shorthair Pointer

Current history:
Between Nov 1-12 was in B6 wasn't hunting but still in B6 Had a lot of exercise with no issues noted. Evening of the 7th and 8th were cold (in the teens) - was in a dog trailer with six compartments. Morning of the 9th he seemed a little bit stiff and had less interest in breakfeast but ultimately ate a small amount (unusual for him). On the evening of the 13th, back legs folded under him and he collapsed onto his side in the kitchen (hardwood floor). Didn't cry, just laid there. Was eventually put on his feet by the owner and walked fine. Next night, same thing happened. Took to rDVM on Wednesday (came back with a little bit of a cough after hunting trip) - placed on B6 at rDVM. Owner gone 15-18th so dog walker watched at home - was in crate or on carpeted floor the whole time - no exercise/long walks. Sunday night he collapsed again - seemed like his back legs gave out. This morning O's younger dog bumped into him and he fell down again. Owner put on his feet but patient was unable to stand, tried this several times, eventually was able to stand after 2-3 minutes. Later ate his whole meal. Came straight here. O notes collapsing primarily occurs in evenings apart from this AM but is not associated with anything. Was able to jump into truck to get here. No crying, doesn't seem to be in pain. No V/D/S. Little bit of a cough. His breathing has seemed a little ragid to owner recently.

Prior medical history: B6 (seen here) - treated conservatively, recovered fully.
Current medications: B6 since Wednesday
Diet: Nutrena Loyall - 30% Protein 20% fat
Vaccination status/flea & tick preventative use: unknown
Travel history: B6 November 1-12

EXAM:
S: BAR

FDA-CVM-FOIA-2019-1704-010255

Client: B6
Patient:

B6

C/V: Tachycardic, irregularly irregular rhythm, femoral pulses poor

B6

ASSESSMENT:
A1: Collapsing episodes (cardiogenic (DCM vs DMVD) vs neurologic)

PLAN:

B6

Diagnostics completed:
NOVA: Mg B6 (H), Lactate B6 (H)
AFAST/TFAST: Dilated cardiac compartments, thinned walls, poor contractility, no FF in either cavity, few B lines
EKG-- consistent with A fib
Radiographs: Generalized cardiomegaly, caudodorsal interstitial infiltrates - final report pending
Cardio Consult: Dilated cardiomyopathy, mitral valve degeneration - final report pending

Diagnostics pending:
None

Client communication:
Confirmed history. Discussed that on presentation, tachycardic with arrythmia. Discusssed based on TFAST suspect DCM and EKG consistent with atrial fribrilation.Recommend I B6

FDA-CVM-FOIA-2019-1704-010256

Client: B6
Patient:

B6

Deposit & estimate status: B6

Resuscitation code (if admitting to ICU B6

SOAP approved (DVM to sign): B6

SOAP Text B6 **6:51AM -** B6

History:

B6 is a 10 year old male german shorthaired pointer pesenting for recurrent episodes of collapse, mild cough and mild labored breathing starting 11/13.

He was diagnosed with DCM, active CHF, and atrial fibrillation yesterday.

Subjective:

T: 99.1*F (rectal)
HR: 160 beats per minute
RR: 36 breaths per minute
Mentation: BAR
Hydration: Mild dehydration, MM light pink & tacky, CRT B6 ec,

Overall impression since arrival or since last exam: B6 y has been noted to be in A-fibb for the entire evening (on every 1 hour telemetry reading). He had occasional VPC's on B6 at 10pm. His heart rate has ranged from 119-238 overnight. B6 rcvd B6 on B6 at 8am, 4pm and 12am B6 He has received B6 ER at 12pm or B6 and 12am on B6 He has had no to mild effort overnight with his respiratory rate ranging from 28-36. He urinated frequently overnight. B6 ate well when offered food overnight.

Appetite: Ate 1 cup of proplan dry and 1/2 can proplan wet at 8pm and then ate 2/4 can chicken and barley SD wet.

Objective:

B6

Heart: Irregularly irregular rhythm, II/VI left apical systolic murmur, femoral pulse fair with pulse deficits, jugular vein pronounced but still in the bottom 1/3 of the neck.

B6

Diagnostics Completed:

B6

FDA-CVM-FOIA-2019-1704-010257

Client: B6
Patient:

AFAST/TFAST: Dilated cardiac compartments, thinned walls, poor contractility, no FF in either cavity, few B lines
Radiographs: Generalized cardiomegaly with LAE, diffuse interstitial infiltrates worse on the right, VHS 13.5, consistent with cardiogenic pulmonary edema.
Echocardiogram: Marked cardiac enlargement, atrial fibrillation, and CHF with CHF and arrhythmia both being potential causes for the collapse episodes. TSignificant MR and reduced contractile function so it is difficult to determine whether the disease process is primary mitral valve disease with reduced LV contractile function associated with being a large breed dog and atrial fibrillation or primary DCM with secondary functional MR.
ECG: Atrial fibrillation with rapid ventricular response rate of 240 bpm, rare isolated VPCs.

Assessments:
A1: DCM and mitral regurgitation - either primary DCM with secondary mitral valve disease or DCM secondary to mitral valve disease
A2: Diffuse pulmonary infiltrates, enlarged cardiac silhouette with LAE, history of cough - pulmonary edema secondary to CHF
A3: Atrial fibrillation with rapid ventricular response rate and occasional VPC's - secondary to DCM
A4: Collapsing episodes r/o secondary to CHF or arrythmia

Plan:

B6

SOAP completed by: B6
SOAP reviewed by: B6

Disposition/Recommendations

FDA-CVM-FOIA-2019-1704-010258

FDA-CVM-FOIA-2019-1704-010259

Cummings Veterinary Medical Center AT TUFTS UNIVERSITY

Foster Hospital for Small Animals
55 Willard Street
North Grafton, MA 01536
(508) 839-5395

Client:	B6
Veterinarian:	
Patient ID:	B6
Visit ID:	

Patient:	B6
Species:	Canine
Breed:	German Shorthair Pointer
Sex:	Male
Age:	B6 Years Old

Lab Results Report

Nova Full Panel-ICU B6 **8:42:25 AM** **Accession ID:** B6

Test	Results	Reference Range	Units
SO2%	B6	94 - 100	%
HCT (POC)		38 - 48	%
HB (POC)		12.6 - 16	g/dL
NA (POC)		140 - 154	mmol/L
K (POC)		3.6 - 4.8	mmol/L
CL(POC)		109 - 120	mmol/L
CA (ionized)		1.17 - 1.38	mmol/L
MG (POC)		0.1 - 0.4	mmol/L
GLUCOSE (POC)		80 - 120	mg/dL
LACTATE		0 - 2	mmol/L
BUN (POC)		12 - 28	mg/dL
CREAT (POC)		0.2 - 2.1	mg/dL
TCO2 (POC)		0 - 0	mmol/L
nCA		0 - 0	mmol/L
nMG		0 - 0	mmol/L
GAP		0 - 0	mmol/L
CA/MG		0 - 0	mol/mol
BEecf		0 - 0	mmol/L
BEb		0 - 0	mmol/L
A		0 - 0	mmHg
NOVA SAMPLE		0 - 0	

FDA-CVM-FOIA-2019-1704-010260

Client:
Patient: B6

FiO2	B6	0 - 0	%
PCO2		36 - 44	mmHg
PO2		80 - 100	mmHg
PH		7.337 - 7.467	
PCO2		36 - 44	mmHg
PO2		80 - 100	mmHg
HCO3		18 - 24	mmol/L

Nova Full Panel-ICU B6 **8:48:24 AM** **Accession ID** B6

Test	Results	Reference Range	Units
TS (FHSA)	B6	0 - 0	B6
PCV **		0 - 0	
TS (FHSA)		0 - 0	

Nova Full Panel-ICU B6 **1:15:53 PM** **Accession ID:** B6

Test	Results	Reference Range	Units
Troponin I Research - FHSA	B6	0 - 0.08	mg/dl

Nova Full Panel-ICU B6 **:32:21 PM** **Accession ID:** B6

Test	Results	Reference Range	Units
GLUCOSE	B6	67 - 135	mg/dL
UREA		8 - 30	mg/dL
CREATININE		0.6 - 2	mg/dL
PHOSPHORUS		2.6 - 7.2	mg/dL
CALCIUM2		9.4 - 11.3	mg/dL
T. PROTEIN		5.5 - 7.8	g/dL
ALBUMIN		2.8 - 4	g/dL
GLOBULINS		2.3 - 4.2	g/dL
A/G RATIO		0.7 - 1.6	
SODIUM		140 - 150	mEq/L
CHLORIDE		106 - 116	mEq/L
POTASSIUM		3.7 - 5.4	mEq/L
NA/K		29 - 40	
T BILIRUBIN		0.1 - 0.3	mg/dL
D.BILIRUBIN		0 - 0.1	mg/dL
I BILIRUBIN		0 - 0.2	mg/dL
ALK PHOS		12 - 127	U/L
ALT		14 - 86	U/L
AST		9 - 54	U/L
CHOLESTEROL		82 - 355	mg/dL
OSMOLALITY (CALCULATED)		291 - 315	mmol/L
COMMENTS (CHEMISTRY)		0 - 0	
Slight lipemia Slight hemolysis			

FDA-CVM-FOIA-2019-1704-010261

FDA-CVM-FOIA-2019-1704-010262

TUFTS UNIVERSITY

Document: Case Summary
Copy To: B6
Status: FINAL
Finalized: by B6 on 12/11/2013

Client Information

Client#:
Name:
Address:
City:
Zip:
Home#:
Work#:

B6

Patient Information

Case#: 22876
Name: B6
Species: CANINE Breed: GSHP
Sex: M DOB: B6
RVet:

B6

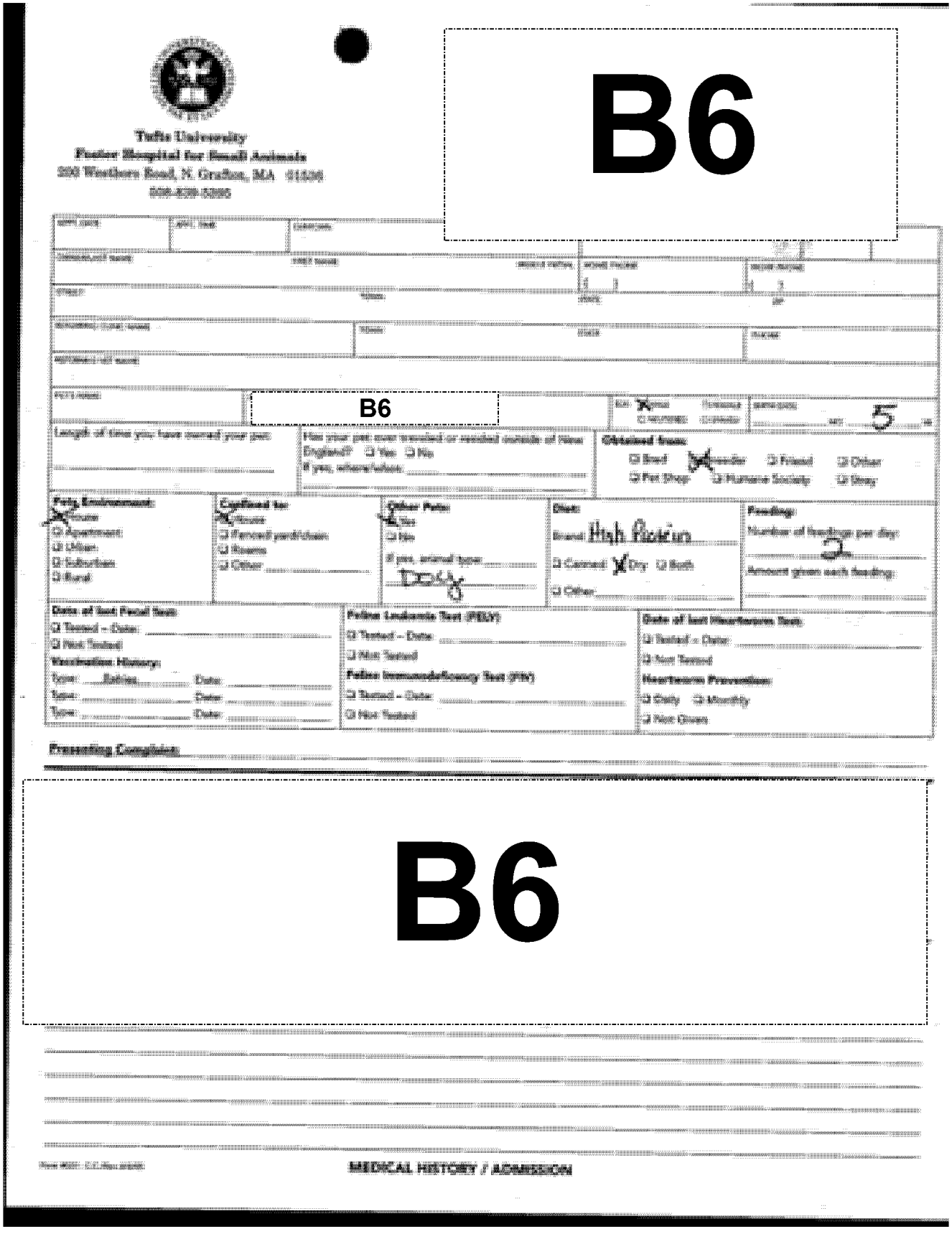
Dates

B6

FDA-CVM-FOIA-2019-1704-010263

B6

FDA-CVM-FOIA-2019-1704-010264



FDA-CVM-FOIA-2019-1704-010265

Tufts University
Foster Hospital for Small Animals
200 Westboro Road, N. Grafton, MA 01536

B6

Date: 12/11/13 Time: 10:10 am

Body Condition (1-9)	Body Weight	Temperament	Temperature	Pulse	Respiratory
5	27.5 lb				pant

(1) General Appearance	N.A.F. ✓ Abnorm. ☐ Not Ex. ☐	(2) Integumentary	N.A.F. ✓ Abnorm. ☐ Not Ex. ☐	(3) Musculo-Skeletal	N.A.F. ✓ Abnorm. ☐ Not Ex. ☐
(4) Respiratory	N.A.F. ✓ Abnorm. ☐ Not Ex. ☐	(5) Digestive	N.A.F. ✓ Abnorm. ☐ Not Ex. ☐	(6) Genito-Urinary intact	N.A.F. ✓ Abnorm. ☐ Not Ex. ☐
(7) Circulatory	N.A.F. ✓ Abnorm. ☐ Not Ex. ☐	(8) Lymph Nodes	N.A.F. ✓ Abnorm. ☐ Not Ex. ☐	(9) Nervous	N.A.F. ✓ Abnorm. ☐ Not Ex. ☐
(10) Eyes	N.A.F. ✓ Abnorm. ☐ Not Ex. ☐	(11) Ears	N.A.F. ✓ Abnorm. ☐ Not Ex. ☐	(12) Mucous Membranes CRT <B6	N.A.F. ✓ Abnorm. ☐ Not Ex. ☐
Describe abnormal, using code numbers as above, for systems				(13) Pain Assessment not painful	N.A.F. ✓ Abnorm. ☐ Not Ex. ☐

overall healthy

PHYSICAL EXAMINATION

FDA-CVM-FOIA-2019-1704-010266

Tufts University
Foster Hospital for Small Animals
200 Westboro Road,
N. Grafton, MA 01536

B6

STANDARD CONSENT FORM

I am the owner, or agent for the owner, of the above described animal and have the authority to execute this consent. I hereby authorize Tufts Cummings School of Veterinary Medicine (herein after TCSVM) to prescribe for treatment of said animal according to the following terms and conditions.

TCSVM and its officers, agents and employees will provide such veterinary medical care as they deem reasonable and appropriate under the circumstances.

TCSVM and its officers, agents, and employees will use all reasonable care in the treatment of the above mentioned animal, but will not be liable for any loss or accident that may occur or any disease that may develop as a result of the care and treatment provided.

I understand that the above identified animal may be treated by TCSVM students under the supervision and assistance of TCSVM staff members.

In executing this form, I hereby expressly acknowledge that risks, benefits and alternative forms of treatment have been explained to me. I understand said explanation, and I consent to treatment. Should any additional treatments or diagnostics be required during the continued care of my animal, I understand that I will be given the opportunity to discuss and consent to these additional procedures. I understand that further or additional treatment may be required without an opportunity for discussion and consideration by me, in the case of the development of any life-threatening emergency during the continued care of my animal and I expressly consent to all such reasonable treatment as required. I realize and understand that results cannot be guaranteed.

If any equipment is left with the animal, it will be accepted with the understanding that TCSVM assumes no responsibility for any loss of equipment that may occur.

I agree to pick up the animal when notified that it is ready for release.

In the event the animal is not picked up, and if ten (10) days have expired since a registered letter was sent to the address given above, notifying me to call for the animal, the animal may be sold or otherwise disposed of in a humane manner and the proceeds applied to the charges incurred in caring and treating the animal. Failure to remove said animal will not and does not relieve me from obligation for the costs of services rendered.

I hereby grant to Tufts Cummings School of Veterinary Medicine, its officers and employees (collectively referred to herein as TCSVM), and its agents and assigns the irrevocable rights to: (1) photograph/videotape the operation or procedure to be performed, including appropriate portions of the animal's body, and (2) reproduce, distribute, display, create derivative works of and otherwise use such photographs and images for, and in connection with, the University's medical, scientific, educational, and publicity purposes, for all but third-party commercial purposes, by any means, methods and media (print and electronic)now known or, in the future, developed that the University deems appropriate.

[redacted]

FDA-CVM-FOIA-2019-1704-010267

Standard Consent Form

As surgical treatment necessitates the removal of tissue or body parts of my animal, I authorize TCSVM to dispose of or use this tissue for scientific purposes.

I understand that a FINANCE CHARGE will be applied to all accounts unpaid after 30 days. The FINANCE CHARGE is computed on a monthly rate of 1.83% per month, which is an annual percentage rate of 18% applied to the average daily balance outstanding, with a minimum fee of $.50.

I do further agree that should any payment, or the full amount of the sum stated above, become overdue more than 29 days from the above-agreed upon time of payment or payments, the entire balance shall be considered in default and become due and payable. **I further agree to be responsible for any or all collection agency and/or attorney fees necessary to collect the full amount.**

I do further agree to comply with hours of visitation in conjunction with our Hospital's policy.

I have read, understand, and agree to accept the terms and conditions herein.

B6

Owner's Name (Please Print)

B6

Owner's Signature

12-17-13

Date

B6

Owner's Address

B6

Town/City State Zip

If the individual admitting the animal is someone other than the legal owner, please complete the portion below:

The owner of the animal, _____, has granted me authority to obtain medical treatment and to bind this owner to pay the veterinary medical services provided at TCSVM pursuant to the terms and conditions described above.

Authorized Agent - Please Print

Agent's Signature

Street Address

Date

Town/City State Zip

FDA-CVM-FOIA-2019-1704-010268

B6

FDA-CVM-FOIA-2019-1704-010269

Texas A&M Troponin - 11/27/2018

B6

FDA-CVM-FOIA-2019-1704-010270

Gastrointestinal Laboratory
Dr. J.M. Steiner
Department of Small Animal Clinical Sciences
Texas A&M University
4474 TAMU
College Station, TX 77843-4474

Important Notices

Ongoing studies

Cobalamin Supplementation Study- Dogs and cats with cobalamin deficiency with normal PLI and either normal or low consistent with EPI TLI to compare the efficacy of oral vs parenteral cobalamin supplementation. Contact Dr. Chang at cschang@cvm.tamu.edu for further information

Chronic Pancreatitis with Uncontrolled Diabetes Mellitus- Seeking dogs with chronic pancreatitis and uncontrolled diabetes mellitus for enrollment into a drug trial/medication provided at no cost). Contact Dr. Soo Yee Lim at slim@cvm.tamu.edu or Dr. Silva Marsilio at smarsilio@cvm.tamu.edu

Dogs with Primary Hyperlipidemia- Prescription diet naive dogs newly diagnosed with primary hyperlipidemia are eligible to be enrolled in a dietary trial. Contact Dr. Lawrence at ylawrence@cvm.tamu.edu for more information

Dogs with Chronic Pancreatitis-Dogs with chronic pancreatitis (cPLI: >400µg/L) and hypertriglyceridemia (>300 mg/dl) are eligible to be enrolled in a dietary trial. Contact Dr. Lawrence at ylawrence@cvm.tamu.edu

Chronic enteropathies in dogs-Please fill out this brief form http://tinyurl.com/cid-cei/ to see if your patient qualifies

Feline Chronic Pancreatitis- Cats with chronic pancreatitis for more than 2 weeks and fPLI >10 µg/L are eligible for enrollment into a treatment trial investigating the efficacy of prednisolone or cyclosporine. Please contact Dr. Yaminata for further information at pyaminata@cvm.tamu.edu

We can not accept packages that are marked "Will Recieve"

Use our preprinted shipping labels to save on shipping. Call 979-862-2661 for assistance. The GI Lab is not here to accept packages on the weekend. Samples may be compromised if you ship for arrival on Saturday or Sunday or if shipped via U.S Mail

GI Lab Contact Information

Phone: (979) 862-2661
Fax: (979) 862-2664

Email: gilab@cvm.tamu.edu
vetmed.tamu.edu/gilab

FDA-CVM-FOIA-2019-1704-010271

Client: B6
Patient:

Vitals Results

B6

9:32:14 AM	Heart Rate (/min)	
9:32:15 AM	Respiratory Rate	
9:32:16 AM	Temperature (F)	
9:32:17 AM	Weight (kg)	
10:43:05 AM	Nursing note	
10:46:20 AM	Cardiac rhythm	
10:46:21 AM	Heart Rate (/min)	
10:46:41 AM	Respiratory Rate	
11:09:38 AM	Cardiac rhythm	
11:09:39 AM	Heart Rate (/min)	
11:36:36 AM	Eliminations	
12:00:19 PM	Cardiac rhythm	
12:00:20 PM	Heart Rate (/min)	
12:01:51 PM	Respiratory Rate	
1:30:26 PM	Cardiac rhythm	
1:30:27 PM	Heart Rate (/min)	
1:30:48 PM	Respiratory Rate	
1:31:11 PM	Cardiac rhythm	
1:31:12 PM	Heart Rate (/min)	
3:34:08 PM	Cardiac rhythm	
3:34:09 PM	Heart Rate (/min)	
4:01:56 PM	Cardiac rhythm	
4:01:57 PM	Heart Rate (/min)	
4:02:06 PM	Respiratory Rate	
4:07:23 PM	Lasix treatment note	
5:13:50 PM	Cardiac rhythm	
5:13:51 PM	Heart Rate (/min)	
5:14:02 PM	Eliminations	
6:10:01 PM	Cardiac rhythm	
6:10:02 PM	Heart Rate (/min)	
6:10:13 PM	Respiratory Rate	
6:33:47 PM	Eliminations	
6:54:42 PM	Cardiac rhythm	
6:54:43 PM	Heart Rate (/min)	
8:22:20 PM	Cardiac rhythm	
8:22:21 PM	Heart Rate (/min)	
8:22:41 PM	Respiratory Rate	
8:26:31 PM	Amount eaten	
8:26:56 PM	Weight (kg)	
8:27:02 PM	Temperature (F)	

B6

FDA-CVM-FOIA-2019-1704-010272

Client: B6
Patient:

Vitals Results

B6

9:08:09 PM	Cardiac rhythm
9:08:10 PM	Heart Rate (/min)
10:00:15 PM	Cardiac rhythm
10:00:16 PM	Heart Rate (/min)
10:01:20 PM	Respiratory Rate
10:55:05 PM	Cardiac rhythm
10:55:06 PM	Heart Rate (/min)
11:58:52 PM	Cardiac rhythm
11:58:53 PM	Heart Rate (/min)
11:59:28 PM	Respiratory Rate
12:20:21 AM	Eliminations
12:46:44 AM	Lasix treatment note
12:56:50 AM	Cardiac rhythm
12:56:51 AM	Heart Rate (/min)
1:53:38 AM	Cardiac rhythm
1:53:39 AM	Heart Rate (/min)
1:53:55 AM	Respiratory Rate
2:57:07 AM	Cardiac rhythm
2:57:08 AM	Heart Rate (/min)
3:31:02 AM	Eliminations
3:31:21 AM	Amount eaten
3:58:44 AM	Cardiac rhythm
3:58:45 AM	Heart Rate (/min)
3:59:11 AM	Respiratory Rate
4:53:54 AM	Cardiac rhythm
4:53:55 AM	Heart Rate (/min)
6:05:40 AM	Cardiac rhythm
6:05:41 AM	Heart Rate (/min)
6:05:52 AM	Respiratory Rate
6:26:43 AM	Cardiac rhythm
6:26:44 AM	Heart Rate (/min)
7:18:29 AM	Weight (kg)
7:18:38 AM	Temperature (F)
7:18:53 AM	Respiratory Rate
7:22:20 AM	Eliminations
8:29:28 AM	Cardiac rhythm
8:29:29 AM	Heart Rate (/min)
9:05:04 AM	Cardiac rhythm
9:05:05 AM	Heart Rate (/min)
9:46:31 AM	Cardiac rhythm
9:46:32 AM	Heart Rate (/min)

B6

FDA-CVM-FOIA-2019-1704-010273

Client:
Patient: B6

Vitals Results

B6

	9:47:40 AM	Respiratory Rate
	10:26:23 AM	Nursing note
	10:31:09 AM	Amount eaten
	10:44:02 AM	Eliminations
	10:46:48 AM	Cardiac rhythm
	10:46:49 AM	Heart Rate (/min)
	10:47:58 AM	Respiratory Rate
	11:51:53 AM	Cardiac rhythm
	11:51:54 AM	Heart Rate (/min)
	11:56:14 AM	Respiratory Rate
	12:59:54 PM	Cardiac rhythm
	12:59:55 PM	Heart Rate (/min)
	1:01:14 PM	Respiratory Rate
	1:03:22 PM	Respiratory Rate
	1:06:27 PM	Eliminations
	1:07:30 PM	Catheter Assessment
	1:48:44 PM	Cardiac rhythm
	1:48:45 PM	Heart Rate (/min)
	3:33:29 PM	Cardiac rhythm
	3:33:30 PM	Heart Rate (/min)
	3:35:21 PM	Respiratory Rate
	3:53:21 PM	Cardiac rhythm
	3:53:22 PM	Heart Rate (/min)
	3:57:55 PM	Respiratory Rate
	4:01:46 PM	Lasix treatment note
	4:08:16 PM	Eliminations
	5:13:51 PM	Eliminations

B6

FDA-CVM-FOIA-2019-1704-010274

ECG from Cardio

B6

B6

FDA-CVM-FOIA-2019-1704-010275

Client: B6
Patient:

ECG from Cardio

B6

B6

FDA-CVM-FOIA-2019-1704-010276

Client: B6
Patient:

ECG from Cardio

B6

B6

B6

FDA-CVM-FOIA-2019-1704-010277

Client: B6
Patient:

Patient History

10/29/2014	08:22 AM	Appointment
	01:31 PM	UserForm
	02:06 PM	Purchase
	09:38 AM	Appointment
	08:42 AM	Purchase
	08:48 AM	Labwork
	09:07 AM	UserForm
	09:07 AM	UserForm
	09:16 AM	UserForm
	09:32 AM	Vitals
	09:32 AM	Vitals
	09:32 AM	Vitals
	09:32 AM	Vitals
	09:50 AM	Purchase
	09:50 AM	Purchase
	09:51 AM	Purchase
	09:51 AM	Purchase
	09:51 AM	Purchase
	10:18 AM	Treatment
	10:42 AM	Purchase
	10:42 AM	Treatment
	10:42 AM	Purchase
	10:43 AM	Vitals
	10:46 AM	Treatment
	10:46 AM	Vitals
	10:46 AM	Vitals
	10:46 AM	Treatment
	10:46 AM	Treatment
	10:46 AM	Vitals
	11:09 AM	Treatment
	11:09 AM	Vitals
	11:09 AM	Vitals
	11:36 AM	Treatment
	11:36 AM	Vitals
	11:44 AM	Prescription
	11:59 AM	Prescription
	11:59 AM	Prescription
	12:00 PM	Treatment

B6

B6

B6

FDA-CVM-FOIA-2019-1704-010278

Client: B6
Patient:

Patient History

	12:00 PM	Vitals
	12:00 PM	Vitals
	12:01 PM	Treatment
	12:01 PM	Vitals
	12:22 PM	Purchase
	12:22 PM	Purchase
	12:34 PM	Treatment
	12:34 PM	Treatment
	12:35 PM	Treatment
	01:30 PM	Treatment
	01:30 PM	Vitals
	01:30 PM	Vitals
	01:30 PM	Treatment
	01:30 PM	Vitals
	01:31 PM	Treatment
	01:31 PM	Vitals
	01:31 PM	Vitals
	02:16 PM	Treatment
	03:34 PM	Treatment
B6	03:34 PM	Vitals
	03:34 PM	Vitals
	04:01 PM	Treatment
	04:01 PM	Vitals
	04:01 PM	Vitals
	04:02 PM	Treatment
	04:02 PM	Vitals
	04:07 PM	Vitals
	04:07 PM	Treatment
	05:13 PM	Treatment
	05:13 PM	Vitals
	05:13 PM	Vitals
	05:14 PM	Treatment
	05:14 PM	Vitals
	06:10 PM	Treatment
	06:10 PM	Vitals
	06:10 PM	Vitals
	06:10 PM	Treatment
	06:10 PM	Vitals
	06:33 PM	Vitals
	06:54 PM	Treatment
	06:54 PM	Vitals

B6

FDA-CVM-FOIA-2019-1704-010279

Client: B6
Patient:

Patient History

B6

06:54 PM	Vitals
08:22 PM	Treatment
08:22 PM	Vitals
08:22 PM	Vitals
08:22 PM	Treatment
08:22 PM	Vitals
08:22 PM	Treatment
08:26 PM	Treatment
08:26 PM	Treatment
08:26 PM	Vitals
08:26 PM	Treatment
08:26 PM	Vitals
08:27 PM	Treatment
08:27 PM	Vitals
09:08 PM	Vitals
09:08 PM	Vitals
09:13 PM	Purchase
09:48 PM	Treatment
10:00 PM	Treatment
10:00 PM	Vitals
10:00 PM	Vitals
10:01 PM	Treatment
10:01 PM	Vitals
10:55 PM	Treatment
10:55 PM	Vitals
10:55 PM	Vitals
11:13 PM	Treatment
11:17 PM	Treatment
11:17 PM	Treatment
11:58 PM	Treatment
11:58 PM	Vitals
11:58 PM	Vitals
11:59 PM	Treatment
11:59 PM	Vitals
12:20 AM	Vitals
12:46 AM	Vitals
12:46 AM	Treatment
12:56 AM	Treatment
12:56 AM	Vitals
12:56 AM	Vitals
01:53 AM	Treatment

B6

FDA-CVM-FOIA-2019-1704-010280

Client: B6
Patient:

Patient History

B6	01:53 AM	Vitals
	01:53 AM	Vitals
	01:53 AM	Treatment
	01:53 AM	Vitals
	02:57 AM	Treatment
	02:57 AM	Vitals
	02:57 AM	Vitals
	03:16 AM	Treatment
	03:30 AM	Treatment
	03:31 AM	Treatment
	03:31 AM	Vitals
	03:31 AM	Treatment
	03:31 AM	Vitals
	03:58 AM	Treatment
	03:58 AM	Vitals
	03:58 AM	Vitals
	03:59 AM	Treatment
	03:59 AM	Vitals
	04:53 AM	Treatment
	04:53 AM	Vitals
	04:53 AM	Vitals
	06:05 AM	Treatment
	06:05 AM	Vitals
	06:05 AM	Vitals
	06:05 AM	Treatment
	06:05 AM	Vitals
	06:26 AM	Treatment
	06:26 AM	Vitals
	06:26 AM	Vitals
	07:12 AM	Treatment
	07:18 AM	Treatment
	07:18 AM	Vitals
	07:18 AM	Treatment
	07:18 AM	Vitals
	07:18 AM	Treatment
	07:18 AM	Vitals
	07:22 AM	Vitals
	08:29 AM	Treatment
	08:29 AM	Vitals
	08:29 AM	Vitals
	09:05 AM	Treatment

B6

FDA-CVM-FOIA-2019-1704-010281

Client: B6
Patient:

Patient History

B6

09:05 AM	Vitals	
09:05 AM	Vitals	
09:11 AM	Purchase	
09:11 AM	Purchase	
09:43 AM	Purchase	
09:46 AM	Treatment	
09:46 AM	Vitals	
09:46 AM	Vitals	
09:47 AM	Treatment	
09:47 AM	Vitals	
10:16 AM	Treatment	
10:26 AM	Vitals	
10:31 AM	Treatment	
10:31 AM	Treatment	
10:31 AM	Vitals	
10:44 AM	Vitals	
10:46 AM	Treatment	
10:46 AM	Vitals	
10:46 AM	Vitals	
10:47 AM	Treatment	
10:47 AM	Vitals	
11:51 AM	Treatment	
11:51 AM	Vitals	
11:51 AM	Vitals	
11:56 AM	Treatment	
11:56 AM	Treatment	
11:56 AM	Vitals	
12:07 PM	UserForm	Cardio Discharge - DCM CHF Form Saved to Record
12:59 PM	Treatment	
12:59 PM	Vitals	
12:59 PM	Vitals	
01:01 PM	Treatment	
01:01 PM	Vitals	
01:03 PM	Treatment	
01:03 PM	Vitals	
01:06 PM	Treatment	
01:06 PM	Vitals	
01:07 PM	Treatment	
01:07 PM	Vitals	
01:16 PM	Labwork	
01:16 PM	Purchase	

B6

B6

FDA-CVM-FOIA-2019-1704-010282

Client: B6
Patient:

Patient History

B6

01:32 PM	Purchase
01:48 PM	Treatment
01:48 PM	Vitals
01:48 PM	Vitals
03:33 PM	Treatment
03:33 PM	Vitals
03:33 PM	Vitals
03:35 PM	Treatment
03:35 PM	Vitals
03:53 PM	Treatment
03:53 PM	Vitals
03:53 PM	Vitals
03:57 PM	Treatment
03:57 PM	Vitals
04:01 PM	Vitals
04:01 PM	Treatment
04:08 PM	Vitals
04:49 PM	Prescription
04:54 PM	Prescription
04:55 PM	Prescription
04:56 PM	Prescription
05:02 PM	Purchase
05:13 PM	Treatment
05:13 PM	Vitals
06:42 PM	Appointment
10:14 AM	Treatment
10:54 AM	Patient Merge

B6

DCM study

B6

FDA-CVM-FOIA-2019-1704-010283

FDA-CVM-FOIA-2019-1704-010284

FDA-CVM-FOIA-2019-1704-010285

Tufts University | Cummings School of Veterinary Medicine

Healing Animals. Helping Humans. Transforming Global Health

Foster Hospital for Small Animals
200 Westboro Road
North Grafton, MA 01536
Telephone (508) 839-5395
Fax (508) 839-8739
http://www.tufts.edu/vet/

B6

B6

B6

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B6

B6

B6

Cummings
Veterinary Medical Center
AT TUFTS UNIVERSITY

Foster Hospital for Small Animals
55 Willard Street
North Grafton, MA 01536
Telephone: (508) 839-5395
Fax (508) 839-7951
http://vetmed.tufts.edu/
Referring Vet Direct Line: 508-887-4988

Notice of Patient Admit

Date: B6 8:23:54 AM

Case #: B6

Referring Doct
Client Name:
Patient Name: B6

Dear Colleague,

Your patient presented to our Emergency service. Please make note of the following information to facilitate communication with our team.

The attending doctor is B6
The reason for admission to the FHSA is: DCM, A fib, CHF

If you have any questions regarding this particular case, please call 508-887-4988 to reach the Cardiology Service. Information is updated daily, by noon.

Thank you for your referral to our Emergency Service.

Cummings
Veterinary Medical Center
AT TUFTS UNIVERSITY

Foster Hospital for Small Animals
55 Willard Street
North Grafton, MA 01536
Telephone: (508) 839-5395
Fax: (508) 839-7951
http://vetmed.tufts.edu/Coby

B6

B6

Daily Update From the Cardiology Service

Today's date: B6

Dear B6

Thank you for referring patients to the Foster Hospital for Small Animals at the Cummings School of Tufts University.

Your patient B6 was admitted and is being cared for by the Cardiology Service.

Today B6

- [x] is in stable condition
- [ ] is still in the oxygen cage
- [ ] is critically ill
- [x] discharged from the hospital today

Today's treatments include:

- [x] bloodwork planned/pending
- [x] echocardiography
- [ ] cardiac catheter procedure planned
- [x] treatment for CHF resulting from either MR with secondary reduced contractile function or DCM with secondary MR or a combination
- [ ] ongoing treatment for thrombosis
- [x] ongoing treatment for arrhythmia - atrial fibrillation with rapid ventricular response rate

Additional plans:
Please allow 3-5 business days for reports to be finalized upon patient discharge.

Please call (508) 887-4096 before 5pm or email us at sunflower@tufts.edu if you have any questions. Thank you!

Attending Clinician: B6 dent, Cardiology)
Faculty Clinician: John Rush DVM, DACVIM, DACVECC

FDA-CVM-FOIA-2019-1704-010289

Senior student:

Cummings
Veterinary Medical Center
AT TUFTS UNIVERSITY

Foster Hospital for Small Animals
35 Willard Street
North Grafton, MA 01536
Telephone: (508) 839-5395
Fax: (508) 839-7951
http://vetmed.tufts.edu/

B6

B6

B6

Dear D B6

Thank you for referring B6 with their pet B6

If you have any questions, or concerns, please contact us at 508-887-4988.

Thank you,

B6 VM (Resident, Cardiology)

From: Jones, Jennifer L </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0F6CA12EAA9348959A4CBB1E829AF244-JENNIFER.JO>
To: Jones, Jennifer L
Sent: 3/14/2019 6:38:55 PM
Subject: 02- MRx summary cc-253

B6 10 yr MI German Shorthaired Pointer
Presented 11/14/2018 to rDVM: syncope, hunting in B6 hyporexia, stiff, cough
Tx doxy
B6 To Cardio: syncopal episodes esp at pm, ragged breathing/mild dyspnea; eats Nutrena Loyall
PE: 240 bpm, irreg irreg rhythm, mild inc BV bilat, mild tense abd
Labs: Mg B6 Lact B6
ECG-afib w/ rapid V response rate, rare isolated VPCs
AFAST/TFAST: dilated cardiac chambers, thin walls, poor contraction, few B lines, no free fluid either cavity
Rads: gen'd cardiomeg w/ LAE, VHS B6 PE
Echo: marked cardiac enl, Afib, CHF, sign MR, dec contraction
B6
11/21: ECG-occ VPCs, mild mm wasting, Gr II/VI L apical sys murmur, bottom pronounced jug v.
B6

Hx: hunting, partially B6

Jennifer L. A. Jones, DVM
Veterinary Medical Officer
U.S. Food & Drug Administration
Center for Veterinary Medicine
Office of Research
Veterinary Laboratory Investigation and Response Network (Vet-LIRN)
8401 Muirkirk Road, G704
Laurel, Maryland 20708
new tel: 240-402-5421
fax: 301-210-4685
e-mail: *jennifer.jones@fda.hhs.gov*
Web: http://www.fda.gov/AnimalVeterinary/ScienceResearch/ucm247334.htm

U.S. FOOD & DRUG ADMINISTRATION

From: PFR Event <pfreventcreation@fda.hhs.gov>

To: Cleary, Michael *; HQ Pet Food Report Notification; B6

Sent: 1/1/2019 9:24:38 PM

Subject: Orijen Adult Original dry (until Aug 2018): Lisa Freeman - EON-375110

Attachments: 2060739-report.pdf; 2060739-attachments.zip

A PFR Report has been received and PFR Event [EON-375110] has been created in the EON System.

A "PDF" report by name "2060739-report.pdf" is attached to this email notification for your reference. Please note that all documents received in the report are compressed into a zip file by name "2060739-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-375110
ICSR #: 2060739
EON Title: PFR Event created for Orijen Adult Original dry (until Aug 2018); 2060739

AE Date	12/19/2018	**Number Fed/Exposed**	2
Best By Date		**Number Reacted**	1
Animal Species	Dog	**Outcome to Date**	Stable
Breed	Terrier - Border		
Age	B6 Years		
District Involved	PFR-New England DO		

Product information
Individual Case Safety Report Number: 2060739
Product Group: Pet Food
Product Name: Orijen Adult Original dry (until Aug 2018)
Description: Diagnosed with degenerative mitral valve disease in Aug 2017. Progressed to CHF. On B6. At regular re-evaluation on 12/19/18, reduced contractile function was noted on echo. Dog was noted to be eating BEG diet. Taurine pending Will recheck in 3 months Will evaluate other dog in household also eating same diet (asymptomatic). Owner is ok to provide further info.
Submission Type: Initial
Report Type: Adverse Event (a symptom, reaction or disease associated with the product)

Outcome of reaction/event at the time of last observation: Stable
Number of Animals Treated With Product: 2
Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Orijen Adult Original dry (until Aug 2018)		

Sender information
Lisa Freeman
200 Westboro Rd
North Grafton, MA 01536
USA

Owner information
B6
USA

To view this PFR Event, please click the link below:
https://eon.fda.gov/eon//browse/EON-375110

To view the PFR Event Report, please click the link below:
https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jspa?decorator=none&e=0&issueType=12&issueId=392119

==========

This email and attached document are being provided to you in your capacity as a Commissioned Official with the U.S. Department of Health and Human Services as authorized by law. You are being provided with this information pursuant to your signed Acceptance of Commission.

This email message is intended for the exclusive use of the recipient(s) named above. It may contain information that is protected, privileged, or confidential. Any dissemination, distribution, or copying is strictly prohibited.

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Failure to adhere to the above provisions could result in removal from the approved distribution list. If you think you received this email in error, please send an email to FDAReportableFoods@fda.hhs.gov immediately.

Report Details - EON-375110

ICSR:	2060739		
Type Of Submission:	Initial		
Report Version:	FPSR.FDA.PETF.V.V1		
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)		
Reporting Type:	Voluntary		
Report Submission Date:	2019-01-01 16:15:01 EST		
Reported Problem:	**Problem Description:**	Diagnosed with degenerative mitral valve disease in Aug 2017. Progressed to CHF. On B6 At regular re-evaluation on 12/19 /18, reduced contractile function was noted on echo. Dog was noted to be eating BEG diet. Taurine pending Will recheck in 3 months Will evaluate other dog in household also eating same diet (asymptomatic). Owner is ok to provide further info.	
	Date Problem Started:	12/19/2018	
	Concurrent Medical Problem:	Yes	
	Pre Existing Conditions:	Degenerative mitral valve disease	
	Outcome to Date:	Stable	
Product Information:	**Product Name:**	Orijen Adult Original dry (until Aug 2018)	
	Product Type:	Pet Food	
	Lot Number:		
	Package Type:	BAG	
	Product Use Information:	**Description:**	See diet history for additional details/diets
	Manufacturer /Distributor Information:		
	Purchase Location Information:		
Animal Information:	**Name:**	B6	
	Type Of Species:	Dog	
	Type Of Breed:	Terrier - Border	
	Gender:	Male	
	Reproductive Status:	Intact	
	Weight:	20.6 Kilogram	
	Age:	B6	
	Assessment of Prior Health:	Good	
	Number of Animals Given the Product:	2	
	Number of Animals Reacted:	1	
	Owner Information:	**Owner Information provided:**	Yes
		Contact:	**Name:** B6 **Phone:** **Email:**
		Address:	B6 United States
	Healthcare Professional Information:	**Practice Name:**	Tufts Cummings School of Veterinary Medicine

FDA-CVM-FOIA-2019-1704-010295

		Contact:	**Name:**	Lisa Freeman
			Phone:	(508) 887-4523
			Email:	lisa.freeman@tufts.edu
		Address:	200 Westboro Rd North Grafton Massachusetts 01536 United States	

Sender Information:	**Name:**	Lisa Freeman	
	Address:	200 Westboro Rd North Grafton Massachusetts 01536 United States	
	Contact:	**Phone:**	5088874523
		Email:	lisa.freeman@tufts.edu
	Permission To Contact Sender:	Yes	
	Preferred Method Of Contact:	Email	

Additional Documents:		
	Attachment:	**B6** edical record.pdf
	Description:	ecords
	Type:	Medical Records

FDA-CVM-FOIA-2019-1704-010296

Cummings Veterinary Medical Center AT TUFTS UNIVERSITY

Foster Hospital for Small Animals
55 Willard Street
North Grafton, MA 01536
(508) 839-5395

All Medical Records

Client:
Address: B6

Patient: B6
Breed: Border Collie
DOB: B6

Species: Canine
Sex: Male

Home Phone:
Work Phone:
Cell Phone: (B6

B6

Referring Information

B6

Client:
Patient: B6

Initial Complaint:
Scanned Record

Initial Complaint:
New - Rush - murmur

Initial Complaint:
Recheck-Rush

SOAP Text Jul 2 2018 10:58AM - Rush, John

Initial Complaint:
Recheck - Rush

FDA-CVM-FOIA-2019-1704-010297

Client:
Patient: B6

SOAP Text Jul 2 2018 11:08AM - Rush, John

Initial Complaint:
Recheck - Rush

SOAP Text Dec 19 2018 12:11PM - Rush, John

Disposition/Recommendations

FDA-CVM-FOIA-2019-1704-010298

FDA-CVM-FOIA-2019-1704-010299

Cummings Veterinary Medical Center
AT TUFTS UNIVERSITY

Foster Hospital for Small Animals
55 Willard Street
North Grafton, MA 01536
(508) 839-5395

Client:	B6
Veterinarian:	
Patient ID:	B6
Visit ID:	

Patient:	B6
Species:	Canine
Breed:	Border Collie
Sex:	Male
Age:	B6 Years Old

Lab Results Report

Chem Prof - Small Animal (Cobas) **7/2/2018 12:52:27 PM** **Accession ID:** B6

Test	Results	Reference Range	Units
GLUCOSE		67 - 135	mg/dL
UREA		8 - 30	mg/dL
CREATININE		0.6 - 2	mg/dL
PHOSPHORUS		2.6 - 7.2	mg/dL
CALCIUM2		9.4 - 11.3	mg/dL
MAGNESIUM 2+		1.8 - 3	mEq/L
T. PROTEIN		5.5 - 7.8	g/dL
ALBUMIN		2.8 - 4	g/dL
GLOBULINS		2.3 - 4.2	g/dL
A/G RATIO		0.7 - 1.6	
SODIUM	B6	140 - 150	mEq/L
CHLORIDE		106 - 116	mEq/L
POTASSIUM		3.7 - 5.4	mEq/L
tCO2 (BICARB)		14 - 28	mEq/L
AGAP		8 - 19	
NA/K		29 - 40	
T BILIRUBIN		0.1 - 0.3	mg/dL
D.BILIRUBIN		0 - 0.1	mg/dL
I BILIRUBIN		0 - 0.2	mg/dL
ALK PHOS		12 - 127	U/L
GGT		0 - 10	U/L

FDA-CVM-FOIA-2019-1704-010300

Client:
Patient: **B6**

ALT	**B6**	14 - 86	U/L
AST		9 - 54	U/L
CK		22 - 422	U/L
CHOLESTEROL		82 - 355	mg/dL
TRIGLYCERIDES		30 - 338	mg/dl
AMYLASE		409 - 1250	U/L
OSMOLALITY (CALCULATED)		291 - 315	mmol/L

5/88 **B6**

stringsoft

Printed Tuesday, January 01, 2019

FDA-CVM-FOIA-2019-1704-010301

B6

FDA-CVM-FOIA-2019-1704-010302

B6

FDA-CVM-FOIA-2019-1704-010303

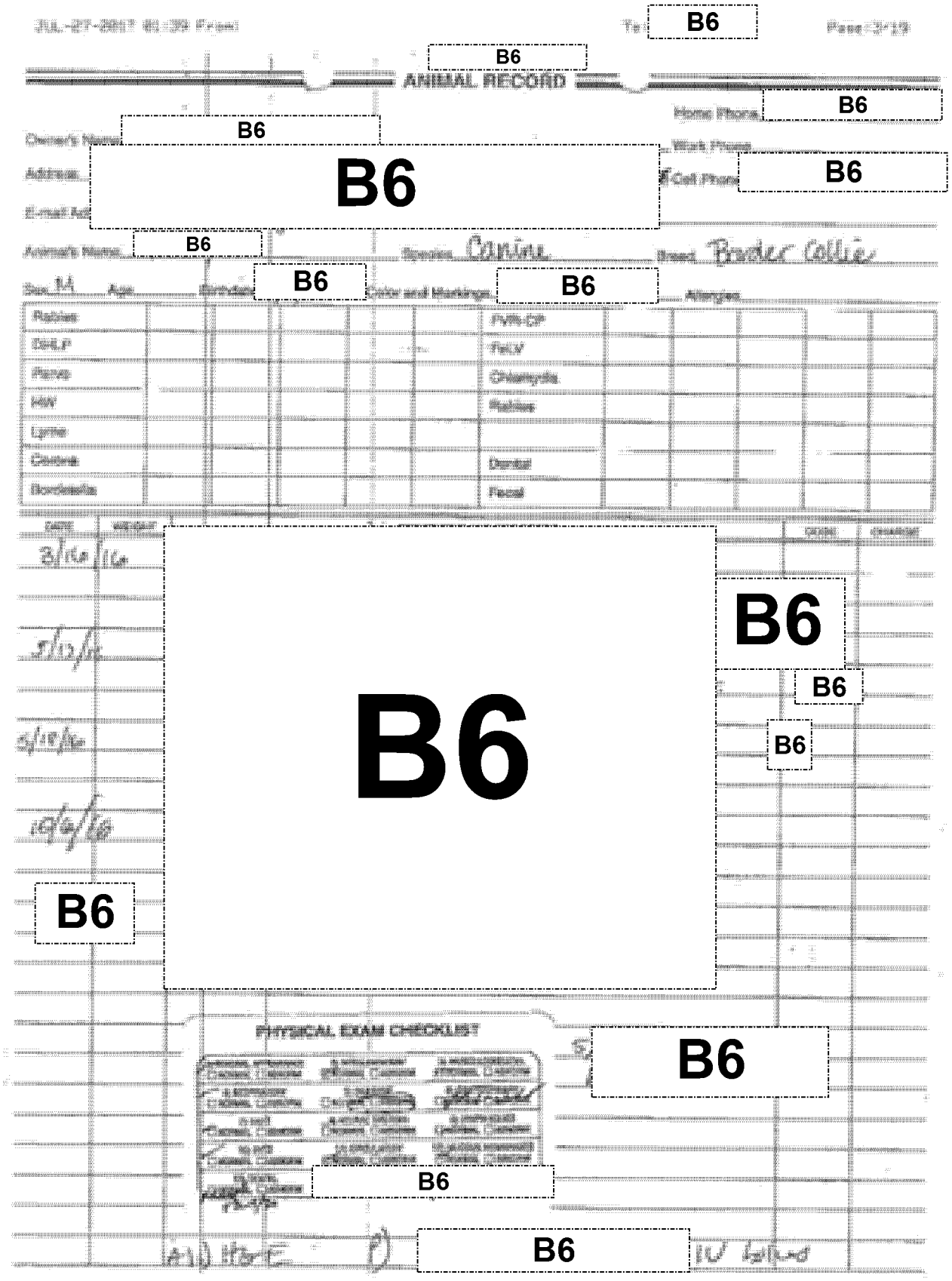
B4

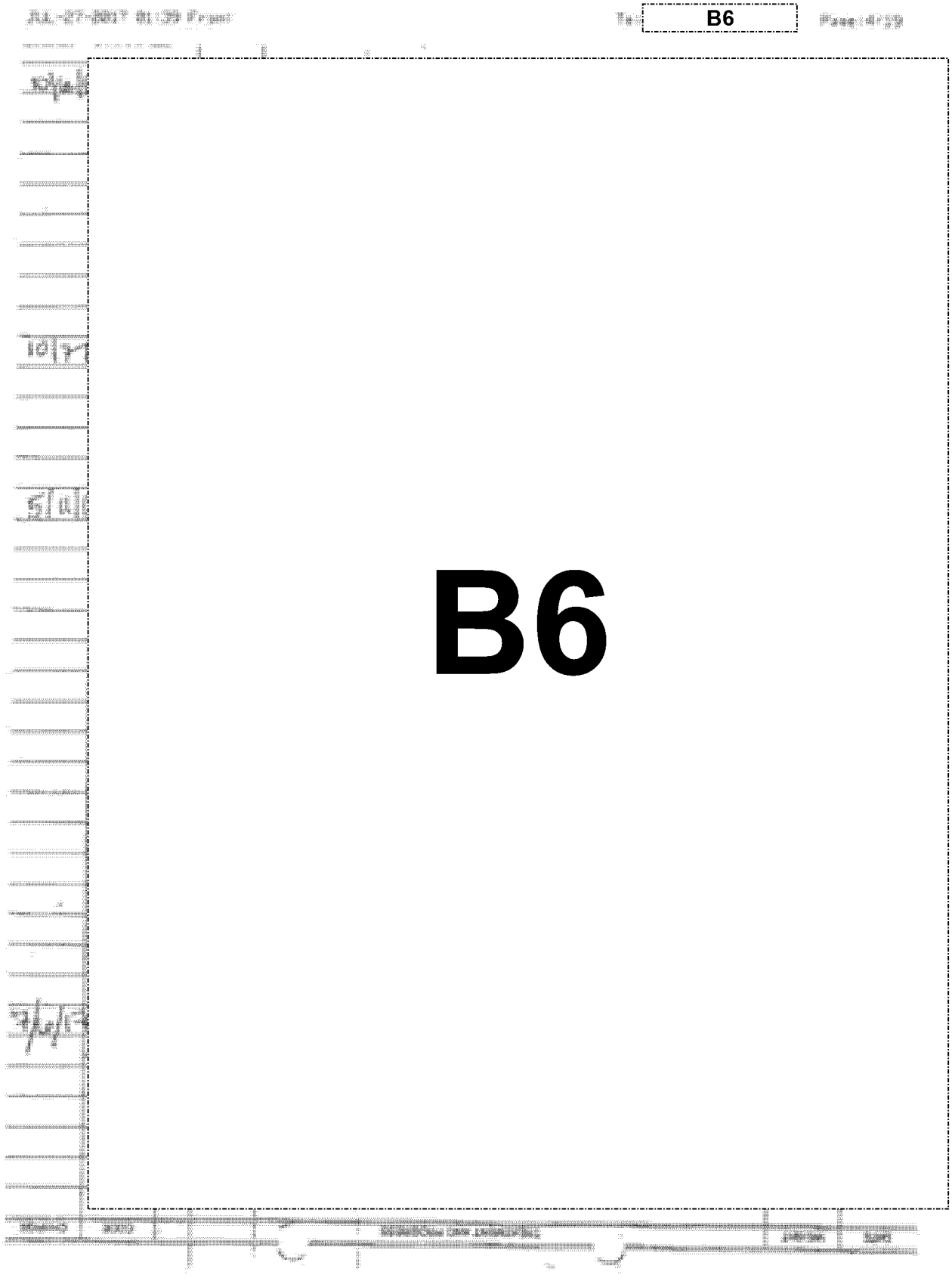
B6

FDA-CVM-FOIA-2019-1704-010304

Client: B6
Patient:

rDVM B6 **hx 3/6/16-7/7/17**


B6
ANIMAL RECORD
B6
B6
B6

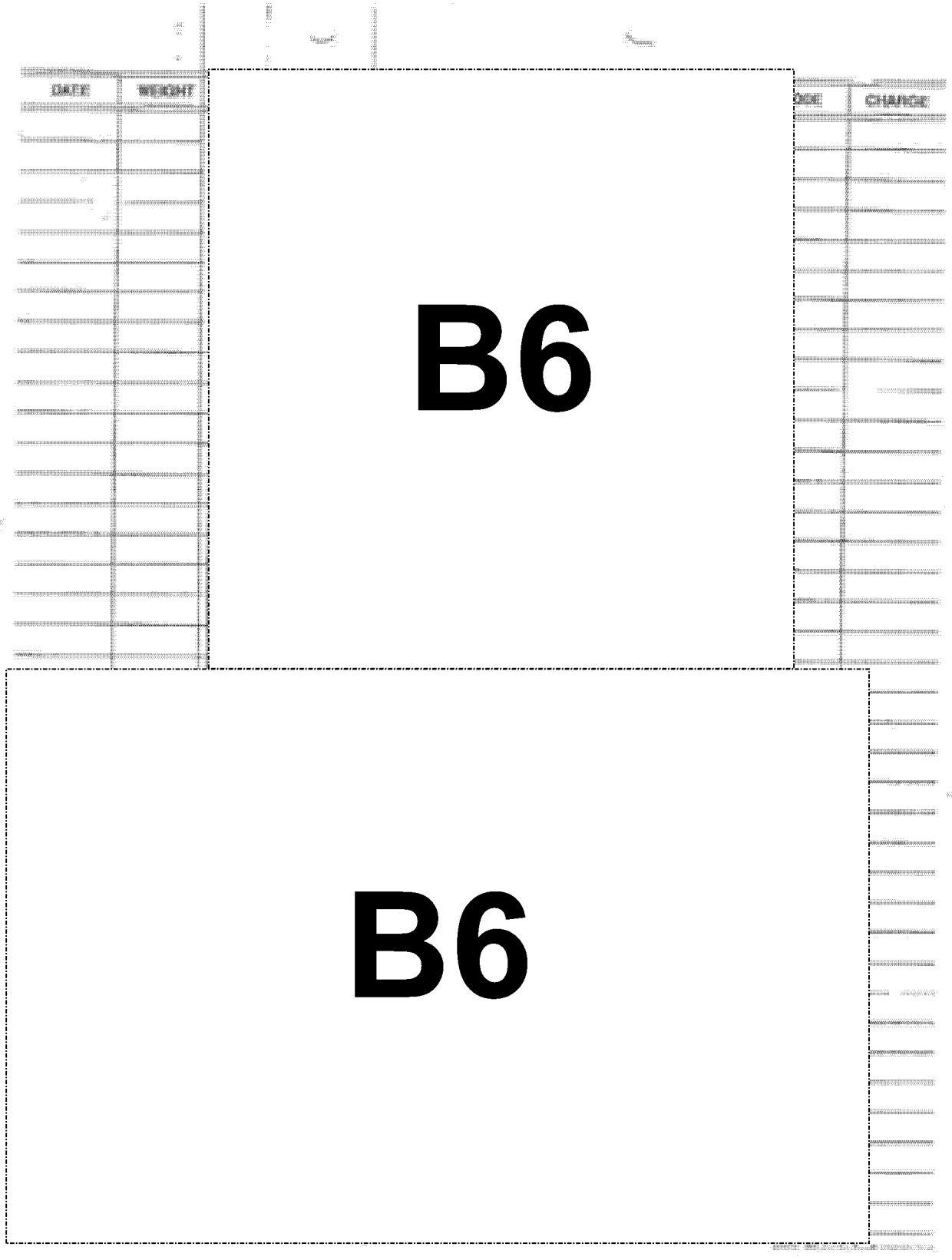


FDA-CVM-FOIA-2019-1704-010306

Client: B6
Patient:

rDVM B6 **hx 3/6/16-7/7/17**

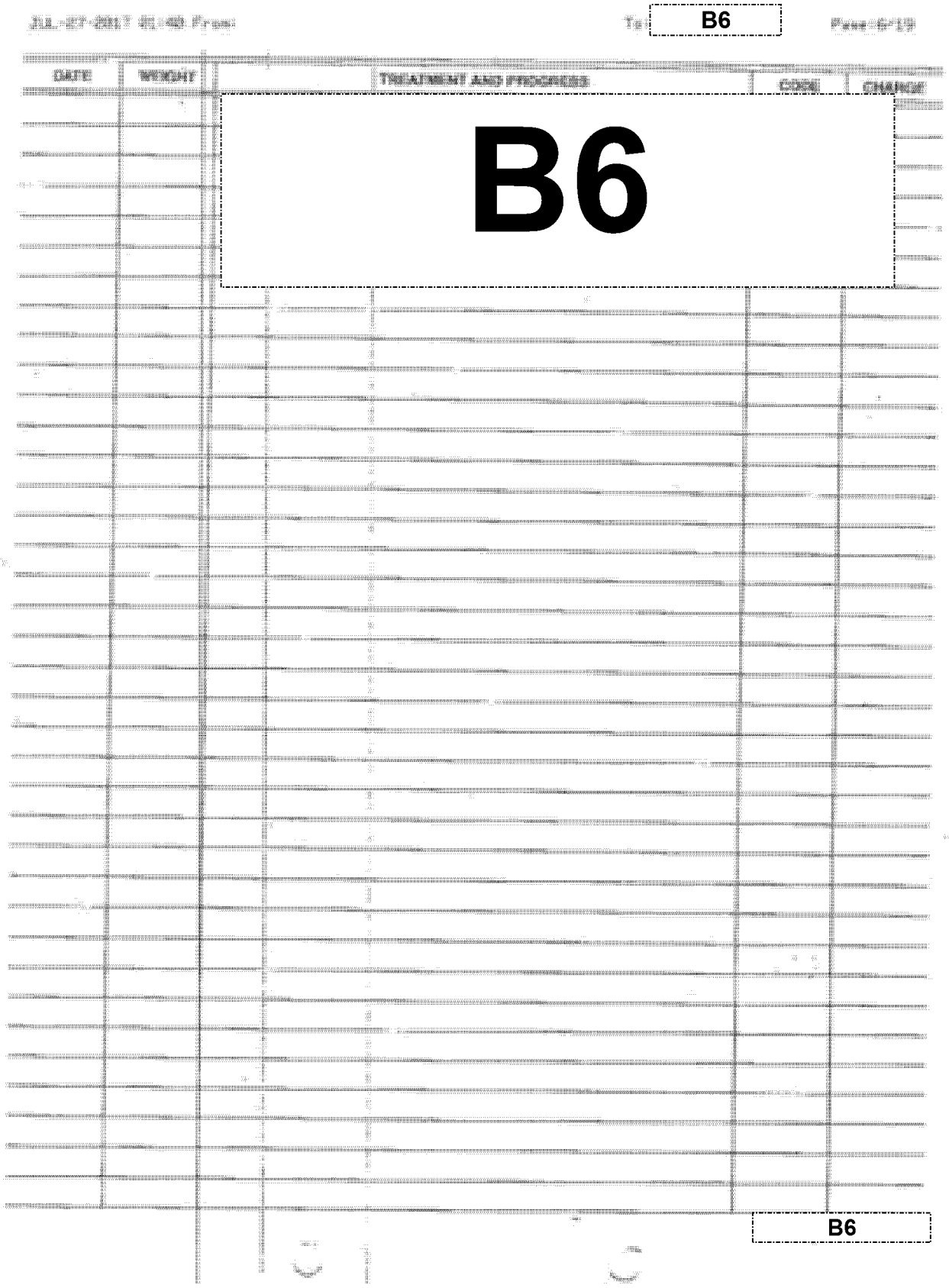
B6



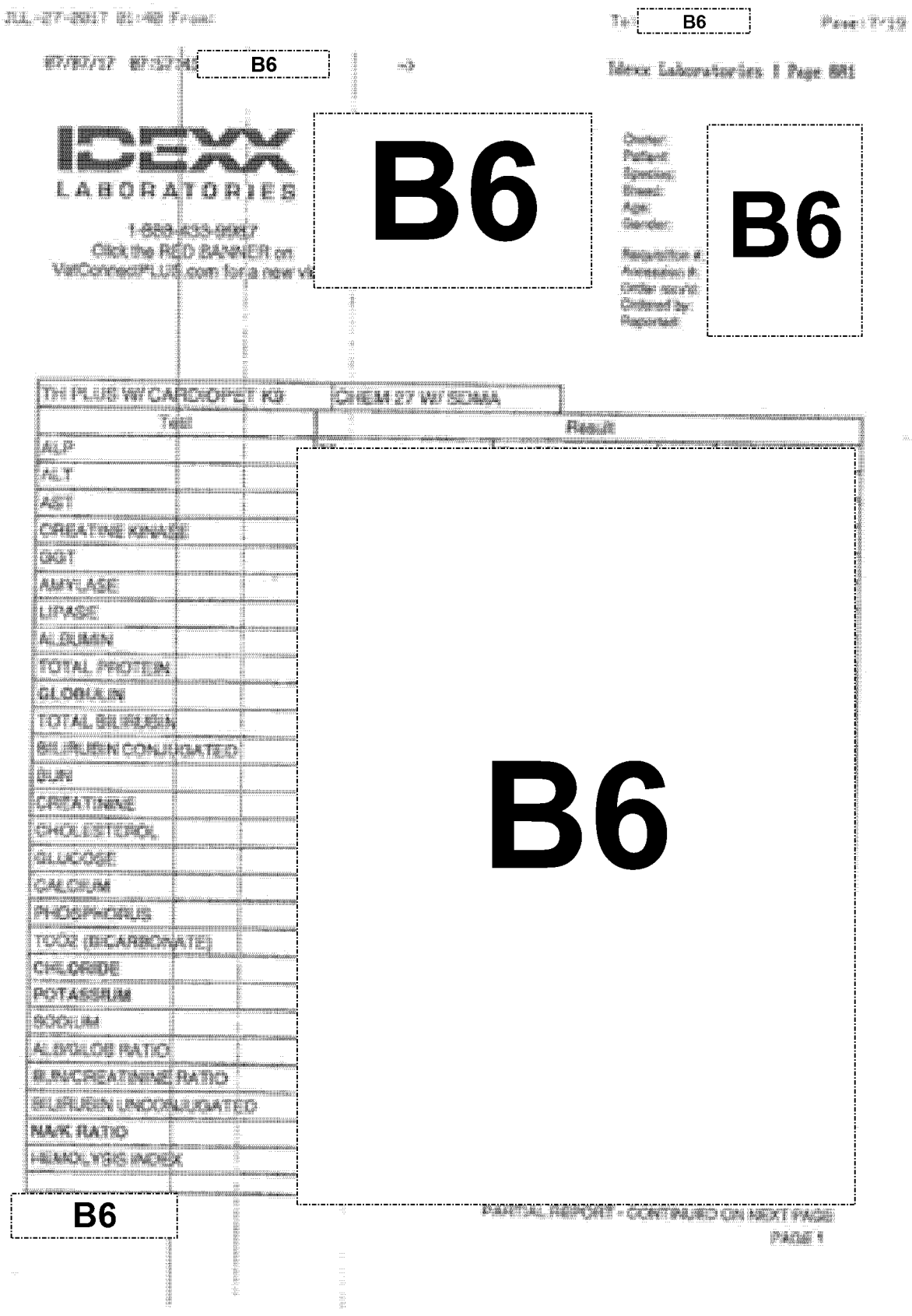
FDA-CVM-FOIA-2019-1704-010307

Client: B6
Patient:

rDVM B6 hx 3/6/16-7/7/17



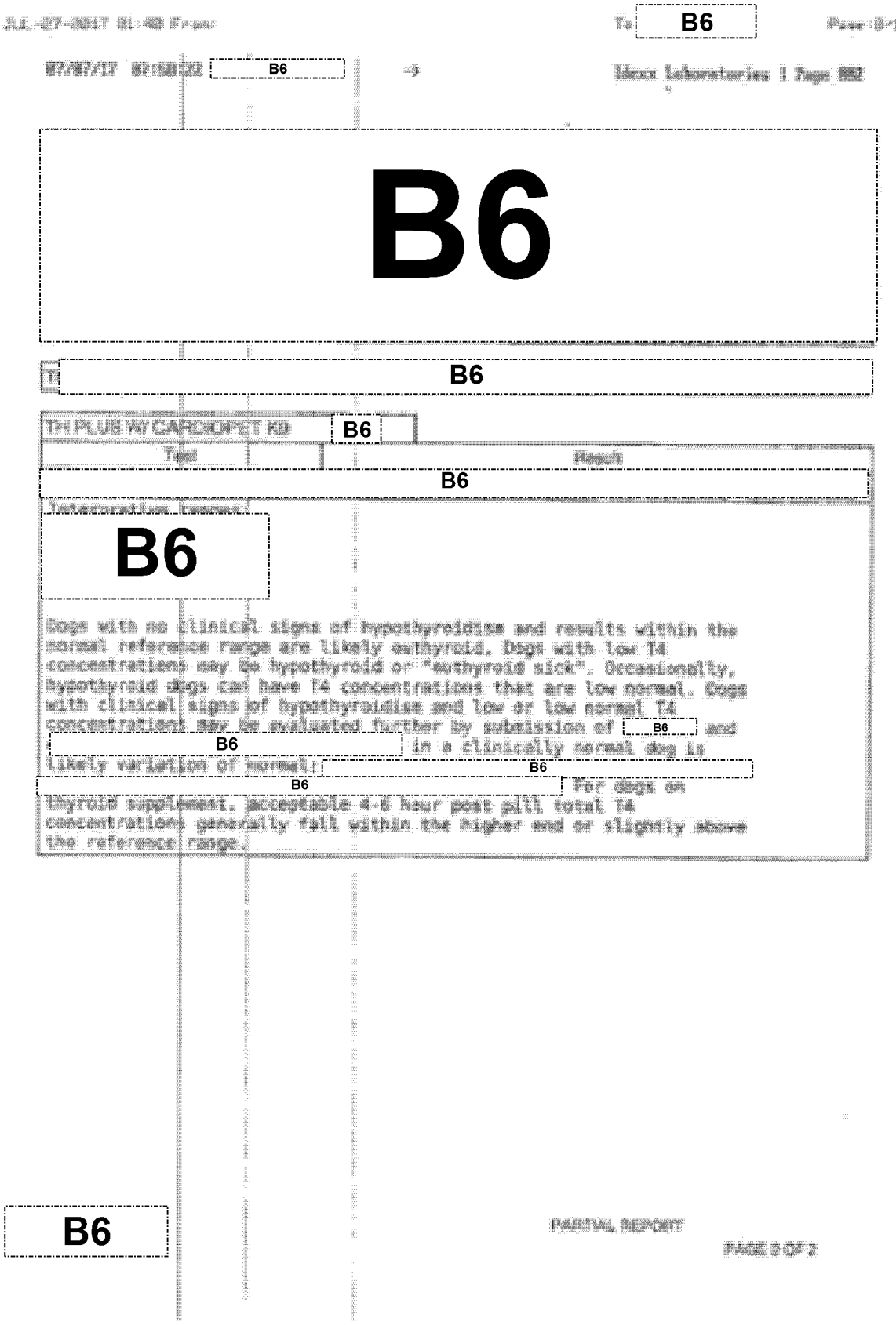
FDA-CVM-FOIA-2019-1704-010308



FDA-CVM-FOIA-2019-1704-010309

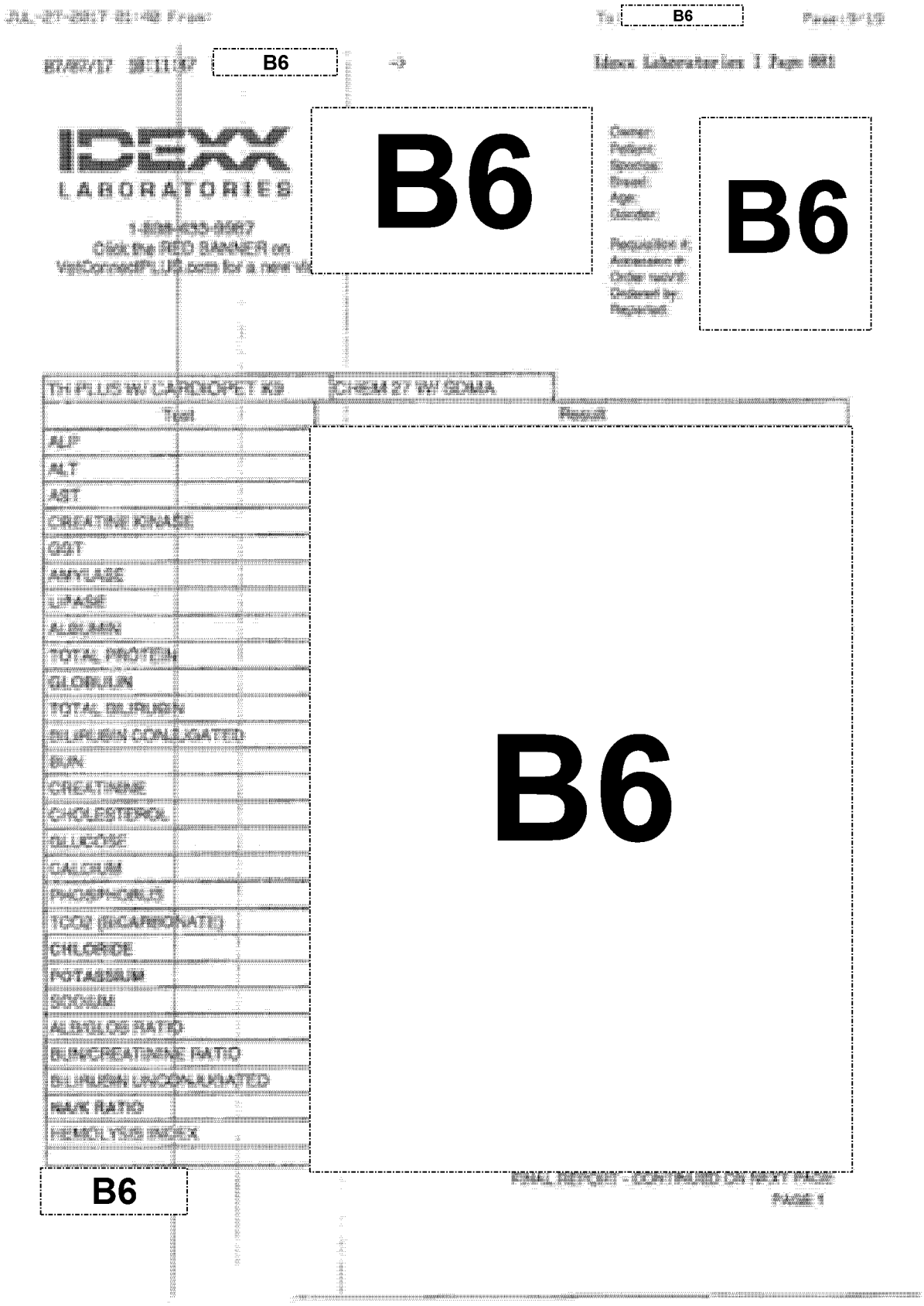
Client: B6
Patient:

rDVM B6 **hx 3/6/16-7/7/17**


B6
B6
B6

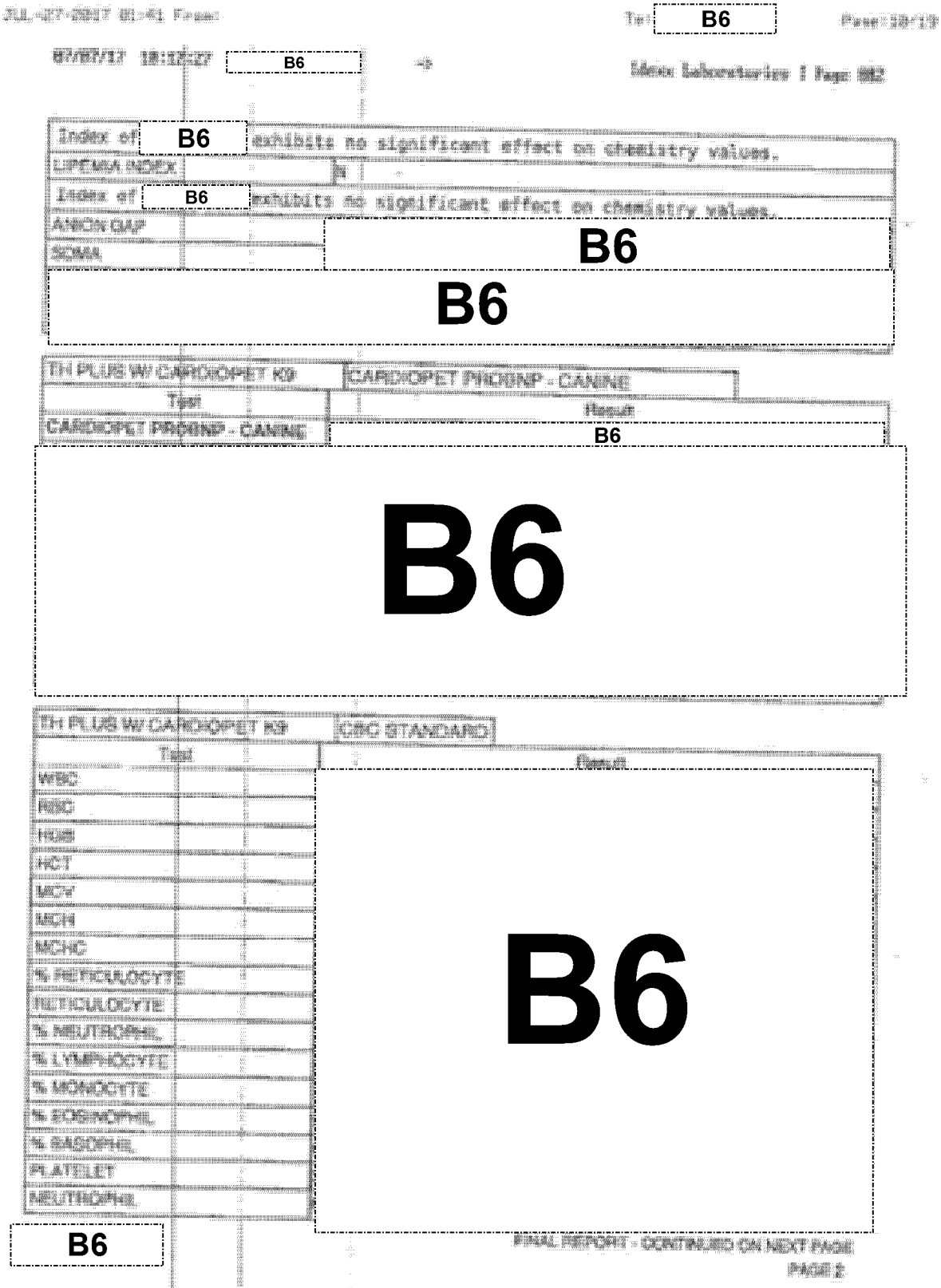
Client: B6
Patient:

rDVM B6 **hx 3/6/16-7/7/17**


B6
B6
B6

Client: B6
Patient:

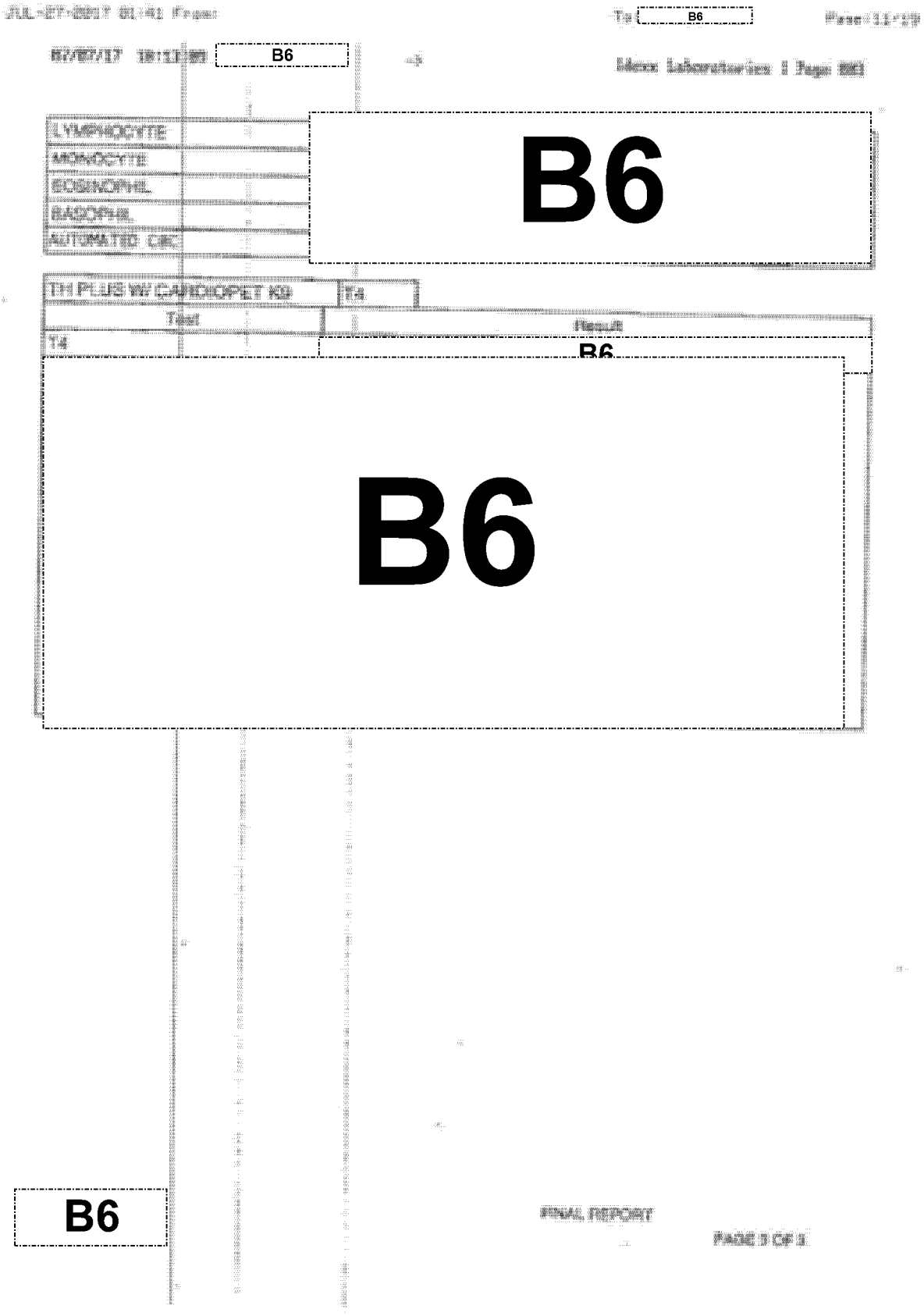
rDVM B6 **hx 3/6/16-7/7/17**



FDA-CVM-FOIA-2019-1704-010312

Client: B6
Patient:

rDVM B6 **hx 3/6/16-7/7/17**



FDA-CVM-FOIA-2019-1704-010313

Client: B6
Patient:

rDVM B6 **hx 3/6/16-7/7/17**

JUL-27-2017 01:41 From: To: B6 Page 12/13

B6

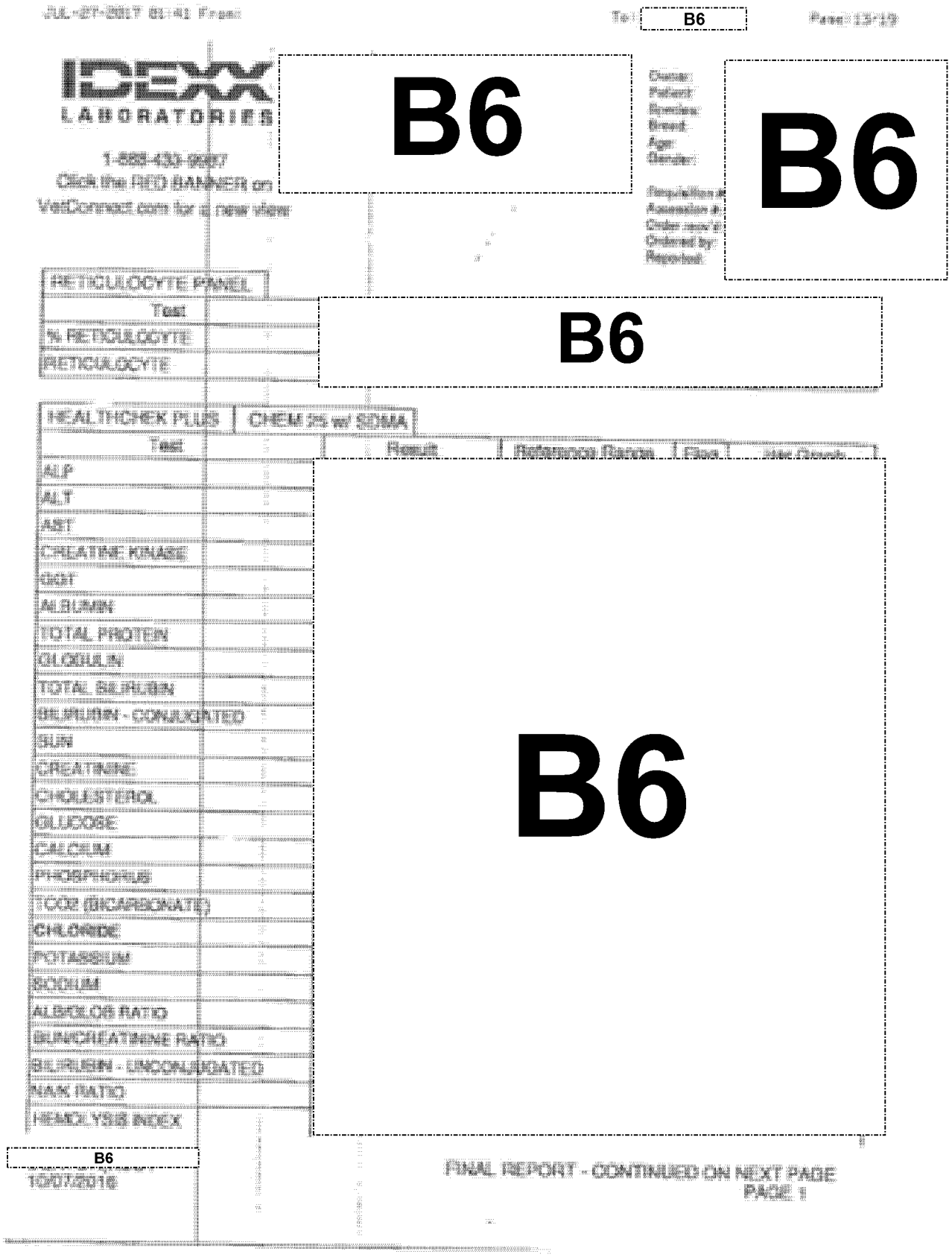
Printed: May 11, 2017 6:51 PM Page 1 of 1

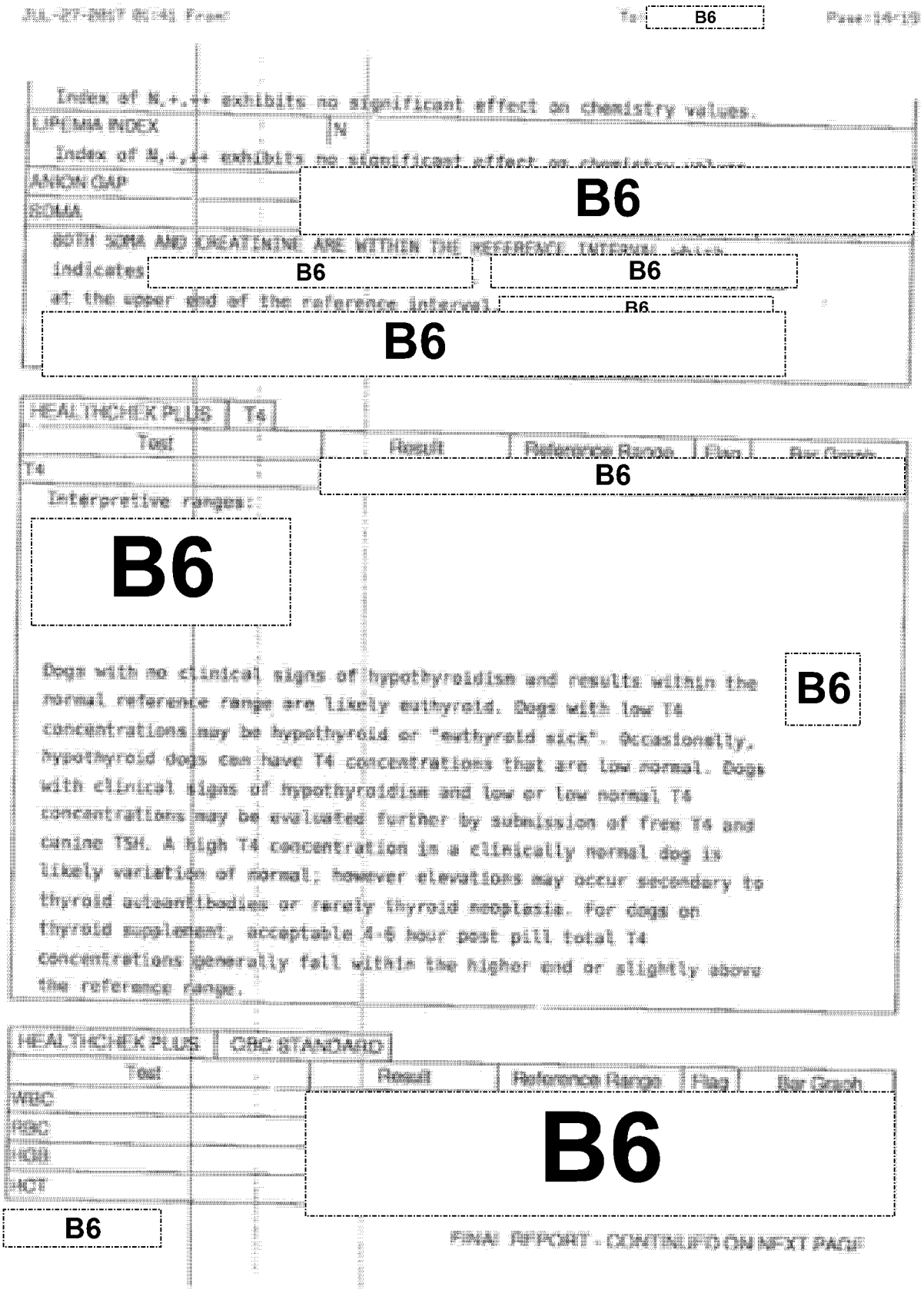
IDEXX

FDA-CVM-FOIA-2019-1704-010314

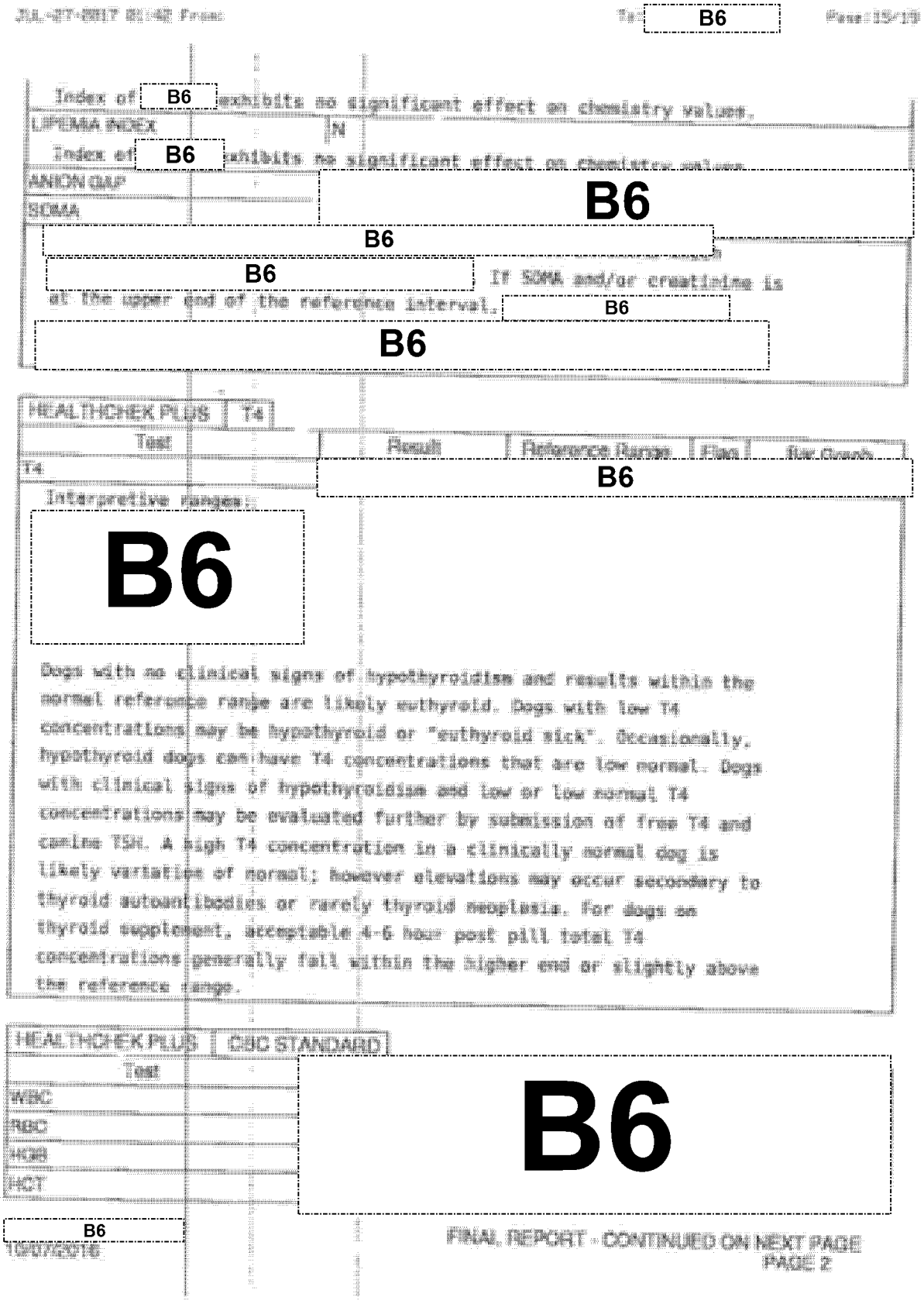
Client: B6
Patient:

rDVM B6 **hx 3/6/16-7/7/17**


B6
B6
B6



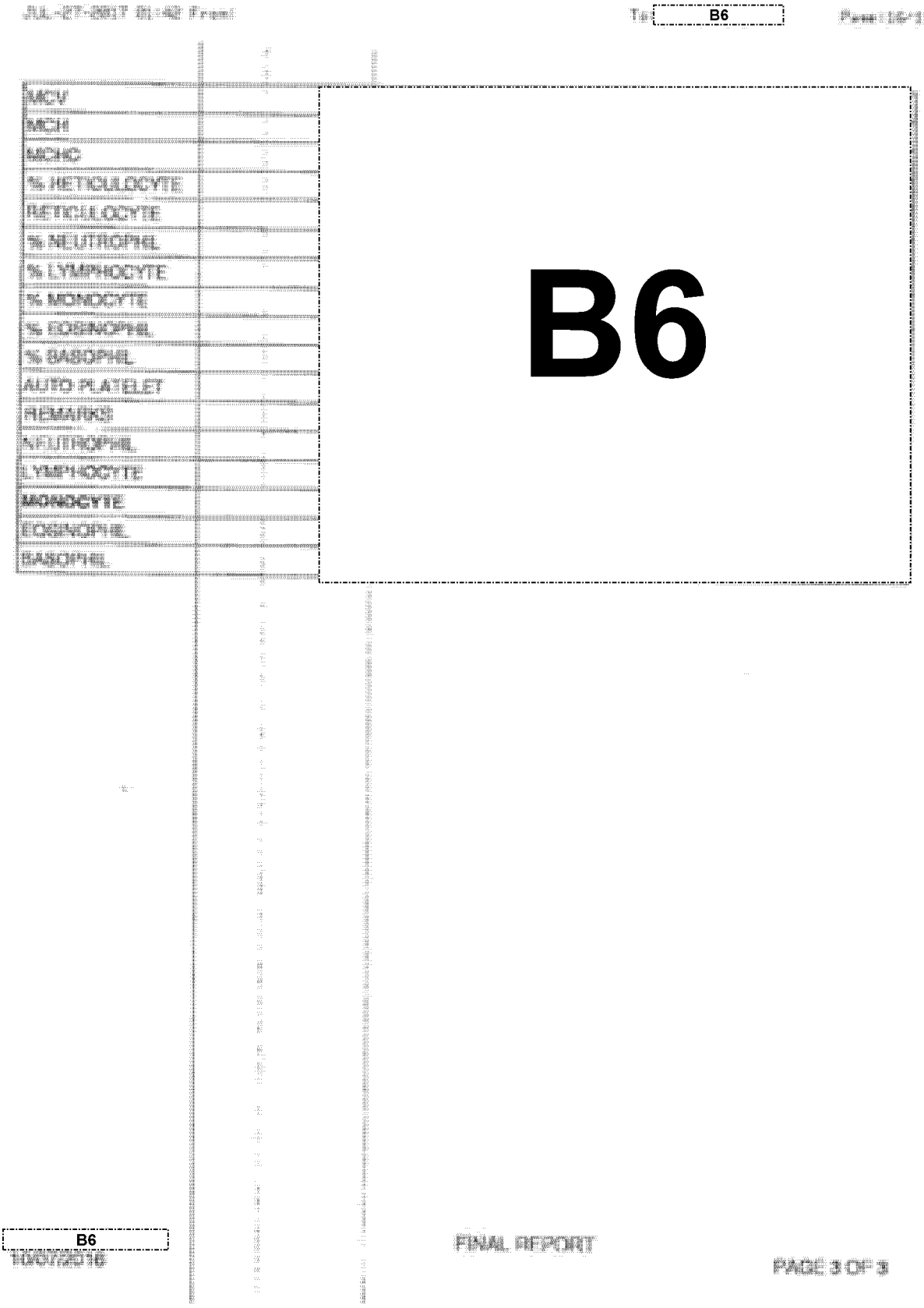
FDA-CVM-FOIA-2019-1704-010316



FDA-CVM-FOIA-2019-1704-010317

Client: B6
Patient:

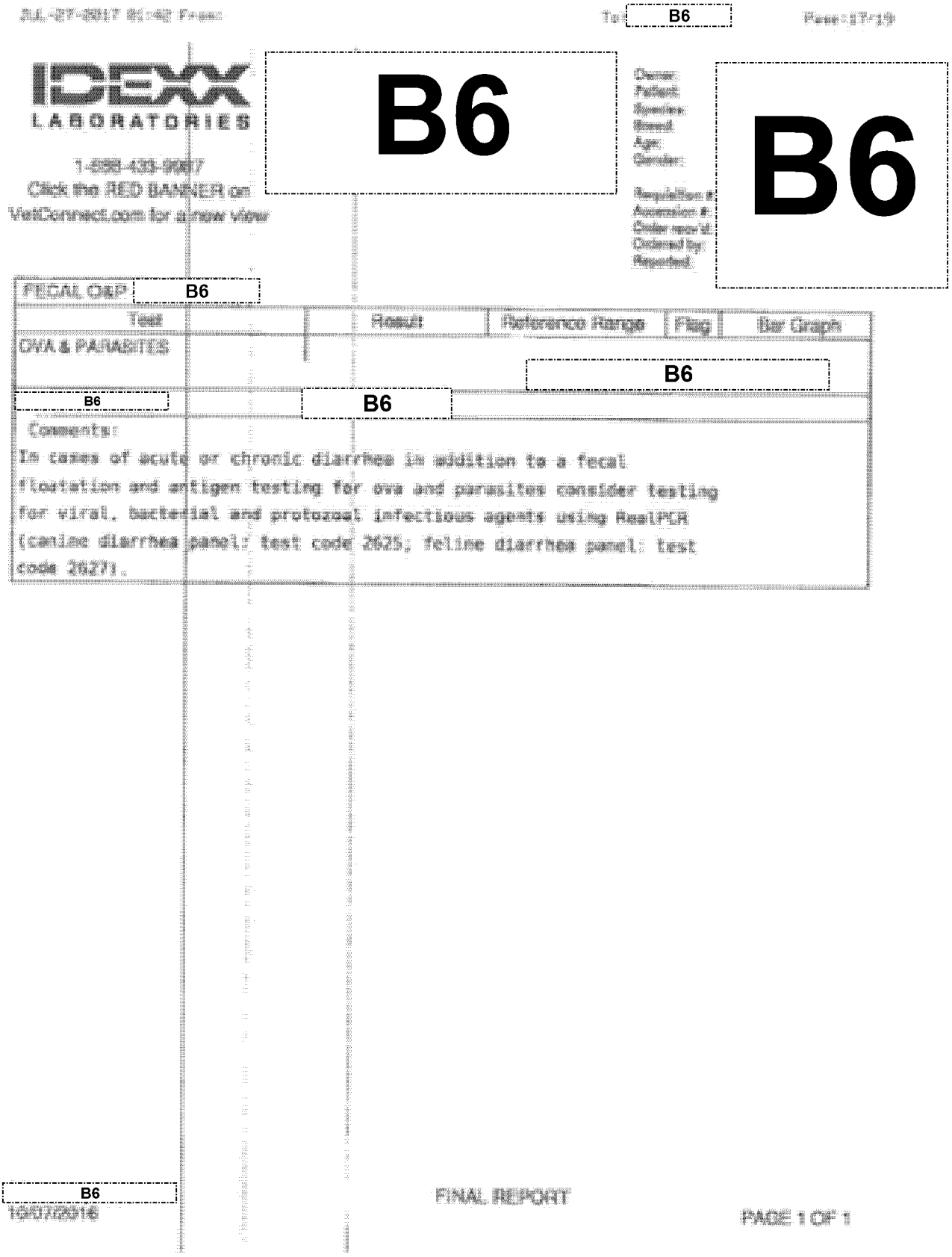
rDVM B6 **3/6/16-7/7/17**



FDA-CVM-FOIA-2019-1704-010318

Client: B6
Patient:

rDVM B6 **3/6/16-7/7/17**



Jul-27-2017 01:42 From: To: B6 Page: 17/19

IDEXX LABORATORIES

1-888-433-9697
Click the RED BANNER on VetConnect.com for a new view

B6

Client
Patient
Species
Breed
Age
Gender

Requisition #
Accession #
Date rec'd
Ordered By
Reported

B6

FECAL O&P B6

Test	Result	Reference Range	Flag	Bar Graph
OVA & PARASITES				

B6

B6 B6

Comments:
In cases of acute or chronic diarrhea in addition to a fecal flotation and antigen testing for ova and parasites consider testing for viral, bacterial and protozoal infectious agents using RealPCR (canine diarrhea panel: test code 2625; feline diarrhea panel: test code 2627).

B6
10/27/2016

FINAL REPORT

PAGE 1 OF 1

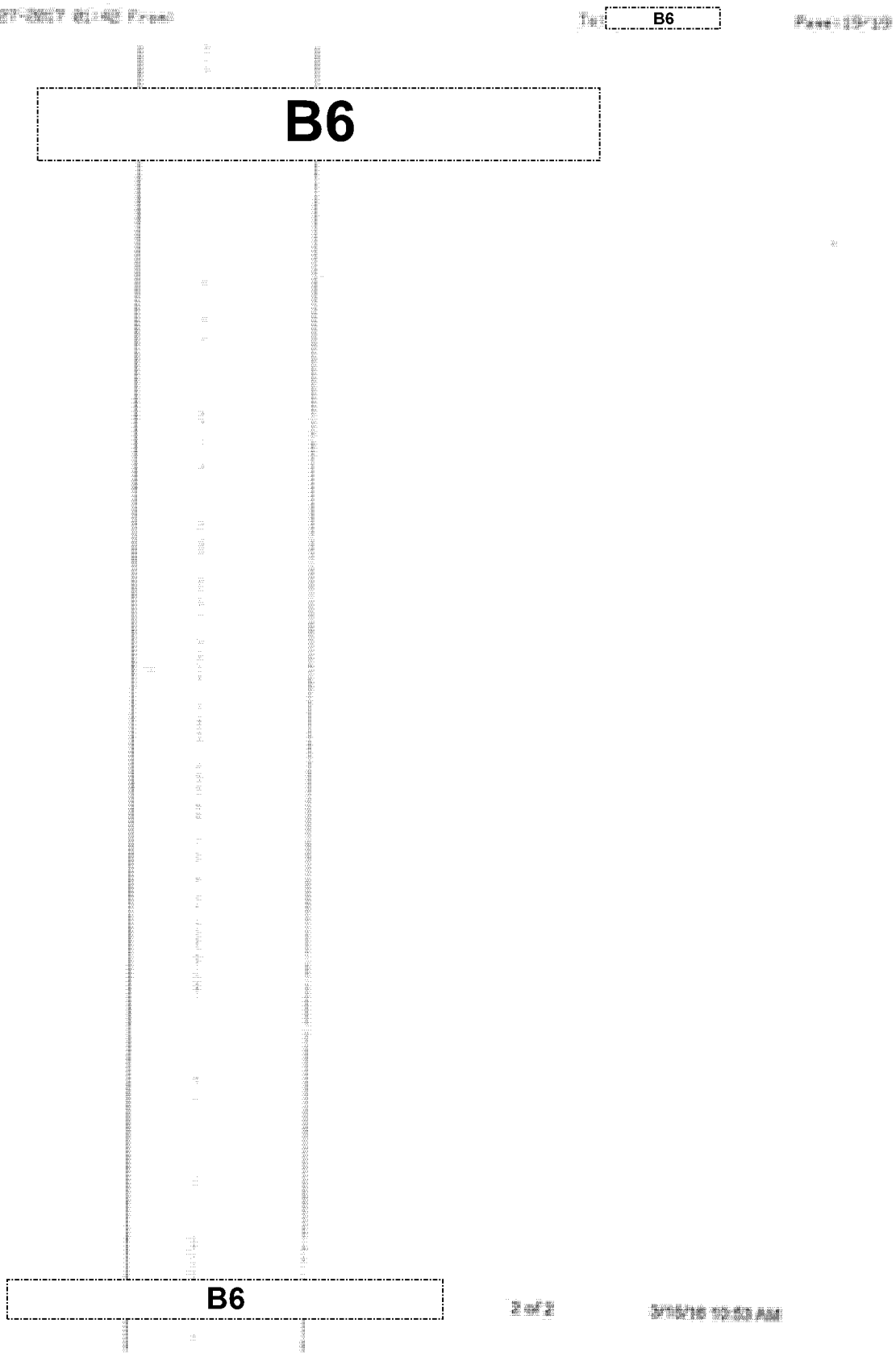
FDA-CVM-FOIA-2019-1704-010319

B6

B6

B6

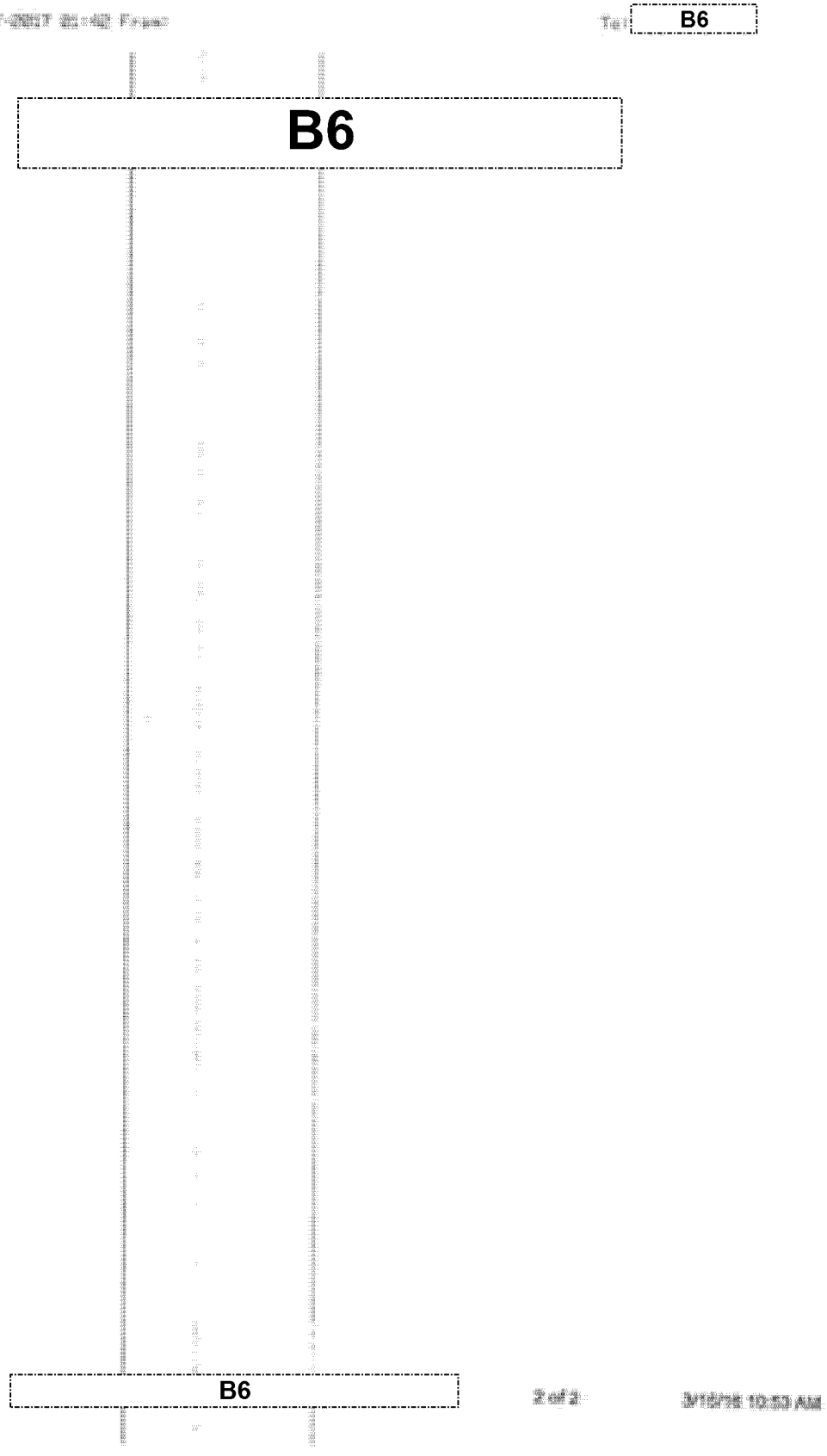
FDA-CVM-FOIA-2019-1704-010320



FDA-CVM-FOIA-2019-1704-010321

Client: B6
Patient:

rDVM B6 **hx 3/6/16-7/7/17**



FDA-CVM-FOIA-2019-1704-010322

Client: B6
Patient:

Prescription B6 3/25/17

B6

B6

Dear DVM,

B6

CLIENT INFO

Name:
Email:
Address:

B6

Phone:
Pet's Name:
Weight:
Species:
Product:
Quantity:

VETERINARIAN INFO

Hospital Name: TUFTS VETS - FOSTER HOSPITAL FOR SMALL ANIMALS
Name: DR. JOHN RUSH, D.V.M.
Address: 200 WESTBORO ROAD NORTH GRAFTON, MA 01536-1895, grafton, MA 01536
Phone: 5088395095
Fax: 5088397091
Email:

Prescription Directions: Give B6 by mouth twice daily.

Refills allowed: 11 Date/Time: 3/25/17

Vet Signature: B6

Vet Name: Current License#: B6

B6

Questions?

B6

FDA-CVM-FOIA-2019-1704-010323

B6

Patient History Report

Client: B6
Phone:
Address:

Patient: B6
Species: Canine
Age: B6
Color:

Breed: Collie, Border
Sex: Male

Date	Type	Staff	History
4/24/2018	V		
4/24/2018	L		
4/24/2018	R		
4/24/2018	P		
4/24/2018	P		
4/24/2018	B		
4/24/2018	B		
4/24/2018	B		
4/24/2018	B		
4/24/2018	B		
7/7/2017	E		

B6

B6

FDA-CVM-FOIA-2019-1704-010324

B6

Patient History Report

Client: B6
Phone:
Address:

Patient: B6
Species: Canine
Age: B6
Color:

Breed: Collie, Border
Sex: Male

Date Type Staff History

B6

FDA-CVM-FOIA-2019-1704-010325

B6

Patient History Report

Client: B6
Phone:
Address:

Patient: B6
Species: Canine
Age: 0 Yrs. 11 Mos.
Color: Black and White

Breed: B6
Sex: Male

Date Type Staff History

B6

B6

FDA-CVM-FOIA-2019-1704-010326

Client: B6
Patient:

RDVM B6 **10/6/16-4/24/18**

B6 PAGE

Patient History Report

Client: B6
Phone:
Address:

Patient: B6
Species: Canine
Age: B6
Color:

Breed: Collie, Border
Sex: Male

Date	Type	Staff	History
7/6/2017			
7/6/2017			
7/6/2017			
7/6/2017			
7/6/2017			
7/6/2017			
7/6/2017			
7/6/2017			
7/6/2017			
6/11/2017			
5/11/2017			
5/11/2017			

B6

B6

FDA-CVM-FOIA-2019-1704-010327

B6

Patient History Report

Client: B6
Phone:
Address:

Patient: B6
Species: Canine
Age:
Color: B6

Breed: Collie, Border
Sex: Male

Date	Type	Staff	History
3/11/2017			
5/11/2017			
5/11/2017			
5/11/2017			
5/11/2017			
10/6/2016			
10/5/2016			
10/5/2016			
10/5/2016			

B6

B6

B6

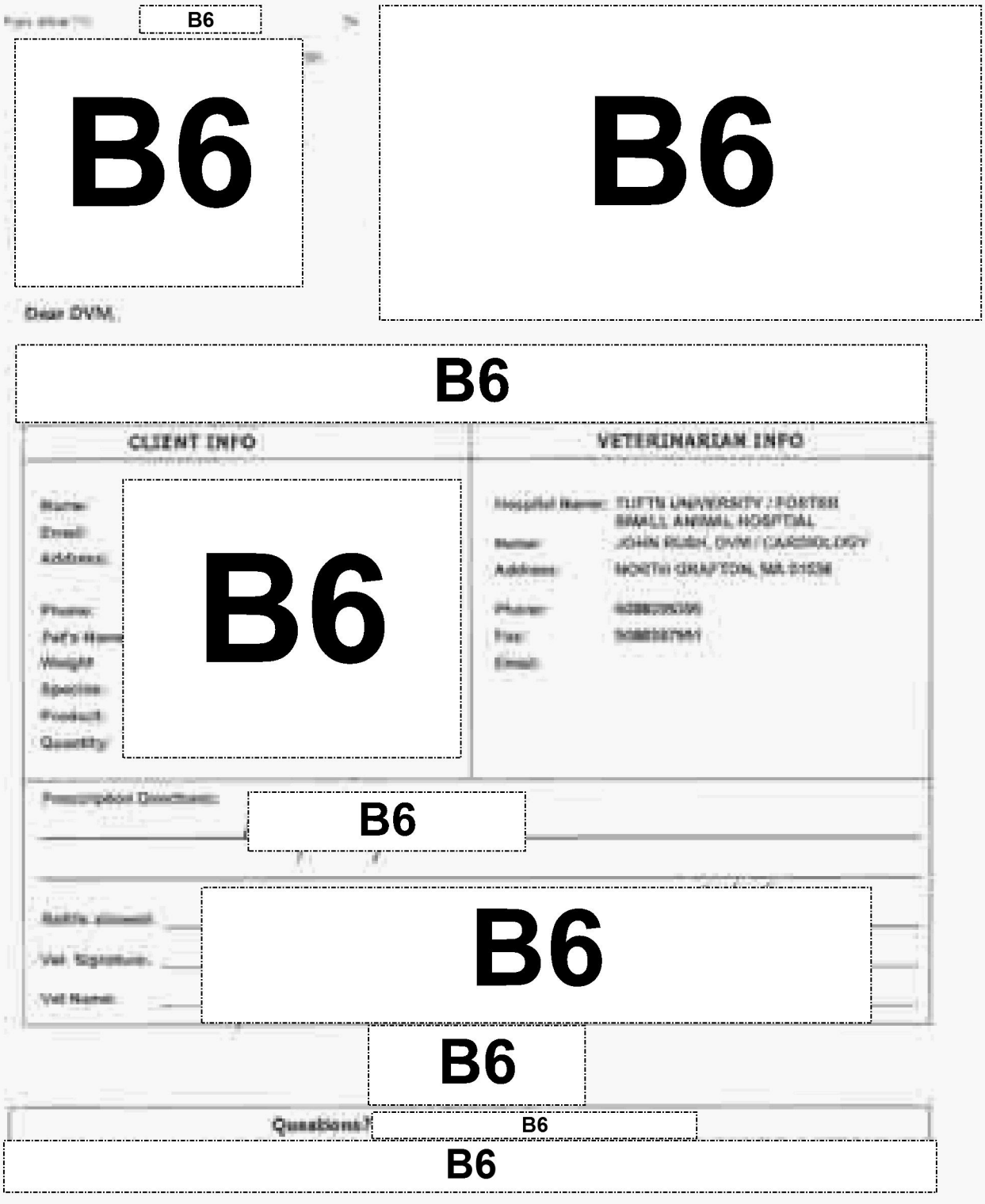
Page 5 of 9

B6

FDA-CVM-FOIA-2019-1704-010328

Client: B6
Patient:

B6 7/5/18



FDA-CVM-FOIA-2019-1704-010329

Client: B6
Patient:

B6 /5/18

B6

B6

B6

B6

B6

CLIENT INFO

VETERINARIAN INFO

Name:
Email:
Address:

Phone:
Pet's Name:
Weight
Species:
Product:
Quantity:

B6

Hospital Name: TUFTS UNIVERSITY / FOSTER SMALL ANIMAL HOSPITAL
Name: JOHN RUSH, DVM / CARDIOLOGY
Address: NORTH GRAFTON, MA 01536
Phone: 5088852280
Fax: 5088337001
Email:

B6

Prescription Directions:

B6

B6

Refills allowed:
Vet Signature:
Vet Name:

B6

Questions? B6

B6

FDA-CVM-FOIA-2019-1704-010330

Aug 01 18 09:18a p.1

B6

DATE: 8/1/18

TO: TUFTS

FAX NUMBER: 1-508-839-7961

SUBJECT: B6 Blood work

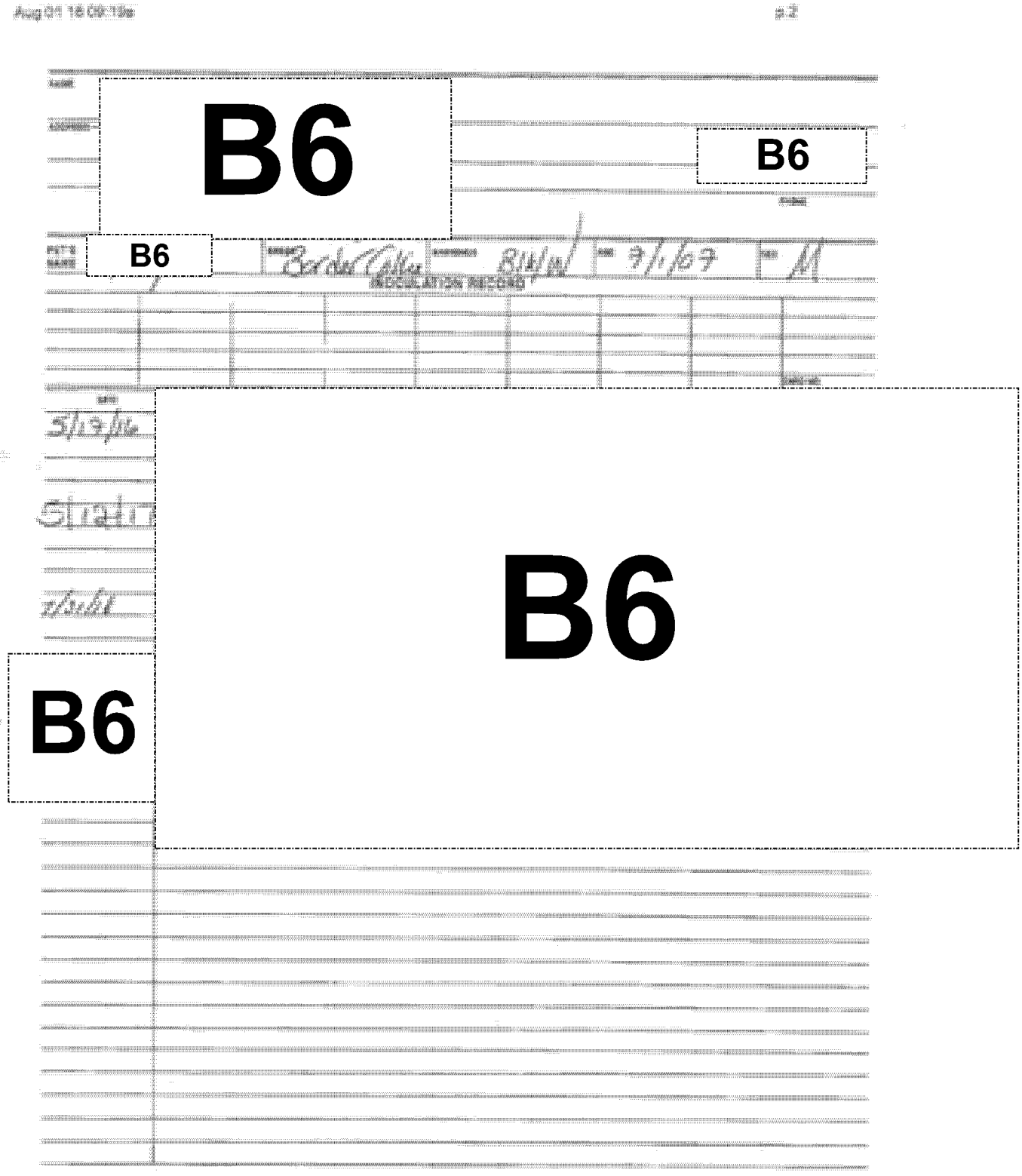
FROM:

NUMBER OF PAGES (including cover sheet): 3

FDA-CVM-FOIA-2019-1704-010331

Client: B6
Patient:

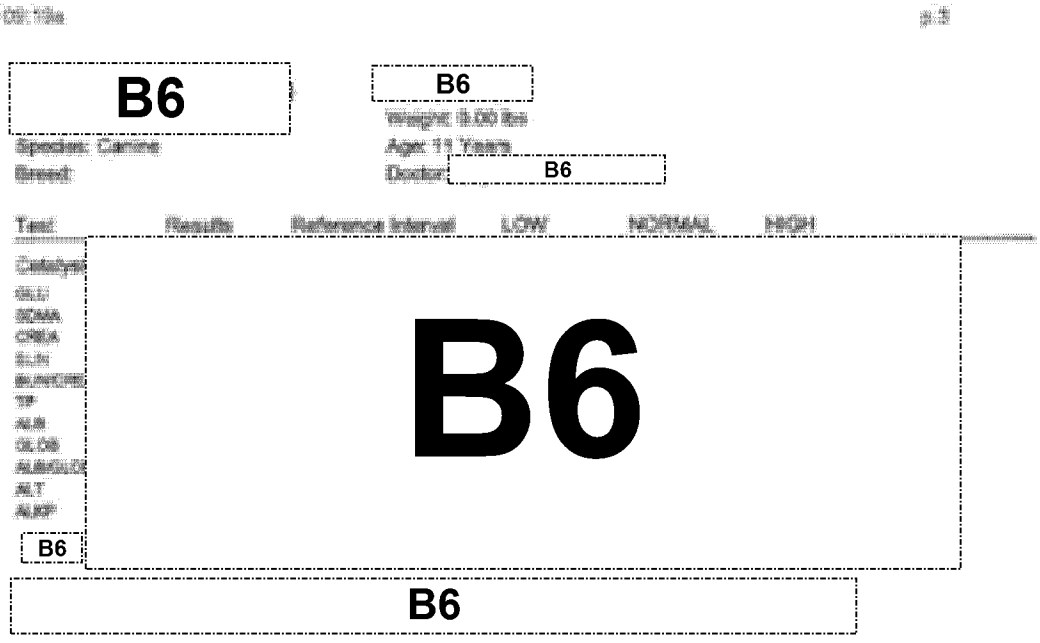
RDVM: B6 | appt notes and catalyst from 7/31/18



FDA-CVM-FOIA-2019-1704-010332

Client: B6
Patient:

RDVM B6 **ppt notes and catalyst from 7/31/18**



FDA-CVM-FOIA-2019-1704-010333

B6

DATE: 9/18/18

TO: Tivets - Atte B6

FAX NUMBER: B6

SUBJECT: Bloodwork for B6

FROM: B6

NUMBER OF PAGES (including cover sheet): 3

FDA-CVM-FOIA-2019-1704-010334

Client: B6
Patient:

RDVM B6 **Bloodwork 9/18/18**

B6

B6

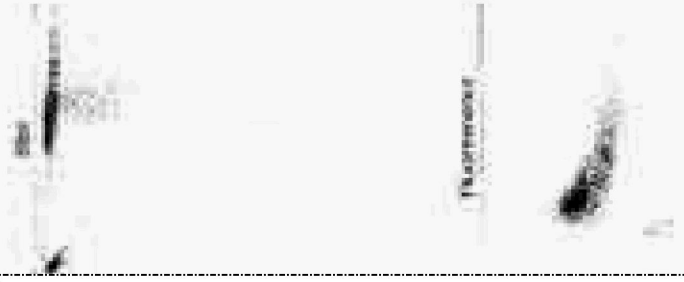
Species: Canine
Breed:

B6

B6

B6

B6



B6

FDA-CVM-FOIA-2019-1704-010335

Client: B6
Patient:

RDVM B6 **Bloodwork 9/18/18**

Sep 18 '18 02:00 (90y) p.1

Client: B6
Patient:
Species: Canine
Breed:

B6
Weight: 0.00 lbs
Age: 11 Years

B6

Test	Results	Reference Interval	LOW	NORMAL	HIGH
Comment					
GLU					
SDMA					
CREA					
BUN					
BUN/CREA					
TP					
ALB					
GLOB					
A/G RATIO					
ALT					
ALKP					
TBIL					
K					
NaK					
Ca					
Other					

B6

B6

B6

Page 2 of 2

IDEXX LABORATORIES

FDA-CVM-FOIA-2019-1704-010336

Client: B6
Patient:

B6 11/29/18

B6

B6

B6

Dear DVM,

FAXED 11-29-18

B6

CLIENT INFO	VETERINARIAN INFO
Name:	Hospital Name: TUFTS UNIVERSITY / FOSTER SMALL ANIMAL HOSPITAL
Email:	Name: JOHN RUSH, DVM / CARDIOLOGY
Address:	Address: NORTH GRAFTON, MA 01536
Phone:	Phone:
Pet's Name:	Fax:
Weight:	Email:
Species:	
Product:	
Quantity:	

B6

B6

B6

Questions? B6

B6

FDA-CVM-FOIA-2019-1704-010337

IDEXX BNP - 12/19/2018

[redacted]

B6

[redacted]

FDA-CVM-FOIA-2019-1704-010338

Client: B6
Patient:

Diet history 12/19/19

CARDIOLOGY DIET HISTORY FORM

Pet's name: B6 Owner's name: B6 Today's date: [illegible]

1. How would you evaluate your pet's appetite? (mark the point on the line below that best represents your pet's appetite)

Example: Poor ——— Excellent

Poor ——— Excellent B6

2. Have you noticed a change in your pet's appetite over the last 1-3 weeks? (check all that apply)
☑Eats about the same amount as usual ☐Eats less than usual ☐Eats more than usual
☐Seems to prefer different foods than usual ☐Other: _____

3. Over the last few weeks, has your pet (check one)
☐Lost weight ☐Gained weight ☑Stayed about the same weight ☐Don't know

4. Please list below ALL pet foods, people food, treats, snacks, dental chews, rawhides, and any other food item that your pet currently eats. Please include the brand, specific product, and flavor so we know exactly what you pet is eating.

Examples are shown in the table – please provide enough detail that we could go to the store and buy the exact same food.

Food (include type, Rx product and flavor)	Form	Amount	How often?	Fed since
Nutro Grain Free Chicken, Lamb, & Sweet Potato Adult	dry	1 ½ cup	2x/day	Jan 2019
90% lean hamburger	microwaved	3 oz	1x/week	Jan 2019
Pepperoni original beef flavor	treat	5x	1x/day	Aug 2019
Rawhide	treat	6 inch twist	1x/week	Dec 2015
[illegible]				
[illegible]				
[illegible]				
[illegible]				
[illegible]				
[illegible]				
[illegible]				

*Any additional diet information can be listed on the back of this sheet

5. Do you give any dietary supplements to your pet (for example: vitamins, glucosamine, fatty acids, or any other supplements)? ☐Yes ☑No If yes, please list which ones and give brands and amounts.

	Brand/Concentration	Amount per day
Taurine	☐Yes ☐No	
Carnitine	☐Yes ☐No	
Antioxidants	☐Yes ☐No	
Multivitamin	☐Yes ☐No	
Fish oil	☐Yes ☐No	
Coenzyme Q10	☐Yes ☐No	
Other (please list):		
Example: Vitamin C	Melody Blueity	500 mg tablets – 1 per day
[illegible]	[illegible]	[illegible]

6. How do you administer pills to your pet?
☐I do not give any medications
☑I put them directly in my pet's mouth without food
☑I put them in my pet's dog/cat food
☐I put them in a Pill Pocket or similar product
☐I put them in foods (list foods): _____

FDA-CVM-FOIA-2019-1704-010339

Client:
Patient: B6

Vitals Results

B6	10:47:35 AM	Weight (kg)
	11:31:06 AM	Blood Pressure (mmHg)
	17 11:31:13 AM	Blood Pressure (mmHg)
	11:48:18 AM	Weight (kg)
	18 11:03:43 AM	Weight (kg)

B6

FDA-CVM-FOIA-2019-1704-010340

B6

FDA-CVM-FOIA-2019-1704-010341

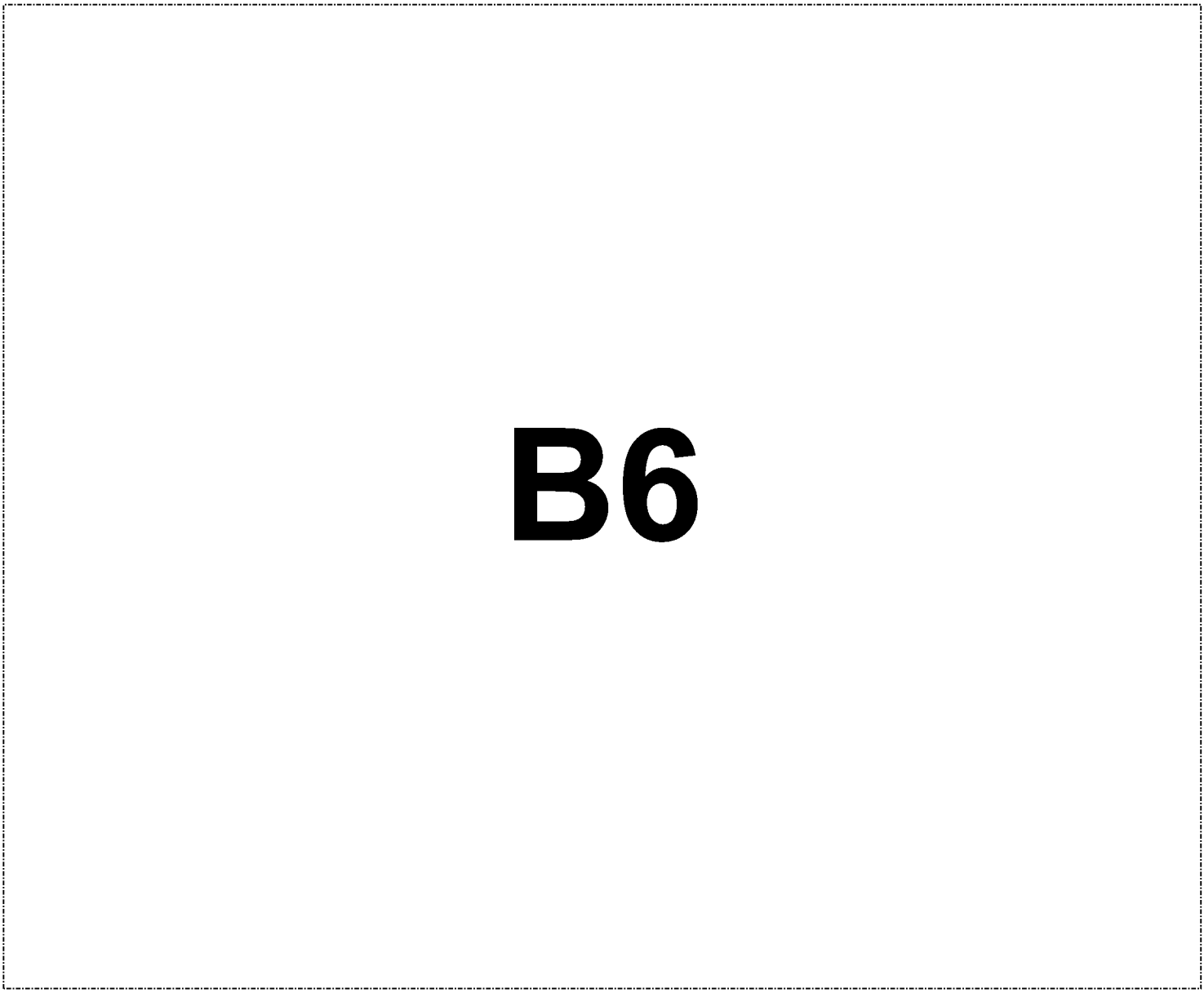
B6

FDA-CVM-FOIA-2019-1704-010342

B6

FDA-CVM-FOIA-2019-1704-010343

FDA-CVM-FOIA-2019-1704-010344



FDA-CVM-FOIA-2019-1704-010345

Client: B6
Patient:

Patient History

B6	10:47 AM	Appointment
	03:47 PM	Appointment
	10:02 AM	UserForm
	10:22 AM	Purchase
	10:47 AM	Vitals
	10:53 AM	Treatment
	10:59 AM	UserForm
	11:31 AM	Purchase
	11:31 AM	Vitals
	11:31 AM	Purchase
	12:11 PM	Prescription
	12:12 PM	Prescription
	12:14 PM	Purchase
	04:44 PM	UserForm
	01:12 PM	Appointment
	10:12 AM	UserForm
	10:33 AM	Purchase
	10:34 AM	Treatment
	11:18 AM	Purchase
	11:31 AM	Vitals
	11:31 AM	Purchase
	11:39 AM	UserForm
	09:29 AM	Appointment
	10:51 AM	Appointment
	10:51 AM	Appointment
	03:55 PM	Appointment
	11:08 AM	UserForm
	11:48 AM	Vitals
	11:48 AM	Purchase
	11:50 AM	Treatment
	11:53 AM	Purchase
	12:13 PM	UserForm
	12:51 PM	Purchase
	08:46 AM	Email

B6

FDA-CVM-FOIA-2019-1704-010346

Client:
Patient: B6

Patient History

B6

03:54 PM	Appointment
04:28 PM	Appointment
02:38 PM	Appointment
11:00 AM	UserForm
11:01 AM	Treatment
11:03 AM	Vitals
12:25 PM	UserForm
01:05 PM	Deleted Reason
01:05 PM	Deleted Reason
01:10 PM	Purchase
05:12 PM	Appointment

B6

FDA-CVM-FOIA-2019-1704-010347

Cummings Veterinary Medical Center
AT TUFTS UNIVERSITY

Foster Hospital for Small Animals
55 W Road Street
North Grafton, MA 01536
Telephone: (508) 839-5395
Fax: (508) 839-7951
http://vetmed.tufts.edu/

Discharge Instructions

Patient
Name: B6
Species: Canine
B6 Male Border Collie
Birthdate: B6

Owner
Name:
Addre: B6

Patient ID: B6

Attending Cardiologist:
☑ John F. Rush DVM, MS, DACVIM (Cardiology), DACVECC
B6

Cardiology Resident:
B6

Student:
Cardiology Technician:
B6

Admit Date: 8/2/2017 9:57:51 AM
Discharge Date: 8/2/2017

Diagnoses: B6

Diagnostic test results and findings:
B6

Case summary:
B6

Monitoring at home:
B6

- B6
- B6
- B6

Recommended Medications:

B6

B6

Diet suggestions:

B6

B6

B6

Cummings
Veterinary Medical Center
AT TUFTS UNIVERSITY
Cardiology Liaison: 508-887-4096

B6

Patient ID: B6
B6 Canine:
B6 Years Old Male Border Collie
B6

Cardiology Appointment Report

Date: 8/2/2017

Attending Cardiologist:
☑ John E. Rush DVM, MS, DACVIM (Cardiology), DACVECC (primary)

B6

Cardiology Resident:
B6

Cardiology Technician:
B6

Student: B6

Presenting Complaint:
B6

Concurrent Diseases:
B6

General Medical History:
B6

Diet and Supplements:
B6

Cardiovascular History:
B6

B6

Current Medications Pertinent to CV System:

B6

Cardiac Physical Examination:

B6

Muscle condition:

- [x] Normal
- [ ] Mild muscle loss
- [ ] Moderate cachexia
- [ ] Marked cachexia

Cardiovascular Physical Exam:

Murmur Grade:

- [ ] None
- [ ] I/VI
- [ ] II/VI
- [ ] III/VI
- [ ] IV/VI
- [x] V/VI third left
- [ ] VI/VI

Murmur location/description: Left apex with systolic click

Jugular vein:

- [x] Bottom 1/3 of neck to
- [x] Middle 1/3 of neck
- [ ] Top 2/3rd of neck

Arterial pulses:

- [ ] Weak
- [ ] Fair
- [x] Good
- [ ] Strong
- [ ] Bounding
- [ ] Pulse deficits
- [ ] Pulsus paradoxus
- [ ] Other:

Arrhythmias:

- [x] None
- [ ] Sinus arrhythmia
- [ ] Premature beats
- [ ] Bradycardia
- [ ] Tachycardia

Gallop: Maybe

- [ ] Yes
- [x] No
- [ ] Intermittent
- [ ] Pronounced
- [ ] Other:

Pulmonary assessments:

- [x] Eupneic
- [x] Mild dyspnea (+/- nervous)
- [ ] Marked dyspnea
- [x] Normal BV sounds
- [ ] Pulmonary crackles
- [ ] Wheezes
- [ ] Upper airway stridor

FDA-CVM-FOIA-2019-1704-010352

Abdominal exam:

- ☑ Normal
- ☐ Hepatomegaly
- ☐ Abdominal distension
- ☐ Mild ascites
- ☐ Marked ascites

Problems:

V/VI murmur
Hyperkalemia

Differential Diagnoses:

Degenerative valve disease - mitral

Diagnostic plan:

- ☑ Echocardiogram
- ☐ Chemistry profile
- ☑ ECG
- ☐ Renal profile:
- ☐ Blood pressure
- ☐ Dialysis profile
- ☐ Thoracic radiographs
- ☐ NT-proBNP
- ☐ Troponin I
- ☐ Other tests:

Echocardiogram Findings:

B6

Doppler findings:

B6

Mitral inflow:

- ☐ Summated
- ☐ Normal
- ☐ Delayed relaxation
- ☐ Pseudonormal
- ☐ Restrictive

Blood Pressure:

84 80 140-150mmHg

ECG findings:

HR 90-100; sinus rhythm during echocardiogram

Assessment and recommendations:

Echocardiogram reveals compensated valvular disease of the MV and TV, more so the MV. The LA is moderately dilated. Patient remains asymptomatic at home B6

B6 on hand in case there is shortness of breath and/or coughing noted.

B6

Final Diagnosis:

Degenerative valvular disease with moderate left atrial enlargement

Heart Failure Classification Score:

FDA-CVM-FOIA-2019-1704-010353

ISACHC Classification:

- ☐ Ia
- ☐ Ib
- ☐ II
- ☐ IIIa
- ☐ IIIb

ACVIM Classification:

- ☐ A
- ☐ B1
- ☐ B2
- ☐ C
- ☐ D

B6

M-Mode:	
IVSd	cm
LVIDd	cm
LVPWd	cm
IVSs	cm
LVIDs	cm
LVPWs	cm
%FS	%
Ao Diam	cm
LA Diam	cm
LA/Ao	
Max LA	cm

M-Mode Normalized	
IVSdN	(0.29 - 0.52) !
LVIDdN	(1.35 - 1.73) !
LVPWdN	(0.33 - 0.53)
IVSsN	(0.43 - 0.71)
LVIDsN	(0.79 - 1.14) !
LVPWsN	(0.53 - 0.78)
Ao Diam N	(0.68 - 0.89)
LA Diam N	(0.64 - 0.90) !

2D	
SA LA	cm
Ao Diam	cm
SA LA / Ao Diam	
IVSd	cm
LVIDd	cm
LVPWd	cm
LDV(Teich)	ml
IVSs	cm
LVIDs	cm
LVPWs	cm
ESV(Teich)	ml
EF(Teich)	%
%FS	%
SV(Teich)	ml

FDA-CVM-FOIA-2019-1704-010354

Doppler		
MR Vmax		m/s
MR maxPG		mmHg
MV E Vel		m/s
MV DecT		ms
MV A Vel		m/s
MV E/A Ratio		
E'		m/s
A'		m/s
E/E'		
S'		m/s
PV Vmax		m/s
PV maxPG		mmHg
AV Vmax		m/s
AV maxPG		mmHg
TR Vmax		m/s
TR maxPG		mmHg

B6

FDA-CVM-FOIA-2019-1704-010355

Cummings Veterinary Medical Center AT TUFTS UNIVERSITY

Foster Hospital for Small Animals
55 Willard Street
North Grafton, MA 01536
Telephone: (508) 839-5395
Fax (508) 839-7953
http://vetmed.tufts.edu/

Discharge Instructions

Patient
Name: B6
Species: Canine
B6 Male Border Collie
Birthdate: B6

Owner
Name:
Addre: B6

Patient ID: B6

Attending Cardiologist:
John E. Rush DVM, MS, DACVIM (Cardiology), DACVECC
B6

Cardiology Resident:
B6

Student: B6

Cardiology Technician:
B6

Admit Date: 12/28/2017 10:04:01 AM
Discharge Date: 12/28/2017

Diagnoses: Degenerative mitral valvular disease with moderate left atrial enlargement

Clinical Findings: Kody presented today for a recheck of his degenerative valvular disease and left atrial enlargement. He has been doing well at home, other than an occasional cough when B6 is exercising vigorously. On cardiac exam today, Kody's murmur continues to be a grade V-VI/VI systolic murmur. This means that we can hear B6 murmur with a stethoscope off the chest. His femoral pulses, mucous membrane color and jugular veins all look good. On echocardiogram B6 left atrium remains enlarged, but the size is mostly stable, or even a bit smaller, than his last exam. His mitral regurgitation also appears to be stable since his last visit. It appears that the pimobendan has shrunken the heart a tiny bit, which may help it take a little longer for him to move into congestive heart failure (pulmonary edema, fluid in the lungs).

B6 blood pressure was a bit high today between 160-170 mmHg. We recommend rechecking this measurement, as it is a factor in our discussion on starting B6 on another medication (an ACE inhibitor). You can bring B6 back in for a technician appointment to recheck the blood pressure and further discuss adding on the medication. We would also need to check blood work before starting this medication, if we decide to, to get baseline kidney values and potassium level now and then 10-21 days after starting the medication.

B6

FDA-CVM-FOIA-2019-1704-010356

Recheck Visits: Please e-mail our technician B6 to schedule an appointment to recheck Kody's blood pressure.

A recheck cardiac visit and echocardiogram and blood pressure is recommended for 4 to 6 months from now - sooner if you notice difficulty breathing, worsening cough, exercise intolerance, or a fainting episode.

Thank you for entrusting us with B6 care. Please contact our Cardiology liaison B6 at (608)-887-4696 or email us at cardiosetup@tufts.edu for scheduling and non-emergent questions or concerns.

Please visit our HeartSmart website for more information
http://vet.tufts.edu/heartsmart/

Prescription Refill Disclaimer:
For the safety and well-being of our patients, your pet must have had an examination by one of our veterinarians within the past year in order to obtain prescription medications.

Ordering Food:
Please check with your primary veterinarian to purchase the recommended diet(s). If you wish to purchase your food from us, please call 7-10 days in advance (508-887-4670) to ensure the food is in stock. Alternatively, veterinary diets can be ordered from online retailers with a prescription/veterinary approval.

Clinical Trials:
Clinical trials are studies in which our veterinary doctors work with you and your pet to investigate a specific disease process or a promising new test or treatment. Please see our website: vet.tufts.edu/cvm/clinical-studies

---

B6 Discharge Instructions:

FDA-CVM-FOIA-2019-1704-010357

Cummings
Veterinary Medical Center
AT TUFTS UNIVERSITY
Cardiology Liaison: 508-887-4096

B6

Patient ID: B6
B6 Canine
B6 years Old Male Border Collie
B6

Cardiology Appointment Report

Date: 12/28/2017

Attending Cardiologist:
☑ John E. Rush DVM, MS, DACVIM (Cardiology), DACVECC (primary)

B6

Cardiology Resident:
B6

Cardiology Technician:
B6

Student: B6

Presenting Complaint: recheck degenerative valvular disease with B6

Concurrent Diseases: None

General Medical History: Otherwise healthy. Seemed to feel better after starting B6

Diet and Supplements: origin dry kibble with cooked hamburger

Cardiovascular History:
Prior CHF diagnosis? No
Prior ATE? No
Prior arrhythmia? No
Cough? Has occasional cough when vigorously exercising
Shortness of breath or difficulty breathing? No
Syncope or collapse? No
Sudden onset lameness? No
Exercise intolerance? No, has slowed down a bit but still very active
Prior heart murmur? Yes

Current Medications Pertinent to CV System:
Medication: B6

B6

Administration Frequency: 1 tab PO BID
Need refills? No

Medication: B6

B6

Administration Frequency: PO as needed for increased RR/effort
Need refills? No; has not given yet.

Cardiac Physical Examination:

B6

Muscle condition:
- [x] Normal
- [ ] Mild muscle loss
- [ ] Moderate cachexia
- [ ] Marked cachexia

Cardiovascular Physical Exam:

Murmur Grade:
- [ ] None
- [ ] I/VI
- [ ] II/VI
- [ ] III/VI
- [ ] IV/VI
- [x] V/VI
- [ ] VI/VI

Murmur location/description: systolic murmur, PMI left apex, thrill on left

Jugular vein:
- [x] Bottom 1/3 of neck
- [ ] Middle 1/3 of neck
- [ ] Top 2/3rd of neck

Arterial pulses:
- [ ] Weak
- [ ] Fair
- [x] Good
- [ ] Strong
- [ ] Bounding
- [ ] Pulse deficits
- [ ] Pulsus paradoxus
- [ ] Other:

Arrhythmia:
- [x] None
- [ ] Sinus arrhythmia
- [ ] Premature beats
- [ ] Bradycardia
- [ ] Tachycardia

Gallop:
- [ ] Yes
- [x] No
- [ ] Intermittent
- [ ] Pronounced
- [ ] Other:

Pulmonary assessments:
- [x] Eupneic
- [ ] Mild dyspnea
- [ ] Marked dyspnea
- [ ] Normal BV sounds
- [ ] Pulmonary crackles
- [ ] Wheezes
- [ ] Upper airway stridor

FDA-CVM-FOIA-2019-1704-010359

Abdominal exam:

- [x] Normal
- [ ] Hepatomegaly
- [ ] Abdominal distension
- [ ] Mild ascites
- [ ] Marked ascites

Problems:
History of V/VI murmur and CHF

Diagnostic plan:

- [x] Echocardiogram
- [x] Chemistry profile +/-
- [ ] ECG
- [ ] Renal profile
- [x] Blood pressure +/-
- [ ] Dialysis profile
- [ ] Thoracic radiographs
- [ ] NT-proBNP
- [ ] Troponin I
- [ ] Other tests:

Echocardiogram Findings:

B6

Mitral inflow:

- [ ] Summated
- [ ] Normal
- [ ] Delayed relaxation
- [ ] Pseudonormal
- [ ] Restrictive

B6

Assessment and recommendations:
Echocardiogram reveals stable, compensated valvular disease of the MV and TV, more so of the MV. The LA is moderately dilated and is similar size to smaller than the last exam. The LV is smaller than the last exam on most measures. Patient remains asymptomatic at home. B6

B6

Recommend a recheck in 4 to 6 months.

Final Diagnosis:
Degenerative valvular disease with moderate left atrial enlargement

Heart Failure Classification Score:
ISACHC Classification:

- [ ] Ia
- [ ] Ib
- [ ] IIIa
- [ ] IIIb

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☐ II

ACVIM Classifications:

☐ A
☐ B1
☐ B2
☐ C
☐ D

2D

SA LA	cm
Ao Diam	cm
SA LA / Ao Diam	
IVSd	cm
LVIDd	cm
LVPWd	cm
EDV(Teich)	ml
IVSs	cm
LVIDs	cm
LVPWs	cm
ESV(Teich)	ml
EF(Teich)	%
%FS	%
SV(Teich)	ml

M-Mode

IVSd	cm
LVIDd	cm
LVPWd	cm
IVSs	cm
LVIDs	cm
LVPWs	cm
%FS	%
Ao Diam	cm
LA Diam	cm
LA/Ao	
Ao Diam N	
LA Diam N	
Max LA	cm

Doppler

MR Vmax	m/s
MR maxPG	mmHg
MV E Vel	m/s
MV DecT	ms
MV A Vel	m/s
MV E/A Ratio	
E'	m/s
A'	m/s
E/E'	
S'	m/s
PV Vmax	m/s

B6

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PV maxPG
AV Vmax
AV maxPG

B6

mmHg
m/s
mmHg

FDA-CVM-FOIA-2019-1704-010362

Cummings
Veterinary Medical Center
AT TUFTS UNIVERSITY

B6

B6

B6 Male

Canine: Border Collie Black/White

Patient ID: B6

Outside Prescription Log

B6

[redacted]

Cummings
Veterinary Medical Center
AT TUFTS UNIVERSITY
Cardiology Liaison: 508-887-4696

Foster Hospital for Small Animals
55 Willard Street
North Grafton, MA 01536
Telephone: (508) 839-5395
Fax (508) 839-7951
http://vetmed.tufts.edu/

Discharge Instructions

Patient
Name: B6
Species: B6
Black/White Male Border Collie
Birthdate: B6

Owner
Name:
Addre: B6

Patient ID: B6

Attending Cardiologist:
John L. Rush DVM, MS, DACVIM (Cardiology), DACVECC
B6

Cardiology Resident:
B6

Student: B6

Cardiology Technician:
B6

Admit Date: 7/2/2018 11:33:02 AM
Discharge Date: 7/2/2018

Diagnoses: Chronic valvular disease (asymptomatic) with progressive cardiac enlargement

Clinical findings: B6 was previously diagnosed with a leak in his mitral valve (the valve between the atrium and ventricle on the left side of his heart, and the leak has resulted in a heart murmur and some enlargement of the heart. Today his valve continues to look thickened with a significant amount of regurgitation (backflow) at the valve. His left heart chambers are both measurably larger than at the previous visit, which suggests that his he is slowly progressing towards congestive heart failure. Unfortunately, there is no medication that can fix the thickening or look at the valve, so the goal will be to continue to monitor the heart enlargement, which will give us an idea if we are getting close to congestive heart failure (fluid accumulating in the lungs). We will be adding a second medication to his daily routine to help slow down the development of heart failure.

Echocardiogram findings: B6 heart chambers are moderately enlarged, especially in the left side of his heart
ECG findings: Normal sinus rhythm with very infrequent premature beats (APCs)
Labwork findings: pending

B6

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B6

Recheck Visit: B6 week to have bloodwork 10-14 days after he gets on twice a day benazepril (kidney values and electrolytes). This can be done at his primary care veterinarian. We would like to recheck the echocardiogram and possibly chest x-rays in 4-6 months.

Thank you for entrusting us with B6 care. Please contact our Cardiology liaison, B6 (508) 887-4696 or email us at cardiowest@tufts.edu for scheduling and non-emergent questions or concerns.

Please visit our HeartSmart website for more information
http://vet.tufts.edu/heartsmart/

Prescription Refill Disclaimer:
For the safety and well-being of our patients, your pet must have had an examination by one of our veterinarians within the past year in order to obtain prescription medications.

Ordering Food:
Please check with your primary veterinarian to purchase the recommended diet(s). If you wish to purchase your food from us, please call 7-10 days in advance (508-887-4670) to ensure the food is in stock. Alternatively, veterinary diets can be ordered from online retailers with a prescription/veterinary approval.

Clinical Trials:
Clinical trials are studies in which our veterinary doctors work with you and your pet to investigate a specific disease process or a promising new test or treatment. Please see our website: vet.tufts.edu/cvm/clinical-studies

---

B6

Discharge Instructions

Cummings
Veterinary Medical Center
AT TUFTS UNIVERSITY
Cardiology Liaison: 508-887-4096

B6

Patient ID: B6
B6 Canine:
B6 Years Old Male Border Collie
Black/White

Cardiology Appointment Report

Date: 7/2/2018

Attending Cardiologist:
☑ John E. Rush DVM, MS, DACVIM (Cardiology), DAVECC (Primary)

B6

Cardiology Resident:
B6

Cardiology Technician:
B6

Student: B6

Presenting Complaint: recheck echo, hx of MVD

Concurrent Diseases: none

General Medical History:
5/2017: murmur at rDVM
7/2017: BNP at rDVM 1458, CXR showed enlarged heart, bloodwork WNL
8/2017: seen here – NSR, MVD, LAE, MR, mild TR
12/2017: Recheck echo, MVD, 2/3+ MR, V/VI murmur, LAE, 160-170 mm Hg, B6 needed

Diet and Supplements:
Origins Adult dry kibble, 1.5 cups SID (sometimes doesnt finish) occationally hamburger meat on top

Cardiovascular History:
Prior CHF diagnosis? no
Prior ATE? no
Prior arrhythmia? no
Cough? very occasionally
Shortness of breath or difficulty breathing? not reported
Syncope or collapse? no

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Sudden onset lameness? no
Exercise intolerance? some decreased exercise tolerance
Prior heart murmur? yes

Current Medications Pertinent to CV System:

B6

Cardiac Physical Examination:

B6

Muscle condition:
- [x] Normal
- [ ] Mild muscle loss
- [ ] Moderate cachexia
- [ ] Marked cachexia

Cardiovascular Physical Exam:

Murmur Grade:
- [ ] None
- [ ] I/VI
- [ ] II/VI
- [ ] III/VI
- [ ] IV/VI
- [x] V/VI
- [ ] VI/VI

Murmur location/description: left apical systolic murmur

Jugular veins:
- [x] Bottom 1/3 of neck
- [ ] Middle 1/3 of neck
- [ ] Top 2/3rd of neck

Arterial pulses:
- [ ] Weak
- [ ] Fair
- [x] Good
- [ ] Strong
- [ ] Bounding
- [ ] Pulse deficits
- [ ] Pulses paradoxus
- [ ] Other:

Arrhythmia:
- [x] None
- [ ] Sinus arrhythmia
- [ ] Premature beats
- [ ] Bradycardia
- [ ] Tachycardia

Gallop:
- [ ] Yes
- [x] No
- [ ] Intermittent
- [ ] Pronounced
- [ ] Other:

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Pulmonary assessments:

- [x] Eupneic
- [ ] Mild dyspnea
- [ ] Marked dyspnea
- [ ] Normal BV sounds
- [ ] Pulmonary crackles
- [ ] Wheezes
- [ ] Upper airway stridor

Abdominal exam:

- [x] Normal
- [ ] Hepatomegaly
- [ ] Abdominal distension
- [ ] Mild ascites
- [ ] Marked ascites

Problems:
MVD with LAE

Diagnostic plan:

- [x] Echocardiogram
- [x] Chemistry profile
- [ ] ECG
- [ ] Renal profile
- [x] Blood pressure +/-
- [ ] Dialysis profile
- [ ] Thoracic radiographs
- [ ] NT-proBNP
- [ ] Troponin I
- [ ] Other tests:

Echocardiogram Findings:

B6

Mitral inflow:

- [ ] Summated
- [ ] Normal
- [ ] Delayed relaxation
- [ ] Pseudonormal
- [x] Restrictive

ECG findings:

B6

Assessment and recommendations:
Echocardiogram reveals progression of the previously diagnosed DMVD. The LA is bigger today and there is some concern that the patient is closer to CHF today than at the last examination. B6

B6

at home. Since there has been progression of the cardiac disease, B6

started B6

10-14 days late B6 the RR should be monitored closely and if higher than B6 should be started. Monitor for cough and exercise intolerance. Recheck echocardiogram in 4 to 6 months.

Final Diagnosis:

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DMVD with moderate to at most markedly enlarged LA that has progress since the last visit.

Heart Failure Classification Score:

ISACHC Classification:

- ☐ Ia
- ☑ Ib
- ☐ II
- ☐ IIIa
- ☐ IIIb

ACVIM Classification:

- ☐ A
- ☑ B1
- ☑ B2
- ☐ C
- ☑ D

M-Mode

IVSd	cm
LVIDd	cm
LVPWd	cm
IVSs	cm
LVIDs	cm
LVPWs	cm
%FS	%
Ao Diam	cm
LA Diam	cm
LA/Ao	
Max LA	cm

M-Mode Normalized

IVSdN	(0.29 - 0.52) !
LVIDdN	(1.35 - 1.73) !
LVPWdN	(0.33 - 0.53)
IVSsN	(0.43 - 0.71)
LVIDsN	(0.79 - 1.14) !
LVPWsN	(0.53 - 0.78) !
Ao Diam N	(0.68 - 0.89)
LA Diam N	(0.64 - 0.90) !

2D

SA LA	cm
Ao Diam	cm
SA LA / Ao Diam	
IVSd	cm
LVIDd	cm
LVPWd	cm
EDV(Teich)	ml
IVSs	cm
LVIDs	cm
LVPWs	cm
ESV(Teich)	ml
EF(Teich)	%

B6

FDA-CVM-FOIA-2019-1704-010370

%FS	%
SV(Teich)	ml
LA Area	cm
Doppler	
MR Vmax	m/s
MR maxPG	mmHg
MV E Vel	m/s
MV DecT	ms
MV A Vel	m/s
MV E/A Ratio	
E'	m/s
A'	m/s
E/E'	
S'	m/s
PV Vmax	m/s
PV maxPG	mmHg
PR Vmax	m/s
PR maxPG	mmHg
AV Vmax	m/s
AV maxPG	mmHg
TR Vmax	m/s
TR maxPG	mmHg

B6

FDA-CVM-FOIA-2019-1704-010371

Cummings Veterinary Medical Center
AT TUFTS UNIVERSITY

Foster Hospital for Small Animals
56 Willard Street
North Grafton, MA 01536
Telephone: (508) 839-5395
Fax (508) 839-7951
http://vetmed.tufts.edu/

Discharge Instructions

Patient
Name: B6
Species: Canine
Black/White Male Border Collie
Birthdate: B6

Owner
Name:
Addres B6

Patient ID: B6

Attending Cardiologist:
☑ John E. Rush DVM, MS, DACVIM (Cardiology), DACVECC
B6

Cardiology Resident:
B6

Cardiology Technician:
B6

Student: B6

Admit Date: 12/19/2018 10:53:58 AM
Discharge Date: 12/19/2018

Diagnosis: Chronic valvular disease with mitral regurgitation with suspected congestive heart failure; reducing myocardial function

Clinical findings:
B6 was previously diagnosed with a leak at mitral valve, and this leak has resulted in a loud heart murmur and enlargement of his heart. Today his valve continues to look thickened with a significant amount of regurgitation (backflow) at the mitral valve. His left atrium is mildly larger than at the previous visit and the strength of contraction of his heart muscle have decreased. Based on the improvement of his coughing with furosemide, we suspect that his heart enlargement had progressed to the point where fluid was backing up into the lungs causing pulmonary edema, a condition called congestive heart failure. We cannot do anything to change the thickening or leak at the valve, but the cardiac medications he is receiving and some changes to the diet to make Kody comfortable and have him breathing easier. Unfortunately, this is a progressive disease and the treatment options cannot reverse the damage to the valve.

Diagnostic test results:

- **Echocardiogram findings:** All chambers of the heart are enlarged and there is a large leak at the mitral valve. The strength of contraction of his heart has decreased compared to prior exams. He has one small ruptured chordae tendineae (a cord attaching a heart valve to his heart wall).
- **ECG findings:** Normal sinus rhythm with a single premature beat (APC)
- **Labwork findings:** Pending. We will call you with the results in a few days.

B6

B6

B6

Recheck Visits: Please schedule a recheck visit for B6 in 3 months. At this visit we will want to check B6 breathing effort and heart function, do a blood test to recheck kidney values, a recheck echocardiogram, and/or chest radiographs. (x-rays).

Thank you for entrusting us with B6 care. Please contact our Cardiology liaison at (508)-887-4696 or email us at cardiowt@tufts.edu for scheduling and non-emergent questions or concerns.

Please visit our HeartSmart website for more information
http://vet.tufts.edu/heartsmart/

Prescription Refill Disclosure:
For the safety and well-being of our patients, your pet must have had an examination by one of our veterinarians within the past year in order to obtain prescription medications.

Ordering Food:
Please check with your primary veterinarian to purchase the recommended diet(s). If you wish to purchase your food from us, please call 7-10 days in advance (508-887-4634) to ensure the food is in stock. Alternatively, veterinary diets can be ordered from online retailers with a prescription/veterinary approval.

Clinical Trials:
Clinical trials are studies in which our veterinary doctors work with you and your pet to investigate a specific disease process or a promising new test or treatment. Please see our website: vet.tufts.edu/vcm/clinical-studies

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B6 Discharge Instructions

Cummings
Veterinary Medical Center
AT TUFTS UNIVERSITY
Cardiology Liaison: 508-887-4096

B6

Patient ID: B6
B6 Canine:
B6 Years Old Male Border Collie
Black/White

Cardiology Appointment Report

Date: 12/19/2018

Attending Cardiologist:
☑ John E. Rush DVM, MS, DACVIM (Cardiology), DAVECC (primary)

B6

Cardiology Resident:
B6

Cardiology Technician:
B6

Student: B6

Presenting Complaint:
Recheck of asymptomatic CVD and progressive left atrial enlargement

Concurrent Diseases:
B6

General Medical History:
B6

Diet and Supplements:
Orijen Senior dry kibble + fit and trim dry: < 2 cups/day, occasionally ground hamburger on top, no treats

Cardiovascular History:
Prior CHF diagnosis? N
Prior heart murmur? Y
Prior ATE? N
Prior arrhythmia? N
Monitoring respiratory rate and effort at home? N – more relaxed breathing at rest with keds
Cough? Y – occasional
Shortness of breath or difficulty breathing? N

Syncope or collapse? N
Sudden onset lameness? N
Exercise intolerance? N

Current Medications Pertinent to CV System:

B6

Cardiac Physical Examination:

B6

Muscle condition:
- [x] Normal
- [ ] Mild muscle loss
- [ ] Moderate cachexia
- [ ] Marked cachexia

Cardiovascular Physical Exam:

Murmur Grade:
- [ ] None
- [ ] I/VI
- [ ] II/VI
- [ ] III/VI
- [ ] IV/VI
- [x] V/VI
- [ ] VI/VI

Murmur location/description: left apical systolic, radiating

Jugular vein:
- [x] Bottom 1/3 of the neck
- [ ] Middle 1/3 of the neck
- [ ] 1/2 way up the neck
- [ ] Top 2/3 of the neck

Arterial pulses:
- [ ] Weak
- [ ] Fair
- [x] Good
- [ ] Strong
- [ ] Bounding
- [ ] Pulse deficits
- [ ] Pulses paradoxus
- [ ] Other:

Arrhythmia:
- [x] None
- [ ] Bradycardia

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- ☐ Sinus arrhythmia
- ☐ Premature beats
- ☐ Tachycardia

Gallop:
- ☐ Yes
- ☒ No
- ☐ Intermittent
- ☐ Pronounced
- ☐ Other:

Pulmonary assessments:
- ☒ Eupneic
- ☐ Mild dyspnea
- ☐ Marked dyspnea
- ☒ Normal BV sounds
- ☐ Pulmonary crackles
- ☐ Wheezes
- ☐ Upper airway stridor

Abdominal exam:
- ☒ Normal
- ☐ Hepatomegaly
- ☐ Abdominal distension
- ☐ Mild ascites
- ☐ Marked ascites

Problems:
MVD and LAE and likely CHF

Diagnostic plan:
- ☒ Echocardiogram
- ☒ Chemistry profile
- ☐ ECG
- ☐ Renal profile
- ☐ Blood pressure
- ☐ Dialysis profile
- ☒ Thoracic radiographs +/-
- ☒ NT-proBNP +/-
- ☐ Troponin I
- ☒ Other tests: +/- diet change

Echocardiogram Findings:

B6

Mitral inflow:
- ☐ Summated
- ☐ Normal
- ☐ Delayed relaxation
- ☐ Pseudonormal
- ☒ Restrictive

ECG findings:
HR 140; sinus rhythm during echocardiogram

Assessment and recommendations:
Echocardiogram reveals mild progression of the previously diagnosed DMVD, with LV contractile function that has dropped off a bit since the last exam. The LA is slightly bigger today (maybe) and the dog seems to feel better while getting once a day furosemide. Recommend continuing with the current dose of

B6

B6

grain free study. Recheck echocardiogram and exam in 3 months.

Final Diagnosis:
DMVD with moderate to markedly enlarged LA and now the dog has a degree of reduced LV contractile function.

Addendum: B6

B6

Heart Failure Classification Score:
ISACHC Classification:

- ☐ Ia
- ☐ Ib
- ☑ II (suspected based on furosemide need and clinical improvement)
- ☐ IIIa
- ☐ IIIb

ACVIM Classification:

- ☐ A
- ☐ B1
- ☐ B2
- ☑ C Suspected; see above
- ☐ D

B6

M-Mode		
IVSd		cm
LVIDd		cm
LVPWd		cm
IVSs		cm
LVIDs		cm
LVPWs		cm
EDV(Teich)		ml
ESV(Teich)		ml
EF(Teich)		%
%FS		%
SV(Teich)		ml
Ao Diam		cm
LA Diam		cm
LA/Ao		
Max LA		cm

M-Mode Normalized	
IVSdN	(0.290 - 0.570)
LVIDdN	(1.350 - 1.730) !
LVPWdN	(0.330 - 0.530)
IVSsN	(0.430 - 0.710) !
LVIDsN	(0.790 - 1.140) !
LVPWsN	(0.530 - 0.780)
Ao Diam N	(0.680 - 0.890)
LA Diam N	(0.640 - 0.900) !

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2D	
SA IA	cm
Ao Diam	cm
SA IA / Ao Diam	
IVSd	cm
LVIDd	cm
LVPWd	cm
EDV(Teich)	ml
IVSs	cm
LVIDs	cm
LVPWs	cm
ESV(Teich)	ml
EF(Teich)	%
%FS	%
SV(Teich)	ml
LV Major	cm
LV Minor	cm
Sphericity Index	
LA Area	cm
LVLd LAX	cm
LVAd LAX	cm
LVEDV A-L LAX	ml
LVEDV MOD LAX	ml
LVLs LAX	cm
LVAs LAX	cm
LVESV A-L LAX	ml
LVESV MOD LAX	ml
HR	BPM
EF A-L LAX	%
LVEF MOD LAX	%
SV A-L LAX	ml
SV MOD LAX	ml
CO A-L LAX	l/min
CO MOD LAX	l/min
R-R	ms
HR	BPM
CO A-L LAX	l/min
CO MOD LAX	l/min
Doppler	
MR Vmax	m/s
MR maxPG	mmHg
MV E Vel	m/s
MV DecT	ms
MV Dec Slope	m/s
MV A Vel	m/s
MV E/A Ratio	
E'	m/s
E/E'	

B6

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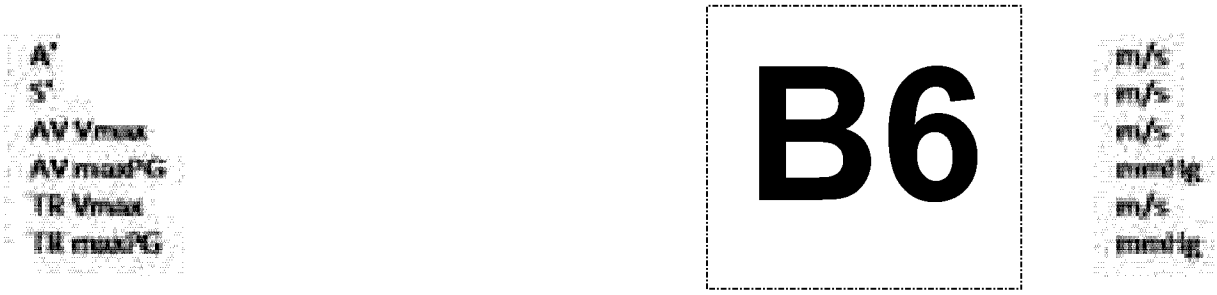
A'
S'
AV Vmax
AV maxPG
TR Vmax
TR maxPG
B6
m/s
m/s
m/s
mmHg
m/s
mmHg

Cummings
Veterinary Medical Center
AT TUFTS UNIVERSITY

B6

Foster Hospital for Small Animals
25 Willard Street
North Grafton, MA 01536
Telephone: (508) 839-5395
Fax: (508) 839-7951
http://vetmed.tufts.edu/

B6
B6 Male
Canine Border Collie Black/White
B6

8/4/2017

Dear B6

Thank you for referring B6 with their pet B6

If you have any questions, or concerns, please contact us at 508-887-4988.

Thank you,

John Rush DVM, DACVIM (Cardiology), DACVECC

Cummings
Veterinary Medical Center
AT TUFTS UNIVERSITY

Foster Hospital for Small Animals
25 Willard Street
North Grafton, MA 01536
Telephone (508) 839-5395
Fax (508) 839-7951
http://vetmed.tufts.edu/

B6

B6

B6

B6 Male
Canine Border Collie Black/White

B6

12/29/2017

Dear Dr. B6

Thank you for referring B6 with their pet B6

If you have any questions, or concerns, please contact us at 508-887-4988.

Thank you,

John Rush DVM, DACVIM (Cardiology), DACVECC

Cummings
Veterinary Medical Center
AT TUFTS UNIVERSITY

B6

Foster Hospital for Small Animals
25 Willard Street
North Grafton, MA 01536
Telephone: (508) 839-5395
Fax: (508) 839-7951
http://vetmed.tufts.edu/

B6
B6 Male
Canine Border Collie Black/White
B6

7/5/2018

Dear B6

Thank you for referring B6 with their pet B6

If you have any questions, or concerns, please contact us at 508-887-4988.

Thank you,

John Rush DVM, DACVIM (Cardiology), DACVECC

Cummings
Veterinary Medical Center
AT TUFTS UNIVERSITY

Foster Hospital for Small Animals
35 Willard Street
North Grafton, MA 01536
Telephone (508) 839-5395
Fax (508) 839-7951
http://vetmed.tufts.edu/

B6

B6

B6

B6 Male
Canine Border Collie Black/White

B6

12/21/2018

Dear B6

Thank you for referring B6 with their pet B6

If you have any questions, or concerns, please contact us at 508-887-4988.

Thank you,

John Rush DVM, DACVIM (Cardiology), DACVECC

Report Details - EON-323515

ICSR:	2023228		
Type Of Submission:	Initial		
Report Version:	FPSR.FDA.PETF.V.V1		
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)		
Reporting Type:	Voluntary		
Report Submission Date:	2017-07-11 17:06:59 EDT		
Reported Problem:	**Problem Description:**	Please note: Dr. Jennifer Jones was consulted prior to submission of this report. She would like to be involved in the case review 3 week history of cough treated unsuccessfully with B6 3 day history of inappetence and vomiting prior to presentation to NCSU emergency service for dyspnea. Radiographs showed severe pulmonary edema and echocardiogram showed severe Dilated Cardiomyopathy. There was an initial response to diuretic therapy however, he declined and was placed on the ventilator for respiratory support and continued CHF treatment. Attempts to wean off the ventilator were unsuccessful and aquaphoresis was performed. He continued to decline despite aggressive therapy and was euthanized. Infectious disease testing was negative and taurine and carnitine analysis showed adequate levels. Necropsy initially did not reveal a cause for DCM and supported alveolar injury (possibly ventilator related). A re-review of the myocardial histopathology by one of our pathologist showed B6 B6 B6 B6 had been fed California Naturals Adult - both kangaroo with lentils and venison with lentils along with Milo's kitchen treats. We have samples of these foods from 6/17 but not the original bags from when he was presented B6 These samples were provided at the time his housemate, B6 (unrelated, older miniature schnauzer) also presented with severe DCM and CHF. I will enter this dog as a separate affected patient. Both dogs had extensive infectious disease testing which was negative and nutritional amino acid deficiencies were ruled out. Because of this, their unrelated lineages (although the same breed, they were from different lines), different ages but similar time of presentation B6 had clinical signs at the time B6 was treated, but didn't present with CHF for several months), we are considering common environmental factors which could precipitate DCM, including food contamination or toxin exposure.
	Date Problem Started:	B6	
	Concurrent Medical Problem:	No	
	Outcome to Date:	Died Euthanized	
	Date of Death:	B6	
Product Information:	**Product Name:**	Alternated between: -California Natural Adult Limited Ingredient Grain Free Venison & Green Lentils and Kangaroo & Red Lentils Recipe	
	Product Type:	Pet Food	
	Lot Number:		
	UPC:	not available	
	Package Type:	BAG	
	Package Size:	26 Pound	
	Purchase Date:	06/01/2017	
	Possess Unopened Product:	No	
	Possess Opened Product:	Yes	
	Storage Conditions:	In a cabinet, in the original bag	
	Product Use Information:	**Description:**	twice daily feeding The sample we have is from 6/17, however, we do not have food samples from 2/17 when both dogs started with clinical signs.
		Time Interval between Product	2 Years

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		Use and Adverse Event:	
		Product Use Stopped After the Onset of the Adverse Event:	No
		Perceived Relatedness to Adverse Event:	Possibly related
		Other Foods or Products Given to the Animal During This Time Period:	Yes
	Manufacturer /Distributor Information:		
	Purchase Location Information:	Address:	United States
Animal Information:	Name:	B6	
	Type Of Species:	Dog	
	Type Of Breed:	Schnauzer - Miniature	
	Gender:	Male	
	Reproductive Status:	Neutered	
	Weight:	8.2 Kilogram	
	Age:	B6 Years	
	Assessment of Prior Health:	Excellent	
	Number of Animals Given the Product:	2	
	Number of Animals Reacted:	2	
	Owner Information:	Owner Information provided:	Yes
		Contact:	Name: B6 Phone: Email:
		Address:	B6 United States
	Healthcare Professional Information:	Practice Name:	North Carolina State University, College of Veterinary Medicine
		Contact:	Name: Darcy Adin Phone: (919) 513-6694 Other Phone: B6 Email: dbadin@ncsu.edu
		Address:	1060 William Moore Dr Raleigh New York 27607 United States
		Practice Name:	North Carolina State University College of Veterinary Medici
		Contact:	Name: B6 Phone:

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		Other Phone:	B6
		Practice Name:	North Carolina state University, College of Veterinary Medic
		Contact: Name:	B6
		Phone:	B6
		Other Phone:	
Sender Information:	**Name:**	Darcy Adin	
	Address:	1060 William Moore Dr Raleigh New York 27607 United States	
	Contact:	**Phone:**	9195136694
		Other Phone:	B6
		Email:	dbadin@ncsu.edu
	Permission To Contact Sender:	Yes	
	Preferred Method Of Contact:	Email	
	Reported to Other Parties:	Manufacturer	
Additional Documents:			

From: PFR Event <pfreventcreation@fda.hhs.gov>

To: Cleary, Michael *; HQ Pet Food Report Notification; B6

Sent: 2/24/2019 10:08:57 PM

Subject: Acana: Lisa Freeman - EON-380708

Attachments: 2063115-report.pdf; 2063115-attachments.zip

A PFR Report has been received and PFR Event [EON-380708] has been created in the EON System.

A "PDF" report by name "2063115-report.pdf" is attached to this email notification for your reference. Please note that all documents received in the report are compressed into a zip file by name "2063115-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-380708
ICSR #: 2063115
EON Title: PFR Event created for Acana Natural Balance Petcurean (see diet history for additional details); 2063115

AE Date	02/16/2019	**Number Fed/Exposed**	1
Best By Date		**Number Reacted**	1
Animal Species	Dog	**Outcome to Date**	Stable
Breed	Terrier - Bull - American Pit		
Age	B6 Years		
District Involved	PFR-New England DO		

Product information
Individual Case Safety Report Number: 2063115
Product Group: Pet Food
Product Name: Acana, Natural Balance, Petcurean (see diet history for additional details)
Description: DCM and CHF diagnosed 2/16/19. Eating multiple BEG diets Taurine and troponin pending Dog changed to Purina HA vegetarian dry while in hospital and owner has continued this. Will try switching to Pro Plan Sensitive Skin and Stomach Salmon when bag of HA runs out. If she tolerates that, will stay on it. If not, will switch back to HA since she's done well on that.
Submission Type: Initial

Report Type: Adverse Event (a symptom, reaction or disease associated with the product)
Outcome of reaction/event at the time of last observation: Stable
Number of Animals Treated With Product: 1
Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Acana, Natural Balance, Petcurean (see diet history for additional details)		

Sender information
Lisa Freeman
200 Westboro Rd
North Grafton, MA 01536
USA

Owner information
B6
USA

To view this PFR Event, please click the link below:
https://eon.fda.gov/eon//browse/EON-380708

To view the PFR Event Report, please click the link below:
https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jspa?decorator=none&e=0&issueType=12&issueId=397717

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Report Details - EON-380708

ICSR:	2063115			
Type Of Submission:	Initial			
Report Version:	FPSR.FDA.PETF.V.V1			
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)			
Reporting Type:	Voluntary			
Report Submission Date:	2019-02-24 17:00:13 EST			
Reported Problem:	**Problem Description:**	DCM and CHF diagnosed 2/16/19. Eating multiple BEG diets Taurine and troponin pending Dog changed to Purina HA vegetarian dry while in hospital and owner has continued this. Will try switching to Pro Plan Sensitive Skin and Stomach Salmon when bag of HA runs out. If she tolerates that, will stay on it. If not, will switch back to HA since she's done well on that.		
	Date Problem Started:	02/16/2019		
	Concurrent Medical Problem:	Yes		
	Pre Existing Conditions:	Diarrhea would develop 2-3 weeks after starting a new food. Owner rotated foods to try to avoid this.		
	Outcome to Date:	Stable		
Product Information:	**Product Name:**	Acana, Natural Balance, Petcurean (see diet history for additional details)		
	Product Type:	Pet Food		
	Lot Number:			
	Package Type:	BAG		
	Product Use Information:	**Description:**	Please see diet history for more info ("Natural Products" written on diet history form is "Natural Balance"	
	Manufacturer /Distributor Information:			
	Purchase Location Information:			
Animal Information:	**Name:**	B6		
	Type Of Species:	Dog		
	Type Of Breed:	Terrier - Bull - American Pit		
	Gender:	Female		
	Reproductive Status:	Neutered		
	Weight:	18 Kilogram		
	Age:	B6 Years		
	Assessment of Prior Health:	Excellent		
	Number of Animals Given the Product:	1		
	Number of Animals Reacted:	1		
	Owner Information:	**Owner Information provided:**	Yes	
		Contact:	**Name:** B6	
			Phone:	
			Email:	
		Address:	B6 United States	
	Healthcare Professional Information:	**Practice Name:**	Tufts Cummings School of Veterinary Medicine	

FDA-CVM-FOIA-2019-1704-010391

		Contact:	**Name:**	Lisa Freeman
			Phone:	(508) 887-4523
			Email:	lisa.freeman@tufts.edu
		Address:	200 Westboro Rd North Grafton Massachusetts 01536 United States	

Sender Information:	**Name:**	Lisa Freeman	
	Address:	200 Westboro Rd North Grafton Massachusetts 01536 United States	
	Contact:	**Phone:**	5088874523
		Email:	lisa.freeman@tufts.edu
	Permission To Contact Sender:	Yes	
	Preferred Method Of Contact:	Email	

Additional Documents:		
	Attachment:	rpt_medical_record_preview.pdf
	Description:	Medical records
	Type:	Medical Records

FDA-CVM-FOIA-2019-1704-010392

Cummings Veterinary Medical Center
AT TUFTS UNIVERSITY

Foster Hospital for Small Animals
55 Willard Street
North Grafton, MA 01536
(508) 839-5395

All Medical Records

Client: **B6**
Address:

Patient: **B6**
Breed: Pit Bull
DOB: **B6**

Species: Canine
Sex: Female (Spayed)

Home Phone: **B6**
Work Phone: (___) _-____
Cell Phone: (___) _-____

Referring Information

B6

Client: **B6**
Patient:

Initial Complaint:
Emergency

SOAP Text **B6** 9:00AM - **B6**

Subjective
NEW VISIT (ER)

Doctor: **B6**
Student: **B6** V'20
Presenting complaint: CHF
Referral visit? **B6** animal health in **B6**
Diagnostics completed prior to visit: rads
Chest x-rays (at rDVM) - in ER email

HISTORY:

Signalment: 5yo FS Pitbull
Current history:
Coughing 2-3 weeks ago - after physical exercise gotten worse after any exercise, hacking some fluid a little productive, labored breathing, low energy. still eating/drinking, normal bathroom, no v/d. lost weight, looking skinny.
Prior medical history: allergies
Current medications: none
Diet: dry. 2 cups a day (o unsure exactly which diet - rotates through 4 different types of food)
Vaccination status/flea & tick preventative use: UTD, no heartworm preventative or flea/tick

FDA-CVM-FOIA-2019-1704-010393

Client: B6
Patient:

Travel history: none

EXAM:

B6

C/V: grade 2/6 apical systolic murmur, no arrhythmia, ssfp
RESP: harsh lung sounds bilaterally/wheezes; moderate/severe respiratory effort

B6

ASSESSMENT:

A1: Congestive heart failue r/o secondary to DCM vs other

PLAN:

B6

- Chest x-rays (at rDVM) - in ER email
  - Diffuse interstitial pattern bilaterally, pulmonary vessels not easily visible. Severe cardiomegaly with left mainstem bronchi compression and trachea is dorsally deviated.

Treatments/monitoring:

B6

Client communication:
Discussed hospitalizing for supportive care to manage CHF as well as diagnostics (bloodwork, BP, echo, etc) to diagnose underlying heart disease and get her on the right medications. O ok with this plan.

Deposit & estimate status B6

FDA-CVM-FOIA-2019-1704-010394

Client: B6
Patient:

Resuscitation code (if admitting to ICU): B6

SOAP approved (DVM to sign): B6, DVM

SOAP Text B6 **9:49AM -** B6

DUPLICATE. IGNORE.

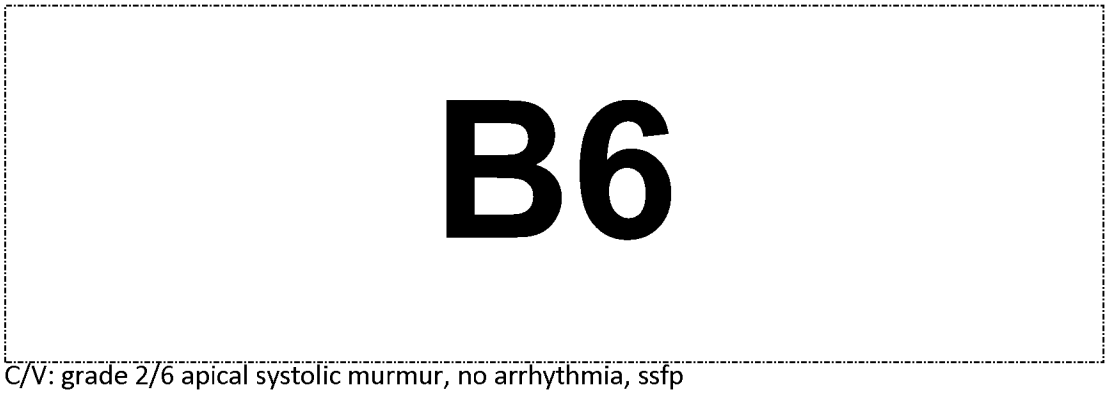
SOAP Text B6 **10:25AM -** B6

B6

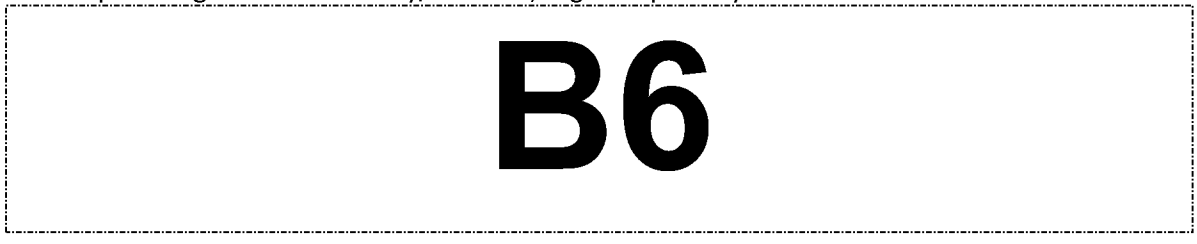
Signalment: 5yo FS Pitbull presenting for biventricular heart failure due to DCM, respiratory distress. Day 1 of hospitalization

Presenting history:
Coughing 2-3 weeks ago - after physical exercise gotten worse after any exercise, hacking some fluid a little productive, labored breathing, low energy. still eating/drinking, normal bathroom, no v/d. lost weight, looking skinny to the owner.
Prior medical history: allergies
Current medications: none
Diet: dry. 2 cups a day (o unsure exactly which diet - rotates through 4 different types of food)- brought in samples to fill out forms for the diet study she is enrolled in.
Vaccination status/flea & tick preventative use: UTD, no heartworm preventative or flea/tick
Travel history: none

EXAM:



C/V: grade 2/6 apical systolic murmur, no arrhythmia, ssfp
RESP: quiet lung sounds bilaterally/wheezes; slight respiratory effort



ASSESSMENT:
A1: Congestive heart failue r/o secondary to DCM vs other

FDA-CVM-FOIA-2019-1704-010395

Client: B6
Patient:

Diagnostics performed B6):

B6

- Chest x-rays (at rDVM) - in ER email
  - Diffuse interstitial pattern bilaterally, pulmonary vessels not easily visible. Severe cardiomegaly with left mainstem bronchi compression and trachea is dorsally deviated.

Diagnostics performed B6
Blood chemistry: U B6

PLAN:

Treatments/monitoring:

B6

-continue in diet study

Deposit & estimate status: B6

Resuscitation code (if admitting to ICU): B6

SOAP approved (DVM to sign): B6 DVM

SOAP Text B6 **) 11:55AM -** B6

Signalment: 5yo FS Pitbull presenting for biventricular heart failure due to DCM, respiratory distress. Day 1 of hospitalization

Presenting history:
Coughing 2-3 weeks ago - after physical exercise gotten worse after any exercise, hacking some fluid a little productive, labored breathing, low energy. still eating/drinking, normal bathroom, no v/d. lost weight, looking skinny to the owner.
Prior medical history: allergies
Current medications: none
Diet: dry. 2 cups a day (o unsure exactly which diet - rotates through 4 different types of food)- brought in samples to fill out forms for the diet study she is enrolled in.
Vaccination status/flea & tick preventative use: UTD, no heartworm preventative or flea/tick
Travel history: none

Overnight update:
Very bright, RR 24-36, eating well and passing urine frequently.

Subjective

FDA-CVM-FOIA-2019-1704-010396

Client: B6
Patient:

EXAM, GENERAL

Subjective (S)
Very BAR

Objective (O)

B6

H/L: regualr rhythm, II/VI murmur LHS. Strong and synchronous peripheral pulses.
Abd: soft, NAD

B6

ASSESSMENT:
A1: Dilated Cardiomyopathy

Diagnostics performed: B6

B6

- Chest x-rays (at rDVM) - in ER email
  - Diffuse interstitial pattern bilaterally, pulmonary vessels not easily visible. Severe cardiomegaly with left mainstem bronchi compression and trachea is dorsally deviated.

Diagnostics performed: B6
Blood chemistry: B6

Plan:
-NOVA
-TGH
-Recheckk with cardio in one week.

SOAP completed by: B6 BVSc

Initial Complaint:
Recheck - B6 - DCM Study

FDA-CVM-FOIA-2019-1704-010397

Client: B6
Patient:

SOAP Text B6 **1:53PM -** B6

Disposition/Recommendations

FDA-CVM-FOIA-2019-1704-010398

FDA-CVM-FOIA-2019-1704-010399

Cummings Veterinary Medical Center
AT TUFTS UNIVERSITY

Foster Hospital for Small Animals
55 Willard Street
North Grafton, MA 01536
(508) 839-5395

Client:	B6
Veterinarian:	
Patient ID:	B6
Visit ID:	

Patient:	B6
Species:	Canine
Breed:	Pit Bull
Sex:	Female (Spayed)
Age:	B6 Years Old

Lab Results Report

Nova Full Panel-ICU B6 **9:28:25 AM** **Accession ID:** B6

Test	Results	Reference Range	Units
SO2%		94 - 100	%
HCT (POC)		38 - 48	%
HB (POC)		12.6 - 16	g/dL
NA (POC)		140 - 154	mmol/L
K (POC)		3.6 - 4.8	mmol/L
CL(POC)		109 - 120	mmol/L
CA (ionized)		1.17 - 1.38	mmol/L
MG (POC)		0.1 - 0.4	mmol/L
GLUCOSE (POC)		80 - 120	mg/dL
LACTATE		0 - 2	mmol/L
BUN (POC)	B6	12 - 28	mg/dL
CREAT (POC)		0.2 - 2.1	mg/dL
TCO2 (POC)		0 - 0	mmol/L
nCA		0 - 0	mmol/L
nMG		0 - 0	mmol/L
GAP		0 - 0	mmol/L
CA/MG		0 - 0	mol/mol
BEecf		0 - 0	mmol/L
BEb		0 - 0	mmol/L
A		0 - 0	mmHg
NOVA SAMPLE		0 - 0	

FDA-CVM-FOIA-2019-1704-010400

FiO2	B6	0 - 0	%
PCO2		36 - 44	mmHg
PO2		80 - 100	mmHg
PH		7.337 - 7.467	
PCO2		36 - 44	mmHg
PO2		80 - 100	mmHg
HCO3		18 - 24	mmol/L

Nova Full Panel-ICU B6 9:36:03 AM **Accession ID:** B6

Test	Results	Reference Range	Units
Blood Glucose (Glucometer) - FHSA	B6	0 - 0	mg/dl

Nova Full Panel-ICU B6 9:56:38 AM **Accession ID:** B6

Test	Results	Reference Range	Units
TS (FHSA)	5.8	0 - 0	g/dl
PCV **	44	0 - 0	%
TS (FHSA)	5.8	0 - 0	g/dl

Nova Full Panel-ICU B6 10:12:18 AM **Accession ID:** B6

Test	Results	Reference Range	Units
GLUCOSE	B6	67 - 135	mg/dL
UREA		8 - 30	mg/dL
CREATININE		0.6 - 2	mg/dL
PHOSPHORUS		2.6 - 7.2	mg/dL
CALCIUM2		9.4 - 11.3	mg/dL
T. PROTEIN		5.5 - 7.8	g/dL
ALBUMIN		2.8 - 4	g/dL
GLOBULINS		2.3 - 4.2	g/dL
A/G RATIO		0.7 - 1.6	
SODIUM		140 - 150	mEq/L
CHLORIDE		106 - 116	mEq/L
POTASSIUM		3.7 - 5.4	mEq/L
NA/K		29 - 40	
T BILIRUBIN		0.1 - 0.3	mg/dL
ALK PHOS		12 - 127	U/L
ALT		14 - 86	U/L
AST		9 - 54	U/L
CHOLESTEROL		82 - 355	mg/dL
OSMOLALITY (CALCULATED)		291 - 315	mmol/L

Nova Full Panel-ICU B6 9:19:25 AM **Accession ID:** B6

Test	Results	Reference Range	Units
SO2%	B6	94 - 100	%
HCT (POC)		38 - 48	%

FDA-CVM-FOIA-2019-1704-010401

Client:
Patient: B6

HB (POC)	B6	12.6 - 16	g/dL
NA (POC)		140 - 154	mmol/L
K (POC)		3.6 - 4.8	mmol/L
CL(POC)		109 - 120	mmol/L
CA (ionized)		1.17 - 1.38	mmol/L
MG (POC)		0.1 - 0.4	mmol/L
GLUCOSE (POC)		80 - 120	mg/dL
LACTATE		0 - 2	mmol/L
BUN (POC)		12 - 28	mg/dL
CREAT (POC)		0.2 - 2.1	mg/dL
TCO2 (POC)		0 - 0	mmol/L
nCA		0 - 0	mmol/L
nMG		0 - 0	mmol/L
GAP		0 - 0	mmol/L
CA/MG		0 - 0	mol/mol
BEecf		0 - 0	mmol/L
BEb		0 - 0	mmol/L
A		0 - 0	mmHg
NOVA SAMPLE		0 - 0	
FiO2		0 - 0	%
PCO2		36 - 44	mmHg
PO2		80 - 100	mmHg
PH		7.337 - 7.467	
PCO2		36 - 44	mmHg
PO2		80 - 100	mmHg
HCO3		18 - 24	mmol/L

Nova Full Panel-ICU B6 **9:27:23 AM** **Accession ID:** B6

Test	Results	Reference Range	Units
TS (FHSA)	B6	0 - 0	g/dl
PCV **		0 - 0	%
TS (FHSA)		0 - 0	g/dl

B6

stringsoft

Printed Sunday, February 24, 2019

Vitals Results

B6

9:09:11 AM	Weight (kg)	
9:09:38 AM	Notes	
9:10:28 AM	B6	treatment note
9:45:06 AM		treatment note
10:45:50 AM		treatment note

B6

FDA-CVM-FOIA-2019-1704-010402

Client: B6
Patient:

Vitals Results

B6

11:21:04 AM	FiO2 (%)
11:21:11 AM	Respiratory Rate
11:21:41 AM	Nursing note
12:19:43 PM	Nursing note
12:37:05 PM	Quantify IV Fluids (CRI) in mls
12:37:06 PM	Catheter Assessment
12:37:44 PM	FiO2 (%)
12:38:25 PM	Respiratory Rate
12:39:49 PM	Heart Rate (/min)
1:47:10 PM	Eliminations
1:48:12 PM	FiO2 (%)
2:01:58 PM	FiO2 (%)
2:02:58 PM	Heart Rate (/min)
2:06:40 PM	Respiratory Rate
2:07:31 PM	Quantify IV Fluids (CRI) in mls
2:07:32 PM	Catheter Assessment
2:11:44 PM	B6 reatment note
3:19:35 PM	Nursing note
3:20:12 PM	Respiratory Rate
3:20:33 PM	FiO2 (%)
3:20:55 PM	Quantify IV Fluids (CRI) in mls
3:45:02 PM	Quantify IV Fluids (CRI) in mls
3:45:03 PM	Catheter Assessment
4:07:19 PM	FiO2 (%)
4:07:46 PM	Respiratory Rate
4:09:20 PM	Eliminations
4:18:29 PM	Heart Rate (/min)
4:18:40 PM	Quantify IV Fluids (CRI) in mls
4:18:41 PM	Catheter Assessment
5:12:04 PM	Respiratory Rate
5:12:14 PM	FiO2 (%)
5:13:48 PM	Eliminations
5:17:48 PM	Amount eaten
5:19:29 PM	Heart Rate (/min)
5:19:47 PM	FiO2 (%)
5:26:16 PM	B6 reatment note
5:47:32 PM	Respiratory Rate

B6

FDA-CVM-FOIA-2019-1704-010403

Client: B6
Patient:

Vitals Results

B6	9 5:47:46 PM	Quantify IV Fluids (CRI) in mls
	9 5:47:47 PM	Catheter Assessment
	9 6:01:17 PM	Eliminations
	9 6:54:17 PM	FiO2 (%)
	9 6:54:24 PM	Respiratory Rate
	9 7:11:55 PM	Heart Rate (/min)
	9 7:12:08 PM	Temperature (F)
	9 7:44:34 PM	FiO2 (%)
	9 7:44:43 PM	Quantify IV Fluids (CRI) in mls
	9 7:44:44 PM	Catheter Assessment
	9 7:45:08 PM	Respiratory Rate
	9 9:03:32 PM	FiO2 (%)
	9 9:03:41 PM	Respiratory Rate
	9 9:17:37 PM	Weight (kg)
	9 9:18:17 PM	Heart Rate (/min)
	9 9:19:05 PM	Quantify IV Fluids (CRI) in mls
	9 9:19:06 PM	Catheter Assessment
	9 9:19:42 PM	Eliminations
	9 9:21:04 PM	B6 eatment note
	9 9:45:41 PM	Respiratory Rate
	9 9:45:54 PM	FiO2 (%)
	9 10:49:36 PM	Respiratory Rate
	9 10:50:01 PM	FiO2 (%)
	9 11:31:31 PM	Quantify IV Fluids (CRI) in mls
	9 11:31:32 PM	Catheter Assessment
	9 11:32:09 PM	Heart Rate (/min)
	9 11:46:46 PM	Respiratory Rate
	9 11:47:01 PM	FiO2 (%)
	9 12:46:34 AM	FiO2 (%)
	9 12:46:44 AM	Respiratory Rate
	9 1:07:50 AM	Eliminations
	9 1:38:01 AM	Quantify IV Fluids (CRI) in mls
	9 1:38:02 AM	Catheter Assessment
	9 1:39:26 AM	Heart Rate (/min)
	9 1:56:06 AM	FiO2 (%)
	9 1:56:16 AM	Respiratory Rate
	9 3:06:11 AM	FiO2 (%)
	9 3:06:25 AM	Respiratory Rate
	9 3:12:19 AM	Lasix treatment note
	9 3:12:37 AM	Quantify IV Fluids (CRI) in mls
	9 3:12:38 AM	Catheter Assessment

B6

FDA-CVM-FOIA-2019-1704-010404

Client: B6
Patient:

Vitals Results

B6

4:06:40 AM	Respiratory Rate	
4:07:00 AM	FiO2 (%)	
4:07:08 AM	Heart Rate (/min)	
4:49:25 AM	FiO2 (%)	
4:49:37 AM	Respiratory Rate	
4:52:42 AM	Eliminations	
4:59:34 AM	Amount eaten	
5:24:06 AM	Nursing note	
5:24:55 AM	Heart Rate (/min)	
5:45:41 AM	Respiratory Rate	
5:45:53 AM	FiO2 (%)	
6:44:05 AM	FiO2 (%)	
6:44:44 AM	Respiratory Rate	
7:57:10 AM	Respiratory Rate	
7:57:26 AM	FiO2 (%)	
7:59:14 AM	Nursing note	
8:02:34 AM	Heart Rate (/min)	
8:05:21 AM	Temperature (F)	
8:08:24 AM	B6 reatment note	
8:14:38 AM	Weight (kg)	
8:16:10 AM	Eliminations	
9:02:29 AM	FiO2 (%)	
9:03:17 AM	Respiratory Rate	
10:02:20 AM	FiO2 (%)	
10:04:29 AM	Heart Rate (/min)	
10:08:31 AM	Respiratory Rate	
10:59:22 AM	FiO2 (%)	
10:59:52 AM	Respiratory Rate	
11:47:25 AM	FiO2 (%)	
11:47:53 AM	Respiratory Rate	
11:53:10 AM	Heart Rate (/min)	
11:53:48 AM	Eliminations	
12:59:52 PM	FiO2 (%)	
1:00:37 PM	Respiratory Rate	
2:17:38 PM	Respiratory Rate	
2:17:51 PM	Heart Rate (/min)	
2:22:20 PM	B6 eatment note	
2:59:31 PM	Respiratory Rate	
3:30:08 PM	Heart Rate (/min)	
3:52:22 PM	Respiratory Rate	
4:58:59 PM	Respiratory Rate	

B6

FDA-CVM-FOIA-2019-1704-010405

Client: B6
Patient:

Vitals Results

B6	5:16:42 PM	Amount eaten	B6
	5:17:09 PM	Eliminations	
	5:28:18 PM	Heart Rate (/min)	
	6:03:04 PM	Respiratory Rate	
	6:54:20 PM	Respiratory Rate	
	6:56:33 PM	Weight (kg)	
	7:20:10 PM	Temperature (F)	
	7:20:22 PM	Heart Rate (/min)	
	7:56:01 PM	Respiratory Rate	
	8:17:54 PM	Eliminations	
	9:00:37 PM	Respiratory Rate	
	9:15:46 PM	Heart Rate (/min)	
	9:41:52 PM	Respiratory Rate	
	9:43:34 PM	B6 reatment note	
	10:40:52 PM	Respiratory Rate	
	11:31:23 PM	Heart Rate (/min)	
	11:31:28 PM	Respiratory Rate	
	12:28:12 AM	Respiratory Rate	
	1:05:10 AM	Eliminations	
	1:12:38 AM	Heart Rate (/min)	
	1:12:45 AM	Respiratory Rate	
	2:47:00 AM	Respiratory Rate	
	3:16:57 AM	Heart Rate (/min)	
	3:37:24 AM	Respiratory Rate	
	4:23:24 AM	Respiratory Rate	
	5:36:11 AM	Amount eaten	
	5:36:20 AM	Heart Rate (/min)	
	5:36:27 AM	Respiratory Rate	
	5:40:28 AM	B6 treatment note	
	5:59:29 AM	Eliminations	
	6:21:11 AM	Eliminations	
	6:51:01 AM	Respiratory Rate	
	7:42:21 AM	Weight (kg)	
	8:08:18 AM	Temperature (F)	
	8:08:28 AM	Respiratory Rate	
	8:08:42 AM	Heart Rate (/min)	
	9:06:23 AM	Eliminations	
	9:07:04 AM	Respiratory Rate	

FDA-CVM-FOIA-2019-1704-010406

Client: B6
Patient:

Vitals Results

B6

9:20:15 AM	Catheter Assessment
10:02:30 AM	Heart Rate (/min)
10:02:36 AM	Respiratory Rate
10:02:52 AM	Eliminations
11:09:18 AM	Respiratory Rate
12:17:30 PM	Respiratory Rate
12:17:40 PM	Heart Rate (/min)
12:17:48 PM	Eliminations
1:05:31 PM	Respiratory Rate
1:36:34 PM	Catheter Assessment
1:36:42 PM	Respiratory Rate
1:36:58 PM	Heart Rate (/min)
1:25:45 PM	Weight (kg)
1:53:45 PM	B6 eatment note

B6

Patient History

B6

09:09 AM	Vitals
09:09 AM	Vitals
09:09 AM	Purchase
09:10 AM	Purchase
09:10 AM	Purchase
09:10 AM	Vitals
09:28 AM	Purchase
09:36 AM	Labwork
09:45 AM	Vitals
09:55 AM	Treatment
09:56 AM	Labwork
09:57 AM	Treatment
10:04 AM	Prescription
10:08 AM	Prescription
10:45 AM	Vitals
10:55 AM	Treatment
11:21 AM	Treatment
11:21 AM	Vitals
11:21 AM	Treatment
11:21 AM	Vitals
11:21 AM	Vitals
11:23 AM	Purchase
11:23 AM	Purchase

B6

FDA-CVM-FOIA-2019-1704-010407

Client: B6
Patient:

Patient History

B6

11:42 AM	UserForm	
11:54 AM	Treatment	
11:56 AM	Purchase	
11:56 AM	Purchase	
12:19 PM	Vitals	
12:37 PM	Treatment	
12:37 PM	Vitals	
12:37 PM	Vitals	
12:37 PM	Vitals	
12:37 PM	Treatment	
12:37 PM	Vitals	
12:38 PM	Treatment	
12:38 PM	Vitals	
12:39 PM	Treatment	
12:39 PM	Vitals	
01:47 PM	Treatment	
01:47 PM	Vitals	
01:48 PM	Treatment	
01:48 PM	Vitals	
02:01 PM	Treatment	
02:01 PM	Vitals	
02:02 PM	Treatment	
02:02 PM	Vitals	
02:06 PM	Treatment	
02:06 PM	Treatment	
02:06 PM	Vitals	
02:06 PM	Treatment	
02:07 PM	Treatment	
02:07 PM	Vitals	
02:07 PM	Vitals	
02:11 PM	Vitals	
02:11 PM	Treatment	
03:19 PM	Vitals	
03:20 PM	Treatment	
03:20 PM	Vitals	
03:20 PM	Treatment	
03:20 PM	Vitals	

B6

FDA-CVM-FOIA-2019-1704-010408

Client: B6
Patient:

Patient History

B6

03:20 PM	Vitals
03:22 PM	Treatment
03:23 PM	Treatment
03:45 PM	Treatment
03:45 PM	Vitals
03:45 PM	Vitals
04:07 PM	Treatment
04:07 PM	Vitals
04:07 PM	Treatment
04:07 PM	Vitals
04:09 PM	Vitals
04:18 PM	Treatment
04:18 PM	Vitals
04:18 PM	Treatment
04:18 PM	Vitals
04:18 PM	Vitals
04:38 PM	Purchase
04:39 PM	Purchase
05:12 PM	Treatment
05:12 PM	Vitals
05:12 PM	Treatment
05:12 PM	Vitals
05:12 PM	Treatment
05:13 PM	Treatment
05:13 PM	Vitals
05:17 PM	Treatment
05:17 PM	Treatment
05:17 PM	Vitals
05:18 PM	Treatment
05:19 PM	Treatment
05:19 PM	Vitals
05:19 PM	Treatment
05:19 PM	Vitals
05:26 PM	Vitals
05:27 PM	Treatment
05:47 PM	Treatment
05:47 PM	Vitals
05:47 PM	Treatment
05:47 PM	Vitals

B6

FDA-CVM-FOIA-2019-1704-010409

Patient History

B6

05:47 PM	Vitals
06:01 PM	Vitals
06:54 PM	Treatment
06:54 PM	Vitals
06:54 PM	Treatment
06:54 PM	Vitals
07:11 PM	Treatment
07:11 PM	Vitals
07:12 PM	Treatment
07:12 PM	Vitals
07:44 PM	Treatment
07:44 PM	Vitals
07:44 PM	Treatment
07:44 PM	Vitals
07:44 PM	Vitals
07:45 PM	Treatment
07:45 PM	Vitals
09:03 PM	Treatment
09:03 PM	Vitals
09:03 PM	Treatment
09:03 PM	Vitals
09:04 PM	Treatment
09:17 PM	Treatment
09:17 PM	Vitals
09:18 PM	Treatment
09:18 PM	Vitals
09:19 PM	Treatment
09:19 PM	Vitals
09:19 PM	Vitals
09:19 PM	Treatment
09:19 PM	Vitals
09:21 PM	Vitals
09:21 PM	Treatment
09:45 PM	Treatment
09:45 PM	Vitals
09:45 PM	Treatment
09:45 PM	Vitals
10:49 PM	Treatment
10:49 PM	Vitals
10:50 PM	Treatment
10:50 PM	Vitals

B6

FDA-CVM-FOIA-2019-1704-010410

Client: B6
Patient:

Patient History

	9 11:07 PM	Purchase
	9 11:31 PM	Treatment
	9 11:31 PM	Vitals
	9 11:31 PM	Vitals
	9 11:32 PM	Treatment
	9 11:32 PM	Vitals
	9 11:46 PM	Treatment
	9 11:46 PM	Vitals
	9 11:47 PM	Treatment
	9 11:47 PM	Vitals
	9 12:46 AM	Treatment
	9 12:46 AM	Vitals
	9 12:46 AM	Treatment
	9 12:46 AM	Vitals
	9 01:04 AM	Treatment
	9 01:07 AM	Treatment
	9 01:07 AM	Vitals
	9 01:08 AM	Treatment
	9 01:38 AM	Treatment
B6	9 01:38 AM	Vitals
	9 01:38 AM	Vitals
	9 01:39 AM	Treatment
	9 01:39 AM	Vitals
	9 01:56 AM	Treatment
	9 01:56 AM	Vitals
	9 01:56 AM	Treatment
	9 01:56 AM	Vitals
	9 03:06 AM	Treatment
	9 03:06 AM	Vitals
	9 03:06 AM	Treatment
	9 03:06 AM	Vitals
	9 03:12 AM	Vitals
	9 03:12 AM	Treatment
	9 03:12 AM	Treatment
	9 03:12 AM	Vitals
	9 03:12 AM	Vitals
	9 04:06 AM	Treatment
	9 04:06 AM	Vitals
	9 04:07 AM	Treatment

B6

FDA-CVM-FOIA-2019-1704-010411

Patient History

B6

04:07 AM	Vitals
04:07 AM	Treatment
04:07 AM	Vitals
04:49 AM	Treatment
04:49 AM	Vitals
04:49 AM	Treatment
04:49 AM	Vitals
04:52 AM	Treatment
04:52 AM	Vitals
04:53 AM	Treatment
04:59 AM	Treatment
04:59 AM	Vitals
05:00 AM	Treatment
05:24 AM	Vitals
05:24 AM	Treatment
05:24 AM	Vitals
05:45 AM	Treatment
05:45 AM	Vitals
05:45 AM	Treatment
05:45 AM	Vitals
06:44 AM	Treatment
06:44 AM	Vitals
06:44 AM	Treatment
06:44 AM	Vitals
07:57 AM	Treatment
07:57 AM	Vitals
07:57 AM	Treatment
07:57 AM	Vitals
07:59 AM	Vitals
08:02 AM	Treatment
08:02 AM	Vitals
08:05 AM	Treatment
08:05 AM	Vitals
08:08 AM	Vitals
08:08 AM	Treatment
08:14 AM	Treatment
08:14 AM	Vitals
08:16 AM	Vitals
09:02 AM	Treatment
09:02 AM	Vitals
09:03 AM	Treatment
09:03 AM	Vitals
09:10 AM	Treatment

B6

FDA-CVM-FOIA-2019-1704-010412

Client: B6
Patient:

Patient History

B6

09:10 AM	Treatment
09:14 AM	Treatment
10:02 AM	Treatment
10:02 AM	Vitals
10:04 AM	Treatment
10:04 AM	Vitals
10:08 AM	Treatment
10:08 AM	Vitals
10:12 AM	Purchase
10:13 AM	Treatment
10:59 AM	Treatment
10:59 AM	Vitals
10:59 AM	Treatment
10:59 AM	Vitals
11:05 AM	Purchase
11:05 AM	Purchase
11:30 AM	Purchase
11:45 AM	Deleted Reason
11:47 AM	Treatment
11:47 AM	Vitals
11:47 AM	Treatment
11:47 AM	Vitals
11:53 AM	Treatment
11:53 AM	Vitals
11:53 AM	Vitals
12:59 PM	Treatment
12:59 PM	Vitals
01:00 PM	Treatment
01:00 PM	Vitals
01:01 PM	Treatment
02:13 PM	Treatment
02:17 PM	Treatment
02:17 PM	Vitals
02:17 PM	Treatment
02:17 PM	Vitals
02:22 PM	Vitals
02:22 PM	Treatment
02:59 PM	Treatment
02:59 PM	Vitals
03:30 PM	Treatment
03:30 PM	Vitals

B6

FDA-CVM-FOIA-2019-1704-010413

Patient History

B6

03:52 PM	Treatment
03:52 PM	Vitals
04:58 PM	Treatment
04:58 PM	Vitals
05:02 PM	Treatment
05:03 PM	UserForm
05:16 PM	Treatment
05:16 PM	Vitals
05:17 PM	Treatment
05:17 PM	Treatment
05:17 PM	Treatment
05:17 PM	Vitals
05:28 PM	Treatment
05:28 PM	Vitals
06:03 PM	Treatment
06:03 PM	Vitals
06:54 PM	Treatment
06:54 PM	Vitals
06:56 PM	Treatment
06:56 PM	Vitals
07:20 PM	Treatment
07:20 PM	Vitals
07:20 PM	Treatment
07:20 PM	Vitals
07:56 PM	Treatment
07:56 PM	Vitals
08:17 PM	Treatment
08:17 PM	Vitals
09:00 PM	Treatment
09:00 PM	Vitals
09:00 PM	Treatment
09:15 PM	Treatment
09:15 PM	Vitals
09:41 PM	Treatment
09:41 PM	Vitals
09:43 PM	Vitals
09:43 PM	Treatment
10:40 PM	Treatment
10:40 PM	Vitals
11:07 PM	Purchase
11:31 PM	Treatment
11:31 PM	Vitals
11:31 PM	Treatment
11:31 PM	Vitals
12:28 AM	Treatment

B6

FDA-CVM-FOIA-2019-1704-010414

Client: B6
Patient:

Patient History

B6	12:28 AM	Vitals
	01:05 AM	Treatment
	01:05 AM	Vitals
	01:05 AM	Treatment
	01:06 AM	Treatment
	01:09 AM	Treatment
	01:12 AM	Treatment
	01:12 AM	Vitals
	01:12 AM	Treatment
	01:12 AM	Vitals
	02:47 AM	Treatment
	02:47 AM	Vitals
	03:16 AM	Treatment
	03:16 AM	Vitals
	03:37 AM	Treatment
	03:37 AM	Vitals
	04:23 AM	Treatment
	04:23 AM	Vitals
	05:33 AM	Treatment
	05:33 AM	Treatment
	05:36 AM	Treatment
	05:36 AM	Vitals
	05:36 AM	Treatment
	05:36 AM	Vitals
	05:36 AM	Treatment
	05:36 AM	Vitals
	05:40 AM	Vitals
	05:40 AM	Treatment
	05:59 AM	Treatment
	05:59 AM	Vitals
	06:21 AM	Vitals
	06:51 AM	Treatment
	06:51 AM	Vitals
	07:42 AM	Treatment
	07:42 AM	Vitals
	08:08 AM	Treatment
	08:08 AM	Vitals
	08:08 AM	Treatment
	08:08 AM	Vitals
	08:08 AM	Treatment
	08:08 AM	Vitals
	09:06 AM	Treatment
	09:06 AM	Vitals
	09:07 AM	Treatment
	09:07 AM	Vitals
	09:16 AM	Treatment
	09:19 AM	Purchase

B6

FDA-CVM-FOIA-2019-1704-010415

Client: B6
Patient:

Patient History

B6

09:20 AM	Treatment
09:20 AM	Treatment
09:20 AM	Vitals
09:27 AM	Labwork
10:02 AM	Treatment
10:02 AM	Vitals
10:02 AM	Treatment
10:02 AM	Vitals
10:02 AM	Vitals
11:05 AM	Purchase
11:05 AM	Purchase
11:09 AM	Treatment
11:09 AM	Vitals
11:29 AM	Appointment
12:17 PM	Treatment
12:17 PM	Vitals
12:17 PM	Treatment
12:17 PM	Vitals
12:17 PM	Treatment
12:17 PM	Vitals
01:05 PM	Treatment
01:05 PM	Vitals
01:07 PM	Treatment
01:27 PM	Deleted Reason
01:27 PM	Purchase
01:32 PM	Prescription
01:36 PM	Prescription
01:36 PM	Treatment
01:36 PM	Vitals
01:36 PM	Treatment
01:36 PM	Vitals
01:36 PM	Treatment
01:36 PM	Vitals
02:35 PM	Email
12:59 PM	UserForm
01:22 PM	Treatment
01:23 PM	UserForm
01:25 PM	Vitals
01:37 PM	Purchase
01:38 PM	Purchase
01:53 PM	Vitals
02:20 PM	Prescription

B6

B6

FDA-CVM-FOIA-2019-1704-010416

Client: B6
Patient:

Patient History

B6

	02:22 PM	Purchase
	03:19 PM	Appointment
	03:21 PM	Email

B6

FDA-CVM-FOIA-2019-1704-010417

Cummings
Veterinary Medical Center
AT TUFTS UNIVERSITY

Foster Hospital for Small Animals
55 Willard Street
North Grafton, MA 01536
Telephone (508) 839-5395
Fax (508) 839-7951
http://vetmed.tufts.edu/

Discharge Instructions

Patient
Name:
Signalment: B6 Years Old Brown/White Female (Spayed) Pit Bull

Owner
Name:
Address: B6

Patient ID: B6
Emergency Clinician: B6 **DVM (Intern – SAM),** B6 **BVSc (Resident- Emergency and Critical Care)**
Consulting Clinician:

ER Supervisor:

B6

Admit Date B6 **8:55:09 AM**
Check Out Date B6

Diagnosis:
1. Congestive Heart Failure: dilated cardiomyopathy

Case Summary B6 **presented to the ER in significant respiratory distress. She was diagnosed with heart failure and required hospitalisation in an oxygen kennel alongside intravenous medications** B6 B6 **to control her breathing. Echocardiography (heart scan) showed that she had a dilated heart, a condition called dilated cardiomyopathy.** B6 **has responded well to treatment and soon started breathing well outside of oxygen. She has done well today and can now go home.** B6 **must receive all her medications in order to manage her heart condition. It is also very important that is fed the prescription hypoallergenic food ONLY.**

B6

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B6

B6

B6

Diet suggestions:
B6 **should continue to be fed Purina HA dry. She seemed to like that food while in hospital.**

Dogs with heart failure accumulate more fluid in their body if they eat large amounts of sodium (salt). Sodium can be found in all foods, but some foods are lower in sodium than others. Many pet treats, people foods, and supplements used to give pills often have more sodium than is desirable – a sheet that has suggestions for low sodium treats can be found on the HeartSmart web site (http://vet.tufts.edu/heartsmart/diet/).

Your dog's usual diet may also have more sodium than recommended –we want your dog to continue to eat their normal diet for the first 7 to 14 days so we can make sure they are tolerating medications well. After that time, we would recommend slowly introducing one of the lower sodium diets on the HeartSmart list (25% of the new diet and 75% old diet for 2-3 days, then 50:50, etc.). You can find a diet on the list that your dog likes to eat. Alternatively, if you are attached to the current diet you can research the amount of sodium in the diet to ensure that the sodium content is similar to those on the list.

- **The FDA is currently investigating an apparent association between diet and a type of heart disease called dilated cardiomyopathy. The exact cause is still unclear, but it appears to be associated with boutique diets and those containing exotic ingredient or are grain-free. Therefore, we are currently recommending that dogs do not eat these types of diets.**
- **We recommend switching B6 to commercial diet made by a well-established company that is not grain-free and does not contain any exotic ingredients, such as kangaroo, duck, lamb, venison, lentils, peas, beans, buffalo, tapioca, barley, and chickpeas.**
- **The FDA issued a statement regarding this issue (https://www.fda.gov/AnimalVeterinary/NewsEvents/CVMUpdates/ucm613305.htm) and a recent article published by Dr. Lisa Freeman on the Cummings School's Petfoodology blog can further explain these findings (http://vetnutrition.tufts.edu/2018/06/a-broken-heart-risk-of-heart-disease-in-boutique-or-grain-free-diets-and-exotic-ingredients/).**
- **Our nutritionists have compiled a list of dog foods that are good options for dogs with heart disease.**

If your dog has special nutritional needs or requires a homecooked diet, we recommend you schedule an appointment with our nutritionists (508-887-4696).

Exercise Recommendations:
For the first 7 to 10 days after starting medications for heart failure, we recommend very limited activity. Leash walking only is ideal, and short walks to start. Once the heart failure is better controlled, then slightly longer walks are acceptable. However, if you find that B6 is lagging behind or needs to stop on a walk then this was too long a walk and shorter walks are advised in the future. Repetitive or strenuous high-energy activities (repetitive ball chasing, running fast off-leash, etc.) are generally not advised at this stage of heart failure.

Recheck/Follow-up:
A recheck exam has been scheduled for

Friday, February 22, 2019 at 1:00pm with B6

Cummings
Veterinary Medical Center
AT TUFTS UNIVERSITY
Cardiology Liaison: 508-887-4696

B6

Patient ID: B6
B6 Canine
Years Old Female (Spayed) Pit Bull
Brown/White BW: Weight (kg) 19.00

Cardiology Consultation
ENROLLED IN DCM STUDY

Date: B6
Weight: Weight (kg) 19.00
Requesting Clinician: B6 DVM (Intern - SAM)

Attending Cardiologist:
☐ John E. Rush DVM, MS, DACVIM (Cardiology), DACVECC

B6

Cardiology Resident:

B6

Thoracic radiographs available for review?
☑ Yes - in ER email
☐ Yes - in PACS
☐ No

Patient location: ER

Presenting complaint and important concurrent diseases: Dyspnea

***STOP** - remainder of form to be filled out by Cardiology*

Physical Examination

B6

Muscle condition:
☐ Normal
☑ Mild muscle loss
☐ Moderate cachexia
☐ Marked cachexia

Cardiovascular Physical Exam
Murmur Grade:
☐ None
☐ I/VI
☐ IV/VI
☐ V/VI

- [x] II/VI
- [ ] III/VI
- [ ] VI/VI

Murmur location/description: left apical systolic (animal panting, difficult auscultation)

Jugular vein:
- [x] Bottom 1/3 of the neck
- [ ] Middle 1/3 of the neck
- [ ] Top 2/3 of the neck
- [ ] 1/2 way up the neck

Arterial pulses:
- [x] Weak vs.
- [x] Fair at most
- [ ] Good
- [ ] Strong
- [ ] Bounding
- [ ] Pulse deficits
- [ ] Pulsus paradoxus
- [ ] Other (describe):

Arrhythmia:
- [x] None
- [ ] Sinus arrhythmia
- [ ] Premature beats
- [ ] Bradycardia
- [ ] Tachycardia

Gallop:
- [ ] Yes
- [x] No
- [ ] Intermittent
- [ ] Pronounced
- [ ] Other:

Pulmonary assessments:
- [ ] Eupneic
- [ ] Mild dyspnea
- [x] Marked dyspnea
- [ ] Normal BV sounds
- [x] Pulmonary Crackles
- [ ] Wheezes
- [ ] Upper airway stridor
- [ ] Other auscultatory findings:

Abdominal exam:
- [ ] Normal
- [ ] Hepatomegaly
- [ ] Abdominal distension
- [ ] Mild ascites

Echocardiogram Findings:

B6

Mitral inflow: not assessed
- [ ] Summated
- [ ] Normal
- [ ] Pseudonormal
- [ ] Restrictive

☐ Delayed relaxation

Blood Pressure (mmHg): recommended

Radiographic findings:

B6

Assessment and recommendations:

Marked LV contractile dysfunction with severe LA dilation, and thoracic radiographs are suggestive of CHF. Severe PTHN could be post (L-CHF) or pre-capillary (primary lung disease). As patient has no history of HW preventative, recommend 4DX. Unclear whether there is TV dysplasia or severe TR is just secondary to severe RV dilation and PHT. Recommend repeat echo when patient is more stable and r/o PS and +/- bubble study. Keep patient in O2 chamber B6 B6 depending on clinical response. As patient is BAR and gets excited when manipulated, hold BP for now. As patient has been on a variety of diets with uncertain quality, recommend switch to a grain-based, nonboutique diet made by a well-established company. Recommend complete echocardiogram in 1-2 days or as soon as patient is stable.

Addendum

B6 - Patient improved resp rate overnight and nitroprusside was discontinued; patient should tolerate oxygen trial this morning. Echocardiogram revealed slight decrease in PHTN (PG was 71mmHg is 54mmHg this morning), No PDA or PS visualized, MR PG 98mmHg, E/A 2, E/e' 18. Heart rate is lower (100bpm) and no crackles bilaterally. B6 recommended q6-8h and assess respiratory rate hourly and kidney values today.

Treatment plan:

B6

Final Diagnosis: DCM with LCHF; PHTN

Heart Failure Classification Score:

ISACHC Classification:

- ☐ Ia
- ☐ Ib
- ☐ II
- ☑ IIIa
- ☐ IIIb

ACVIM CHF Classification:

- ☐ A
- ☐ B1
- ☐ B2
- ☑ C
- ☐ D

M-Mode		
IVSd	B6	cm
LVIDd		cm
LVPWd		cm
IVSs		cm
LVIDs		cm
LVPWs		cm
EDV(Teich)		ml
ESV(Teich)		ml
EF(Teich)		%
%FS		%
SV(Teich)		ml
Ao Diam		cm
LA Diam		cm
LA/Ao		
Max LA		cm
Time		ms
HR		BPM
CO(Teich)		l/min
CI(Teich)		l/minm
Ao Diam		cm
LA Diam		cm
LA/Ao		
EPSS		cm
M-Mode Normalized		
IVSdN	B6	(0.290 - 0.520)
LVIDdN		(1.350 - 1.730) !
LVPWdN		(0.330 - 0.530)
IVSsN		(0.430 - 0.710)
LVIDsN		(0.790 - 1.140) !
LVPWsN		(0.530 - 0.780) !
2D		
SA LA	B6	cm
Ao Diam		cm
SA LA / Ao Diam		
IVSd		cm
LVIDd		cm
LVPWd		cm
EDV(Teich)		ml
IVSs		cm
LVIDs		cm
LVPWs		cm
ESV(Teich)		ml
EF(Teich)		%
%FS		%
SV(Teich)		ml
LV Major		cm

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LV Minor	B6	cm
Sphericity Index		
LVLd LAX		cm
LVAd LAX		cm
LVEDV A-L LAX		ml
LVEDV MOD LAX		ml
LVLs LAX		cm
LVAs LAX		cm
LVESV A-L LAX		ml
LVESV MOD LAX		ml
HR		BPM
EF A-L LAX		%
LVEF MOD LAX		%
SV A-L LAX		ml
SV MOD LAX		ml
CO A-L LAX		l/min
CO MOD LAX		l/min
RVIDD		cm
RVIDS		cm

<u>Doppler</u>

MR Vmax	B6	m/s
MR maxPG		mmHg
MV E Vel		m/s
MV DecT		ms
MV Dec Slope		m/s
MV A Vel		m/s
MV E/A Ratio		
E'		m/s
E/E'		
A'		m/s
S'		m/s
IVRT		ms
AV Vmax		m/s
AV maxPG		mmHg
PV Vmax		m/s
PV maxPG		mmHg
TR Vmax		m/s
TR maxPG		mmHg

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Cummings
Veterinary Medical Center
AT TUFTS UNIVERSITY

Foster Hospital for Small Animals
55 Willard Street
North Grafton, MA 01536
Telephone (508) 839-5395
Fax (508) 839-7951
http://vetmed.tufts.edu/

Discharge Instructions

Patient
Name: B6
Species: Canine
Brown/White Female (Spayed) Pit Bull
Birthdate: B6

Owner
Name: B6
Address: B6

Patient ID: B6

Attending Cardiologist:
☐ John E. Rush DVM, MS, DACVIM (Cardiology), DACVECC
B6

Cardiology Resident:
B6

Cardiology Technician:
B6

Student: B6 V19

Admit Date: 2/22/2019 12:37:33 PM
Discharge Date: 2/22/2019

Diagnoses: Dilated cardiomyopathy (DCM) with congestive heart failure

Diagnostic test results and findings:
- **Labwork findings:** The labwork results are pending. We will call you with these results.
- **ECG:** The ECG did not show any arrhythmias on examination today.

Case summary:
Thank you for bringing B6 in for evaluation by the Tufts cardiology department for her recently diagnosed heart disease.

On exam today, B6 was bright and alert. You report that she is doing well at home and her respiratory rate has been between 18-24 when she is sleeping. ECG did not show any arrhythmias. B6 was breathing slightly harder after her exam so she was given one dose of furosemide. We are going to keep her on her current medication regimen and add an ACE inhibitor (enalapril) to reduce the workload on her heart.

B6

B6

Recommended Medications:

B6

Exercise Recommendations:

For the first 7 to 10 days after starting medications for heart failure we recommend very limited activity. Leash walking only is ideal, and short walks to start. Once the heart failure is better controlled, then slightly longer walks are acceptable. However, if you find that B6 is lagging behind or needs to stop on a walk then this was too long a walk and shorter walks are advised in the future. Repetitive or strenuous high energy activities (repetitive ball chasing, running fast off-leash, etc.) are generally not advised at this stage of heart failure.

Recheck Visits:

A recheck has been scheduled for

Monday, May 13, 2019 at 1:00PM with B6

Thank you for entrusting us with B6 care. Please contact our Cardiology liaison at (508)-887-4696 or email us at cardionet@tufts.edu for scheduling and non-emergent questions or concerns.

Please visit our HeartSmart website for more information
http://vet.tufts.edu/heartsmart/

Prescription Refill Disclaimer:

For the safety and well-being of our patients, your pet must have had an examination by one of our veterinarians within the past year in order to obtain prescription medications.

Ordering Food:

Please check with your primary veterinarian to purchase the recommended diet(s). If you wish to purchase your food from us, please call 7-10 days in advance (508-887-4629) to ensure the food is in stock. Alternatively, veterinary diets can be ordered from online retailers with a prescription/veterinary approval.

Clinical Trials:

Clinical trials are studies in which our veterinary doctors work with you and your pet to investigate a specific disease process or a promising new test or treatment. Please see our website: vet.tufts.edu/cvmc/clinical-studies

---

Case: B6 **Owner:** B6 **Discharge Instructions**

Cummings
Veterinary Medical Center
AT TUFTS UNIVERSITY
Cardiology Liaison: 508-887-4696

B6

Patient ID: B6
B6 Canine
Years Old Female (Spayed) Pit Bull
Brown/White

Cardiology Appointment Report
-Patient enrolled in the DCM study-

Date: 2/22/2019

Attending Cardiologist:
☐ John E. Rush DVM, MS, DACVIM (Cardiology), DACVECC
B6

Cardiology Resident:
B6

Cardiology Technician:
B6

Student: B6 V19

Presenting Complaint:
DCM

General Medical History:
Presented to ER for dyspnea B6 On exam, grade II/VI murmur. Echo showed decreased contractility. marked RH dilation, thickened MV and TV, 2+ MR.
O reports doing well at home since discharge

Diet and Supplements:
Prescription purina cardiac diet, eating well
coconut oil to give medication

Cardiovascular History:
Prior CHF diagnosis? N
Prior heart murmur? Y
Prior ATE? N
Prior arrhythmia? N
Monitoring respiratory rate and effort at home? Yes, once a day, around 18-24
Cough? Coughed a few times last night, otherwise no cough, some sneezing
Shortness of breath or difficulty breathing? No
Syncope or collapse? No

Sudden onset lameness? No
Exercise intolerance? No

Current Medications Pertinent to CV System:

B6

Cardiac Physical Examination:

B6

Muscle condition:

- [ ] Normal
- [x] Mild muscle loss
- [ ] Moderate cachexia
- [ ] Marked cachexia

Cardiovascular Physical Exam:

Murmur Grade:

- [ ] None
- [ ] I/VI
- [ ] II/VI
- [x] III/VI
- [ ] IV/VI
- [ ] V/VI
- [ ] VI/VI

Murmur location/description: left apical systolic

Jugular vein:

- [x] Bottom 1/3 of the neck
- [ ] Middle 1/3 of the neck
- [ ] 1/2 way up the neck
- [ ] Top 2/3 of the neck

Arterial pulses:

- [ ] Weak
- [ ] Fair
- [x] Good
- [ ] Strong
- [ ] Bounding
- [ ] Pulse deficits
- [ ] Pulsus paradoxus
- [ ] Other:

Arrhythmia:

- [x] None
- [ ] Sinus arrhythmia
- [ ] Premature beats
- [ ] Bradycardia
- [ ] Tachycardia

Gallop:

- [ ] Yes
- [x] No
- [ ] Intermittent
- [ ] Pronounced
- [ ] Other:

Pulmonary assessments:

- [x] Eupneic
- [x] Mild dyspnea with excitement
- [ ] Marked dyspnea
- [x] Normal BV sounds
- [ ] Pulmonary crackles
- [ ] Wheezes
- [ ] Upper airway stridor

Abdominal exam:

- [x] Normal
- [ ] Hepatomegaly
- [ ] Abdominal distension
- [ ] Mild ascites
- [ ] Marked ascites

Problems:

DCM - CHF

Differential Diagnoses:

Diet-induced DCM vs. primary DCM

Diagnostic plan:

- [ ] Echocardiogram
- [ ] Chemistry profile
- [ ] ECG
- [x] Renal profile
- [ ] Blood pressure
- [ ] Dialysis profile
- [ ] Thoracic radiographs
- [ ] NT-proBNP
- [ ] Troponin I
- [ ] Other tests:

B6

Assessment and recommendations:

Patient improved since discharge, normal appetite, good energy level and respiratory rate is ~18-20brpm. ACE inhibitor was started today (10mg SID for 3-4 days) and then increase to 10mg in the morning and 5mg in the evening, unless patient does not tolerate this dose or bloodwork performed today reveals any kidney change that may need dose adjustments. Patient will be on hydrolyzed diet (HA) until she's through with current bag and then will try the ProPlan Sensitive Skin and Stomach. If she develops diarrhea on this diet, client is instructed to go back to HA. Recheck scheduled for 3 months, or sooner in

case patient develops clinical signs consistent with worsening of the disease.

Final Diagnosis:
DCM - r/o primary vs. diet-induced.

Heart Failure Classification Score:
ISACHC Classification:

- ☐ Ia
- ☐ Ib
- ☑ II
- ☐ IIIa
- ☐ IIIb

ACVIM Classification:

- ☐ A
- ☐ B1
- ☐ B2
- ☑ C
- ☐ D

Cummings
Veterinary Medical Center
AT TUFTS UNIVERSITY

Foster Hospital for Small Animals
55 Willard Street
North Grafton, MA 01536
Telephone (508) 839-5395
Fax (508) 839-7951
http://vetmed.tufts.edu/
Referring Vet Direct Line 508-887-4988

Notice of Patient Admit

Date: B6 8:55:09 AM **Case No:** B6
Referring Doctor: B6
Client Name: B6
Patient Name: B6

Dear B6

Your patient presented to our Emergency service. Please make note of the following information to facilitate communication with our team.

The attending doctor is: B6
The reason for admission to the FHSA is: DCM, PHT, CHF

If you have any questions regarding this particular case, please call 508-887-4988 to reach the ECC Service. Information is updated daily, by noon.

Thank you for your referral to our Emergency Service.

Cummings
Veterinary Medical Center
AT TUFTS UNIVERSITY

Foster Hospital for Small Animals
55 Willard Street
North Grafton, MA 01536
Telephone (508) 839-5395
Fax (508) 839-7951
http://vetmed.tufts.edu/

B6

B6 Female (Spayed)
Canine Pit Bull Brown/White
B6

B6

Dear B6

Thank you for referring B6 with their pet B6.

If you have any questions, or concerns, please contact us at 508-887-4988.

Thank you,

B6 DVM (Resident - Cardiology)

Cummings
Veterinary Medical Center
AT TUFTS UNIVERSITY

Foster Hospital for Small Animals
55 Willard Street
North Grafton, MA 01536
Telephone (508) 839-5395
Fax (508) 839-7951
http://vetmed.tufts.edu/

B6

B6 Female (Spayed)
Canine Pit Bull Brown/White
B6

B6

Dear B6

Thank you for referring B6 with their pet B6

B6 presented to the Tufts ER on B6 in significant respiratory distress. She was diagnosed with congestive heart failure secondary to dilated cardiomyopathy (DCM). B6 was stabilised with oxygen therapy, B6 B6 B6 was enrolled into a research project with our Cardiology Service investigating an association between DCM and dogs fed grain free diets. She has done well and was discharged on B6 with B6 B6 taurine and Purina HA dry food.

B6 has a recheck appointment scheduled with B6, Resident in Cardiology, on B6

If you have any questions, or concerns, please contact us at 508-887-4988.

Thank you,

B6 BVSc (Resident – Emergency & Critical Care)

From: Related PFR Event <pfrsignificantactivitycreation@fda.hhs.gov>

To: Carey, Lauren; Cleary, Michael *; HQ Pet Food Report Notification; B6

Sent: 6/10/2019 9:32:54 PM

Subject: Acana: Lisa Freeman - EON-390104

Attachments: 2068046-report.pdf; 2068046-attachments.zip

A PFR Report has been received and Related PFR Event [EON-390104] has been created in the EON System.

A "PDF" report by name "2068046-report.pdf" is attached to this email notification for your reference. Please note that all documents received in the report are compressed into a zip file by name "2068046-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-390104
ICSR #: 2068046
EON Title: Related PFR Event created for Acana Natural Balance Petcurean (see diet history for additional details); 2068046

AE Date	02/16/2019	**Number Fed/Exposed**	1
Best By Date		**Number Reacted**	1
Animal Species	Dog	**Outcome to Date**	Better/Improved/Recovering
Breed	Terrier - Bull - American Pit		
Age	B6 Years		
District Involved	PFR-New England DO		

Product information
Individual Case Safety Report Number: 2068046
Product Group: Pet Food
Product Name: Acana, Natural Balance, Petcurean (see diet history for additional details)
Description: DCM and CHF diagnosed 2/16/19. Eating multiple BEG diets Taurine and troponin pending Dog changed to Purina HA vegetarian dry while in hospital and owner has continued this. Will try switching to Pro Plan Sensitive Skin and Stomach Salmon when bag of HA runs out. If she tolerates that, will stay on it. If not, will switch back to HA since she's done well on that.

Submission Type: Followup
Report Type: Adverse Event (a symptom, reaction or disease associated with the product)
Outcome of reaction/event at the time of last observation: Better/Improved/Recovering
Number of Animals Treated With Product: 1
Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Acana, Natural Balance, Petcurean (see diet history for additional details)		

This report is linked to:
Initial EON Event Key: EON-380708
Initial ICSR: 2063115

Sender information
Lisa Freeman
200 Westboro Rd
North Grafton, MA 01536
USA

Owner information
B6 USA

To view this Related PFR Event, please click the link below:
https://eon.fda.gov/eon//browse/EON-390104

To view the Related PFR Event Report, please click the link below:
https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jspa?decorator=none&e=0&issueType=10100&issueId=407376&parentIssueTypeId=12

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Failure to adhere to the above provisions could result in removal from the approved distribution list. If you think you received this email in error, please send an email to FDAReportableFoods@fda.hhs.gov immediately.

{

Report Details - EON-390104

ICSR:	2068046		
Type Of Submission:	Followup		
Report Version:	FPSR.FDA.PETF.V.V1		
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)		
Reporting Type:	Voluntary		
Report Submission Date:	2019-06-10 17:24:05 EDT		
Initial Report Date:	02/24/2019		
Parent ICSR:	2063115		
Follow-up Report to FDA Request:	Yes		
Reported Problem:	**Problem Description:**	DCM and CHF diagnosed 2/16/19. Eating multiple BEG diets Taurine and troponin pending Dog changed to Purina HA vegetarian dry while in hospital and owner has continued this. Will try switching to Pro Plan Sensitive Skin and Stomach Salmon when bag of HA runs out. If she tolerates that, will stay on it. If not, will switch back to HA since she's done well on that.	
	Date Problem Started:	02/16/2019	
	Concurrent Medical Problem:	Yes	
	Pre Existing Conditions:	Diarrhea would develop 2-3 weeks after starting a new food. Owner rotated foods to try to avoid this.	
	Outcome to Date:	Better/Improved/Recovering	
Product Information:	**Product Name:**	Acana, Natural Balance, Petcurean (see diet history for additional details)	
	Product Type:	Pet Food	
	Lot Number:		
	Package Type:	BAG	
	Product Use Information:	**Description:**	Please see diet history for more info ("Natural Products" written on diet history form is "Natural Balance"
	Manufacturer /Distributor Information:		
	Purchase Location Information:		
Animal Information:	**Name:**	B6	
	Type Of Species:	Dog	
	Type Of Breed:	Terrier - Bull - American Pit	
	Gender:	Female	
	Reproductive Status:	Neutered	
	Weight:	18 Kilogram	
	Age:	B6 Years	
	Assessment of Prior Health:	Excellent	
	Number of Animals Given the Product:	1	
	Number of Animals Reacted:	1	
	Owner Information:	**Owner Information provided:**	Yes
		Contact:	**Name:** B6
			Phone:
			Email:
		Address:	B6

FDA-CVM-FOIA-2019-1704-010442

			B6 United States
	Healthcare Professional Information:	Practice Name:	Tufts Cummings School of Veterinary Medicine
		Contact:	Name: Lisa Freeman Phone: (508) 887-4523 Email: lisa.freeman@tufts.edu
		Address:	200 Westboro Rd North Grafton Massachusetts 01536 United States
Sender Information:	Name:		Lisa Freeman
	Address:		200 Westboro Rd North Grafton Massachusetts 01536 United States
	Contact:	Phone:	5088874523
		Email:	lisa.freeman@tufts.edu
	Permission To Contact Sender:		Yes
	Preferred Method Of Contact:		Email
Additional Documents:			
	Attachment:		Diet hx 5-13-2019.pdf
	Description:		Diet History form
	Type:		Medical Records
	Attachment:		Troponin 3-6-2019.pdf
	Description:		Lab work
	Type:		Laboratory Report
	Attachment:		Follow-up records pt 2.pdf
	Description:		Medical Records
	Type:		Medical Records
	Attachment:		Follow-up records pt 1.pdf
	Description:		Medical Records
	Type:		Medical Records
	Attachment:		Recheck chem 21 5-13-2019.pdf
	Description:		Lab work
	Type:		Laboratory Report

FDA-CVM-FOIA-2019-1704-010443

B6

CARDIOLOGY DIET HISTORY FORM
Please answer the following questions about your pet

Pet's name: B6 Owner's name: B6 Today's date: 5/13/19

1. How would you assess your pet's appetite? (mark the point on the line below that best represents your pet's appetite)

Example: **Poor**_____|_____**Excellent**

Poor_____/_____**Excellent**

2. Have you noticed a change in your pet's appetite over the last 1-2 weeks? (check all that apply)
☒ Eats about the same amount as usual ☐ Eats less than usual ☐ Eats more than usual
☐ Seems to prefer different foods than usual ☐ Other_____

3. Over the last few weeks, has your pet (check one)
☐ Lost weight ☒ Gained weight ☐ Stayed about the same weight ☐ Don't know

1. Please list below ALL pet foods, people food, treats, snack, dental chews, rawhides, and any other food item that your pet currently eats and that you have fed in the last 2 years.

Please provide enough detail that we could go to the store and buy the exact same food - examples are shown in the table

Food (include specific product and flavor)	Form	Amount	How often?	Dates fed
Nutro Grain Free Chicken, Lentil, & Sweet Potato Adult	*dry*	*1 ½ cup*	*2x/day*	*Jan 2016-present*
85% lean hamburger	*microwaved*	*3 oz*	*1x/week*	*June -Aug 2016*
Pupperoni original beef flavor	*treat*	*½*	*1x/day*	*Sept 2016-present*
Rawhide	*treat*	*6 inch twist*	*1x/week*	*Dec 2018-present*
Purina Pro Plan Salmon Sensitive Skin + Stomach	dry	1.5 ~~½~~	X2	my lab - Present

**Any additional diet information can be listed on the back of this sheet*

2. Do you give any dietary supplements to your pet (for example: vitamins, glucosamine, fatty acids, or any other supplements)? ☐ Yes ☐ No If yes, please list which ones and give brands and amounts:

			Brand/Concentration	Amount per day
Taurine	☒ Yes	☐ No	NOW	2 g/day
Carnitine	☐ Yes	☐ No		
Antioxidants	☐ Yes	☐ No		
Multivitamin	☐ Yes	☐ No		
Fish oil	☐ Yes	☐ No		
Coenzyme Q10	☐ Yes	☐ No		
Other (please list):				
Example: Vitamin C			*Nature's Bounty*	*500 mg tablets – 1 per day*

3. How do you administer pills to your pet?
☐ I do not give any medications
☐ I put them directly in my pet's mouth without food
☐ I put them in my pet's dog/cat food
☐ I put them in a Pill Pocket or similar product
☒ I put them in foods (list foods): coconut oil

Client:
Patient: B6

Chem 21 - 5/13/2019

Tufts Cummings School Of Veterinary Medicine

200 Westboro Road
North Grafton, MA 01536

DUPLICATE

Name/DOB:
Patient ID: B6
Phone number:
Collection Date: 5/13/2019 1:50 PM
Approval date: 5/13/2019 2:51 PM

Sex: SF
Age: 5
Species: Canine
Breed: Pit Bull

Provider: B6
Order Location: V320559: Investigation into
Sample ID: 1905130113

Research Chemistry Profile - Small Animal (Cobas)

B6

SMACHUNSKI	Ref. Range/Females
Glucose	67-135 mg/dL
Urea	8-30 mg/dL
Creatinine	0.6-2.0 mg/dL
Phosphorus	2.6-7.2 mg/dL
Calcium 2	9.4-11.3 mg/dL
Magnesium 2+	1.8-3.0 mEq/L
Total Protein	5.5-7.8 g/dL
Albumin	2.8-4.0 g/dL
Globulins	2.3-4.2 g/dL
A/G Ratio	0.7-1.6
Sodium	140-150 mEq/L
Chloride	106-116 mEq/L
Potassium	3.7-5.4 mEq/L
tCO2(Bicarb)	14-28 mEq/L
AGAP	8.0-19.0
NA/K	29-40
Total Bilirubin	0.10-0.30 mg/dL
Alkaline Phosphatase	12-127 U/L
GGT	0-10 U/L
ALT	14-86 U/L
AST	9-54 U/L
Creatine Kinase	22-422 U/L
Cholesterol	82-355 mg/dL
Triglycerides	30-338 mg/dl
Amylase	409-1250 U/L
Osmolality (calculated)	291-315 mmol/L

Sample ID: 1905130113/1
END OF REPORT (Final)

Reviewed by: _____

FDA-CVM-FOIA-2019-1704-010445

Client: B6
Patient:

Idexx NT-proBNP 5/13/2019

IDEXX

B6

PET OWNER: B6
SPECIES: Canine
BREED: Pit Bull, American
GENDER: Female
AGE:
PATIENT ID:

Tufts University Attn: Lisa Freeman
200 Westboro Rd.
North Grafton, MA 01536
508-839-5395
ACCOUNT #: 88933
ATTENDING VET: B6

LAB ID: 2301800020
ORDER ID: 1A
COLLECTION DATE: **5/12/19**
DATE OF RECEIPT: **5/13/19**
DATE OF RESULT: **5/14/19**

IDEXX Services: **Cardiopet® proBNP-Canine***

Chemistry

5/13/19 (Order Received)
5/14/19 11:57 AM (Last Updated)

2/16/19

TEST		RESULT	REFERENCE VALUE		
Cardiopet proBNP (Canine)	a	B6	0 - 900 pmol/L	B6	B6

B6

Please note: Complete interpretive comments for all concentrations of Cardiopet proBNP are available in the online directory of services. Serum specimens received at room temperature may have decreased NT-proBNP concentrations.

Generated by VetConnect® PLUS May 14, 2019 12:50 PM

Page 1 of 1

FDA-CVM-FOIA-2019-1704-010446

Client: B6
Patient:

Troponin 5/31/2019

Gastrointestinal Laboratory
Dr. J.M. Steiner
Department of Small Animal Clinical Sciences
Texas A&M University
4474 TAMU
College Station, TX 77843-4474

Website User ID: lisa.freeman@tufts.edu OR B6

GI Lab Assigned Clinic ID: 23523

B6
Tufts Cummings School of Vet Med - Cardiology/Nutrition
200 Westboro Road
North Grafton, MA 01536
USA

Phone: 508 887 4696
Fax:
Animal Name: B6
Owner Name:
Species: Canine
Date Received: May 30, 2019

Tufts Cummings School of Vet Med - Cardiology/Nutrition Tracking Number: 439571

GI Lab Accession: B6

Test	Result	Reference Interval	Assay Date
Ultra-Sensitive Troponin I Fasting	B6 ng/mL	≤0.06	05/31/19

B6

Comments:

GI Lab Contact Information
Phone: (979) 862-2861
Fax: (979) 862-2864
Email: gilab@cvm.tamu.edu
vetmed.tamu.edu/gilab

FDA-CVM-FOIA-2019-1704-010447

Cummings
Veterinary Medical Center
AT TUFTS UNIVERSITY

Foster Hospital for Small Animals
55 Willard Street
North Grafton, MA 01536
Telephone (508) 839-5395
Fax (508) 839-7951
http://vetmed.tufts.edu/

Discharge Instructions

Patient
Name: B6
Species: Canine
Brown/White Female (Spayed) Pit Bull
Birthdate: B6

Owner
Name: B6
Address: B6

Patient ID: B6

Attending Cardiologist:
☐ John E. Rush DVM, MS, DACVIM (Cardiology), DACVECC
B6

Cardiology Resident:
B6

Cardiology Technician:
B6

Student: B6 V'20

Admit Date: B6 1:00 PM
Discharge Date: B6

Diagnoses: Dilated cardiomyopathy (DCM) with congestive heart failure

Diagnostic test results and findings:

- **Echocardiogram findings:** The heart is smaller and has better contractile function. There is still dilation but there is marked improvement.
- **Labwork findings:** We will call you with the results

Case summary:
Thank you for bringing B6 for her 3 month recheck! He are glad that she is doing well at home and happy she gained weight! On her three month discharge today, her heart function has improved and her heart has decreased in size, however there is enough dilation that requires long term medication. At this point it is unclear whether her problem is a primary heart disease, secondary to diet or a combination of both. Despite there is a marked improvement in her heart, we will still keep her on her current medications and increase the Enalapril dose (see section below).

B6

FDA-CVM-FOIA-2019-1704-010448

Diet suggestions:
B6 can continue with her current diet.

Exercise Recommendations:
B6 can continue with her walks, but should not be stimulated to go any faster than the current pacing rhythm she is on. However, if you find that B6 is lagging behind or needs to stop on a walk then this was too long a walk and shorter walks are advised in the future. Repetitive or strenuous high energy activities (repetitive ball chasing, running fast off-leash, etc.) are generally not advised at this stage.

Recheck Visits:
You have a recheck visit scheduled for **Friday, August 16th at 2 pm.** Please contact our Cardiology liaison at (508)-887-4696 or email us at cardiovet@tufts.edu for scheduling and non-emergent questions or concerns.

Please visit our HeartSmart website for more information
http://vet.tufts.edu/heartsmart/

Prescription Refill Disclaimer:
For the safety and well-being of our patients, your pet must have had an examination by one of our veterinarians within the past year in order to obtain prescription medications.

Ordering Food:
Please check with your primary veterinarian to purchase the recommended diet(s). If you wish to purchase your food from us, please call 7-10 days in advance (508-887-4629) to ensure the food is in stock. Alternatively, veterinary diets can be ordered from online retailers with a prescription/veterinary approval.

Clinical Trials:
Clinical trials are studies in which our veterinary doctors work with you and your pet to investigate a specific disease process or a promising new test or treatment. Please see our website: vet.tufts.edu/cvmc/clinical-studies

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FDA-CVM-FOIA-2019-1704-010449

Cummings
Veterinary Medical Center
AT TUFTS UNIVERSITY
Cardiology Liaison: 508-887-4696

B6

Patient ID: B6
B6 Canine
Years Old Female (Spayed) Pit Bull
Brown/White

Cardiology Appointment Report

Date: B6

Attending Cardiologist:
☐ John E. Rush DVM, MS, DACVIM (Cardiology), DACVECC
B6

Cardiology Resident:
B6

Cardiology Technician:
B6

Student: B6 V'20

Presenting Complaint:
Recheck
Doing well at home, breathing rate still pretty low, short walks again (10-15min) and doing fine, does not appear lame in the hind.
O is not checking respiratory rate at home.

Concurrent Diseases:
DCM;

General Medical History:
- 3 months ago, came in through ER

Diet and Supplements:
Purina Pro-Plan Sensitive

Cardiovascular History:
Prior CHF diagnosis? Yes
Prior heart murmur? Unknown
Prior ATE? No
Prior arrhythmia? No
Monitoring respiratory rate and effort at home? Yes, high 20s-low 30s consistently, some effort; stopped monitoring in past few months, breathing better but has not been counting
Cough? No, very rarely, when drinking water

Shortness of breath or difficulty breathing? No
Syncope or collapse? No
Sudden onset lameness? No
Exercise intolerance? No, haven't been doing too much exercise, 10-15 minutes walks in past month, has been doing well on those

Current Medications Pertinent to CV System:

B6

Cardiac Physical Examination:

B6

Muscle condition:

- [x] Normal
- [ ] Mild muscle loss
- [ ] Moderate cachexia
- [ ] Marked cachexia

Cardiovascular Physical Exam:

Murmur Grade:

- [ ] None
- [ ] I/VI
- [x] II/VI
- [ ] III/VI
- [ ] IV/VI
- [ ] V/VI
- [ ] VI/VI

Murmur location/description: -

Jugular vein:

- [x] Bottom 1/3 of the neck
- [ ] Middle 1/3 of the neck
- [ ] 1/2 way up the neck
- [ ] Top 2/3 of the neck

Arterial pulses:

- [ ] Weak
- [ ] Fair
- [x] Good
- [ ] Strong
- [ ] Bounding
- [ ] Pulse deficits
- [ ] Pulsus paradoxus
- [ ] Other:

Arrhythmia:

- [ ] None
- [x] Sinus arrhythmia
- [ ] Premature beats
- [ ] Bradycardia
- [ ] Tachycardia

Gallop:

- [ ] Yes
- [x] No
- [ ] Intermittent
- [ ] Pronounced
- [ ] Other:

Pulmonary assessments:

- [x] Eupneic
- [ ] Pulmonary crackles

- ☐ Mild dyspnea
- ☐ Marked dyspnea
- ☑ Normal BV sounds
- ☐ Wheezes
- ☐ Upper airway stridor

Abdominal exam:

- ☑ Normal
- ☐ Hepatomegaly
- ☐ Abdominal distension
- ☐ Mild ascites
- ☐ Marked ascites

Problems:

- DCM (diet induced vs. primary)
- History of CHF;
- Allergies / GI disturbances

Diagnostic plan:

- ☑ Echocardiogram
- ☑ Chemistry profile
- ☐ ECG
- ☐ Renal profile
- ☐ Blood pressure
- ☐ Dialysis profile
- ☐ Thoracic radiographs
- ☑ NT-proBNP
- ☑ Troponin I
- ☐ Other tests:

Echocardiogram Findings:

B6

Mitral inflow:

- ☐ Summated
- ☑ Normal
- ☐ Delayed relaxation
- ☐ Pseudonormal
- ☐ Restrictive

ECG findings:

HR: 108bpm

Normal sinus rhythm during echocardiogram.

Assessment and recommendations:

Patient improved clinically and energy level is back to normal. Echocardiogram revealed improved systolic function and LA size, however still lower than desirable. PHTN is decreased, likely due to management of CHF overall and improved systolic function. Blood work revealed normal kidney values, thes B6 B6 Recommend B6 Recommend recheck echocardiogram in 3 months.

Final Diagnosis:

DCM with history of L-CHF.

FDA-CVM-FOIA-2019-1704-010453

Heart Failure Classification Score:

ISACHC Classification:

- ☐ Ia
- ☐ Ib
- ☑ II
- ☐ IIa
- ☐ IIb

ACVIM Classification:

- ☐ A
- ☐ B1
- ☐ B2
- ☑ C
- ☐ D

M-Mode

B6

IVSd	cm
LVIDd	cm
LVPWd	cm
IVSs	cm
LVIDs	cm
LVPWs	cm
EDV(Teich)	ml
ESV(Teich)	ml
EF(Teich)	%
%FS	%
SV(Teich)	ml
Max LA	cm
Ao Diam	cm
LA Diam	cm
LA/Ao	
TAPSE	cm
EPSS	cm

2D

B6

SA LA	cm
Ao Diam	cm
SA LA / Ao Diam	
IVSd	cm
LVIDd	cm
LVPWd	cm
EDV(Teich)	ml
IVSs	cm
LVIDs	cm
LVPWs	cm
ESV(Teich)	ml
EF(Teich)	%
%FS	%
SV(Teich)	ml
LV Major	cm
LV Minor	cm
Sphericity Index	
LVLd A4C	cm

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LVEDV MOD A4C	B6	ml
LVLs A4C		cm
LVESV MOD A4C		ml
LVEF MOD A4C		%
SV MOD A4C		ml

Doppler

MR Vmax	B6	m/s
MR maxPG		mmHg
MV E Vel		m/s
MV DecT		ms
MV Dec Slope		m/s
MV A Vel		m/s
MV E/A Ratio		
E'		m/s
E/E'		
A'		m/s
IVRT		ms
AV Vmax		m/s
AV maxPG		mmHg
PV Vmax		m/s
PV maxPG		mmHg
TR Vmax		m/s
TR maxPG		mmHg

FDA-CVM-FOIA-2019-1704-010455

Tufts Cummings School Of Veterinary Medicine
200 Westboro Road
North Grafton, MA 01536

DUPLICATE

Name/DOB: B6
Patient ID:
Phone number:
Collection Date: B6 1:50 PM
Approval date: 2:51 PM
Sex: SF
Age: 5
Species: Canine
Breed: Pit Bull
Provider: B6
Order Location: V320539: Investigation into
Sample ID: 1905130113

Research Chemistry Profile - Small Animal (Cobas)

SMACHUNSKI B6

	Ref. Range/Females
Glucose	67-135 mg/dL
Urea	8-30 mg/dL
Creatinine	0.6-2.0 mg/dL
Phosphorus	2.6-7.2 mg/dL
Calcium 2	9.4-11.3 mg/dL
Magnesium 2+	1.8-3.0 mEq/L
Total Protein	5.5-7.8 g/dL
Albumin	2.8-4.0 g/dL
Globulins	2.3-4.2 g/dL
A/G Ratio	0.7-1.6
Sodium	140-150 mEq/L
Chloride	106-116 mEq/L
Potassium	3.7-5.4 mEq/L
tCO2(Bicarb)	14-28 mEq/L
AGAP	8.0-19.0
NA/K	29-40
Total Bilirubin	0.10-0.30 mg/dL
Alkaline Phosphatase	12-127 U/L
GGT	0-10 U/L
ALT	14-86 U/L
AST	9-54 U/L
Creatine Kinase	22-422 U/L
Cholesterol	82-355 mg/dL
Triglycerides	30-338 mg/dl
Amylase	409-1250 U/L
Osmolality (calculated)	291-315 mmol/L

Sample ID: 1905130113/1
END OF REPORT (Final)

Reviewed by: _____

FDA-CVM-FOIA-2019-1704-010456

Gastrointestinal Laboratory
Dr. J.M. Steiner
Department of Small Animal Clinical Sciences
Texas A&M University
4474 TAMU
College Station, TX 77843-4474

Website User ID: Cardiovet@tufts.edu OR clinpath@tufts.edu

GI Lab Assigned Clinic ID: 11405

B6
Tufts University-Clinical Pathology Lab
Attn: B6
200 Westboro Road
North Grafton, MA 01536
USA

Phone: 508 887 4669
Fax: 9 508 839 7936
Animal Name: B6
Owner Name:
Species: Canine
Date Received: Mar 06, 2019

GI Lab Accession: B6

Test	Result	Control Range	Assay Date
Ultra-Sensitive Troponin I Fasting	B6 ng/mL	≤0.06	03/06/19

B6

Comments:

Important Notices:

Internal Medicine Conference

Join us for a unique continuing education event in Phuket, Thailand Oct 7th - 11th, 2019. For details see http://texasimconference.tamu.edu

Ongoing studies

Cobalamin Supplementation Study- Dogs and cats with cobalamin deficiency with normal PLI, and either normal or low(consistent with EPI) TLI to compare the efficacy of oral vs parenteral cobalamin supplementation. Contact Dr. Chang at chchang@cvm.tamu.edu for further information.

Chronic Pancreatitis with Uncontrolled Diabetes Mellitus- Seeking dogs with chronic pancreatitis and uncontrolled diabetes mellitus for enrollment into a drug trial(medication provided at no cost). Contact Dr. Sue Yee Lim at slim@cvm.tamu.edu or Dr. Sina Marsilio at smarsilio@cvm.tamu.edu

Dogs with Primary Hyperlipidemia- Prescription diet naïve dogs newly diagnosed with primary hyperlipidemia are eligible to be enrolled in a dietary trial. Contact Dr. Lawrence at ylawrence@cvm.tamu.edu for more information.

Dogs with Chronic Pancreatitis-Dogs with chronic pancreatitis (cPLi >400µg/L) and hypertriglyceridemia (>300 mg/dl) are eligible to be enrolled in a dietary trial. Contact Dr. Lawrence at ylawrence@cvm.tamu.edu

Chronic enteropathies in dogs-Please fill out this brief form http://tinyurl.com/ibd-enroll to see if your patient qualifies.

Feline Chronic Pancreatitis- Cats with chronic pancreatitis for more than 2 weeks and fPLI >10 µg/L are eligible for enrollment into a treatment trial investigating the efficacy of prednisolone or cyclosporine. Please contact Dr. Yamkate for further information at pyamkate@cvm.tamu.edu.

We can not accept packages that are marked "Bill Receiver"

Use our preprinted shipping labels to save on shipping. Call 979-862-2861 for assistance. The GI Lab is not here to accept packages on the weekend. Samples may be compromised if you ship for arrival on Saturday or Sunday or if shipped via US Mail.

GI Lab Contact Information

Phone: (979) 862-2861
Fax: (979) 862-2864
Email: gilab@cvm.tamu.edu
vetmed.tamu.edu/gilab

From: PFR Event <pfreventcreation@fda.hhs.gov>

To: Cleary, Michael *; HQ Pet Food Report Notification; B6

Sent: 5/28/2019 7:41:41 PM

Subject: Bil Jac Picky No More--Small Breed-Persnickety Recipe w/ chicken liver: B6 - EON-388960

Attachments: 2067506-report.pdf; 2067506-attachments.zip

A PFR Report has been received and PFR Event [EON-388960] has been created in the EON System.

A "PDF" report by name "2067506-report.pdf" is attached to this email notification for your reference. Please note that all documents received in the report are compressed into a zip file by name "2067506-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-388960
ICSR #: 2067506
EON Title: PFR Event created for Bil Jac Picky No More® Small Breed Persnickety Recipe w/ chicken liver; 2067506

AE Date	05/17/2019	**Number Fed/Exposed**	1
Best By Date		**Number Reacted**	1
Animal Species	Dog	**Outcome to Date**	Stable
Breed	Spaniel - Cocker American		
Age	B6 Years		
District Involved	PFR-New England DO		

Product information
Individual Case Safety Report Number: 2067506
Product Group: Pet Food
Product Name: Bil Jac Picky No More® Small Breed Persnickety Recipe w/ chicken liver
Description: Patient presented to rDVM 5/17/2019 for evaluation of a cough x 1 month, extreme lethargy and decreased appetite. rDVM suspected CHF based on radiographs and worsening murmur - now a 4/6. A new arrhythmia was also discovered on ECG. Intermmitent sinus rhythm with frequent APCs, occasional paroxysmal SVTs (short duration), isolated and couplet VPCs (LV and RV in origin). Confirmed patient was in left sided

heart failure w/ advanced DMVD and decreased contractile function which is very uncommon with valvular disease.
Submission Type: Initial
Report Type: Adverse Event (a symptom, reaction or disease associated with the product)
Outcome of reaction/event at the time of last observation: Stable
Number of Animals Treated With Product: 1
Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Bil Jac Picky No More® Small Breed Persnickety Recipe w/ chicken liver		

Sender information

B6

USA

Owner information

B6 USA

To view this PFR Event, please click the link below:
https://eon.fda.gov/eon//browse/EON-388960

To view the PFR Event Report, please click the link below:
https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jspa?decorator=none&e=0&issueType=12&issueId=406137

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Report Details - EON-388960

ICSR:	2067506	
Type Of Submission:	Initial	
Report Version:	FPSR.FDA.PETF.V.V1	
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)	
Reporting Type:	Voluntary	
Report Submission Date:	2019-05-28 15:31:05 EDT	
Reported Problem:	**Problem Description:**	Patient presented to rDVM 5/17/2019 for evaluation of a cough x 1 month, extreme lethargy and decreased appetite. rDVM suspected CHF based on radiographs and worsening murmur - now a 4/6. A new arrhythmia was also discovered on ECG. Intermmitent sinus rhythm with frequent APCs, occasional paroxysmal SVTs (short duration), isolated and couplet VPCs (LV and RV in origin). Confirmed patient was in left sided heart failure w/ advanced DMVD and decreased contractile function which is very uncommon with valvular disease.
	Date Problem Started:	05/17/2019
	Concurrent Medical Problem:	Yes
	Pre Existing Conditions:	Previously diagnosed (Jan 2019) with with a 1-2/6 heart murmur - asymptomatic, rDVM rec rechecking in 1 year.
	Outcome to Date:	Stable
Product Information:	**Product Name:**	Bil Jac Picky No More® Small Breed Persnickety Recipe w/ chicken liver
	Product Type:	Pet Food
	Lot Number:	
	Package Type:	BAG
	Product Use Information:	
	Manufacturer /Distributor Information:	
	Purchase Location Information:	
Animal Information:	**Name:**	
	Type Of Species:	Dog
	Type Of Breed:	Spaniel - Cocker American
	Gender:	Female
	Reproductive Status:	Neutered
	Weight:	14 Kilogram
	Age:	B6 Years
	Assessment of Prior Health:	Excellent
	Number of Animals Given the Product:	1
	Number of Animals Reacted:	1
	Owner Information:	**Owner Information provided:** Yes
		Contact: **Name:** B6 **Phone:**
		Address: B6 United States
	Healthcare Professional	**Practice Name:** Tufts Cummings School of Veterinary Medicine

FDA-CVM-FOIA-2019-1704-010462

	Information:	**Contact:**	**Name:** B6
			Phone:
			Email:
		Address:	200 Westboro Road North Grafton Massachusetts 01536 United States
		Practice Name:	Tufts University Cummings School of Veterinary Medicine
		Contact:	**Name:** Lisa Freeman
			Phone: 508 887 4696
		Type of Veterinarian:	Referred veterinarian
		Permission to Release Records to FDA:	Yes
Sender Information:	**Name:**	B6	
	Address:	200 Westboro Road North Grafton Massachusetts 01536 United States	
	Contact:	**Phone:**	B6
		Email:	B6
	Permission To Contact Sender:	Yes	
	Preferred Method Of Contact:	Email	
	Reported to Other Parties:	None	
Additional Documents:			
	Attachment:	Med Rec pt 1.pdf	
	Description:	Medical Records	
	Type:	Medical Records	
	Attachment:	Med Rec pt 2.pdf	
	Description:	Medical Records	
	Type:	Medical Records	

FDA-CVM-FOIA-2019-1704-010463

Cummings Veterinary Medical Center AT TUFTS UNIVERSITY

Foster Hospital for Small Animals
55 Willard Street
North Grafton, MA 01536
(508) 839-5395

All Medical Records

Client: B6
Address:

Patient: B6
Breed: Cocker Spaniel
DOB: B6

Species: Canine
Sex: Female (Spayed)

Home Phone: B6
Work Phone: ( ) -
Cell Phone: B6

Referring Information

B6

Client: B6
Patient:

Initial Complaint:
Emergency

SOAP Text B6 12:21PM - B6

Subjective
NEW VISIT (ER)

Doctor: B6
Student: B6 V20
Presenting complaint: Cough, cardiomegaly, CHF
Referral visit? Y
Diagnostics completed prior to visit:
Chem/SDMA - all WNL
Radiograph - Severe cardiomegaly with dorsal displacement of the trachea and left mainstem bronchi compression. Pulmonary vessels are increased in diameter and lung lobar veins are bigger than the arteries. There is patchy interstitial pattern in the perihilar area. Caudal liver lobes look enlarged.

HISTORY:

Signalment: 10 yo SF Cocker Spaniel
Current history: O noted that in August of 2018, O+P moved from B6 and into an apartment. At this time, O noted anxiety and a cough. O noted that vet in B6 mentioned P had a heart murmur, but O had not noticed a cough until August. O noted that P is on a medication for anxiety but could not remember which medication. O noted that the last 3 months, the cough has gotten a lot worse. It is a constant cough that happens every 1.5 hours and throughout

FDA-CVM-FOIA-2019-1704-010464

the night. O has also noted that P has become exercise intolerant and cannot walk very far without becoming short of breath. O brought P to the rDVM yesterday, 05/17/19 and the vet noted that P is in CHF and has a very enlarged heart. RDVM started P on B6 hrs and referrred P here for an echocardiogram. No S/V/D/PU/PD.
Prior medical history: none
Current medications: B6
Diet: Bill Jack Persnickety Dry BID
Vaccination status/flea & tick preventative use: UTD per O, f/t/hw prevention per O
Travel history: moved from B6 August 2018

EXAM:

B6

C/V: Grade IV/VI heart murmur ausculated. Arrhythmia appreciated. Fair femoral pulses.

B6

ASSESSMENT:
A1: Grade IV/VI heart murmur with arrhythmia and increased respiratory effort - CHF (due to advanced DMVD with active left sided CHF, moderate PHTN
A2: Frequent ventricular and supraventricular arrhythmias
A3:
A4: B6

PLAN:
P1: Cardio consult

P2:
P3:
P4:

B6

FDA-CVM-FOIA-2019-1704-010465

Client: B6
Patient:

B6

P5 B6

Client communication:
Discussed CHF based on rDVM rads, would recommend hospitalization for injectable lasix, O2 therapy, cardio consult/echo, B6 . Told O that should get us an echocardiogram, which will help us understand the underlying issues with B6 heart and can help us determine how best to modify her medications/address arrhythmia. However, is definitely riskier to send her home. O understands, but cannot hospitalize.

After cardio consult, discussed with O findings of active L-CHF, advanced DMVD, arrhythmias. She is a very unstable patient. Goal now is to address these things with medications. Went discharge instructions, went over how to monitor respiration at home, medications and plan for recheck on Friday. O is a little overwhelmed but up to try. Discussed we cannot cure heart failure, our goal is to get B6 through this episode and try to prolong the amount of time until the next episode, however it will happen again at some point.

Deposit & estimate status:

Resuscitation code (if admitting to ICU):

SOAP approved (DVM to sign): B6 DVM

Initial Complaint:
Recheck - B6 - consult thru ER (DMVD/DCM study?)

Disposition/Recommendations

FDA-CVM-FOIA-2019-1704-010466

FDA-CVM-FOIA-2019-1704-010467

Cummings Veterinary Medical Center
AT TUFTS UNIVERSITY

Foster Hospital for Small Animals
55 Willard Street
North Grafton, MA 01536
(508) 839-5395

Client:	B6
Veterinarian:	
Patient ID:	B6
Visit ID:	

Patient:	B6
Species:	Canine
Breed:	Cocker Spaniel
Sex:	Female (Spayed)
Age:	B6 Years Old

Lab Results Report

None **5/18/2019 12:44:43 PM** **Accession ID:** B6

Test	Results	Reference Range	Units
AGAP (i-STAT)		8 - 25	mmol/L
AGAP (i-STAT)		8 - 25	mmol/L
Hb		12 - 17	g/dL
Hb		12 - 17	g/dL
HCT		35 - 50	%
HCT		35 - 50	%
Creat		0.5 - 1.3	
Creat		0.5 - 1.3	
BUN		10 - 26	mg/dL
BUN		10 - 26	mg/dL
K+	B6	3.4 - 4.9	mEq/L
Glucose (i-STAT)		60 - 115	mg/dL
Glucose (i-STAT)		60 - 115	mg/dL
iCa		1.12 - 1.4	mmol/L
TCO2		17 - 25	mmol/L
TCO2		17 - 25	mmol/L
iCa		1.12 - 1.4	mmol/L
iCa		1.12 - 1.4	mmol/L
Cl-		106 - 127	mEq/L
Cl-		106 - 127	mEq/L
K+		3.4 - 4.9	mEq/L

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K+	B6	3.4 - 4.9	mEq/L
Na *		142 - 150	mEq/L
Na *		142 - 150	mEq/L

None **5/18/2019 12:45:42 PM** **Accession ID:** B6

Test	Results	Reference Range	Units
TS (FIISA)	B6	0 - 0	g/dl
PCV **		0 - 0	%
TS (FHSA)		0 - 0	g/dl

None **5/24/2019 3:29:26 PM** **Accession ID:** B6

Test	Results	Reference Range	Units
GLUCOSE	B6	67 - 135	mg/dL
UREA		8 - 30	mg/dL
CREATININE		0.6 - 2	mg/dL
PHOSPHORUS		2.6 - 7.2	mg/dL
CALCIUM2		9.4 - 11.3	mg/dL
MAGNESIUM 2+		1.8 - 3	mEq/L
T. PROTEIN		5.5 - 7.8	g/dL
ALBUMIN		2.8 - 4	g/dL
GLOBULINS		2.3 - 4.2	g/dL
A/G RATIO		0.7 - 1.6	
SODIUM		140 - 150	mEq/L
CHLORIDE		106 - 116	mEq/L
POTASSIUM		3.7 - 5.4	mEq/L
tCO2 (BICARB)		14 - 28	mEq/L
AGAP		8 - 19	
NA/K		29 - 40	
T BILIRUBIN		0.1 - 0.3	mg/dL
ALK PHOS		12 - 127	U/L
GGT		0 - 10	U/L
ALT		14 - 86	U/L
AST		9 - 54	U/L
CK		22 - 422	U/L
CHOLESTEROL		82 - 355	mg/dL
TRIGLYCERIDES		30 - 338	mg/dl
AMYLASE		409 - 1250	U/L
OSMOLALITY (CALCULATED)		291 - 315	mmol/L
COMMENTS (CHEMISTRY)		0 - 0	

Moderate hemolysis Moderate lipemia

FDA-CVM-FOIA-2019-1704-010469

Patient History Report

Client: B6
Phone:
Address:

Patient: B6
Species: Canine
Age: B6
Color: Black/Tan

Breed: Spaniel, Cocker
Sex: Spayed Female

Date	Type	Staff	History
5/18/2019	TC	B6	pc from owner - she is going to call Tufts and try to get in today - TENTATIVE
5/18/2019	TC	B6	P.C. lab results and recommendations - TENTATIVE Called B6 with Chem results (all wnl). She feels like B6 is doing better; advise continue B6 at present dose until evaluated by cardiologist. She will pursue echo at B6 where her children take their pets. I stressed need cardiologist and if they do not have one available within several days, she can contact us so we can get get info to a referral institution of her choice. B6 today, or B6 or Tufts next week.)
B6		B6	********HAH Blank Document - FINAL B6 Check-couch Veterinarian: B6 DVM B6 Patient Name: B6

Technician: B6

Reason for Visit: cough

	B6	B6
	10:39 AM	3:35 PM
Vital Sign	B6	

B:Billing, C:Med note, CB:Call back, CK:Check-in, CM:Communications, D:Diagnosis, DH:Declined to history, E:Examination, ES:Estimates, I:Departing instr, L:Lab result, M:Image cases, P:Prescription, PA:PVL Accepted, PB:problems, PP:PVL Performed, PR:PVL Recommended, R:Correspondence, T:Images, TC:Tentative medl note, V:Vital signs

FDA-CVM-FOIA-2019-1704-010470

Patient History Report

Client: B6
Phone:
Address:

Patient: B6
Species: Canine
Age: B6
Color: Black/Tan
Breed: Spaniel, Cocker
Sex: Spayed Female

Date	Type	Staff	History
Weight	26 pounds		29 pounds

O reports that B6 has had a cough for about a month now. O says it sounds like a hacking cough. She has no contact with other dogs. O says that B6 had told her that her heart murmer could cause a cough at her last visit. O says that her appetite is normal but that she does have slightly looser stools. O says that she is acting very lethargic. Temp 101.4

Exam: Pigmentary keratitis ventral 1/3 cornea OD. Bilat mild ceruminous otitis. Moderate to severe P+C. Grade 3-4/6 cardiac murmur; some arrythmias ascultated. Mild dypnea; color and CRT wnl.
Lateral thorax: generalized cardiomyopathy, dorsal caudal increased interstitial pattern
A: Cough, long standing murmur, evidence of generalized heart enlargement and CHF
P: Discussed findings with owner. Emphasized seriousness of CHF and need for cardiac evaluation. Chem drawn: administered B6 2 q 6 hours starting 8 p.m. tonight. Advise echo consult ASAP.

B6 TC B6 B6 Technician History - TENTATIVE
Technician: B6

Reason for Visit: cough

	B6 10:39 AM	B6 3:35 PM
Vital Sign	CD	TLD
Weight	26 pounds	29 pounds

O reports that B6 has had a cough for about a month now. O says it sounds like a hacking cough. She has no contact with other dogs. O says that B6 had told her that her heart murmer could cause a cough at her last visit. O says that her appetite is normal but that she does have slightly looser stools. O says that she is acting very lethargic. Temp 101.4

B:Billing, C:Med note, CB:Call back, CK:Check-in, CM:Communications, D:Diagnosis, DH:Declined to history, E:Examination, ES:Estimates, I:Departing instr, L:Lab result, M:Image cases, P:Prescription, PA:PVL Accepted, PB:problems, PP:PVL Performed, PR:PVL Recommended, R:Correspondence, T:Images, TC:Tentative medl note, V:Vital signs

FDA-CVM-FOIA-2019-1704-010471

Patient History Report

Client: B6
Phone:
Address:

Patient: B6
Species: Canine
Age: B6
Color: Black/Tan

Breed: Spaniel, Cocker
Sex: Spayed Female

Date	Type	Staff	History

5/17/2019 L B6

Chemistry results from IDEXX Reference Laboratory Requisition
ID: B6 Posted Final

Test	Result	Reference Range
ALB	B6	2.7 - 3.9
ALKP		5 - 160
ALT		18 - 121
AMYL		337 - 1469
ANION GAP		11 - 26
AST		16 - 55
BICARB		13 - 27
BUN/UREA		9 - 31
Ca		8.4 - 11.8
Chloride		108 - 119
CHOL		131 - 345
CREA		0.5 - 1.5
DBIL		0.0 - 0.1
GGT		0 - 13
GLU		63 - 114
IBIL		0.0 - 0.2
LIPA		138 - 755
PHOS		2.5 - 6.1
Potassium		4.0 - 5.4
TBIL		0.0 - 0.3
TP		5.5 - 7.5
Sodium		142 - 152
A/G Ratio		0.7 - 1.5
B/C Ratio		
Na/K Ratio		28 - 37
GLOB		2.4 - 4.0
CK		10 - 200
SDMA		0 - 14

Ascn: B6

RE: 281 HEMOLYSIS INDEX N
Index of N, 1+, 2+ exhibits no significant effect on chemistry values.
RE: 282 LIPEMIA INDEX N
Index of N, 1+, 2+ exhibits no significant effect on chemistry values.

BOTH SDMA AND CREATININE ARE WITHIN THE REFERENCE INTERVAL which indicates
kidney function is likely good. Evaluate a complete urinalysis and confirm
there is no other evidence of kidney disease.

B:Billing, C:Med note, CB:Call back, CK:Check-in, CM:Communications, D:Diagnosis, DH:Declined to history, E:Examination, ES:Estimates, I:Departing instr, L:Lab result, M:Image cases, P:Prescription, PA:PVL Accepted, PB:problems, PP:PVL Performed, PR:PVL Recommended, R:Correspondence, T:Images, TC:Tentative medl note, V:Vital signs

FDA-CVM-FOIA-2019-1704-010472

Patient History Report

Client: B6
Phone:
Address:

Patient: B6
Species: Canine
Age: B6
Color: Black/Tan

Breed: Spaniel, Cocker
Sex: Spayed Female

Date	Type	Staff	History

B:Billing, C:Med note, CB:Call back, CK:Check-in, CM:Communications, D:Diagnosis, DH:Declined to history, E:Examination, ES:Estimates, I:Departing instr, L:Lab result, M:Image cases, P:Prescription, PA:PVL Accepted, PB:problems, PP:PVL Performed, PR:PVL Recommended, R:Correspondence, T:Images, TC:Tentative medl note, V:Vital signs

FDA-CVM-FOIA-2019-1704-010473

B6 Animal Hospital Records

Patient History Report

Client: B6
Phone:
Address:

Patient: B6
Species: Canine
Age: B6
Color: Black/Tan

Breed: Spaniel, Cocker
Sex: Spayed Female

Date	Type	Staff	History
5/18/2019	TC	B6	pc from owner - she is going to call Tufts and try to get in today - TENTATIVE
5/18/2019	TC	B6	P.C. lab results and recommendations - TENTATIVE Called B6 with Chem results (all wnl). She feels like B6 is doing better; advise continue Furosemide at present dose until evaluated by cardiologist. She will pursue echo at B6 where her children take their pets. I stressed need cardiologist and if they do not have one available within several days, she can contact us so we can get get info to a referral institution of her choice. B6 today, or B6 or Tufts next week.)
5/17/2019	C	B6	******** B6 Blank Document - FINAL B6 - Check cough Veterinarian: B6 DVM B6 Patient Name: B6 Technician: B6 **Reason for Visit: cough** B6 10:39 AM B6 3:35 PM Vital Sign B6

B:Billing, C:Med note, CB:Call back, CK:Check-in, CM:Communications, D:Diagnosis, DH:Declined to history, E:Examination, ES:Estimates, I:Departing instr, L:Lab result, M:Image cases, P:Prescription, PA:PVL Accepted, PB:problems, PP:PVL Performed, PR:PVL Recommended, R:Correspondence, T:Images, TC:Tentative medl note, V:Vital signs

B6 Animal Hospital Records

Patient History Report

Client: B6
Phone:
Address:

Patient: B6
Species: Canine
Age: B6
Color: Black/Tan

Breed: Spaniel, Cocker
Sex: Spayed Female

Date	Type	Staff	History
Weight	26 pounds		29 pounds

O reports that B6 has had a cough for about a month now. O says it sounds like a hacking cough. She has no contact with other dogs. O says that B6 had told her that her heart murmer could cause a cough at her last visit. O says that her appetite is normal but that she does have slightly looser stools. O says that she is acting very lethargic. Temp 101.4

Exam: Pigmentary keratitis ventral 1/3 cornea OD. Bilat mild ceruminous otitis. Moderate to severe P+C. Grade 3-4/6 cardiac murmur; some arrythmias ascultated. Mild dypnea; color and CRT wnl.
Lateral thorax: generalized cardiomyopathy, dorsal caudal increased interstitial pattern
A: Cough, long standing murmur, evidence of generalized heart enlargement and CHF
P: Discussed findings with owner. Emphasized seriousness of CHF and need for cardiac evaluation. Chem drawn: administered B6 2 q 6 hours starting 8 p.m. tonight. Advise echo consult ASAP.

5/17/2019 TC B6 B6 Technician History - TENTATIVE
Technician: B6

Reason for Visit: cough

	B6 11:39 AM	B6 3:35 PM
Vital Sign	B6	
Weight	26 pounds	29 pounds

O reports that B6 has had a cough for about a month now. O says it sounds like a hacking cough. She has no contact with other dogs. O says that B6 had told her that her heart murmer could cause a cough at her last visit. O says that her appetite is normal but that she does have slightly looser stools. O says that she is acting very lethargic. Temp 101.4

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FDA-CVM-FOIA-2019-1704-010475

B6 Animal Hospital Records

Patient History Report

Client: B6
Phone:
Address:

Patient: B6
Species: Canine
Age: B6
Color: Black/Tan

Breed: Spaniel, Cocker
Sex: Spayed Female

Date	Type	Staff	History

5/17/2019 L B6

Chemistry results from IDEXX Reference Laboratory Requisition
ID: B6 Posted Final

Test	Result	Reference Range
ALB	B6	2.7 - 3.9
ALKP		5 - 160
ALT		18 - 121
AMYL		337 - 1469
ANION GAP		11 - 26
AST		16 - 55
BICARB		13 - 27
BUN/UREA		9 - 31
Ca		8.4 - 11.8
Chloride		108 - 119
CHOL		131 - 345
CREA		0.5 - 1.5
DBIL		0.0 - 0.1
GGT		0 - 13
GLU		63 - 114
IBIL		0.0 - 0.2
LIPA		138 - 755
PHOS		2.5 - 6.1
Potassium		4.0 - 5.4
TBIL		0.0 - 0.3
TP		5.5 - 7.5
Sodium		142 - 152
A/G Ratio		0.7 - 1.5
B/C Ratio		
Na/K Ratio		28 - 37
GLOB		2.4 - 4.0
CK		10 - 200
SDMA		0 - 14

Ascn: B6

RE: 281 HEMOLYSIS INDEX N
Index of N, 1+, 2+ exhibits no significant effect on chemistry values.
RE: 282 LIPEMIA INDEX N
Index of N, 1+, 2+ exhibits no significant effect on chemistry values.

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B6 Animal Hospital Records

Patient History Report

Client: B6
Phone:
Address:

Patient: B6
Species: Canine
Age: B6
Color: Black/Tan

Breed: Spaniel, Cocker
Sex: Spayed Female

Date	Type	Staff	History

B:Billing, C:Med note, CB:Call back, CK:Check-in, CM:Communications, D:Diagnosis, DH:Declined to history, E:Examination, ES:Estimates, I:Departing instr, L:Lab result, M:Image cases, P:Prescription, PA:PVL Accepted, PB:problems, PP:PVL Performed, PR:PVL Recommended, R:Correspondence, T:Images, TC:Tentative medl note, V:Vitalsigns

FDA-CVM-FOIA-2019-1704-010477

Client:
Patient: B6

Chem 5/24/2019

Tufts Cummings School Of Veterinary Medicine

200 Westboro Road
North Grafton, MA 01536

DUPLICATE

Name/DOB: B6
Patient ID:
Phone number:
Collection Date: 5/24/2019 3:29 PM
Approval date: 5/24/2019 4:18 PM

Sex: SF
Age: 10
Species: Canine
Breed: Cocker Spaniel

Provider: B6
Order Location: V320559: Investigation into
Sample ID: 1905240076

Research Chemistry Profile - Small Animal (Cobas)

B6

CSTCYR	Ref. Range/Females
Glucose	67-135 mg/dL
Urea	8-30 mg/dL
Creatinine	0.6-2.0 mg/dL
Phosphorus	2.6-7.2 mg/dL
Calcium 2	9.4-11.3 mg/dL
Magnesium 2+	1.8-3.0 mEq/L
Total Protein	5.5-7.8 g/dL
Albumin	2.8-4.0 g/dL
Globulins	2.3-4.2 g/dL
A/G Ratio	0.7-1.6
Sodium	140-150 mEq/L
Chloride	106-116 mEq/L
Potassium	3.7-5.4 mEq/L
tCO2(Bicarb)	14-28 mEq/L
AGAP	8.0-19.0
NA/K	29-40
Total Bilirubin	0.10-0.30 mg/dL
Alkaline Phosphatase	12-127 U/L
GGT	0-10 U/L
ALT	14-86 U/L
AST	9-54 U/L
Creatine Kinase	22-422 U/L
Cholesterol	82-355 mg/dL
Triglycerides	30-338 mg/dl
Amylase	409-1250 U/L
Osmolality (calculated)	291-315 mmol/L
Comments (Chemistry)	

Sample ID: 1905240076/1
END OF REPORT (Final)

Reviewed by: _____

FDA-CVM-FOIA-2019-1704-010478

Client: B6
Patient:

Diet Hx 5/24/2019

CARDIOLOGY DIET HISTORY FORM

Please answer the following questions about your pet

Pet's name: B6 Owner's name: B6 Today's date: 5-24-2019

1. How would you assess your pet's appetite? (mark the point on the line below that best represents your pet's appetite)
   Example: **Poor**_____**Excellent**

   Poor_____**Excellent**

2. Have you noticed a change in your pet's appetite over the last 1-2 weeks? (check all that apply)
   ☐Eats about the same amount as usual ☒Eats less than usual ☐Eats more than usual
   ☐Seems to prefer different foods than usual ☐Other_____

3. Over the last few weeks, has your pet (check one)
   ☒Lost weight ☐Gained weight ☐Stayed about the same weight ☐Don't know

1. Please list below ALL pet foods, people food, treats, snack, dental chews, rawhides, and any other food item that your pet currently eats and that you have fed in the last 2 years.

   Please provide enough detail that we could go to the store and buy the exact same food - examples are shown in the table

Food (include specific product and flavor)	Form	Amount	How often?	Dates fed
Nutro Grain Free Chicken, Lentil, & Sweet Potato Adult	*dry*	*1 ½ cup*	*2x/day*	*Jan 2016-present*
85% lean hamburger	*microwaved*	*3 oz*	*1x/week*	*June -Aug 2016*
Pupperoni original beef flavor	*treat*	*½*	*1x/day*	*Sept 2016-present*
Rawhide	*treat*	*6 inch twist*	*1x/week*	*Dec 2018-present*
CALL OF THE WILD / BLUE JAC	DRY	½ cup	2x/day	JULY 2018-present
CHICKEN -	BOILED			
RICE				
MILK BONE SOFT TREATS	TREAT	6	A DAY	

**Any additional diet information can be listed on the back of this sheet*

2. Do you give any dietary supplements to your pet (for example: vitamins, glucosamine, fatty acids, or any other supplements)? ☐Yes ☒No If yes, please list which ones and give brands and amounts:

		Brand/Concentration	Amount per day
Taurine	☐Yes ☐No		
Carnitine	☐Yes ☐No		
Antioxidants	☐Yes ☐No		
Multivitamin	☐Yes ☐No		
Fish oil	☐Yes ☐No		
Coenzyme Q10	☐Yes ☐No		
Other (please list):			
Example: Vitamin C		*Nature's Bounty*	*500 mg tablets – 1 per day*

3. How do you administer pills to your pet?
   ☐ I do not give any medications
   ☒ I put them directly in my pet's mouth without food
   ☒ I put them in my pet's dog/cat food
   ☐ I put them in a Pill Pocket or similar product
   ☐ I put them in foods (list foods): Dog food

FDA-CVM-FOIA-2019-1704-010479

Client: B6
Patient: B6

B6 - NTproBNP 5/25/2019

IDEXX Reference Laboratories

Client: B6 Patient: B6

B6

Client: B6
Patient: B6
Species: CANINE
Breed: COCKER_SPANIEL
Gender: FEMALE S PAYED
Age: 10Y

Date: 05/24/2019
Requisition #: J
Accession #: B6
Ordered by: B6

TUFTS UNIVERSITY
200 WESTBORO RD
NORTH GRAFTON, Massachusetts 01536
508-839-5395

Account: B6

CARDIOPET proBNP - CANINE

Test	Result	Reference Range	Low	Normal	High
CARDIOPET proBNP - CANINE	B6	0 - 900 pmol/L	HIGH	B6	

Comments:

1. Cardiopet proBNP >1800pmol/L

B6

Please note: Complete interpretive comments for all concentrations of Cardiopet proBNP are available in the online directory of services. Serum specimens received at room temperature may have decreased NT-proBNP concentrations.

Page 1 of 1

FDA-CVM-FOIA-2019-1704-010480

Client: B6
Patient:

Vitals Results

B6	11:14:07 AM 11:14:08 AM 11:14:09 AM 11:14:10 AM 12:43:53 PM 12:54:58 PM 1:33:08 PM 1:33:09 PM 1:33:10 PM 1:33:11 PM 3:08:13 PM 4:11:00 PM 12:04:05 PM	B6

FDA-CVM-FOIA-2019-1704-010481

FDA-CVM-FOIA-2019-1704-010482

Client: B6
Patient:

EKG from cardio

B6 B6 12:42:53 PM
Tufts University
Tufts Cummings School of Vet Med
Cardiology

FDA-CVM-FOIA-2019-1704-010483

Client: B6
Patient:

EKG from cardio

B6 B6 12:44:32 PM Page 1 of 2
Tufts University
Tufts Cummings School of Vet Med
Cardiology

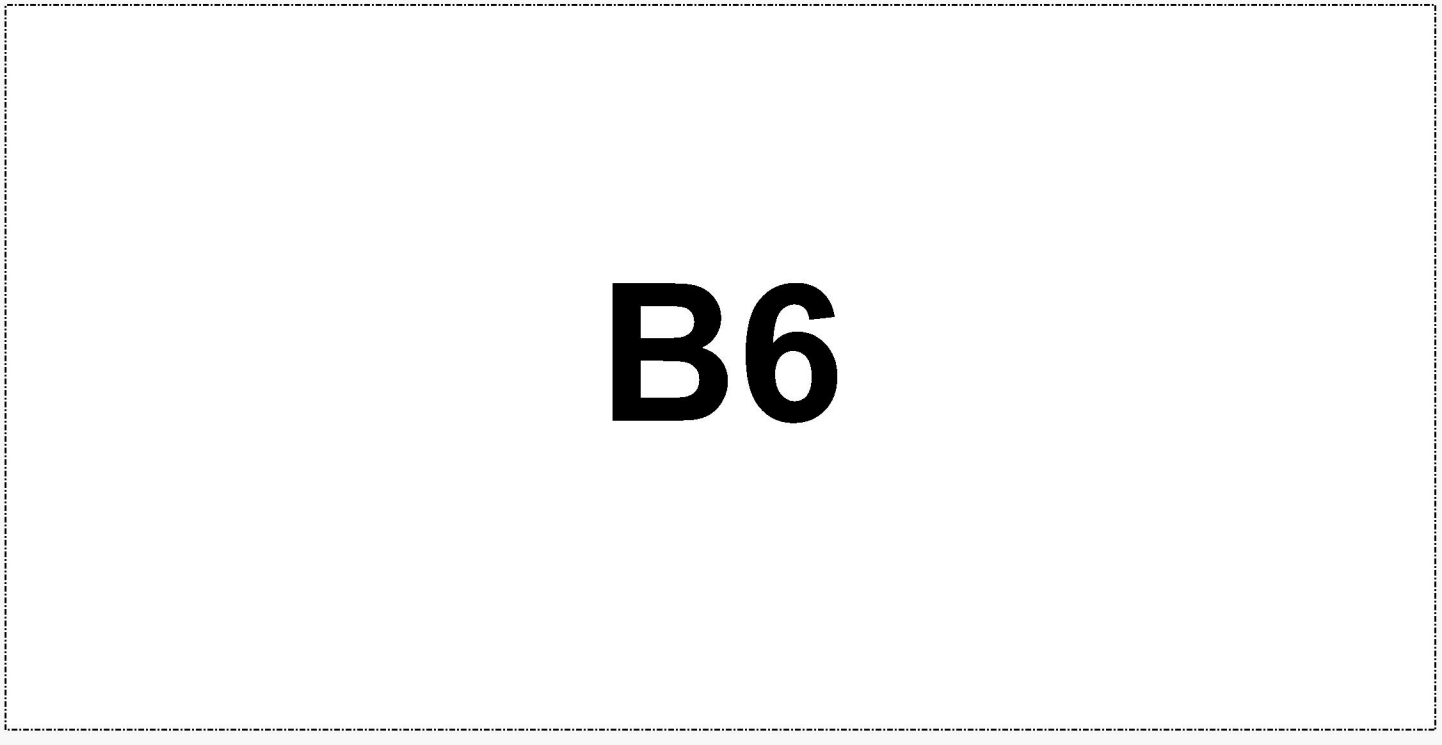
B6

FDA-CVM-FOIA-2019-1704-010484

Client: B6
Patient:

EKG from cardio

B6 B6 12:44:32 PM Page 2 of 2
Tufts University
Tufts Cummings School of Vet Med
Cardiology



FDA-CVM-FOIA-2019-1704-010485

Client: B6
Patient:

EKG from cardio

B6

B6 12:44:37 PM
Tufts University
Tufts Cummings School of Vet Med
Cardiology

B6

FDA-CVM-FOIA-2019-1704-010486

Client: B6
Patient:

EKG from cardio

B6 B6 12:44:59 PM
Tufts University
Tufts Cummings School of Vet Med
Cardiology

12 Lead: Standard Placement

FDA-CVM-FOIA-2019-1704-010487

Client: B6
Patient:

EKG from cardio

B6

B6 12:45:43 PM
Tufts University
Tufts Cummings School of Vet Med
Cardiology

12 Lead: Standard Placement

B6

FDA-CVM-FOIA-2019-1704-010488

Client: B6
Patient:

EKG from cardio

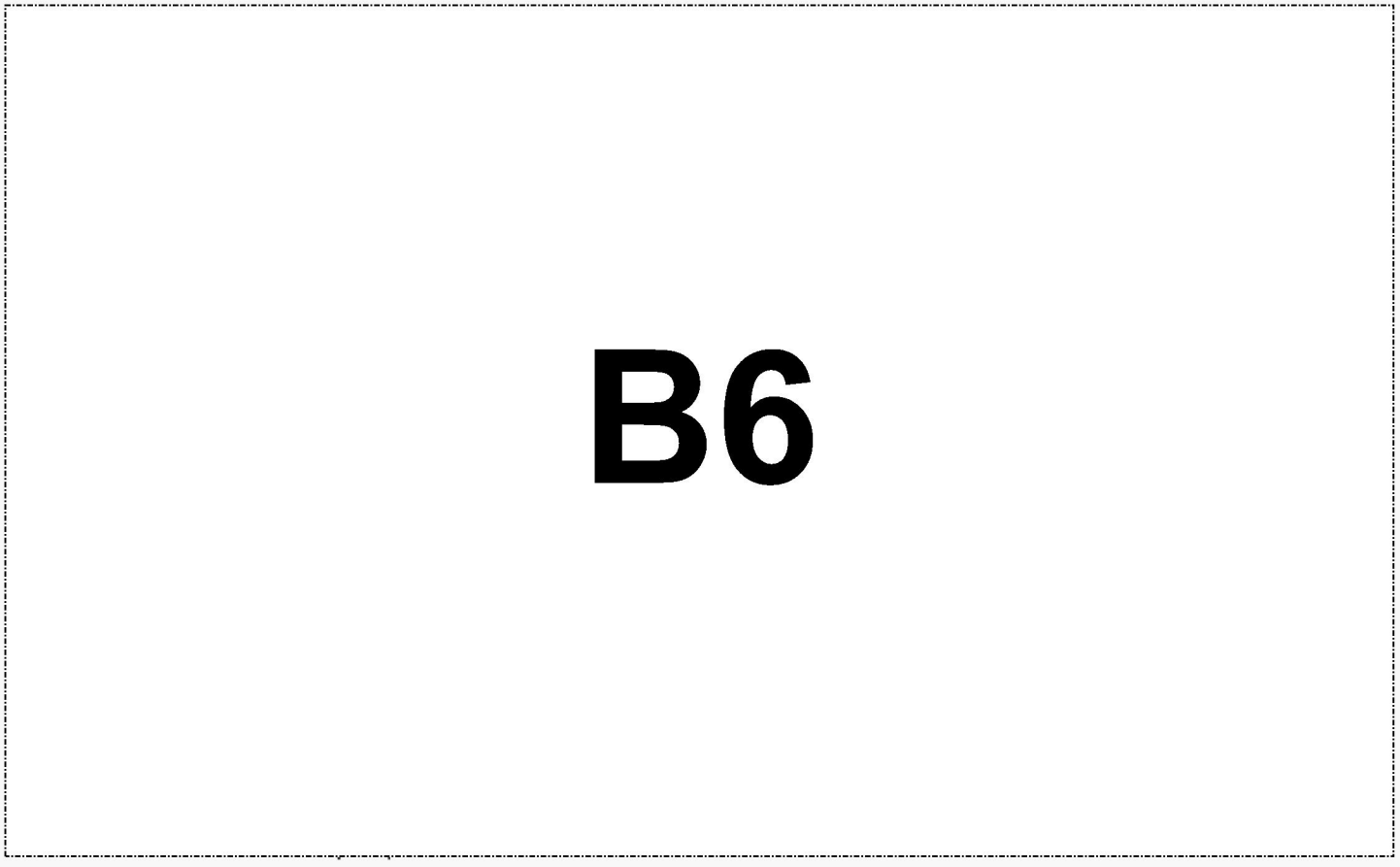
B6 B6 12:45:55 PM
Tufts University
Tufts Cummings School of Vet Med
Cardiology

FDA-CVM-FOIA-2019-1704-010489

Client: B6
Patient:

ECG from Cardio

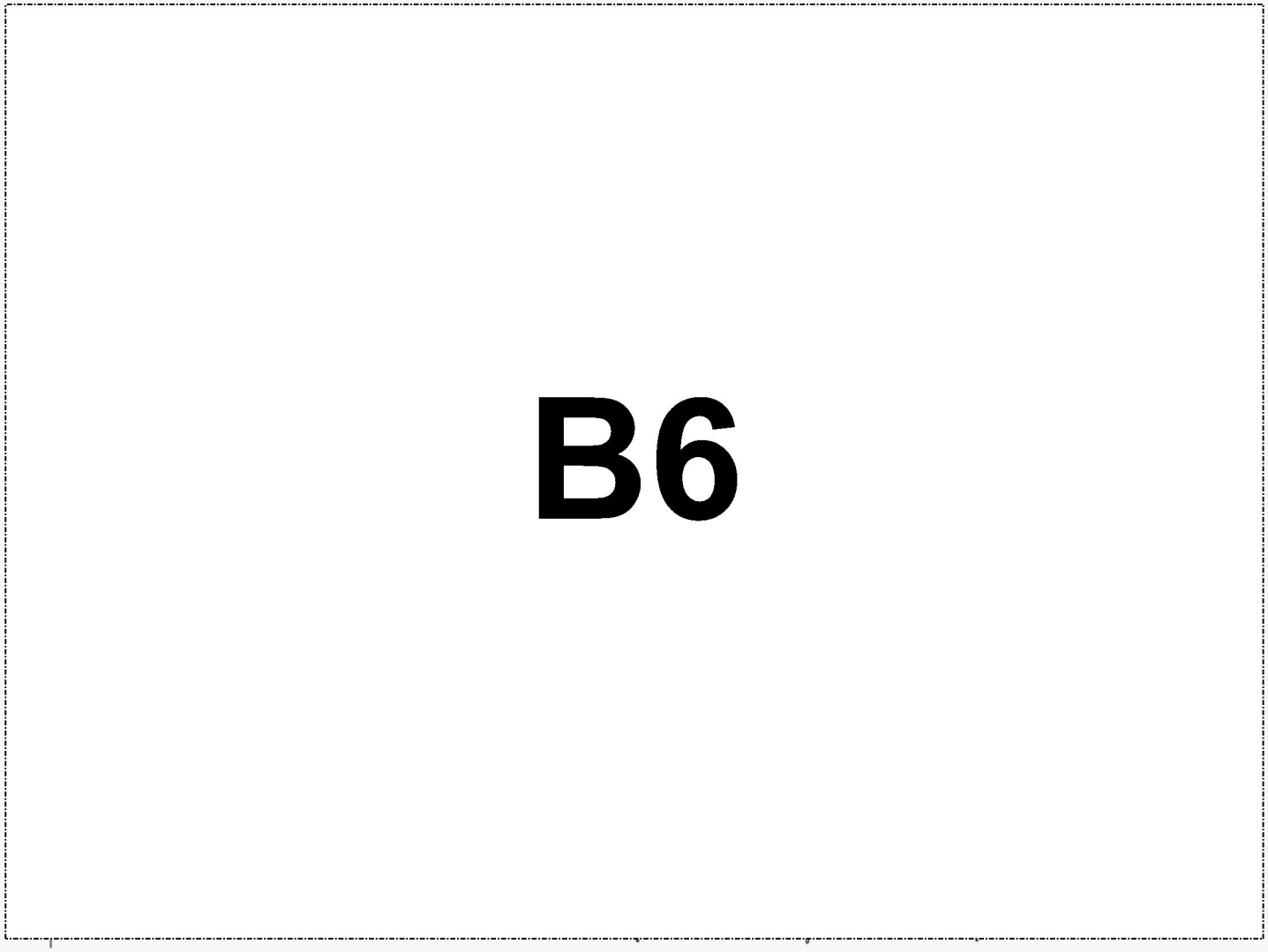
B6 B6 1:57:20 PM
Tufts University
Tufts Cummings School of Vet Med
Cardiology



FDA-CVM-FOIA-2019-1704-010490

Client:
Patient: B6

ECG from Cardio



FDA-CVM-FOIA-2019-1704-010491

Client: B6
Patient:

ECG from Cardio

B6 B6 :57:44 PM Page 2 of 2
Tufts University
Tufts Cummings School of Vet Med
Cardiology

B6

FDA-CVM-FOIA-2019-1704-010492

Client: B6
Patient:

ECG from Cardio

B6 B6 1:57:50 PM Page 1 of 2
Tufts University
Tufts Cummings School of Vet Med
Cardiology

B6

FDA-CVM-FOIA-2019-1704-010493

Client: B6
Patient:

ECG from Cardio

B6 B6 1:57:50 PM

Tufts University
Tufts Cummings School of Vet Med
Cardiology

B6

FDA-CVM-FOIA-2019-1704-010494

Client: B6
Patient:

Patient History

B6	11:14 AM	Vitals
	11:14 AM	Vitals
	11:14 AM	Vitals
	11:14 AM	Vitals
	11:14 AM	Vitals
	11:17 AM	UserForm
	11:17 AM	Email
	11:43 AM	Purchase
	11:43 AM	Purchase
	12:25 PM	UserForm
	12:33 PM	Treatment
	12:43 PM	Vitals
	12:45 PM	Labwork
	12:45 PM	Labwork
	12:54 PM	Vitals
	12:55 PM	Purchase
	12:55 PM	Purchase
	01:07 PM	Purchase
	01:33 PM	Vitals
	01:33 PM	Vitals
	01:33 PM	Vitals
	01:33 PM	Vitals
	02:35 PM	Appointment
	02:39 PM	Treatment
	02:49 PM	Prescription
	02:50 PM	Prescription
	02:50 PM	Prescription
	02:54 PM	Purchase
	03:05 PM	Treatment
	03:06 PM	Vitals
	03:06 PM	Vitals
	03:08 PM	Vitals
	03:09 PM	UserForm
	03:10 PM	Treatment
	04:11 PM	Vitals
	04:11 PM	Treatment
	06:46 PM	Treatment
	09:29 AM	Appointment
	12:00 PM	UserForm
	12:04 PM	Vitals

B6

B6

FDA-CVM-FOIA-2019-1704-010495

Client:
Patient: B6

Patient History

B6	12:20 PM	Treatment
	01:27 PM	UserForm
	01:53 PM	Purchase
	01:58 PM	Purchase
	02:01 PM	Prescription
	02:39 PM	Appointment
	02:44 PM	Appointment

B6

chem - DCM study

Patient Account History	Description	Qty	price	Extended	Disc	Pmt

FDA-CVM-FOIA-2019-1704-010496

Client: B6
Patient:

Patient Account History	Description	Qty	price	Extended	Disc	Pmt
Saturday, B6 11:43	Appointment: Emergency Room Visit	1.000		B6		

FDA-CVM-FOIA-2019-1704-010497

Client: B6
Patient:

Patient Account History	Description	Qty	price	Extended	Disc	Pmt
Saturday, B6 11:43	Oxygen therapy (0 To 6 hrs)	1.000		B6		

FDA-CVM-FOIA-2019-1704-010498

Client:
Patient: B6

Patient Account History	Description	Qty	price	Extended	Disc	Pmt
Saturday 12:45	B6	1.000	B6			

FDA-CVM-FOIA-2019-1704-010499

Client: B6
Patient:

Patient Account History	Description	Qty	price	Extended	Disc	Pmt
Saturday, B6 12:45	PCV/TS - FHSA	1.000		B6		

FDA-CVM-FOIA-2019-1704-010500

Client: B6
Patient:

Patient Account History	Description	Qty	price	Extended	Disc	Pmt
Saturday, B6 12:55	Emergency Cardiology Clinician	1.000		B6		

FDA-CVM-FOIA-2019-1704-010501

Client: B6
Patient:

Patient Account History	Description	Qty	price	Extended	Disc	Pmt
Saturday B6 12:55	Echocardiogram-2d,Mmode,Color,Spec	1.000		B6		

FDA-CVM-FOIA-2019-1704-010502

Client:
Patient: B6

Patient Account History	Description	Qty	price	Extended	Disc	Pmt
Saturday B6 13:07	EKG Cardiology Rhythm Strip	1.000		B6		

FDA-CVM-FOIA-2019-1704-010503

Client: B6
Patient:

Patient Account History	Description	Qty	price	Extended	Disc	Pmt
Saturday 14:49 B6	B6 - FHSA	35.000		B6		

FDA-CVM-FOIA-2019-1704-010504

Client: B6
Patient:

Patient Account History	Description	Qty	price	Extended	Disc	Pmt
Saturday B6 14:50	B6	90.000		B6		

FDA-CVM-FOIA-2019-1704-010505

Client: B6
Patient:

Patient Account History	Description	Qty	price	Extended	Disc	Pmt
Saturday, B6 14:50	B6 - FHSA	100.000	B6			

FDA-CVM-FOIA-2019-1704-010506

Client: B6
Patient:

Patient Account History	Description	Qty	price	Extended	Disc	Pmt
Saturday, B6 14:54	Pharmacy Finished	1.000		B6		

FDA-CVM-FOIA-2019-1704-010507

Client: B6
Patient:

Patient Account History	Description	Qty	price	Extended	Disc	Pmt
Saturday, 16:11	B6	0.600		B6		

FDA-CVM-FOIA-2019-1704-010508

Client:
Patient: B6

Patient Account History	Description	Qty	price	Extended	Disc	Pmt
Saturday, 18:12	B6	0.600		B6		

FDA-CVM-FOIA-2019-1704-010509

Client: B6
Patient:

Patient Account History	Description	Qty	price	Extended	Disc	Pmt
Friday, 24 May 2019 13:53	Appointment: Cardiology Study	1.000	B6			

FDA-CVM-FOIA-2019-1704-010510

Client: B6
Patient:

Patient Account History	Description	Qty	price	Extended	Disc	Pmt
Friday, 24 May 2019 14:01	B6 - FHSA	30.000		B6		

FDA-CVM-FOIA-2019-1704-010511

Cummings
Veterinary Medical Center
AT TUFTS UNIVERSITY

B6

B6 Female (Spayed)
Canine Cocker Spaniel Black
Patient ID: B6

STANDARD CONSENT FORM

I am the owner, or agent for the owner, of the above described animal and have the authority to execute consent. I hereby authorize the Cummings School of Veterinary Medicine at Tufts University (herein after Cummings School) to prescribe for treatment of said animal according to the following terms and conditions.

Cummings School and its officers, agents and employees will provide such veterinary medical care as they deem reasonable and appropriate under the circumstances.

Cummings School and its officers, agents, and employees will use all reasonable care in the treatment of the above mentioned animal, but will not be liable for any loss or accident that may occur or any disease that may develop as a result of the care and treatment provided.

I understand that the above identified animal may be treated by Cummings School students under the supervision and assistance of Cummings School staff members.

In executing this form, I hereby expressly acknowledge that risks, benefits and alternative forms of treatment have been explained to me. I understand said explanation, and I consent to treatment. Should any additional treatments or diagnostics be required during the continued care of my animal, I understand that I will be given the opportunity to discuss and consent to these additional procedures. I understand that further or additional treatment may be required without an opportunity for discussion and consideration by me, in the case of the development of any life-threatening emergency during the continued care of my animal and I expressly consent to all such reasonable treatment as required. I realize and understand that results cannot be guaranteed.

If any equipment is left with the animal, it will be accepted with the understanding that Cummings School assumes no responsibility for any loss of equipment that may occur.

I agree to pick up the animal when notified that it is ready for release.

In the event the animal is not picked up, and if ten (10) days have expired since a registered letter was sent to the address given above, notifying me to call for the animal, the animal may be sold or otherwise disposed of in a humane manner and the proceeds applied to the charges incurred in caring and treating the animal. Failure to remove said animal will not and does not relieve me from obligation for the costs of services rendered.

I hereby grant to the Cummings School of Veterinary Medicine at Tufts University, its officers and employees (collectively referred to herein as Cummings School), and its agents and assigns (the Grantees) the irrevocable rights to photograph / videotape the operation or procedure to be performed, including appropriate and otherwise use such photographs and images for, and in connection with, a Grantee's medical, scientific, educational, and publicity purposes, by any means, methods and media (print and electronic) now known or, in the future, developed that the Grantee deems appropriate (provided that such photographs and images may not be used in for-profit commercials, unless such commercials are publicizing educational programs at Cummings School). As medical and surgical treatment necessitates the removal of tissue, cells, fluids or body parts of my animal, I authorize the Grantees to dispose of or use these tissues, cells, fluids or body parts for scientific and educational purposes.

I understand that a FINANCE CHARGE will be applied to all accounts unpaid after 30 days. The FINANCE CHARGE is computed on a monthly rate of 1.33% per month, which is an annual percentage rate of 16% applied to the average daily balance outstanding, with a minimum fee of $.50.

I do further agree that should any payment, or the full amount of the sum stated above, become overdue more than 20 days from the above-agreed upon time of payment or payments, the entire balance shall be considered in default and become due and payable. I further agree to be responsible for any or all collection agency and/or attorney fees necessary to collect the full amount.

I do further agree to comply with hours of visitation in conjunction with our Hospital's policy.

I have read, understand, and agree to accept the terms and conditions herein.

Owner's name: B6 Date: B6

Owner's address: B6

B6

B6

If the individual admitting the animal is someone other than the legal owner, please complete the portion below:

The owner of the animal, B6, has granted me authority to obtain medical treatment and to bind this owner to pay the veterinary medical services provided at Cummings School pursuant to the terms and conditions described above.

Authorized Agent – Please Print

Agent's Signature

Street Address

Date

Town/City State Zip

Cummings
Veterinary Medical Center
AT TUFTS UNIVERSITY

Foster Hospital for Small Animals
55 Willard Street
North Grafton, MA 01536
Telephone (508) 839-5395
Fax (508) 839-7951
http://vetmed.tufts.edu/

Discharge Instructions

Patient
Name: B6
Signalment: Years Old Black Female (Spayed) Cocker Spaniel

Owner
Name:
Address: B6

Patient ID: B6
Emergency Clinician: B6 DVM

ER Supervisor:

B6

Admit Date: B6 1:15:21 AM
Check Out Date: B6

Diagnoses:
- Chronic valvular disease with mitral regurgitation, congestive heart failure with pulmonary edema
- Arrhythmia
- Moderate pulmonary hypertension

Clinical findings:
B6 has leaky heart valves, the mitral valve and tricuspid valve. This leak has resulted in a loud heart murmur and enlargement of her heart. The problem with her mitral valve is a common one in dogs, due to aging changes to the valve that result in thickening and a subsequent leak of the valve. The heart enlargement has now progressed to the point where fluid is backing up into the lungs causing pulmonary edema, a condition called congestive heart failure. We cannot do anything to change the thickening or leak at the valve, but we can use cardiac medications and some changes to the diet to make B6 comfortable and have him/her breathing easier. Unfortunately, this is a progressive disease and the treatment options cannot reverse the damage to the valve.

Diagnostic test results:
- Chest radiograph (x-ray) findings: The heart is enlarged and there is fluid in the lungs
- Echocardiogram findings: All chambers of the heart are enlarged and there is a large leak at the mitral valve along with a leak at the tricuspid. There is also higher then normal pressure in her lungs which could be secondary to the left sided heart disease.
- ECG findings: The ECG showed a fair amount of arrhythmia – resulting from the lower chambers (ventricles) of the heart
- Labwork findings: The kidney values and electrolytes are within normal limites

Monitoring at home:
We would like you to monitor B6 breathing rate and effort at home, ideally during sleep or at a time of rest. The doses of drugs will be adjusted based on the breathing rate and effort. In general, most dogs with heart failure that is well controlled have a breathing rate at rest of less than 35 to 40 breaths per minute. In addition, the breathing effort, noted

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by the amount of belly wall motion used for each breath, is fairly minimal if heart failure is controlled. An increase in breathing rate or effort will usually mean that you should give an extra dose of B6 If difficulty breathing is not improved within 30-60 minutes after giving extra furosemide then we recommend that a recheck exam be scheduled and/or that B6 be evaluated by an emergency clinic.

There are instructions for monitoring breathing, and a form to help keep track of breathing rate and drug doses, on the Tufts HeartSmart web site (http://vet.tufts.edu/heartsmart/at-home-monitoring/). We also want you to watch for weakness or collapse, a reduction in appetite, worsening cough, or distention of the belly as these findings indicate that we should do a recheck examination.

Recommended Medications:

B6

Diet suggestions:
Continue feeding B6 current diet until her recheck appointment.

Exercise Recommendations:
For the first 7 to 10 days after starting medications for heart failure, we recommend very limited activity. Leash walking only is ideal, and short walks to start. Once the heart failure is better controlled, then slightly longer walks are acceptable. However, if you find that B6 is lagging behind or needs to stop on a walk then this was too long a walk and shorter walks are advised in the future. Repetitive or strenuous high-energy activities (repetitive ball chasing, running fast off-leash, etc.) are generally not advised at this stage of heart failure.

Recheck/Follow-up:
A recheck has been scheduled for B6 on
Friday, May 24th at 12:00pm with B6

Thank you for entrusting us with B6 care.

Prescription Refill Disclaimer:
For the safety and well-being of our patients, your pet must have had an examination by one of our veterinarians within the past year in order to obtain prescription medications.

Ordering Food:
Please check with your primary veterinarian to purchase the recommended diet(s). If you wish to purchase your food from us,

please call 7-10 days in advance (508-887-4629) to ensure the food is in stock. Alternatively, veterinary diets can be ordered from online retailers with a prescription/veterinary approval.

Clinical Trials:
Clinical trials are studies in which our veterinary doctors work with you and your pet to investigate a specific disease process or a promising new test or treatment. Please see our website: vet.tufts.edu/cvmc/clinical-studies

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Month of:
Heart Failure Monitoring Worksheet

Day	Respiratory Rate/Minute	B6 Dose AM	PM	Appetite				
Sample	32	1 tab (12.5mg)	1/2 tab (6.25mg)	☑ Excellent	☐ Good	☐ Fair	☐ Poor	Notes: Breathing better
1:				☐ Excellent	☐ Good	☐ Fair	☐ Poor	Notes:
2:				☐ Excellent	☐ Good	☐ Fair	☐ Poor	Notes:
3:				☐ Excellent	☐ Good	☐ Fair	☐ Poor	Notes:
4:				☐ Excellent	☐ Good	☐ Fair	☐ Poor	Notes:
5:				☐ Excellent	☐ Good	☐ Fair	☐ Poor	Notes:
6:				☐ Excellent	☐ Good	☐ Fair	☐ Poor	Notes:
7:				☐ Excellent	☐ Good	☐ Fair	☐ Poor	Notes:
8:				☐ Excellent	☐ Good	☐ Fair	☐ Poor	Notes:
9:				☐ Excellent	☐ Good	☐ Fair	☐ Poor	Notes:
10:				☐ Excellent	☐ Good	☐ Fair	☐ Poor	Notes:
11:				☐ Excellent	☐ Good	☐ Fair	☐ Poor	Notes:
12:				☐ Excellent	☐ Good	☐ Fair	☐ Poor	Notes:
13:				☐ Excellent	☐ Good	☐ Fair	☐ Poor	Notes:
14:				☐ Excellent	☐ Good	☐ Fair	☐ Poor	Notes:
15:				☐ Excellent	☐ Good	☐ Fair	☐ Poor	Notes:
16:				☐ Excellent	☐ Good	☐ Fair	☐ Poor	Notes:
17:				☐ Excellent	☐ Good	☐ Fair	☐ Poor	Notes:
18:				☐ Excellent	☐ Good	☐ Fair	☐ Poor	Notes:
19:				☐ Excellent	☐ Good	☐ Fair	☐ Poor	Notes:
20:				☐ Excellent	☐ Good	☐ Fair	☐ Poor	Notes:
21:				☐ Excellent	☐ Good	☐ Fair	☐ Poor	Notes:
22:				☐ Excellent	☐ Good	☐ Fair	☐ Poor	Notes:
23:				☐ Excellent	☐ Good	☐ Fair	☐ Poor	Notes:

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24:	☐ Excellent	☐ Good	☐ Fair	☐ Poor	Notes:
25:	☐ Excellent	☐ Good	☐ Fair	☐ Poor	Notes:
26:	☐ Excellent	☐ Good	☐ Fair	☐ Poor	Notes:
27:	☐ Excellent	☐ Good	☐ Fair	☐ Poor	Notes:
28:	☐ Excellent	☐ Good	☐ Fair	☐ Poor	Notes:
29:	☐ Excellent	☐ Good	☐ Fair	☐ Poor	Notes:
30:	☐ Excellent	☐ Good	☐ Fair	☐ Poor	Notes:
31:	☐ Excellent	☐ Good	☐ Fair	☐ Poor	Notes:

Respiration Rate: Count the number of breaths for 30 seconds and multiply times 2 to get the respiratory rate per minute. In dogs, obtain the respiratory rate when they are at rest and not panting. In cats, get the respiratory rate at rest when they are not purring. In animals with well controlled heart failure, the breathing rate is often less than 35-40 breaths per minute. When the breathing rate is climbing, or when there is more effort to the chest wall or belly muscles during breathing, then fluid is likely accumulating in the lungs and more B6 may be indicated. Please bring this sheet with you to your next veterinary exam.

Please visit our HeartSmart Website for further information
http://vet.tufts.edu/heartsmart/at-home monitoring/

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Nutritional Tips for Pets with Heart Disease

Low sodium, high quality pet treats

Notes:

1. Most other dog treats are high in sodium.
2. If your pet has other medical conditions, these treats may not be appropriate. Talk to your veterinarian if you have questions or make an appointment with the Nutrition Service.

Product	Calories per treat
Dogs	
Hill's Science Diet Baked Light Biscuits with Real Chicken Small Dog Treat	8
Hill's Science Diet Baked Light Biscuits with Real Chicken Medium Dog Treat	34
Hill's Science Diet Soft Savories Peanut Butter & Banana, Beef & Cheddar, or Chicken & Yogurt Dog Treat	25-27, depending on flavor
Hill's Ideal Balance Soft-Baked Naturals with Chicken & Carrots, Duck & Pumpkin, or Beef & Sweet Potato Dog Treat	12-13, depending on flavor
Purina Beyond Natural Salmon Dog Biscuit Treat with Oats or Chicken & Barley	27-29, depending on flavor
Purina Alpo Variety Snaps Little Bites (beef, chicken, liver, lamb or beef, bacon, cheese, peanut butter)	16
Purina Alpo Variety Snaps Big Bites (beef, chicken, liver, lamb)	58
Royal Canin Original Canine treat	5
Cats	
Royal Canin Original Feline treat	2
Fancy Feast Duos Natural Rotisserie Chicken Cat treat	2
Fancy Feast Duos Tuna with Accents of Parsley Cat treat	2

Taste enhancers to can make your pet's food tastier to increase food intake

Safe and effective appetite stimulants are now available for dogs and cats. Please talk to your veterinarian if your pet is not eating well, not eating ideal foods, or is losing weight.

Notes:

1. All foods in this list should be prepared without salt
2. These taste enhancers should be added in small amounts. If your pet eats too much of them, they will unbalance the diet and increase your pet's risk for nutritional deficiencies

Dogs

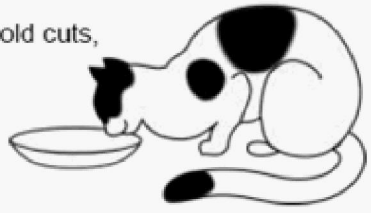
- Honey or maple syrup
- Homemade chicken, beef, or fish broth (made without salt; avoid all deli meats and rotisserie chicken). Avoid store bought broths because even the low sodium brands are too high in sodium.
- Sugar (brown or white) – Domino pourable light brown sugar is a good option
- Vanilla or fruit yogurt – One option that dogs seem to like is Yoplait Custard Yogurt (caramel or vanilla flavors). If you try other brands, just be sure the sodium is less than 100 mg per 100 calories (the Yoplait is 95 mg per 170 calories which comes out to 56 mg sodium per 100 calories). Also avoid yogurts with artificial sweeteners.
- Maple syrup. Low salt brands include Log Cabin All Natural, Maple Grove Farm 100% pure maple syrup, or Stop and Shop Original Syrup
- Applesauce (be sure they have less than 50 mg sodium per serving)
- Ketchup (no salt added). Examples include Hunts or Heinz no salt added
- Pasta sauce (no salt added). Examples: Francesco Rinaldi no salt added or Enrico's no salt added)
- Frosted Mini Wheats Original – these can be crumbled on his food
- Lean meats, cooked (chicken, turkey, beef, or fish) – not deli/sandwich meats/cold cuts, rotisserie chicken, and any canned fish or meat
- Eggs, cooked

Dogs (continued)

- Homemade chicken, beef, or fish broth (even low sodium store-bought broths are too high in sodium). Avoid all canned soups unless labeled as no salt added
- Low-salt breakfast cereal - the label should read, "very low sodium food" or contain less than 20 mg sodium per serving. A good option is Frosted Mini Wheats Original or Little Bites Original
- Fresh vegetables/fruit. Examples include carrots, green beans, apple, orange, banana (avoid grapes, raisins, onions, garlic)
- Low sodium canned dog foods

Cats

- Lean meats, cooked (chicken, turkey, beef, or fish) – not sandwich meats/cold cuts, canned tuna, or rotisserie chicken
- Eggs, cooked
- Homemade chicken, beef, or fish broth (even low sodium store-bought broths are too high in sodium)
- Low sodium canned cat foods



Foods to avoid

- Fatty foods (meat trimmings, cream, ice cream)
- Baby food
- Pickled foods
- Bread
- Pizza
- Condiments (ketchup, soy sauce, barbecue sauce, etc – unless they are unsalted or no salt added)
- Sandwich meats/cold cuts (ham, corned beef, salami, sausages, bacon, hot dogs)
- Rotisserie chicken
- Most cheeses, including "squirtable" cheeses
- Processed foods (such as, potato mixes, rice mixes, macaroni and cheese)
- Canned vegetables (unless "no salt added")
- Potato chips, packaged popcorn, crackers, and other snack foods
- Soups (unless homemade without salt)
- Most commercial pet treats

Tips for administering medications

Foods commonly used to administer your pet's pills can provide a large amount of additional salt to your pet's diet. Preferable ways to give medications include:

- Have one of our staff show you how to give medications without using food
- Insert medications into one of the following foods:

Dogs or cats

- Low-sodium canned pet food
- Home-cooked meat such as chicken or hamburger (made without salt); not lunch meats
- Whipped cream (Reddi Wip)
- Marshmallows
- Greenies Pill Pockets
  - Dog chicken, hickory smoke, or peanut butter flavors; cat chicken or salmon flavor
  - Avoid grain-free duck and pea which is high in sodium
  - Try to use the smallest size possible (ideally, the cat sized Pill Pockets, even for dogs) and as few as possible to avoid excessive salt.
    - Caution: Not all similar products from other companies are low in sodium .

Dogs

- Soft fruit, such as banana, orange, melon, or strawberries (avoid grapes)
- Peanut butter (only if labeled as "no salt added") – examples include Smucker's Natural Creamy Peanut Butter with No Salt Added or Teddie All Natural Smooth Unsalted Butter
- Frosting (should be less than 75 mg/serving and contain no artificial sweeteners or xylitol). Examples include Duncan Hines whipped vanilla frosting, Betty Crocker whipped vanilla frosting)

You may find our Petfoodology post called, "Pill-popping pets" helpful for additional ideas: http://vetnutrition.tufts.edu/2018/09/foods_for_giving_pills/

Cummings
Veterinary Medical Center
AT TUFTS UNIVERSITY
Cardiology Liaison: 508-887-4696

B6

Patient ID: B6
B6 Canine
Years Old Female (Spayed) Cocker Spaniel
Black BW: Weight (kg) 14.40

Cardiology Consultation

Date: B6
Weight: Weight (kg) 14.40
Requesting Clinician: B6 DVM (Intern - SAM)

Attending Cardiologist:
- ☐ John E. Rush DVM, MS, DACVIM (Cardiology), DACVECC

B6

Cardiology Resident:
B6

Thoracic radiographs available for review?
- ☐ Yes - in SS
- ☐ Yes - in PACS
- ☐ No

Yes in ECC email

Patient location: ER

Presenting complaint and important concurrent diseases:
Enlarged heart on rDVM radiographs, cough

Current medications and doses:
B6

At-home diet: (name, form, amount, frequency)
Bill Jack Persnickety - BID

Key indication for consultation: (murmur, arrhythmia, needs fluids, etc.)
Murmur and enlarged heart on radiographs, cough

Is your consult time-sensitive? (e.g., anesthesia today, owner waiting, trying to get biopsy today)
- ☑ Yes (explain): O waiting
- ☐ No

***STOP** - remainder of form to be filled out by Cardiology*

Physical Examination

B6

Muscle condition:

- ☐ Normal
- ☑ Mild muscle loss
- ☐ Moderate cachexia
- ☐ Marked cachexia

Cardiovascular Physical Exam

Murmur Grade:

- ☐ None
- ☐ I/VI
- ☐ II/VI
- ☐ III/VI
- ☑ IV/VI
- ☐ V/VI
- ☐ VI/VI

Murmur location/description: left apical, systolic

Jugular vein:

- ☑ Bottom 1/3 of the neck
- ☐ Middle 1/3 of the neck
- ☐ Top 2/3 of the neck
- ☐ 1/2 way up the neck

Arterial pulses:

- ☐ Weak
- ☑ Fair
- ☐ Good
- ☐ Strong
- ☐ Bounding
- ☐ Pulse deficits
- ☐ Pulsus paradoxus
- ☐ Other (describe):

Arrhythmia:

- ☐ None
- ☐ Sinus arrhythmia
- ☑ Premature beats
- ☐ Bradycardia
- ☐ Tachycardia

Gallop:

- ☐ Yes
- ☑ No
- ☐ Intermittent
- ☐ Pronounced
- ☐ Other:

Pulmonary assessments:

- ☐ Eupneic
- ☐ Mild dyspnea
- ☑ Marked dyspnea
- ☐ Normal BV sounds
- ☑ Pulmonary Crackles
- ☐ Wheezes
- ☐ Upper airway stridor
- ☐ Other auscultatory findings:

Abdominal exam:

- ☑ Normal
- ☐ Hepatomegaly
- ☐ Abdominal distension
- ☐ Mild ascites

Echocardiogram Findings:

General/2-D findings: ***brief exam, patient vocalizing and panting in standing position****
Normal LV wall thicknesses with reduced contractile function. LV cavity is dilated and more spherical. MV is thickened and there is mild prolapse of the anterior leaflet. LA is markedly dilated. RH is subjectively enlarged. Aorta and PA are similar in diameter. Occasional b-lines visualized. No pleural or pericardial effusion.

Doppler findings:

B6

Mitral inflow:

- ☐ Summated
- ☐ Normal
- ☐ Delayed relaxation
- ☐ Pseudonormal
- ☑ Restrictive

ECG findings:

B6

B6

Assessment and recommendations:
Findings consistent with advanced DMVD with active left-sided CHF. Despite patient having received 3 oral doses of lasix over the last 18h (less than 2mg/kg each dose), there is still significant CHF. Since hospitalization is not possible, recommend keeping patient for the day in O2 and administering 30mg furosemide IV every 4 hours. There is moderate PHTN, but LCHF should be adressed first. Reduced contractile function is not routinely seen in DMVD, but there very frequent arrhythmias and BEG diet may contribute. Start B6 D for 1 week (and then decrease to every 24h) and switching to a grain-based low sodium diet are recommended. Recommend recheck bloodwork and EKG in 1 week and echocardiogram in 3 months.

Treatment plan:

B6

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B6

Final Diagnosis:
Advanced DMVD with active L-CHF;
Moderate PHTN;
Frequent ventricular and supraventricular arrhythmias.

Heart Failure Classification Score:
ISACHC Classification:

- ☐ Ia
- ☐ Ib
- ☐ II
- ☑ IIIa
- ☐ IIIb

ACVIM CHF Classification:

- ☐ A
- ☐ B1
- ☐ B2
- ☑ C
- ☐ D

M-Mode

	B6	
IVSd		cm
LVIDd		cm
LVPWd		cm
IVSs		cm
LVIDs		cm
LVPWs		cm
EDV(Teich)		ml
ESV(Teich)		ml
EF(Teich)		%
%FS		%
SV(Teich)		ml
Ao Diam		cm
LA Diam		cm
LA/Ao		
Max LA		cm
Time		ms
HR		BPM
CO(Teich)		l/min
CI(Teich)		l/minm
IVSd		cm
TAPSE		cm
EPSS		cm

M-Mode Normalized

	B6	
IVSdN		(0.290 - 0.520)
LVIDdN		(1.350 - 1.730) !

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LVPWdN	B6	(0.330 - 0.530)
IVSsN		(0.430 - 0.710)
LVIDsN		(0.790 - 1.140) !
LVPWsN		(0.530 - 0.780)
Ao Diam N		(0.680 - 0.890)
LA Diam N		(0.640 - 0.900) !

2D

SA LA	B6	cm
Ao Diam		cm
SA LA / Ao Diam		
IVSd		cm
LVIDd		cm
LVPWd		cm
EDV(Teich)		ml
IVSs		cm
LVIDs		cm
LVPWs		cm
ESV(Teich)		ml
EF(Teich)		%
%FS		%
SV(Teich)		ml
LV Major		cm
LV Minor		cm
Sphericity Index		
LVLd A4C		cm
LVEDV MOD A4C		ml
LVLs A4C		cm
LVESV MOD A4C		ml
LVEF MOD A4C		%
SV MOD A4C		ml

Doppler

MR Vmax	B6	m/s
MR maxPG		mmHg
MV E Vel		m/s
MV DecT		ms
MV Dec Slope		m/s
MV A Vel		m/s
MV E/A Ratio		
AV Vmax		m/s
AV maxPG		mmHg
PV Vmax		m/s
PV maxPG		mmHg
TR Vmax		m/s
TR maxPG		mmHg

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http://vetmed.tufts.edu/

Discharge Instructions

Patient
Name: B6
Species: Canine
Black Female (Spayed) Cocker Spaniel
Birthdate: B6

Owner
Name: B6
Address: B6

Patient ID: B6

Attending Cardiologist:
☑ John E. Rush DVM, MS, DACVIM (Cardiology), DACVECC
B6

Cardiology Resident:
B6

Cardiology Technician:
B6

Student: B6

Admit Date: 5/24/2019 11:54:53 AM
Discharge Date: 5/24/2019

Diagnoses: Chronic valvular disease with mitral regurgitation, congestive heart failure with pulmonary edema.

Clinical findings: Thank you for bringing B6 in for a recheck of her recent diagnosis of chronic valvular disease with mitral regurgitation and congestive heart failure with pulmonary edema. Since her last appointment, you report that she has been coughing, has had a decreased appetite, and you've had some difficulties giving her medication. Her respiratory (breathing) rate at rest, however, has been comfortable with no effort.

On physical examination, B6 is bright, alert, and responsive. B6 has a slower heart rate today and has little to no arrythmias which is excellent news! While it is difficult to assess her breathing rate here due to her stress and anxiety, you indicate that she does start to pant much more frequently when out on a walk. Her tongue is a little blue today, which indicates she is still having issues fully oxygenating, and she coughed occasionally during the exam.

Her arrythmias have dramatically decreased and seems to be pretty well controlled from her anti-arrythmias. Other findings were consistent with her previous echocardiogram. While she has not fully recovered, B6 seems to be doing much better comparatively to her initial presentation this past Saturday.

Monitoring at home:
We would like you to monitor B6 breathing rate and effort at home, ideally during sleep or at a time of rest. The doses of drugs will be adjusted based on the breathing rate and effort. In general, most dogs with heart failure that is well controlled have a breathing rate at rest of less than 35 breaths per minute. In addition, the breathing effort, noted by the amount of belly wall motion used for each breath, is fairly minimal if heart failure is controlled. An increase in breathing

rate or effort will usually mean that you should give an extra dose of B6 . If difficulty breathing is not improved within 30-60 minutes after giving extr B6 then we recommend that a recheck exam be scheduled and/or that B6 be evaluated by an emergency clinic. There are instructions for monitoring breathing, and a form to help keep track of breathing rate and drug doses, on the Tufts HeartSmart web site (http://vet.tufts.edu/heartsmart/at-home-monitoring/). We also want you to watch for weakness or collapse, a reduction in appetite, worsening cough, or distention of the belly as these findings indicate that we should do a recheck examination.

Recommended Medications:

B6

Diet suggestions:

Dogs with heart failure accumulate more fluid in their body if they eat large amounts of sodium (salt). Sodium can be found in all foods, but some foods are lower in sodium than others. Many treats, most people foods, and the supplements used to give pills often have more sodium than is desirable – a sheet that has suggestions for low sodium treats can be found on the HeartSmart web site. In addition, your dog's usual diet may have more sodium than recommended – we want your dog to eat their usual diet for the first 7 to 14 days so we can make sure they are tolerating medications well, but after that time we would recommend slowly introducing one of the lower sodium diets on the HeartSmart list (25% of the new diet and 75% old diet for 2-3 days, then 50:50, etc.). Hopefully you can find a diet on the list that B6 likes to eat. Alternatively, you can research the amount of sodium in your dog's current diet to ensure that the sodium content is similar to those on the list. The HeartSmart web site also has some information on supplements such as fish oil, taurine, and other supplements that you might have questions about (http://vet.tufts.edu/heartsmart/diet/).

- The FDA is currently investigating an apparent association between diet and a type of heart disease called dilated cardiomyopathy. The exact cause is still unclear, but it appears to be associated with boutique diets and those containing exotic ingredient or are grain-free. Therefore, we are currently recommending that dogs do not eat these types of diets.
- We recommend switching B6 to commercial diet made by a well-established company that is not grain-free and does not contain any exotic ingredients, such as kangaroo, duck, lamb, venison, lentils, peas, beans, buffalo, tapioca, barley, and chickpeas.
- The FDA issued a statement regarding this issue (https://www.fda.gov/AnimalVeterinary/NewsEvents/CVMUpdates/ucm613305.htm) and a recent article published by Dr. Lisa Freeman on the Cummings School's Petfoodology blog can further explain these findings (http://vetnutrition.tufts.edu/2018/06/a-broken-heart-risk-of-heart-disease-in-boutique-or-grain-free-diets-and-exotic-ingredients/).
- Our nutritionists have compiled a list of dog foods that are good options for dogs with heart disease.

Dry Food Options:

Royal Canin Early Cardiac (veterinary diet)

Canned Food Options:
Hill's Science Diet Adult 1-6 Healthy Cuisine Roasted Chicken, Carrot, and Spinach Stew
Royal Canin Mature 8+

If your dog has special nutritional needs or requires a homecooked diet, we recommend you schedule an appointment with our nutritionists (508-887-4696).

Exercise Recommendations:
Please continue limiting B6 **activity and avoiding any strenuous exercise when possible.**

Recheck Visits: We want to recheck her in 10-14 days B6 **. At this visit we will want to check** B6 **breathing effort and heart function, do a blood test to recheck kidney values, and probably recheck a blood pressure. A recheck echocardiogram and/or chest radiographs (x-rays) are recommended in 3 months.**

Thank you for entrusting us with B6 **care. Please contact our Cardiology liaison at (508)-887-4696 or email us at cardiovet@tufts.edu for scheduling and non-emergent questions or concerns.**

Please visit our HeartSmart website for more information
http://vet.tufts.edu/heartsmart/

Prescription Refill Disclaimer:
For the safety and well-being of our patients, your pet must have had an examination by one of our veterinarians within the past year in order to obtain prescription medications.

Ordering Food:
Please check with your primary veterinarian to purchase the recommended diet(s). If you wish to purchase your food from us, please call 7-10 days in advance (508-887-4629) to ensure the food is in stock. Alternatively, veterinary diets can be ordered from online retailers with a prescription/veterinary approval.

Clinical Trials:
Clinical trials are studies in which our veterinary doctors work with you and your pet to investigate a specific disease process or a promising new test or treatment. Please see our website: vet.tufts.edu/cvmc/clinical-studies

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Cummings
Veterinary Medical Center
AT TUFTS UNIVERSITY
Cardiology Liaison: 508-887-4696

B6

Patient ID: B6
B6 Canine
Years Old Female (Spayed) Cocker Spaniel
Black

Cardiology Appointment Report

Date: B6

Attending Cardiologist:
☑ John E. Rush DVM, MS, DACVIM (Cardiology), DACVECC

B6

Cardiology Resident:
B6

Cardiology Technician:
B6

Student: B6 V20

Presenting Complaint: Recheck for hx of advanced DMVD with active left sided CHF on B6

Concurrent Diseases: None

General Medical History: Still coughing and doing a lot of panting. When sleeping, has to splay on the ground on a cold surface. When walking any tiny bit, she will start panting. She hasn't been really eating. Having a hard time giving her medication and tries to grind it into her food but P is not really eating much of her food.

Diet and Supplements:
Bill Jack Persnickety - BID

Cardiovascular History:
Prior CHF diagnosis? Y
Prior heart murmur? Y
Prior ATE? N
Prior arrhythmia? Y
Monitoring respiratory rate and effort at home? N
Cough? Y
Shortness of breath or difficulty breathing? Y

Syncope or collapse? Has not collapsed since last Saturday during her last incident.
Sudden onset lameness? N
Exercise intolerance? Y

Current Medications Pertinent to CV System:

B6

Cardiac Physical Examination:

B6

Muscle condition:

- ☐ Normal
- ☑ Mild muscle loss
- ☐ Moderate cachexia
- ☐ Marked cachexia

Cardiovascular Physical Exam:

Murmur Grade:

- ☐ None
- ☐ I/VI
- ☐ II/VI
- ☐ III/VI
- ☑ IV/VI
- ☐ V/VI
- ☐ VI/VI

Murmur location/description: left apical systole

Jugular vein:

- ☑ Bottom 1/3 of the neck
- ☐ Middle 1/3 of the neck
- ☐ 1/2 way up the neck
- ☐ Top 2/3 of the neck

Arterial pulses:

- ☐ Weak
- ☑ Fair
- ☐ Good
- ☐ Strong
- ☐ Bounding
- ☐ Pulse deficits
- ☐ Pulsus paradoxus
- ☐ Other:

Arrhythmia:

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- [x] None
- [ ] Sinus arrhythmia
- [ ] Premature beats
- [ ] Bradycardia
- [ ] Tachycardia

Gallop:
- [ ] Yes
- [x] No
- [ ] Intermittent
- [ ] Pronounced
- [ ] Other:

Pulmonary assessments:
- [ ] Eupneic
- [ ] Mild dyspnea
- [x] Marked dyspnea
- [x] Normal BV sounds
- [ ] Pulmonary crackles
- [ ] Wheezes
- [ ] Upper airway stridor

Abdominal exam:
- [x] Normal
- [ ] Hepatomegaly
- [ ] Abdominal distension
- [ ] Mild ascites
- [ ] Marked ascites

Problems:
CHF with advanced DMVD
Pulmonary hypertension

Diagnostic plan:
- [ ] Echocardiogram
- [x] Chemistry profile
- [x] ECG
- [ ] Renal profile
- [ ] Blood pressure
- [ ] Dialysis profile
- [ ] Thoracic radiographs
- [ ] NT-proBNP
- [ ] Troponin I
- [ ] Other tests:

Echocardiogram Findings:
General/2-D findings:
Normal LV walls thickness with decreased contractile function. LV cavity is volume overloaded. MV is thickened and there is mild prolapse of the anterior leaflet. LA is markedly enlarged. RH is subjectively normal. Aorta and PA are similar in size. No pleural or pericardial effusion.

Doppler findings:

Mitral inflow:
- [ ] Summated
- [ ] Normal
- [ ] Delayed relaxation
- [ ] Pseudonormal
- [x] Restrictive

Assessment and recommendations:
Findings consistent with advanced DMVD with active left-sided CHF. Heart rhythm is better control and rare ventricular arrhythmias were seen today. Patient still has some respiratory effort, but seems brighter and alert. Reduced contractile function is not routinely seen in DMVD, but since there were very frequent arrhythmias and patinet has been on a BEG diet, these factors should also be considered. Recommend give B6 Recheck in 7 days.

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Final Diagnosis:
Advanced DMVD with active CHF.
Reduced contractile function.

Heart Failure Classification Score:
ISACHC Classification:

- ☐ Ia
- ☐ Ib
- ☐ II
- ☑ IIIa
- ☐ IIIb

ACVIM Classification:

- ☐ A
- ☐ B1
- ☐ B2
- ☑ C
- ☐ D

From: Related PFR Event <pfrsignificantactivitycreation@fda.hhs.gov>

To: Rotstein, David; Cleary, Michael *; HQ Pet Food Report Notification; B6

Sent: 6/10/2019 8:13:34 PM

Subject: Bil Jac Picky No More--Small Breed-Persnickety Recipe w/ chicken liver: B6 - EON-390090

Attachments: 2068035-report.pdf; 2068035-attachments.zip

A PFR Report has been received and Related PFR Event [EON-390090] has been created in the EON System.

A "PDF" report by name "2068035-report.pdf" is attached to this email notification for your reference. Please note that all documents received in the report are compressed into a zip file by name "2068035-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-390090
ICSR #: 2068035
EON Title: Related PFR Event created for Bil Jac Picky No More® Small Breed Persnickety Recipe w/ chicken liver; 2068035

AE Date	05/17/2019	**Number Fed/Exposed**	1
Best By Date		**Number Reacted**	1
Animal Species	Dog	**Outcome to Date**	Better/Improved/Recovering
Breed	Spaniel - Cocker American		
Age	B6 Years		
District Involved	PFR-New England DO		

Product information
Individual Case Safety Report Number: 2068035
Product Group: Pet Food
Product Name: Bil Jac Picky No More® Small Breed Persnickety Recipe w/ chicken liver
Description: Patient presented to rDVM 5/17/2019 for evaluation of a cough x 1 month, extreme lethargy and decreased appetite. rDVM suspected CHF based on radiographs and worsening murmur - now a 4/6. A new arrhythmia was also discovered on ECG. Intermmitent sinus rhythm with frequent APCs, occasional paroxysmal

SVTs (short duration), isolated and couplet VPCs (LV and RV in origin). Confirmed patient was in left sided heart failure w/ advanced DMVD and decreased contractile function which is very uncommon with valvular disease.
Submission Type: Followup
Report Type: Adverse Event (a symptom, reaction or disease associated with the product)
Outcome of reaction/event at the time of last observation: Better/Improved/Recovering
Number of Animals Treated With Product: 1
Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Bil Jac Picky No More® Small Breed Persnickety Recipe w/ chicken liver		

This report is linked to:
Initial EON Event Key: EON-388960
Initial ICSR: 2067506

Sender information

B6

USA

Owner information

B6 USA

To view this Related PFR Event, please click the link below:
https://eon.fda.gov/eon//browse/EON-390090

To view the Related PFR Event Report, please click the link below:
https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jspa?decorator=none&e=0&issueType=10100&issueId=407362&parentIssueTypeId=12

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{

Report Details - EON-390090

ICSR:	2068035		
Type Of Submission:	Followup		
Report Version:	FPSR.FDA.PETF.V.V1		
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)		
Reporting Type:	Voluntary		
Report Submission Date:	2019-06-10 16:08:32 EDT		
Initial Report Date:	05/28/2019		
Parent ICSR:	2067506		
Follow-up Report to FDA Request:	Yes		
Reported Problem:	**Problem Description:**	Patient presented to rDVM 5/17/2019 for evaluation of a cough x 1 month, extreme lethargy and decreased appetite. rDVM suspected CHF based on radiographs and worsening murmur - now a 4/6. A new arrhythmia was also discovered on ECG. Intermmitent sinus rhythm with frequent APCs, occasional paroxysmal SVTs (short duration), isolated and couplet VPCs (LV and RV in origin). Confirmed patient was in left sided heart failure w/ advanced DMVD and decreased contractile function which is very uncommon with valvular disease.	
	Date Problem Started:	05/17/2019	
	Concurrent Medical Problem:	Yes	
	Pre Existing Conditions:	Previously diagnosed (Jan 2019) with with a 1-2/6 heart murmur - asymptomatic, rDVM rec rechecking in 1 year.	
	Outcome to Date:	Better/Improved/Recovering	
Product Information:	**Product Name:**	Bil Jac Picky No More® Small Breed Persnickety Recipe w/ chicken liver	
	Product Type:	Pet Food	
	Lot Number:		
	Package Type:	BAG	
	Product Use Information:		
	Manufacturer /Distributor Information:		
	Purchase Location Information:		
Animal Information:	**Name:**		
	Type Of Species:	Dog	
	Type Of Breed:	Spaniel - Cocker American	
	Gender:	Female	
	Reproductive Status:	Neutered	
	Weight:	14 Kilogram	
	Age:	B6 ars	
	Assessment of Prior Health:	Excellent	
	Number of Animals Given the Product:	1	
	Number of Animals Reacted:	1	
	Owner Information:	**Owner Information provided:**	Yes
		Contact:	**Name:** B6
			Phone:
		Address:	B6

FDA-CVM-FOIA-2019-1704-010537

			B6 United States
	Healthcare Professional Information:	Practice Name:	Tufts Cummings School of Veterinary Medicine
		Contact:	Name: B6 Phone: Email:
		Address:	200 Westboro Road North Grafton Massachusetts 01536 United States
		Practice Name:	Tufts University Cummings School of Veterinary Medicine
		Contact:	Name: Lisa Freeman Phone: 508 887 4696
		Type of Veterinarian:	Referred veterinarian
		Permission to Release Records to FDA:	Yes
Sender Information:	Name:		B6
	Address:		200 Westboro Road North Grafton Massachusetts 01536 United States
	Contact:	Phone:	B6
		Email:	B6
	Permission To Contact Sender:		Yes
	Preferred Method Of Contact:		Email
	Reported to Other Parties:		None
Additional Documents:			
	Attachment:		Chem 21 6-7-2019.pdf
	Description:		Lab work
	Type:		Laboratory Report
	Attachment:		troponin 5-30-2019.pdf
	Description:		Lab work
	Type:		Laboratory Report
	Attachment:		Diet Hx 6-7-2019.pdf
	Description:		Diet history form
	Type:		Medical Records

Tufts Cummings School Of Veterinary Medicine

200 Westboro Road
North Grafton, MA 01536

DUPLICATE

Name/DOB:	**B6**		Provider: **B6**
Patient ID:		Sex: SF	Order Location: V320559: Investigation into
Phone number:		Age: 10	Sample ID: 1906070126
Collection Date:	6/7/2019 4:29 PM	Species: Canine	
Approval date:	6/7/2019 5:16 PM	Breed: Cocker Spaniel	

Research Chemistry Profile - Small Animal (Cobas)

B6

CSTCYR	Ref. Range/Females
Glucose	67-135 mg/dL
Urea	8-30 mg/dL
Creatinine	0.6-2.0 mg/dL
Phosphorus	2.6-7.2 mg/dL
Calcium 2	9.4-11.3 mg/dL
Magnesium 2+	1.8-3.0 mEq/L
Total Protein	5.5-7.8 g/dL
Albumin	2.8-4.0 g/dL
Globulins	2.3-4.2 g/dL
A/G Ratio	0.7-1.6
Sodium	140-150 mEq/L
Chloride	106-116 mEq/L
Potassium	3.7-5.4 mEq/L
tCO2(Bicarb)	14-28 mEq/L
AGAP	8.0-19.0
NA/K	29-40
Total Bilirubin	0.10-0.30 mg/dL
Alkaline Phosphatase	12-127 U/L
GGT	0-10 U/L
ALT	14-86 U/L
AST	9-54 U/L
Creatine Kinase	22-422 U/L
Cholesterol	82-355 mg/dL
Triglycerides	30-338 mg/dl
Amylase	409-1250 U/L
Osmolality (calculated)	291-315 mmol/L

Sample ID: 1906070126/1
REPRINT: Orig. printing on 6/7/2019 (Final)

Reviewed by: _____

B6

CARDIOLOGY DIET HISTORY FORM

Please answer the following questions about your pet

Pet's name: B6 Owner's name: B6 Today's date: 6/7/19

1. How would you describe your pet's appetite? (mark the position on the line below that best represents your pet's appetite)

Example: **Poor** ——|—— **Excellent**

Poor ——\—— **Excellent**

2. Have you noticed a change in your pet's appetite over the last 1-2 weeks? (check all that apply)
   - ☒ Eats about the same amount as usual
   - ☐ Eats less than usual
   - ☐ Eats more than usual
   - ☐ Seems to prefer different foods than usual
   - ☐ Other _____

3. Over the last few weeks, has your pet (check one)
   - ☐ Lost weight
   - ☐ Gained weight
   - ☐ Stayed about the same weight
   - ☐ Don't know

4. Please list below ALL pet foods, people food, treats, snack, dental chews, rawhides, and any other food item that your pet currently eats. Please include the brand, specific product, and flavor so we know exactly what you pet is eating.

Examples are shown in the table – please provide enough detail that we could go to the store and buy the exact same food.

Food (include specific product and flavor)	Form	Amount	How often?	Fed since
Nutro Grain Free Chicken, Lentil, & Sweet Potato Adult	*dry*	*1 ½ cup*	*2x/day*	*Jan 2018*
85% lean hamburger	*microwaved*	*3 oz*	*1x/week*	*Jan 2015*
Pupperoni original beef flavor	*treat*	*½*	*1x/day*	*Aug 2015*
Rawhide	*treat*	*6-inch twist*	*1x/week*	*Dec 2015*
Royal Canin Early Cardiac	dry	Mix 1/2 cup	2x/day	May 24th 2019
1 tablespoon chicken broth on food			2x/day	

**Any additional diet information can be listed on the back of this sheet*

5. Do you give any dietary supplements to your pet (for example: vitamins, glucosamine, fatty acids, or any other supplements)? ☐ Yes ☐ No If yes, please list which ones and give brands and amounts:

		Brand/Concentration	Amount per day
Taurine	☐ Yes ☐ No		
Carnitine	☐ Yes ☐ No		
Antioxidants	☐ Yes ☐ No		
Multivitamin	☐ Yes ☐ No		
Fish oil	☐ Yes ☐ No		
Coenzyme Q10	☐ Yes ☐ No		
Other (please list):			
Example: Vitamin C		*Nature's Bounty*	*500 mg tablets – 1 per day*

6. How do you administer pills to your pet?
   - ☐ I do not give any medications
   - ☐ I put them directly in my pet's mouth without food
   - ☒ I put them in my pet's dog/cat food – crushes pills and adds to food
   - ☐ I put them in a Pill Pocket or similar product
   - ☐ I put them in foods (list foods): _____

FDA-CVM-FOIA-2019-1704-010540

Gastrointestinal Laboratory
Dr. J.M. Steiner
Department of Small Animal Clinical Sciences
Texas A&M University
4474 TAMU
College Station, TX 77843-4474

Website User ID: lisa.freeman@tufts.edu OR B6

GI Lab Assigned Clinic ID: 23523

B6
Tufts Cummings School of Vet Med - Cardiology/Nutrition
200 Westboro Road
North Grafton, MA 01536
USA

Phone: 508 887 4696
Fax:
Animal Name: B6
Owner Name:
Species: Canine
Date Received: May 30, 2019

Tufts Cummings School of Vet Med - Cardiology/Nutrition Tracking Number: 446476

GI Lab Accession: B6

Test	Result	Reference Interval	Assay Date
Ultra-Sensitive Troponin I Fasting	B6 ng/mL	≤0.06	05/31/19

B6

Comments:

GI Lab Contact Information

Phone: (979) 862-2861
Fax: (979) 862-2864
Email: gilab@cvm.tamu.edu
vetmed.tamu.edu/gilab

From: PFR Event <pfreventcreation@fda.hhs.gov>

To: Cleary, Michael *; HQ Pet Food Report Notification; B6

Sent: 3/27/2019 6:32:23 PM

Subject: Orijen Original B6 EON-383507

Attachments: 2064779-report.pdf

A PFR Report has been received and PFR Event [EON-383507] has been created in the EON System.

A "PDF" report by name "2064779-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report:

EON Key: EON-383507
ICSR #: 2064779
EON Title: PFR Event created for Orijen Original; 2064779

AE Date	03/01/2019	**Number Fed/Exposed**	3
Best By Date		**Number Reacted**	1
Animal Species	Dog	**Outcome to Date**	Unknown
Breed	Retriever - Golden		
Age	3 Years		
District Involved	PFR-New England DO		

Product information
Individual Case Safety Report Number: 2064779
Product Group: Pet Food
Product Name: Orijen Original
Description: B6 has been on grain free (Origen Original) dog food for her entire life. We decided to change our dog food at the end of January 2019 to Purina Pro Plan after hearing of so many dogs being found to have Dialated Cardiomyopathy, due to grain free foods. On March 1st she went in for her regular physical appt., the vet noticed that she had a grade 1 murmur. on March 7th our vet did a chest X-ray and noticed that her heart was enlarged. May 17th we had a Echocardiogram done. The Cardiologist said she had Moderate to severe Left Ventrical enlargement. A whole blood taurine level was pulled on the same day (results are pending) if levels are low we will supplement with taurine. We will re-echo in 6 months time to see if the issue has resolved.
Submission Type: Initial

Report Type: Adverse Event (a symptom, reaction or disease associated with the product)
Outcome of reaction/event at the time of last observation: Unknown
Number of Animals Treated With Product: 3
Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Orijen Original		

Sender information

B6

USA

To view this PFR Event, please click the link below:
https://eon.fda.gov/eon//browse/EON-383507

To view the PFR Event Report, please click the link below:
https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jspa?decorator=none&e=0&issueType=12&issueId=400605

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Report Details - EON-383507		
ICSR:	2064779	
Type Of Submission:	Initial	
Report Version:	FPSR.FDA.PETF.V.V1	
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)	
Reporting Type:	Voluntary	
Report Submission Date:	2019-03-27 14:24:05 EDT	
Reporter is the Animal Owner:	Yes	
Reported Problem:	**Problem Description:**	B6 has been on grain free (Origen Original) dog food for her entire life. We decided to change our dog food at the end of January 2019 to Purina Pro Plan after hearing of so many dogs being found to have Dialated Cardiomyopathy, due to grain free foods. On March 1st she went in for her regular physical appt., the vet noticed that she had a grade 1 murmur. on March 7th our vet did a chest X-ray and noticed that her heart was enlarged. May 17th we had a Echocardiogram done. The Cardiologist said she had Moderate to severe Left Ventrical enlargement. A whole blood taurine level was pulled on the same day (results are pending) if levels are low we will supplement with taurine. We will re-echo in 6 months time to see if the issue has resolved.
	Date Problem Started:	03/01/2019
	Concurrent Medical Problem:	No
	Outcome to Date:	Unknown
Product Information:	**Product Name:**	Orijen Original
	Product Type:	Pet Food
	Lot Number:	
	UPC:	no longer have
	Package Type:	BAG
	Package Size:	25 Pound
	Purchase Date:	11/01/2018
	Number Purchased:	3
	Possess Unopened Product:	No
	Possess Opened Product:	No
	Storage Conditions:	Food was left in the original bag and sealed with a bag clip.
	Product Use Information:	**Description:** Food was given. 2 times daily with water added
		First Exposure Date: 01/25/2019
		Last Exposure Date: 02/01/2019
		Time Interval between Product Use and Adverse Event: 3 Years
		Product Use Stopped After the Onset of the Adverse Event: Yes
		Adverse Event Abate After Product Stop: Not Applicable
		Product Use Started Again: No
		Perceived Relatedness to Probably related

FDA-CVM-FOIA-2019-1704-010544

		Adverse Event:	
		Other Foods or Products Given to the Animal During This Time Period:	Unknown
	Manufacturer /Distributor Information:		
	Purchase Location Information:	Name:	B6
		Address:	B6 United States
Animal Information:	Name:	B6	
	Type Of Species:	Dog	
	Type Of Breed:	Retriever - Golden	
	Gender:	Female	
	Reproductive Status:	Intact	
	Pregnancy Status:	Not Pregnant	
	Lactation Status:	Not lactating	
	Weight:	63 Pound	
	Age:	3 Years	
	Assessment of Prior Health:	Excellent	
	Number of Animals Given the Product:	3	
	Number of Animals Reacted:	1	
	Owner Information:		
	Healthcare Professional Information:		
Sender Information:	Name:	B6	
	Address:	B6 United States	
	Contact:	Phone:	B6
		Email:	B6
	Permission To Contact Sender:	Yes	
	Preferred Method Of Contact:	Email	
	Reported to Other Parties:	None	
Additional Documents:			

Cummings Veterinary Medical Center AT TUFTS UNIVERSITY

Foster Hospital for Small Animals
55 Willard Street
North Grafton, MA 01536
(508) 839-5395

All Medical Records

Client: B6
Address:

Patient: B6
Breed: Golden Retriever
DOB: B6

Species: Canine
Sex: Male (Neutered)

Home Phone: B6
Work Phone:
Cell Phone: B6

Referring Information

B6

Client:
Patient: B6

Initial Complaint:
Scanned Record

Initial Complaint:
New - B6 - DCM study

SOAP Text Nov 7 2018 12:08PM - B6

Disposition/Recommendations

FDA-CVM-FOIA-2019-1704-010546

FDA-CVM-FOIA-2019-1704-010547

Cummings Veterinary Medical Center AT TUFTS UNIVERSITY

Foster Hospital for Small Animals
55 Willard Street
North Grafton, MA 01536
(508) 839-5395

Client:	B6
Veterinarian:	
Patient ID:	B6
Visit ID:	

Patient:	B6
Species:	Canine
Breed:	Golden Retriever
Sex:	Male (Neutered)
Age:	B6 Years Old

Lab Results Report

11/7/2018 1:29:30 PM **Accession ID:** B6

Test	Results	Reference Range	Units
Troponin I Research - FHSA	B6	0 - 0.08	mg/dl

FDA-CVM-FOIA-2019-1704-010548

B6

FDA-CVM-FOIA-2019-1704-010549

B6

FDA-CVM-FOIA-2019-1704-010550

B6

FDA-CVM-FOIA-2019-1704-010551

B6

FDA-CVM-FOIA-2019-1704-010552

B6

FDA-CVM-FOIA-2019-1704-010553

B6

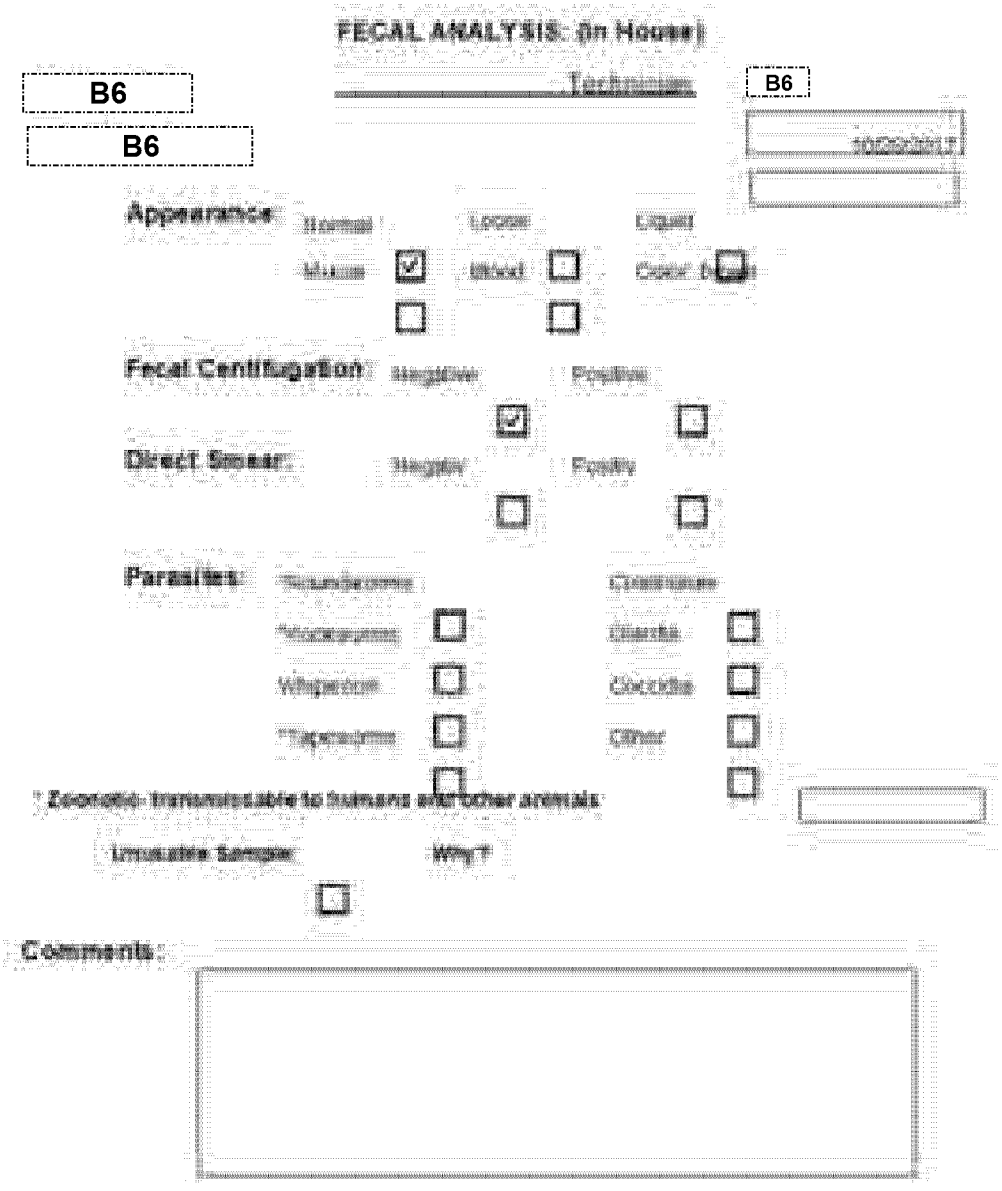
FDA-CVM-FOIA-2019-1704-010554

B6

FDA-CVM-FOIA-2019-1704-010555

Client: B6
Patient:

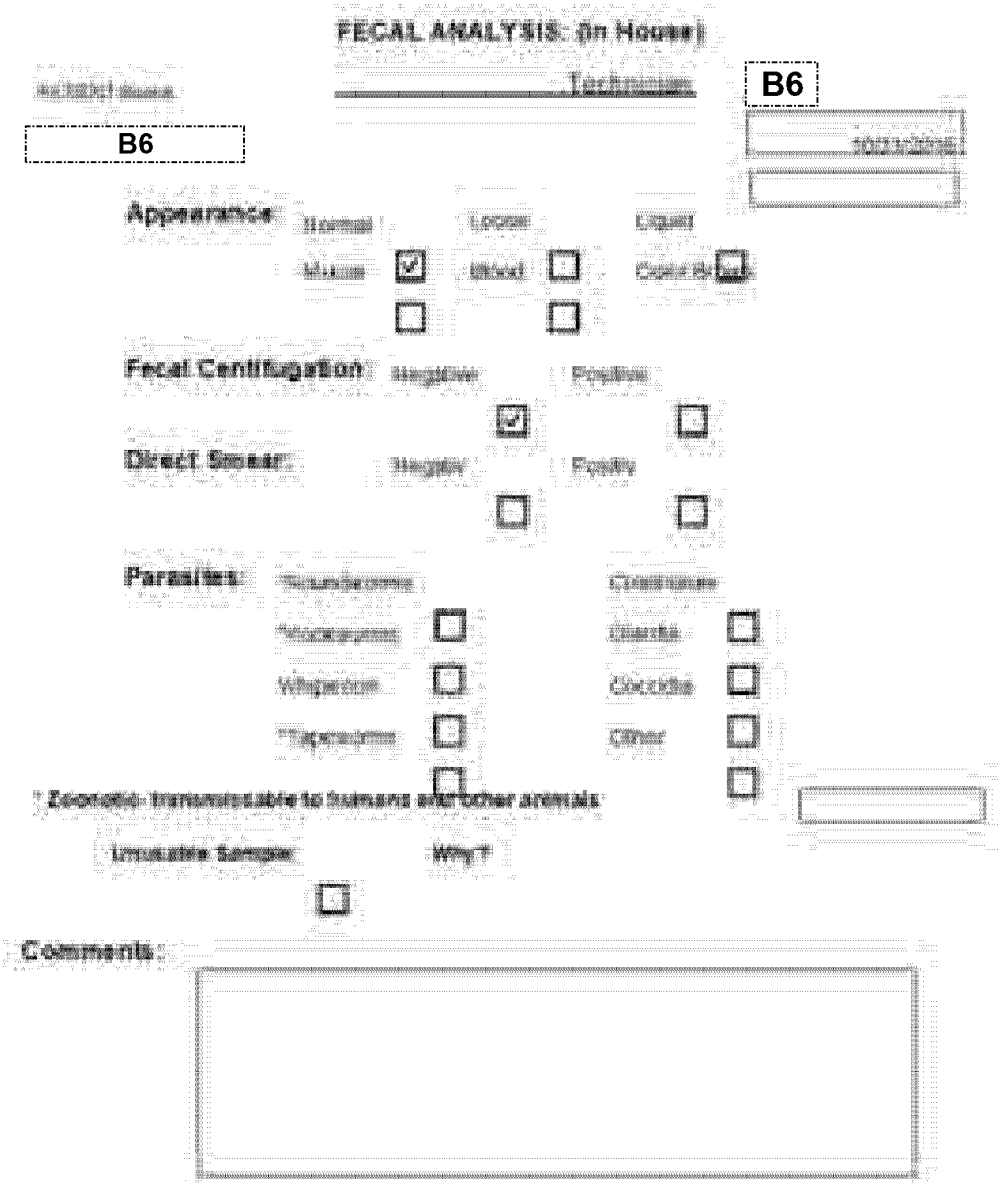
RDVM B6 **records**



FDA-CVM-FOIA-2019-1704-010556

Client:
Patient: B6

RDVM B6 records



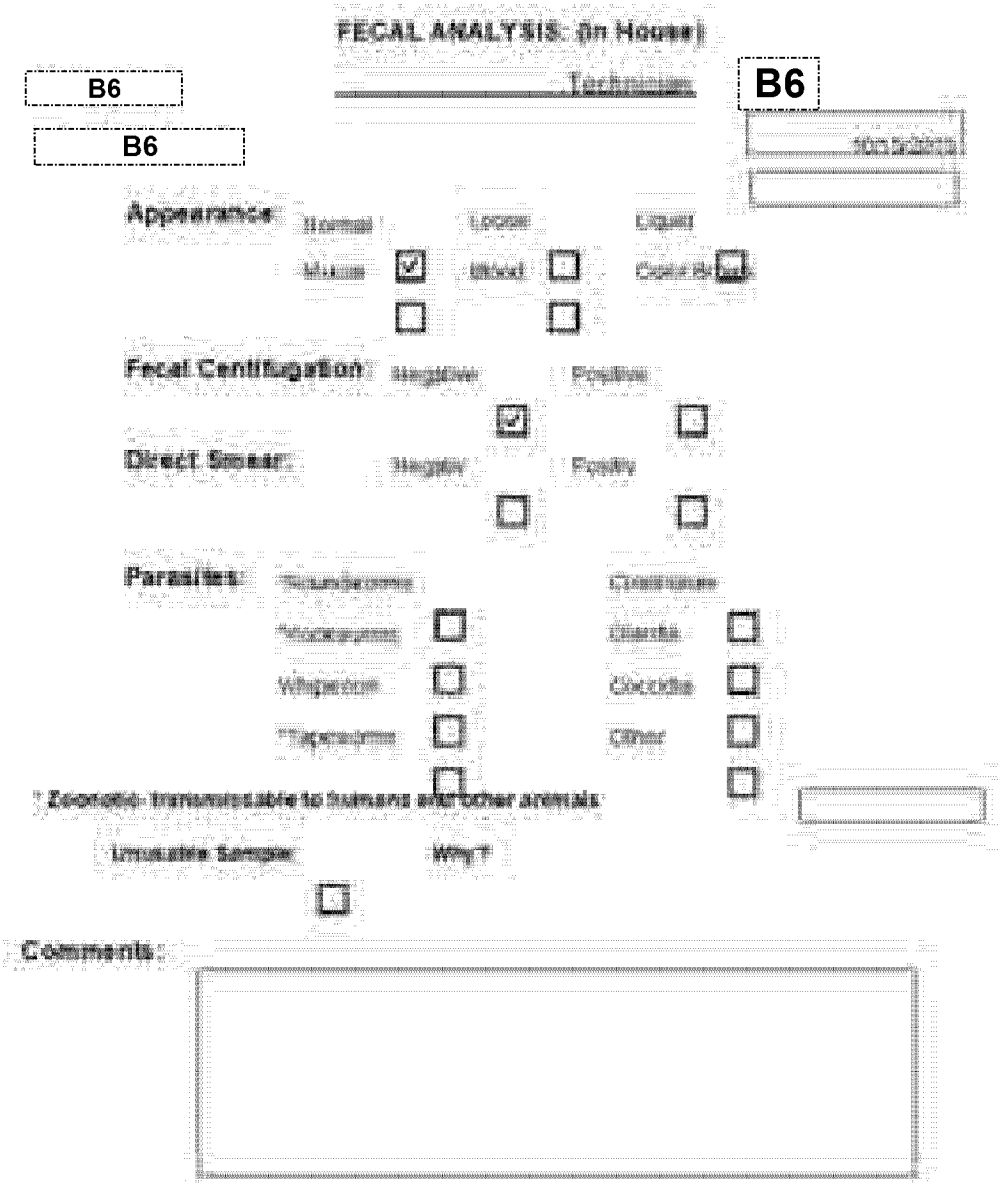
FDA-CVM-FOIA-2019-1704-010557

B6

FDA-CVM-FOIA-2019-1704-010558

Client: B6
Patient:

RDVM B6 **records**



FDA-CVM-FOIA-2019-1704-010559

IDEXX BNP - 11/8/2018

B6

FDA-CVM-FOIA-2019-1704-010560

Client:
Patient: **B6**

CBC/Chem - 11/7/2018

Tufts Cummings School Of Veterinary Medicine

200 Westboro Road
North Grafton, MA 01536

DUPLICATE

Name DOB
Patient ID
Phone number
Collection Date
Approval Date

B6

Provider: **B6**
Location: Tufts Nutrition Whole Food Lipemic Study
Sample ID: **B6**

CBC (Research) (Advia)

ANALYTE		B6	Ref. Range/Units
WBC (ADVIA)			4.48-13.10 K/uL
RBC (Advia)			7.80-9.20 M/uL
Hemoglobin (ADVIA)			13.3-20.2 g/dL
Hematocrit (Advia)			39-53 %
MCV (ADVIA)			64.3-77.3 fL
MCH (ADVIA)			21.3-25.9 pg
MCHC (ADVIA)			31.8-34.3 g/dL
RDW (ADVIA)			15.9-25.2
Comment (Hematology)		Platelets: Giant Platelets 100k 8x10 (estimated count of 200,000-300,000/uL)	

Microscopic Exam of Blood Smear (Advia)

ANALYTE		B6	Ref. Range/Units
Seg Neuts (%)			43-86 %
Lymphocytes (%)			7-47 %
Monocytes (%)			1-12 %
Eosinophils (%)			0-10 %
Seg Neutrophils (Abs)			2,000-11,300 K/uL
Advia			
Lymphs (Abs) Advia	L		1,000-4,800 K/uL
Monos (Abs) Advia			0.200-1.500 K/uL
Eosinophils (Abs) Advia			0.000-0.400 K/uL
WBC Morphology		Morphologic Abnormalities	
Echinocytes			

Research Chemistry Profile - Small Animal (Cobas)

ANALYTE		B6	Ref. Range/Units
Glucose			87-121 mg/dL
Urea			8-30 mg/dL
Creatinine			0.6-2.3 mg/dL
Phosphorus			2.8-7.2 mg/dL
Calcium T			9.4-11.1 mg/dL
Magnesium 2+			1.8-2.4 mEq/L
Total Protein			5.5-7.8 g/dL
Albumin			2.8-4.0 g/dL
Globulin	L		2.3-4.2 g/dL
A/G Ratio	H		0.7-1.6
Sodium	H		140-150 mEq/L
Chloride			106-122 mEq/L
Potassium			3.7-5.4 mEq/L
tCO2(Bicarb)			14-28 mEq/L
AGAP			8.0-19.0
NA/K			26-40
Total Bilirubin			0.10-0.30 mg/dL

Sample ID: 181101005-13
This report contains... (Final)

Reviewed By: _____

FDA-CVM-FOIA-2019-1704-010561

Client: B6
Patient:

CBC/Chem - 11/7/2018

Tufts Cummings School Of Veterinary Medicine

200 Westboro Road
North Grafton, MA 01536

DUPLICATE

Name DOB
Patient ID
Phone number
Collection Date
Approval Date

B6

Provider: B6
Order Location: [illegible] Rodolitic Food Lipemic Study
Sample ID: B6

Research Chemistry Profile - Small Animal (Cobas) (cont'd)

		Ref. Range/Units
ABLASOTTO	B6	
Direct Bilirubin		0.00-0.13 mg/dL
Indirect Bilirubin		0.00-0.20 mg/dL
Alkaline Phosphatase		12-127 U/L
GGT		0-10 U/L
ALT		14-86 U/L
AST		8-34 U/L
Creatine Kinase		57-422 U/L
Cholesterol		82-355 mg/dL
Triglycerides		30-318 mg/dL
Amylase		498-1210 U/L
Osmolality (calculated)		295-313 mmol/L

Sample ID: B6
REPRINT: Orig. printed on 11/7/2018 (Final)

Reference No: _____
Page 2

FDA-CVM-FOIA-2019-1704-010562

Client:
Patient: B6

Vitals Results

11/7/2018 11:32:13 AM	Weight (kg)	25.9000

FDA-CVM-FOIA-2019-1704-010563

Client: B6
Patient:

ECG from cardio

B6 B6

B6

FDA-CVM-FOIA-2019-1704-010564

Client: B6
Patient:

ECG from cardio

B6 B6

FDA-CVM-FOIA-2019-1704-010565

Client: B6
Patient:

ECG from cardio

B6 B6

FDA-CVM-FOIA-2019-1704-010566

Client:
Patient: B6

Patient History

B6

10:46 AM	Appointment
12:36 PM	Appointment
10:07 AM	UserForm
10:48 AM	UserForm
10:53 AM	Treatment
11:32 AM	Vitals
12:08 PM	Purchase
12:18 PM	UserForm
01:29 PM	Labwork
01:30 PM	Purchase
01:30 PM	Purchase
01:30 PM	Purchase

B6

FDA-CVM-FOIA-2019-1704-010567

From: Related PFR Event <pfrsignificantactivitycreation@fda.hhs.gov>

To: Carey, Lauren; Cleary, Michael *; HQ Pet Food Report Notification; B6

Sent: 3/28/2019 9:01:34 PM

Subject: Rachel Ray peak open range recipe (beef: Lisa Freeman - EON-383627

Attachments: 2064872-report.pdf; 2064872-attachments.zip

A PFR Report has been received and Related PFR Event [EON-383627] has been created in the EON System.

A "PDF" report by name "2064872-report.pdf" is attached to this email notification for your reference. Please note that all documents received in the report are compressed into a zip file by name "2064872-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-383627
ICSR #: 2064872
EON Title: Related PFR Event created for Rachel Ray peak open range recipe (beef venison lamb); 2064872

AE Date	10/06/2018	**Number Fed/Exposed**	1
Best By Date		**Number Reacted**	1
Animal Species	Dog	**Outcome to Date**	Stable
Breed	Boxer (German Boxer)		
Age	B6 Years		
District Involved	PFR-New England DO		

Product information
Individual Case Safety Report Number: 2064872
Product Group: Pet Food
Product Name: Rachel Ray peak open range recipe (beef, venison, lamb)
Description: DCM and arrhythmias diagnosed at time of GDV surgery so unclear if sepsis/post-op or true DCM. Had recheck echo B6 and still has DCM. Taurine pending. Owner has changed diet to Royal Canin Boxer
Submission Type: Followup
Report Type: Adverse Event (a symptom, reaction or disease associated with the product)
Outcome of reaction/event at the time of last observation: Stable

Number of Animals Treated With Product: 1
Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Rachel Ray peak open range recipe (beef, venison, lamb)		

This report is linked to:
Initial EON Event Key: EON-370720
Initial ICSR: 2058685

Sender information
Lisa Freeman
200 Westboro Rd
North Grafton, MA 01536
USA

Owner information
B6 USA

To view this Related PFR Event, please click the link below:
https://eon.fda.gov/eon//browse/EON-383627

To view the Related PFR Event Report, please click the link below:
https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jspa?decorator=none&e=0&issueType=10100&issueId=400725&parentIssueTypeId=12

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{

Report Details - EON-383627

ICSR:	2064872
Type Of Submission:	Followup
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)
Reporting Type:	Voluntary
Report Submission Date:	2019-03-28 16:47:21 EDT
Initial Report Date:	11/09/2018
Parent ICSR:	2058685
Follow-up Report to FDA Request:	Yes

Reported Problem:

Problem Description:	DCM and arrhythmias diagnosed at time of B6 surgery so unclear if sepsis/post-op or true DCM. Had recheck echo B6 still has DCM. Taurine pending. Owner has changed diet to Royal Canin Boxer
Date Problem Started:	B6
Concurrent Medical Problem:	Yes
Pre Existing Conditions:	B6
Outcome to Date:	Stable

Product Information:

Product Name:	Rachel Ray peak open range recipe (beef, venison, lamb)
Product Type:	Pet Food
Lot Number:	
Package Type:	BAG
Product Use Information:	**Description:** Rachael Ray's since about 2017- prior to that it has been Purina One chicken and rice. The Rachael Ray that I fed him was "PEAK- open range receipt some with chicken some with lamb or beef. The dry was served with one half a can of newman's organic chicken and brown rice. I also cooked chicken breasts and rice as well as hamburger and rice every other week and used cup of this instead of the canned food. Mixed it in with the dry food. I have as of last Thursday switched him to Royal Canin dry food for Boxers with 1/2 can of science diet healthy cusine-roasted chicken, carrots and spinach stew mixed with about two cups of this dry food..
Manufacturer /Distributor Information:	
Purchase Location Information:	

Animal Information:

Name:	B6
Type Of Species:	Dog
Type Of Breed:	Boxer (German Boxer)
Gender:	Male
Reproductive Status:	Intact
Weight:	34.8 Kilogram
Age:	8.4 Years
Assessment of Prior Health:	Good
Number of Animals Given the Product:	1
Number of Animals Reacted:	1
Owner Information:	**Owner Information** Yes

		provided:	
		Contact:	Name: B6 Phone: B6 Email: B6
		Address:	B6 United States
	Healthcare Professional Information:	Practice Name:	Tufts Cummings School of Veterinary Medicine
		Contact:	Name: Lisa Freeman Phone: (508) 887-4523 Email: lisa.freeman@tufts.edu
		Address:	200 Westboro Rd North Grafton Massachusetts 01536 United States
Sender Information:	Name:		Lisa Freeman
	Address:		200 Westboro Rd North Grafton Massachusetts 01536 United States
	Contact:	Phone:	5088874523
		Email:	lisa.freeman@tufts.edu
	Permission To Contact Sender:		Yes
	Preferred Method Of Contact:		Email
Additional Documents:			
	Attachment:		Diet Hx 3-27-19.pdf
	Description:		Diet History 3/27/19
	Type:		Medical Records
	Attachment:		Med rec 3.pdf
	Description:		Medical record
	Type:		Medical Records
	Attachment:		Med rec 1.pdf
	Description:		Medical record
	Type:		Medical Records
	Attachment:		Med rec 2.pdf
	Description:		Medical record
	Type:		Medical Records
	Attachment:		BNP 3-28-19.pdf
	Description:		BNP
	Type:		Medical Records

FDA-CVM-FOIA-2019-1704-010572

IDEXX VetConnect 1-888-433-9987

Client: B6
Patient: B6
Species: CANINE
Breed:
Gender: MALE
Age: 8Y

Date B6
Requisition #: 1A
Accession # B6
Ordered by: B6

TUFTS UNIVERSITY
200 WESTBORO RD
NORTH GRAFTON, Massachusetts 01536
508-839-5395

Account #88933

B4 **proBNP - CANINE**

Test	Result	Reference Range	Low	Normal	High
CARDIOPET proBNP - CANINE	B6	0 - 900 pmol/L	HIGH	B6	

Comments:

B6

Please note: Complete interpretive comments for all concentrations of Cardiopet proBNP are available in the online directory of services. Serum specimens received at room temperature may have decreased NT proBNP concentrations.

FDA-CVM-FOIA-2019-1704-010573

CARDIOLOGY DIET HISTORY FORM

Please answer the following questions about your pet

Pet's name: B6 Owner's name : B6 Today's date: B6

1. How would you assess your pet's appetite? (mark the point on the line below that best represents your pet's appetite)

Example: ***Poor*** ——|—— ***Excellent***

Poor ——|—— **Excellent**

2. Have you noticed a change in your pet's appetite over the last 1-2 weeks? (check all that apply)

☒ Eats about the same amount as usual ☐ Eats less than usual ☐ Eats more than usual
☐ Seems to prefer different foods than usual ☐ Other_____

3. Over the last few weeks, has your pet (check one)

☐ Lost weight ☐ Gained weight ☒ Stayed about the same weight ☐ Don't know

4. Please list below ALL pet foods, people food, treats, snack, dental chews, rawhides, and any other food item that your pet currently eats. Please include the brand, specific product, and flavor so we know exactly what you pet is eating.

Examples are shown in the table – please provide enough detail that we could go to the store and buy the exact same food

Food (include specific product and flavor)	Form	Amount	How often?	Fed since
Nutro Grain Free Chicken, Lentil, & Sweet Potato Adult	*dry*	*1 ½ cup*	*2x/day*	*Jan 2018*
85% lean hamburger	*microwaved*	*3 oz*	*1x/week*	*Jan 2015*
Pupperoni original beef flavor	*treat*	*½*	*1x/day*	*Aug 2015*
Rawhide	*treat*	*6 inch twist*	*1x/week*	*Dec 2015*
Royal Canine	dry	1½ cup	1x day	Oct 2018
Hills Science Diet – Chick stew	wet	½ can	1x daily	Oct 2018

**Any additional diet information can be listed on the back of this sheet*

5. Do you give any dietary supplements to your pet (for example: vitamins, glucosamine, fatty acids, or any other supplements)? ☐ Yes ☒ No If yes, please list which ones and give brands and amounts:

		Brand/Concentration	Amount per day
Taurine	☐ Yes ☐ No		
Carnitine	☐ Yes ☐ No		
Antioxidants	☐ Yes ☐ No		
Multivitamin	☐ Yes ☐ No		
Fish oil	☐ Yes ☐ No		
Coenzyme Q10	☐ Yes ☐ No		
Other (please list):			
Example: Vitamin C		*Nature's Bounty*	*500 mg tablets – 1 per day*

6. How do you administer pills to your pet?

☐ I do not give any medications
☐ I put them directly in my pet's mouth without food
☐ I put them in my pet's dog/cat food
☐ I put them in a Pill Pocket or similar product
☐ I put them in foods (list foods):_____

FDA-CVM-FOIA-2019-1704-010574

Cummings Veterinary Medical Center
AT TUFTS UNIVERSITY

Foster Hospital for Small Animals
55 Willard Street
North Grafton, MA 01536
(508) 839-5395

Client:	B6
Veterinarian:	
Patient ID:	B6
Visit ID:	

Patient:	B6
Species:	Canine
Breed:	Boxer
Sex:	Male
Age:	B6 Years Old

Lab Results Report

Nova Full Panel-ICU B6 **1:30:25 AM** **Accession ID:** B6

Test	Results	Reference Range	Units
SO2%		94 - 100	%
HCT (POC)		38 - 48	%
HB (POC)		12.6 - 16	g/dL
NA (POC)		140 - 154	mmol/L
K (POC)		3.6 - 4.8	mmol/L
CL(POC)		109 - 120	mmol/L
CA (ionized)		1.17 - 1.38	mmol/L
MG (POC)		0.1 - 0.4	mmol/L
GLUCOSE (POC)		80 - 120	mg/dL
LACTATE		0 - 2	mmol/L
BUN (POC)	B6	12 - 28	mg/dL
CREAT (POC)		0.2 - 2.1	mg/dL
TCO2 (POC)		0 - 0	mmol/L
nCA		0 - 0	mmol/L
nMG		0 - 0	mmol/L
GAP		0 - 0	mmol/L
CA/MG		0 - 0	mol/mol
BEecf		0 - 0	mmol/L
BEb		0 - 0	mmol/L
A		0 - 0	mmHg
NOVA SAMPLE		0 - 0	

FDA-CVM-FOIA-2019-1704-010575

Client:
Patient: B6

FiO2	B6 (room air)	0 - 0	%
PCO2		36 - 44	mmHg
PO2		80 - 100	mmHg
PH	B6	7.337 - 7.467	
PCO2		36 - 44	mmHg
PO2		80 - 100	mmHg
HCO3		18 - 24	mmol/L

Nova Full Panel-ICU B6 **1:52:25 AM** **Accession ID:** B6

Test	Results	Reference Range	Units
TS (FHSA)		0 - 0	g/dL
Lactate (FHSA) *		0 - 0	mmol/L
BG (FHSA)	B6	0 - 0	g/dL
TS (FHSA)		0 - 0	g/dL
PCV		0 - 0	%

Nova Full Panel-ICU B6 **2:06:14 AM** **Accession ID:** B6

Test	Results	Reference Range	Units
PT (ER)-Citrate	15	0 - 0	sec

Nova Full Panel-ICU B6 **3:50:25 AM** **Accession ID:** B6

Test	Results	Reference Range	Units
SO2%		94 - 100	%
HCT (POC)		38 - 48	%
HB (POC)		12.6 - 16	g/dL
NA (POC)		140 - 154	mmol/L
K (POC)		3.6 - 4.8	mmol/L
CL(POC)		109 - 120	mmol/L
CA (ionized)		1.17 - 1.38	mmol/L
MG (POC)		0.1 - 0.4	mmol/L
GLUCOSE (POC)		80 - 120	mg/dL
LACTATE		0 - 2	mmol/L
BUN (POC)	B6	12 - 28	mg/dL
CREAT (POC)		0.2 - 2.1	mg/dL
TCO2 (POC)		0 - 0	mmol/L
nCA		0 - 0	mmol/L
nMG		0 - 0	mmol/L
GAP		0 - 0	mmol/L
CA/MG		0 - 0	mol/mol
BEecf		0 - 0	mmol/L
BEb		0 - 0	mmol/L
Λ		0 - 0	mmHg
NOVA SAMPLE		0 - 0	

FDA-CVM-FOIA-2019-1704-010576

Client:
Patient: B6

FiO2	B6 redacted	0 - 0	%
PCO2		36 - 44	mmHg
PO2		80 - 100	mmHg
PH		7.337 - 7.467	
PCO2		36 - 44	mmHg
PO2		80 - 100	mmHg
HCO3		18 - 24	mmol/L

Nova Full Panel-ICU B6 **30:17 PM** **Accession ID:** B6

Test	Results	Reference Range	Units
TS (FHSA)	B6 redacted	0 - 0	g/dl
PCV **		0 - 0	%
TS (FHSA)		0 - 0	g/dl

Nova Full Panel-ICU B6 **7:54:25 AM** **Accession ID:** B6

Test	Results	Reference Range	Units
SO2%	B6 redacted	94 - 100	%
HCT (POC)		38 - 48	%
HB (POC)		12.6 - 16	g/dL
NA (POC)		140 - 154	mmol/L
K (POC)		3.6 - 4.8	mmol/L
CL(POC)		109 - 120	mmol/L
CA (ionized)		1.17 - 1.38	mmol/L
MG (POC)		0.1 - 0.4	mmol/L
GLUCOSE (POC)		80 - 120	mg/dL
LACTATE		0 - 2	mmol/L
BUN (POC)		12 - 28	mg/dL
CREAT (POC)		0.2 - 2.1	mg/dL
TCO2 (POC)		0 - 0	mmol/L
nCA		0 - 0	mmol/L
nMG		0 - 0	mmol/L
GAP		0 - 0	mmol/L
CA/MG		0 - 0	mol/mol
BEecf		0 - 0	mmol/L
BEb		0 - 0	mmol/L
A		0 - 0	mmHg
NOVA SAMPLE		0 - 0	
FiO2	B6 (room air)	0 - 0	%
PCO2	B6 redacted	36 - 44	mmHg
PO2		80 - 100	mmHg
PH		7.337 - 7.467	
PCO2		36 - 44	mmHg

FDA-CVM-FOIA-2019-1704-010577

Client: B6
Patient:

PO2	B6	80 - 100	mmHg
HCO3		18 - 24	mmol/L

Nova Full Panel-ICU B6 **3:25:41 AM** **Accession ID:** B6

Test	Results	Reference Range	Units
TS (FHSA)	B6	0 - 0	g/dl
PCV **		0 - 0	%
TS (FHSA)		0 - 0	g/dl

Nova Full Panel-ICU B6 **10:31:12 AM** **Accession ID:** B6

Test	Results	Reference Range	Units
WBC (ADVIA)	B6	4.4 - 15.1	K/uL
RBC(ADVIA)		5.8 - 8.5	M/uL
HGB(ADVIA)		13.3 - 20.5	g/dL
HCT(ADVIA)		39 - 55	%
MCV(ADVIA)		64.5 - 77.5	fL
MCH(ADVIA)		21.3 - 25.9	pg
MCHC(ADVIA)		31.9 - 34.3	g/dL
RDW (ADVIA)		11.9 - 15.2	
PLT(ADVIA)		173 - 486	K/uL
MPV (ADVIA)		8.29 - 13.2	fl
PLTCRT		0.129 - 0.403	%
RETIC(ADVIA)		0.2 - 1.6	%
RETICS (ABS) ADVIA		14.7 - 113.7	K/uL

Nova Full Panel-ICU B6 **10:31:27 AM** **Accession ID:** B6

Test	Results	Reference Range	Units
GLUCOSE	B6	67 - 135	mg/dL
UREA		8 - 30	mg/dL
CREATININE		0.6 - 2	mg/dL
PHOSPHORUS		2.6 - 7.2	mg/dL
CALCIUM2		9.4 - 11.3	mg/dL
MAGNESIUM 2+		1.8 - 3	mEq/L
T. PROTEIN		5.5 - 7.8	g/dL
ALBUMIN		2.8 - 4	g/dL
GLOBULINS		2.3 - 4.2	g/dL
A/G RATIO		0.7 - 1.6	
SODIUM		140 - 150	mEq/L
CHLORIDE		106 - 116	mEq/L
POTASSIUM		3.7 - 5.4	mEq/L
tCO2 (BICARB)		14 - 28	mEq/L
AGAP		8 - 19	
NA/K		29 - 40	

FDA-CVM-FOIA-2019-1704-010578

Client:
Patient: B6

T BILIRUBIN	B6	0.1 - 0.3	mg/dL
D.BILIRUBIN		0 - 0.1	mg/dL
I BILIRUBIN		0 - 0.2	mg/dL
ALK PHOS		12 - 127	U/L
GGT		0 - 10	U/L
ALT		14 - 86	U/L
4309 Result(s) verified			
AST		9 - 54	U/L
2648 Result(s) verified			
CK		22 - 422	U/L
16084 Result(s) verified			
CHOLESTEROL	B6	82 - 355	mg/dL
TRIGLYCERIDES		30 - 338	mg/dl
AMYLASE		409 - 1250	U/L
OSMOLALITY (CALCULATED)		291 - 315	mmol/L

Nova Full Panel-ICU B6 **10:31:11 AM** **Accession ID:** B6

Test	Results	Reference Range	Units
SEGS%	B6	43 - 86	%
LYMPHS%		7 - 47	%
MONOS%		1 - 15	%
EOS%		0 - 16	%
SEGS (AB)ADVIA		2.8 - 11.5	K/ul
LYMPHS (ABS)ADVIA		1 - 4.8	K/uL
MONOS (ABS)ADVIA		0.1 - 1.5	K/uL
EOS (ABS)ADVIA		0 - 1.4	K/uL
TOXIC CHANGE		0 - 0	
Occasional Occasional neutrophil appears slightly toxic			
ACANTHOCYTES	B6	0 - 0	
KERATOCYTES/BLISTER CELLS		0 - 0	
POIKILOCYTOSIS		0 - 0	

Nova Full Panel-ICU B6 **3:19:40 PM** **Accession ID:** B6

Test	Results	Reference Range	Units
Troponin I Research - FHSA	B6	0 - 0.08	mg/dl

FDA-CVM-FOIA-2019-1704-010579

Anesthesia Record

Tufts Cummings School of Veterinary Medicine SA Anesthesia Surgical Checklist

App B6

Patient: B6
Client: B6

Species: Canine
Breed: Boxer
Sex: Male
Weight kg: 0.00
Date of Birth: B6
Color: White
Check-in Date: B6 12:54:23 AM

Patient ID: B6
City: B6
Home Phone:
Cell Phone
Ref Facility
Ref Phone
B6

Additional notes:

Before Premedication of Patient	*After Induction in Prep Area*	*Prior to Leaving OR*
Confirmed by Anesthesia Team	**Initiated by Anesthesia Team**	**Initiated by Anesthesia Team**
✓ Patient ID, procedure,& procedure site	Radiology work-up completed o Yes ✓ N/A	
✓ Blood work and SOAP complete	Cefazolin (or other antibiotic) requested and available ✓ Yes o Hold o N/A	Phone call to radiology o Yes ✓ N/A
✓ Body weight matches patient size	Number of catheters placed is appropriate for patient needs ✓ Yes o No, additional catheters placed	**Anesthesia Service States** ✓ Any concerns for patient recovery?
✓ Work-up sheet reviewed & signed by anesthesiologist		**Surgeon States** ✓ Any concerns for patient recovery?
Before Induction of Patient	Does patient need T-set? o Yes (place T set in induction) ✓ No	✓ Ward where patient will spend the evening ICU
Confirmed by Anesthesia Team	*Before Skin Incision*	If patient can receive NSAIDs o Yes ✓ No Which NSAID? _____
Met check cleared o Yes ✓ N/A	**Initiated by Anesthesia Team**	
Red line cleared by accounting ✓ Yes o N/A	✓ Patient's ID, procedure, & procedure site confirmed	Additional analgesics surgery will use ✓ Yes rescue fentanyl o No. Which analgesic? _____
✓ Anesthesia machine checked and pop-off valve open	Cefazolin (or other a/b) requested & given within the prev. 60 min ✓ Yes o Hold o N/A	
Difficult airway or aspiration risk? ✓ No o Yes, nec. equipment available o Yes, Surgeon must be present	**Anesthetist States** ✓ Any specific anesthetic concerns	Bladder o Express o U cath
Risk of significant blood loss o No o Yes, blood type (+/- crossmatch) and appropriate blood available	**Surgeon States** ✓ Critical or non-routine steps ✓ Anticipated blood loss	Surgeon/ Resident: B6 Anesthetist Tech/Student: B6 Surgery Tech: B6 Date: B6
This form remains with the patient through recovery.	**Surgery Technician States** ✓ Sterilization indicators confirmed	

FDA-CVM-FOIA-2019-1704-010580

Anesthesia Record

B6

Surgical(surgeon/tech/student)/Anesthesia(anesthetist/student) Called? Time: _____

If ASA status ≥ III consider (check if done):

Blood Type _____ Coags _____ 2nd IVC (hind leg) ✓

Lumen catheter_____ Doppler BP_____Heat support_____

Other Considerations (check if applicable):

Brachycephalic?_____ vWD protocol_____ Sepsis protocol_____

NOTES:_____

_____

_____

_____

SOAP COMPLETE? Y___ N___SX DEPOSIT COLLECTED? Y___ N___

Place

B6

Patient: B6
Client:

Species: Canine
Breed: Boxer
Sex: Male
Weight kg: 0.00
Date of Birth: B6
Color: White
Check-in Date: B6 12:54:23 AM

Patient ID: B6
City: B6
Home Phone:
Cell Phone:
Ref Facility
Ref Phone

B6

FDA-CVM-FOIA-2019-1704-010581

Tufts University Cummings School of Veterinary Medicine
ANESTHESIA RECORD

B6

B6

FDA-CVM-FOIA-2019-1704-010582

Client: B6
Patient:

Rx B6

B6 07:22 PM B6 via B6 Page 1 of 1 B6

B6

PRESCRIPTION AUTHORIZATION REQUEST

B6

Employee # B6

Dat B6

5243234

Dear Doctor,

Please review and complete the following prescription authorization and fax the form back to our pharmacy at B6 If you need to speak with our pharmacists, or prefer to call us with this prescription, please call 1 B6 Thank you.

FAXED B6

Pet Owner Information

Pet Owner's Name (First) B6 (Last) B6 C# B6

Address B6 City B6

State B6 Zip B6 Phone B6 Ord # B6

Pet & Prescription Information

Attn Veterinarian: Please enter all of the following Rx information.

B6

	Pet Name	Weight	Medication	Strength	Qty	Additional Refills
1	B6		B6	10mg	100	11
	Species: DOG	Directions for Use: Give 1 tablet by mouth twice daily				
	Denied:	Reason:				
2						
	Species	Directions for Use:				
	Denied:	Reason:				

Additional Comments: **Client is requesting additional refills, thank you.**

Veterinarian Information

In compliance with pharmacy law, we are only able to accept prescriptions faxed from a licensed veterinarian. Please fax the completed form to 1-800-447-2404. Thank You

Veterinarian Name B6 State License B6 DEA # (if applicable)

Clinic Name Cummings Medical Center Phone 508-839-5395 Fax 508-839-7951

Address City State Zip

Email ID # (Pharmacy use only)

Patient Information ** To be completed by Veterinarian **

Please indicate any known significant allergies/medical conditions:

Veterinarian's Signature **Per Pharmacy Law, we are unable to accept stamped signatures.** Date B6

B6

Generic Equivalent Permissible ally Necessary B6 Printed Name

Confidentiality Notice: This telecopy contains confidential information belonging to the sender that is legally privileged. This information is intended only for the use of the individual or entity named above. The authorized recipient of this information is prohibited from disclosing this information to any other party. If you are not the intended recipient, you are hereby notified that any disclosure, copying, distribution, or action taken in reliance on the contents of this document is strictly prohibited. If you have received this telecopy in error, please notify the sender immediately to arrange for the return of this document.

FDA-CVM-FOIA-2019-1704-010583

Client: B6
Patient:

BNP 10/31/18

IDEXX Reference Laboratories

Client B6

IDEXX VetConnect 1-888-433-9987

Client: B6
Patient
Species: CANINE
Breed:
Gender:
Age: 0Y

Date: 10/31/2018
Requisition # B6
Accession # B6
Ordered by: NOT SPECIFIED

TUFTS UNIVERSITY
200 WESTBORO RD
NORTH GRAFTON, Massachusetts 01536-1828
508-839-5395

Accou B6

CARDIOPET proBNP - CANINE

Test	Result	Reference Range	Low	Normal	High
CARDIOPET proBNP - CANINE	B6	0 - 900 pmol/L	HIGH	B6	

Comments:

1. Cardiopet proBNP >1800pmol/L

B6

Please note: Complete interpretive comments for all concentrations of Cardiopet proBNP are available in the online directory of services. Serum specimens received at room temperature may have decreased NT-proBNP concentrations.

Page 1 of 1

FDA-CVM-FOIA-2019-1704-010584

Client: B6
Patient:

UCDavis Taurine Panel

PL ~~AB~~ 24345 WB 24346

Amino Acid Laboratory Sample Submission Form

B6

B6 Canine
B6 10:45 AM
TAURINE PANEL
Lithium Heparin

Amino Acid Laboratory, 1089 Veterinary Medicine Drive, Davis, Ca 95616
Telephone: 530-752-5058, Fax: 530-752-4698
Email: ucd.aminoacid.lab@ucdavis.edu
www.vetmed.ucdavis.edu/labs/amino-acid-laboratory

Veterinarian Contact: B6

Clinic/Company Name: Tufts Cummings School of Vet. Med. - Clinical Pathology Laboratory

Address: 200 Westboro Road, North Grafton MA 015369

Email: Clinpath@tufts.edu / cardiovet@tufts.edu.

Telephone: 508-887-4669 **Fax:** 508-839-7936

Billing Contact: B6 **Email:** B6

Billing Contact Phone: B6 **Tax ID:**

Patient Name: B6 **Species:** Canine

Breed: Boxer **Owner's Name:** B6

Current Diet : Rachel Ray super premium dry chicken/vegs iedry, Purina and Chicken/rice canned, Newman's own chicken/rice

Sample type: (Plasma) (Whole Blood) Urine Food Other

Test: (Taurine) Complete Amino Acids Other:

Taurine Results (lab use only)

Plasma: B6 Whole Blood: B6 Urine: Food:

	Plasma (nMol/ml)		Whole Blood (nMol/ml)	
	Normal Range	No known risk for deficiency	Normal Range	No known risk for deficiency
Cat	**80-120**	**>40**	**300-600**	**>200**
Dog	**60-120**	**>40**	**200-350**	**>150**

* Please note with the recent increase in the number of dogs screened for taurine deficiency, we are seeing dogs with values within the reference ranges (or above the "no known risk for deficiency range") yet are still exhibiting signs of cardiac disease. Veterinarians are welcome to contact our laboratory for assistance in evaluating your patient's results.

FDA-CVM-FOIA-2019-1704-010585

Client: B6
Patient:

BNP 3/28/19

IDEXX Reference Laboratories

Client: B6 Patient: B6

IDEXX VetConnect 1-888-433-9987

Client: B6
Patient: B6
Species: CANINE
Breed:
Gender: MALE
Age: 8Y

Date: 03/27/2019
Requisition #: 1A
Accession #: B6
Ordered by: B6

TUFTS UNIVERSITY
200 WESTBORO RD
NORTH GRAFTON, Massachusetts 01536
508-839-5395

Account #88933

CARDIOPET proBNP - CANINE

Test	Result	Reference Range	Low	Normal	High
CARDIOPET proBNP - CANINE	B6	0 - 900 pmol/L	HIGH	B6	

Comments:
1. Cardiopet proBNP >1800pmol/L

B6

Please note: Complete interpretive comments for all concentrations of Cardiopet proBNP are available in the online directory of services. Serum specimens received at room temperature may have decreased NT-proBNP concentrations.

Page 1 of 1

FDA-CVM-FOIA-2019-1704-010586

Client: B6
Patient:

Diet Hx 3/27/19

CARDIOLOGY DIET HISTORY FORM

Please answer the following questions about your pet

Pet's name: B6 Owner's name : B6 Today's date: B6

1. How would you assess your pet's appetite? (mark the point on the line below that best represents your pet's appetite)

Example: *Poor* ——— *Excellent*

Poor ——— Excellent

2. Have you noticed a change in your pet's appetite over the last 1-2 weeks? (check all that apply)
☒ Eats about the same amount as usual ☐ Eats less than usual ☐ Eats more than usual
☐ Seems to prefer different foods than usual ☐ Other ———

3. Over the last few weeks, has your pet (check one)
☐ Lost weight ☐ Gained weight ☒ Stayed about the same weight ☐ Don't know

4. Please list below ALL pet foods, people food, treats, snack, dental chews, rawhides, and any other food item that your pet currently eats. Please include the brand, specific product, and flavor so we know exactly what you pet is eating.

Examples are shown in the table – please provide enough detail that we could go to the store and buy the exact same food.

Food (include specific product and flavor)	Form	Amount	How often?	Fed since
Nutro Grain Free Chicken, Lentil, & Sweet Potato Adult	*dry*	*1 ½ cup*	*2x/day*	*Jan 2018*
85% lean hamburger	*microwaved*	*3 oz*	*1x/week*	*Jan 2015*
Pupperoni original beef flavor	*treat*	*½*	*1x/day*	*Aug 2015*
Rawhide	*treat*	*6 inch twist*	*1x/week*	*Dec 2015*
Royal Canine	dry	1½ cup	1x day	Oct 2018
Hills Science Diet – Chick stew	wet	½ Can	1 x day	Oct 2018

**Any additional diet information can be listed on the back of this sheet*

5. Do you give any dietary supplements to your pet (for example: vitamins, glucosamine, fatty acids, or any other supplements)? ☐ Yes ☒ No If yes, please list which ones and give brands and amounts:

		Brand/Concentration	Amount per day
Taurine	☐ Yes ☐ No		
Carnitine	☐ Yes ☐ No		
Antioxidants	☐ Yes ☐ No		
Multivitamin	☐ Yes ☐ No		
Fish oil	☐ Yes ☐ No		
Coenzyme Q10	☐ Yes ☐ No		
Other (please list):			
Example: Vitamin C		*Nature's Bounty*	*500 mg tablets – 1 per day*

6. How do you administer pills to your pet?
☐ I do not give any medications
☐ I put them directly in my pet's mouth without food
☐ I put them in my pet's dog/cat food
☐ I put them in a Pill Pocket or similar product
☐ I put them in foods (list foods): ———

FDA-CVM-FOIA-2019-1704-010587

Tufts Cummings School Of Veterinary Medicine
200 Westboro Road
North Grafton, MA 01536

DUPLICATE

Name/DOB: B6
Patient ID: B6
Phone number:
Collection Date: 3/27/2019 12:55 PM
Approval date: 3/27/2019 3:15 PM

Sex: U
Age: 8
Species: Canine
Breed: Boxer

Provider: B6
Order Location: V320559: Investigation into
Sample ID: B6

T4/Clin Path (Research)

ABLASOTTO T4/Tosoh	B6	Ref. Range/-- 1.00-4.10 ug/dl

Sample ID: B6
REPRINT: Orig. printing on 3/27/2019 (Final)

Reviewed by: _____

FDA-CVM-FOIA-2019-1704-010588

Client:
Patient: B6

Cbc/Chem 10/31/18

Tufts Cummings School Of Veterinary Medicine

200 Westboro Road
North Grafton, MA 01536

DUPLICATE

Name/DOB: B6
Patient ID: B6
Phone number:
Collection Date: 10/31/2018 10:45 AM
Approval date: 10/31/2018 12:58 PM

Sex: U
Age: 8
Species: Canine
Breed: Boxer

Provider: B6
Order Location: V320422: Barkley Fund Lipitor Study
Sample ID: B6

CBC (Research) (Advia)

B6

SMACHUNSKI		Ref. Range/--
WBC (ADVIA)		4.40-15.10 K/uL
RBC (Advia)		5.80-8.50 M/uL
Hemoglobin (ADVIA)		13.3-20.5 g/dL
Hematocrit (Advia)		39-55 %
MCV (ADVIA)		64.5-77.5 fL
MCH (ADVIA)		21.3-25.9 pg
MCHC (ADVIA)	H	31.9-34.3 g/dL
RDW (ADVIA)		11.9-15.2
Comments (Hematology)		platelets/ 100x field (estimated count of 200,000-500,000/ul)

Microscopic Exam of Blood Smear (Advia)

B6

SMACHUNSKI		Ref. Range/--
Seg Neuts (%)	H	43-86 %
Lymphocytes (%)	L	7-47 %
Monocytes (%)		1-15 %
Eosinophils (%)		0-16 %
Seg Neutrophils (Abs) Advia	H	2.800-11.500 K/ul
Lymphs (Abs) Advia	L	1.00-4.80 K/uL
Mono (Abs) Advia		0.10-1.50 K/uL
Eosinophils (Abs) Advia		0.00-1.40 K/uL

B6

WBC Morphology
Acanthocytes
Poikilocytosis

B6

Research Chemistry Profile - Small Animal (Cobas)

B6

TFRANK	Ref. Range/--
Glucose	67-135 mg/dL
Urea	8-30 mg/dL
Creatinine	0.6-2.0 mg/dL
Phosphorus	2.6-7.2 mg/dL
Calcium 2	9.4-11.3 mg/dL
Magnesium 2+	1.8-3.0 mEq/L
Total Protein	5.5-7.8 g/dL
Albumin	2.8-4.0 g/dL
Globulins	2.3-4.2 g/dL
A/G Ratio	0.7-1.6
Sodium	140-150 mEq/L
Chloride	106-116 mEq/L
Potassium	3.7-5.4 mEq/L
tCO2(Bicarb)	14-28 mEq/L
AGAP	8.0-19.0
NA/K	29-40

Sample ID: B6
This report continues... (Final)

Reviewed by: _____

FDA-CVM-FOIA-2019-1704-010589

Tufts Cummings School Of Veterinary Medicine

200 Westboro Road
North Grafton, MA 01536

DUPLICATE

Name/DOB: B6
Patient ID: B6
Phone number:
Collection Date: 10/31/2018 10:45 AM
Approval date: 10/31/2018 12:58 PM

Sex: U
Age: 8
Species: Canine
Breed: Boxer

Provider: B6
Order Location: V320422: Barkley Fund Lipitor Study
Sample ID: B6

Research Chemistry Profile - Small Animal (Cobas) (cont'd)

TFRANK		B6	Ref. Range/--
Total Bilirubin			0.10-0.30 mg/dL
Direct Bilirubin			0.00-0.10 mg/dL
Indirect Bilirubin			0.00-0.20 mg/dL
Alkaline Phosphatase			12-127 U/L
GGT			0-10 U/L
ALT			14-86 U/L
AST			9-54 U/L
Creatine Kinase			22-422 U/L
Cholesterol	H		82-355 mg/dL
Triglycerides			30-338 mg/dl
Amylase			409-1250 U/L
Osmolality (calculated)	L		291-315 mmol/L
Comments (Chemistry)		B6	

FDA-CVM-FOIA-2019-1704-010590

Client: B6
Patient:

Cbc/Chem 10/7/18

Tufts Cummings School Of Veterinary Medicine

200 Westboro Road
North Grafton, MA 01536

DUPLICATE

Name/DOB: B6
Patient ID: B6
Phone number:
Collection Date: 10/7/2018 10:31 AM
Approval date: 10/7/2018 4:14 PM

Sex: U
Age: 8
Species: Canine
Breed: Boxer

Provider: B6
Order Location: Foster Hospital for Small Animals
Sample ID: B6

CBC, Comprehensive, Sm Animal

TFRANK			Ref. Range/--
WBC (ADVIA)	H	B6	4.40-15.10 K/uL
RBC (Advia)			5.80-8.50 M/uL
Hemoglobin (ADVIA)			13.3-20.5 g/dL
Hematocrit (Advia)			39-55 %
MCV (ADVIA)			64.5-77.5 fL
MCH (ADVIA)			21.3-25.9 pg
MCHC (ADVIA)			31.9-34.3 g/dL
RDW (ADVIA)			11.9-15.2
Platelet Count (Advia)	L		173-486 K/uL
10/07/18 4:11 PM		B6	
Mean Platelet Volume (Advia)		B6	8.29-13.20 fl
10/07/18 1:18 PM		B6	
Platelet Crit		B6	0.129-0.403 %
10/07/18 1:18 PM		B6	
Reticulocyte Count (Advia)		B6	0.20-1.60 %
Absolute Reticulocyte Count (Advia)			14.7-113.7 K/uL

Microscopic Exam of Blood Smear (Advia)

TFRANK			Ref. Range/--
Seg Neuts (%)	H	B6	43-86 %
Lymphocytes (%)	L		7-47 %
Monocytes (%)			1-15 %
Eosinophils (%)			0-16 %
Seg Neutrophils (Abs) Advia	H		2.800-11.500 K/ul
Lymphs (Abs) Advia	L		1.00-4.80 K/uL
Mono (Abs) Advia			0.10-1.50 K/uL
Eosinophils (Abs) Advia			0.00-1.40 K/uL
Toxic Change			
10/07/18 4:14 PM		B6	
Acanthocytes		B6	
Keratocytes/Blister Cells			
Poikilocytosis			

Sample ID: B6
This report continues... (Final)

Reviewed by: _____

FDA-CVM-FOIA-2019-1704-010591

Client: B6
Patient:

Cbc/Chem 10/7/18

Tufts Cummings School Of Veterinary Medicine

200 Westboro Road
North Grafton, MA 01536

DUPLICATE

Name/DOB: B6
Patient ID: B6
Phone number:
Collection Date: 10/7/2018 10:31 AM
Approval date: 10/7/2018 4:14 PM

Sex: U
Age: 8
Species: Canine
Breed: Boxer

Provider: B6
Order Location: Foster Hospital for Small Animals
Sample ID: B6

Chemistry Profile - Small Animal (Package) (Cobas)

			Ref. Range/--
TFRANK			
Glucose			67-135 mg/dL
Urea			8-30 mg/dL
Creatinine			0.6-2.0 mg/dL
Phosphorus			2.6-7.2 mg/dL
Calcium 2			9.4-11.3 mg/dL
Magnesium 2+			1.8-3.0 mEq/L
Total Protein			5.5-7.8 g/dL
Albumin			2.8-4.0 g/dL
Globulins			2.3-4.2 g/dL
A/G Ratio			0.7-1.6
Sodium			140-150 mEq/L
Chloride			106-116 mEq/L
Potassium			3.7-5.4 mEq/L
tCO2(Bicarb)			14-28 mEq/L
AGAP			8.0-19.0
NA/K			29-40
Total Bilirubin			0.10-0.30 mg/dL
Direct Bilirubin			0.00-0.10 mg/dL
Indirect Bilirubin			0.00-0.20 mg/dL
Alkaline Phosphatase	H		12-127 U/L
GGT			0-10 U/L
ALT	H	Result(s) verified	14-86 U/L
AST	H	Result(s) verified	9-54 U/L
Creatine Kinase	H	Result(s) verified	22-422 U/L
Cholesterol	H		82-355 mg/dL
Triglycerides			30-338 mg/dl
Amylase			409-1250 U/L
Osmolality (calculated)			291-315 mmol/L

B6 B6 B6

Sample ID: B6
REPRINT: Orig. printing on 10/7/2018 (Final)

Reviewed by: _____
Page 2

FDA-CVM-FOIA-2019-1704-010592

Client: B6
Patient:

NOVA 10/6/18

ICU/Emergency & Critical Care

Foster Hospital for Small Animals, TCSVM
200 Westboro Rd
North Grafton, MA 01536

DUPLICATE

Name/DOB: B6
Patient ID: B6
Phone number:
Collection Date: B6 1:30 AM
Approval date: 1:58 AM

Sex: U
Age: 8
Species: Canine
Breed: Boxer

Provider: B6
Order Location: Foster Hospital for Small Animals
Sample ID: B6

Nova Full Panel-ICU

B6 1:58 AM k (SO2%)

			Ref. Range/--
RGREENWAY			
pH	L		7.337-7.467
pCO2			36.0-44.0 mmHg
pO2	L		80.0-100.0 mmHg
SO2%	L!		94.0-100.0 %
Hct (POC)			38-48 %
Hb (POC)			12.6-16.0 g/dL
Sodium (POC)			140.0-154.0 mmol/L
K (POC)			3.6-4.8 mmol/L
Cl (POC)			109-120 mmol/L
Ca (ionized)			1.17-1.38 mmol/L
Mg, (ionized) (POC)	H		0.1-0.4 mmol/L
Glucose (POC)	L		80-120 mg/dL
Lactate	H	B6	0.0-2.0 mmol/L
BUN (POC)			12.0-28.0 mg/dL
Creat (POC)	H		0.2-2.1 mg/dL
TCO2 (POC)			mmol/L
nCa			mmol/L
nMg			mmol/L
Gap			mmol/L
Ca/Mg			mol/mol
BEecf			mmol/L
BEb			mmol/L
HCO3	L		18.0-24.0 mmol/L
A			mmHg
NOVA Sample Source			
FiO2		B6 (room air)	%

Sample ID: B6
REPRINT: Orig. printing on 10/6/2018 (Final)

Reviewed by: _____

FDA-CVM-FOIA-2019-1704-010593

FDA-CVM-FOIA-2019-1704-010594

Client: B6
Patient:

ECG from cardio

B6 B6 9:39:52 AM Page 1 of 2
Tufts University
Tufts Cummings School of Vet Med
Cardiology

B6

FDA-CVM-FOIA-2019-1704-010595

Client: B6
Patient:

ECG from cardio

B6 B6 9:39:52 AM Page 2 of 2
Tufts University
Tufts Cummings School of Vet Med
Cardiology

B6

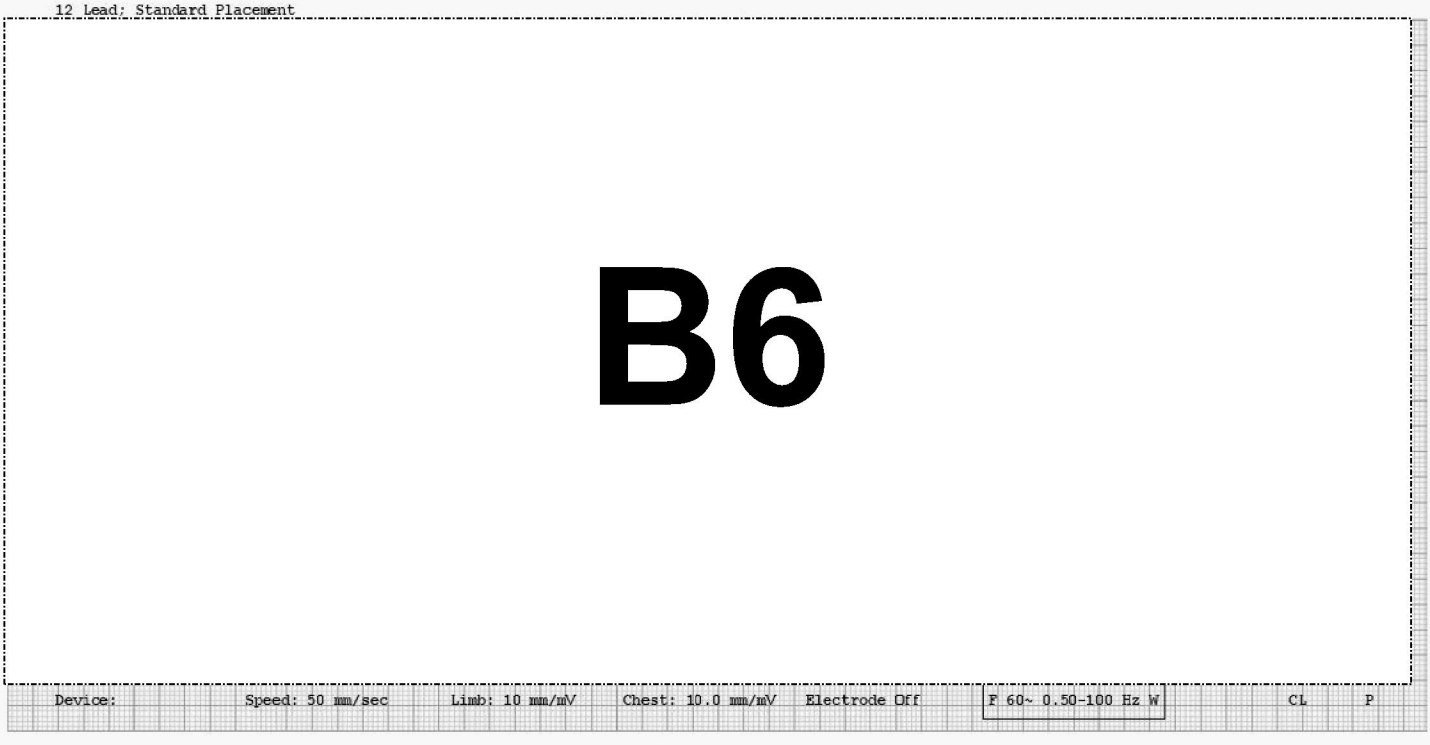
FDA-CVM-FOIA-2019-1704-010596

Client:
Patient: **B6**

ECG from cardio

B6 **B6** 9:40:00 AM Page 1 of 2
Tufts University
Tufts Cummings School of Vet Med
Cardiology

12 Lead; Standard Placement

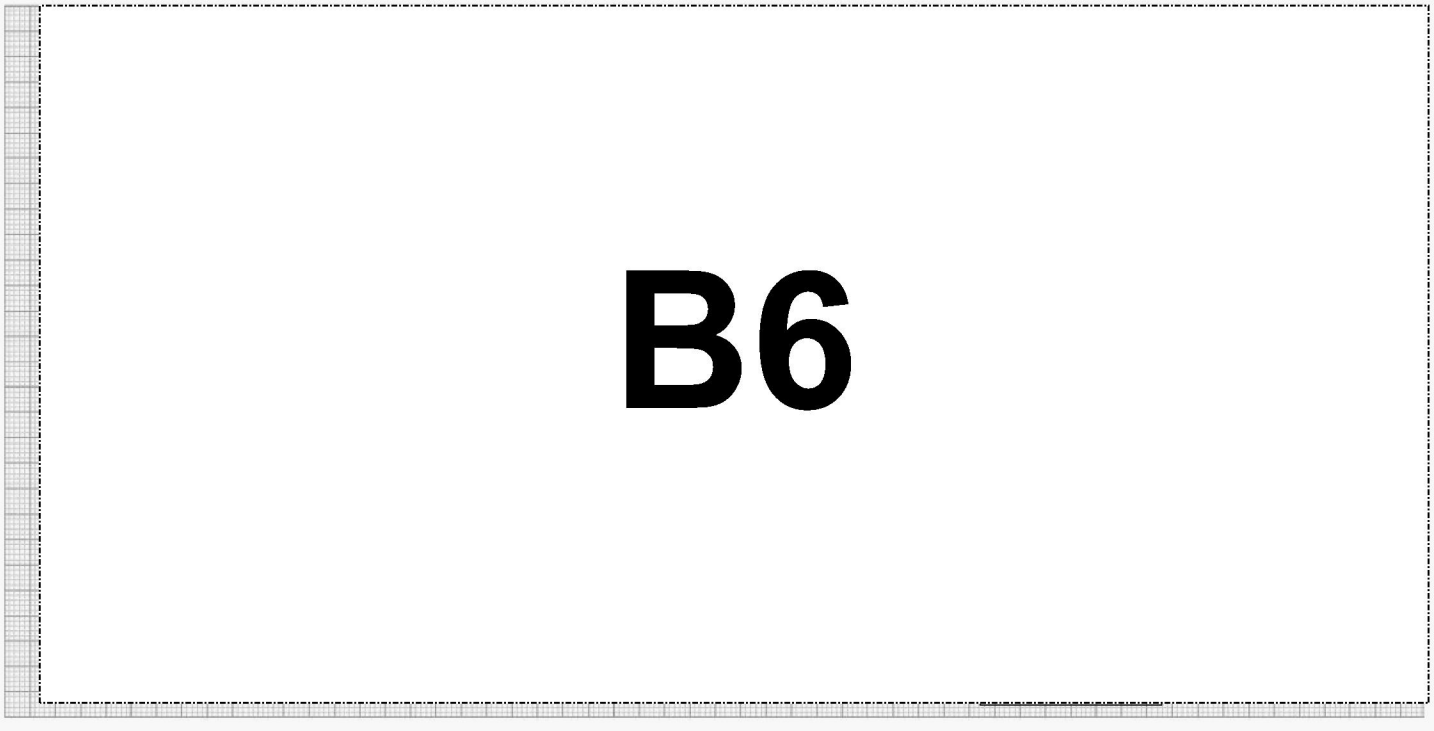


FDA-CVM-FOIA-2019-1704-010597

Client: B6
Patient:

ECG from cardio

B6 B6 9:40:00 AM Page 2 of 2
Tufts University
Tufts Cummings School of Vet Med
Cardiology



FDA-CVM-FOIA-2019-1704-010598

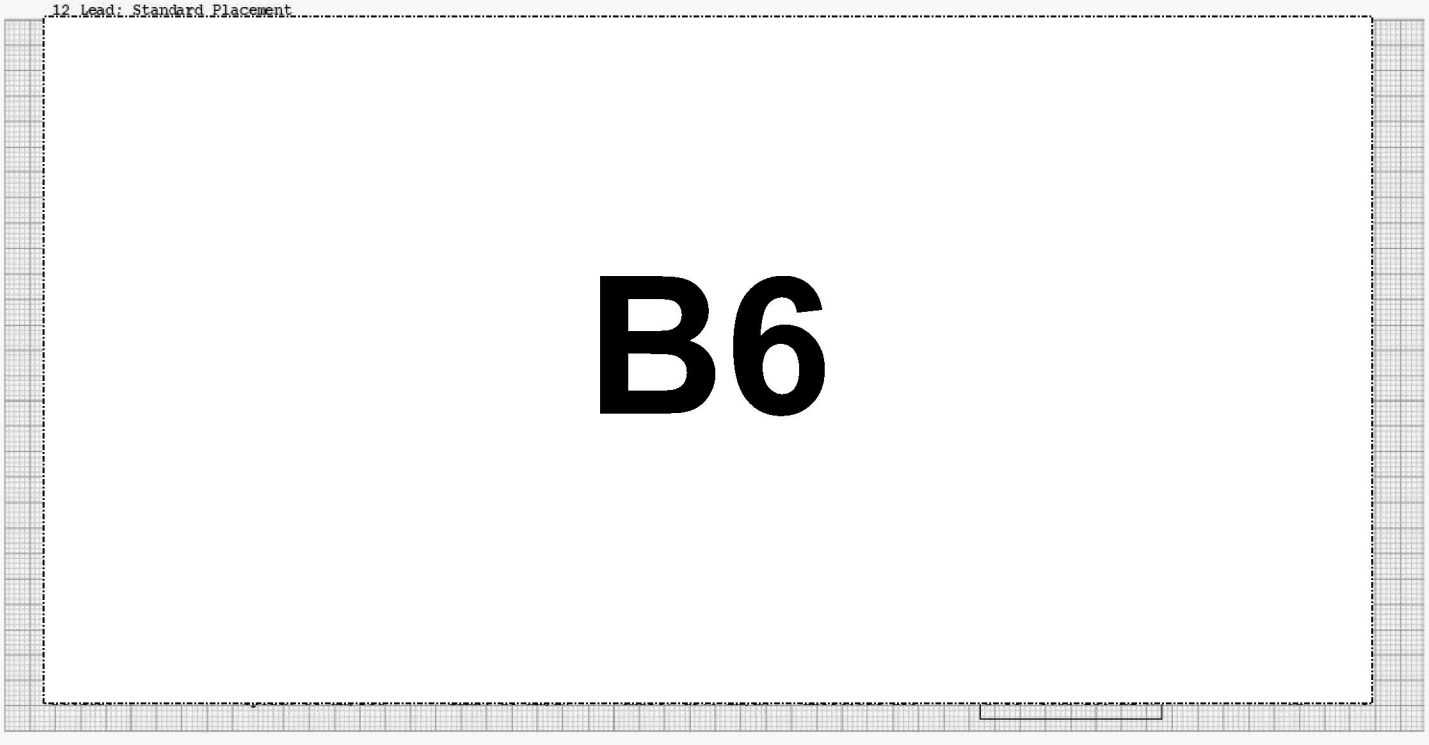
Client:
Patient: B6

ECG from cardio

B6 B6 9:40:52 AM

Tufts University
Tufts Cummings School of Vet Med
Cardiology

12 Lead: Standard Placement

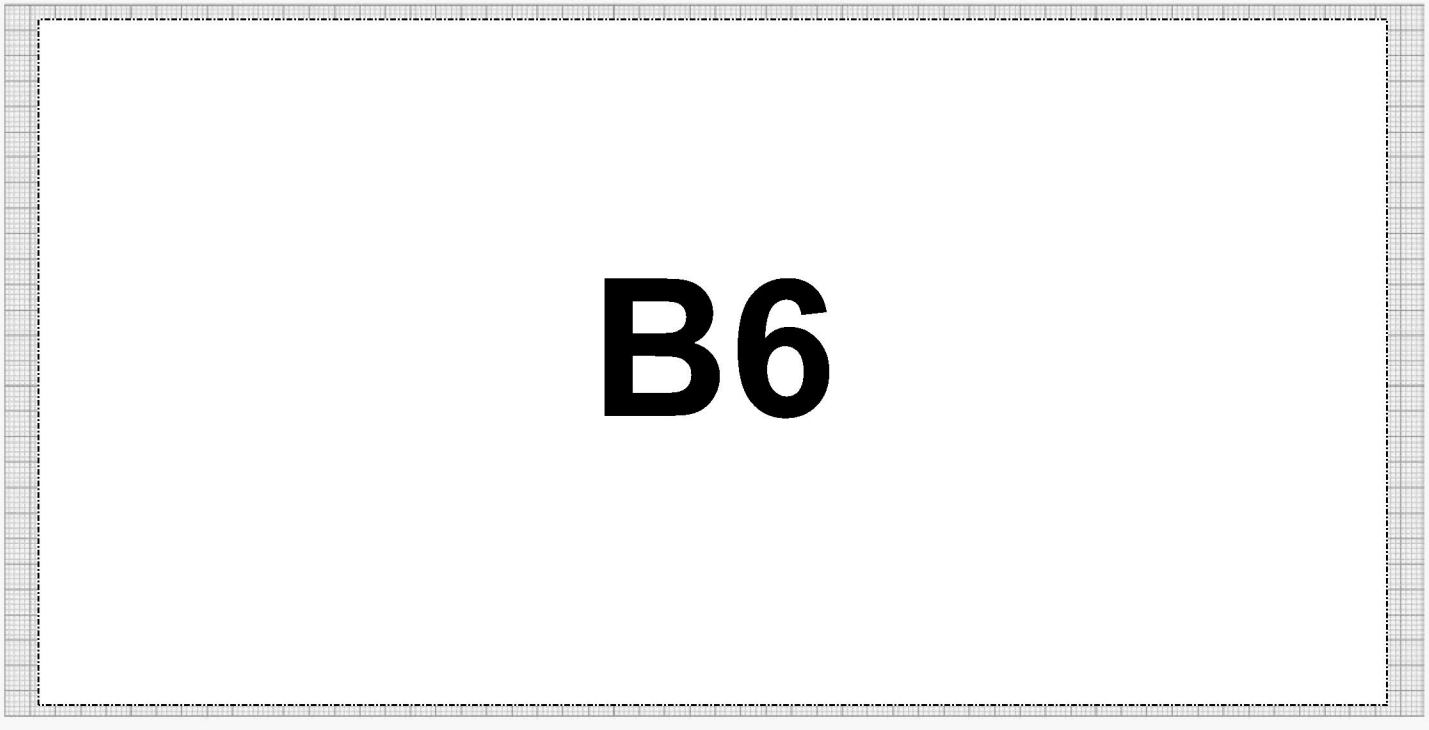


FDA-CVM-FOIA-2019-1704-010599

Client: B6
Patient:

ECG from cardio

B6 B6 9:40:52 AM Page 2 of 2
Tufts University
Tufts Cummings School of Vet Med
Cardiology



FDA-CVM-FOIA-2019-1704-010600

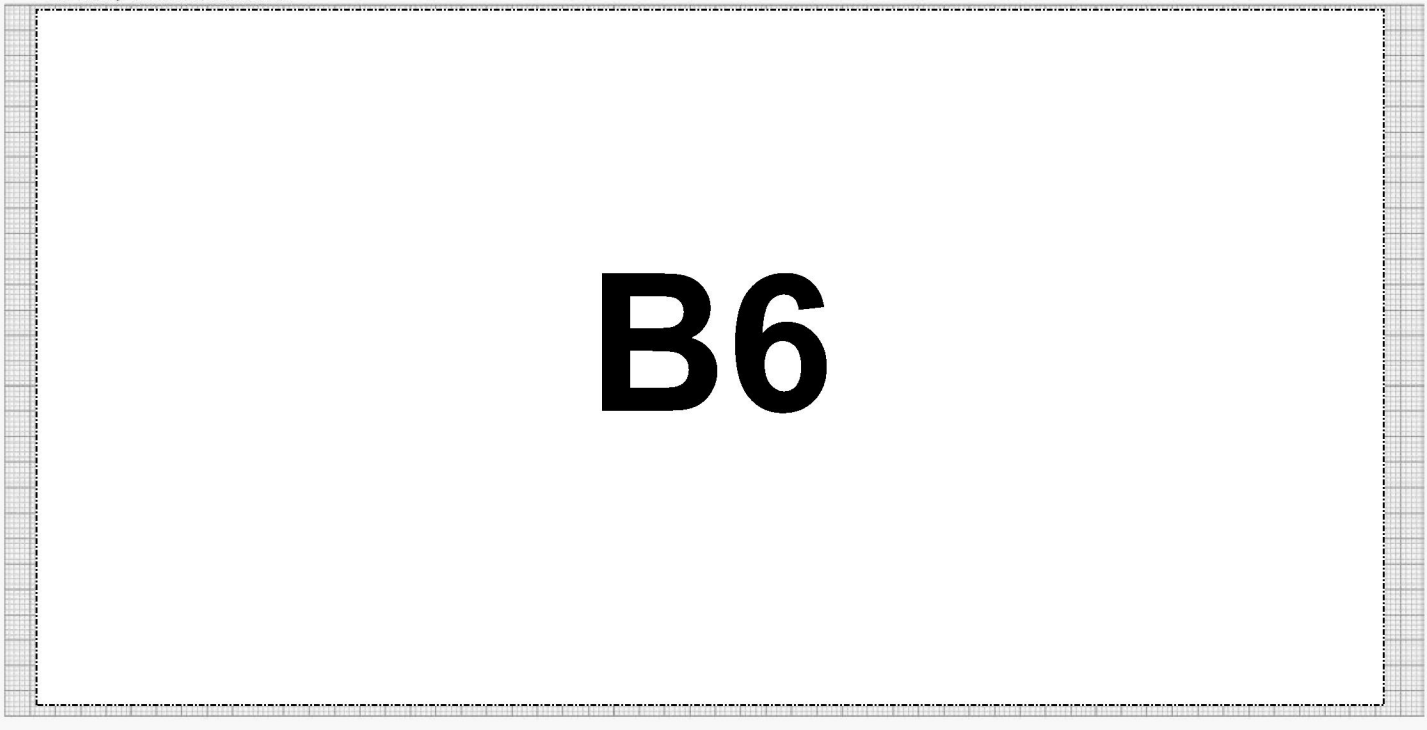
Client: B6
Patient:

ECG from cardio

B6

B6 9:40:52 AM Page 1 of 2
Tufts University
Tufts Cummings School of Vet Med
Cardiology

12 Lead; Standard Placement

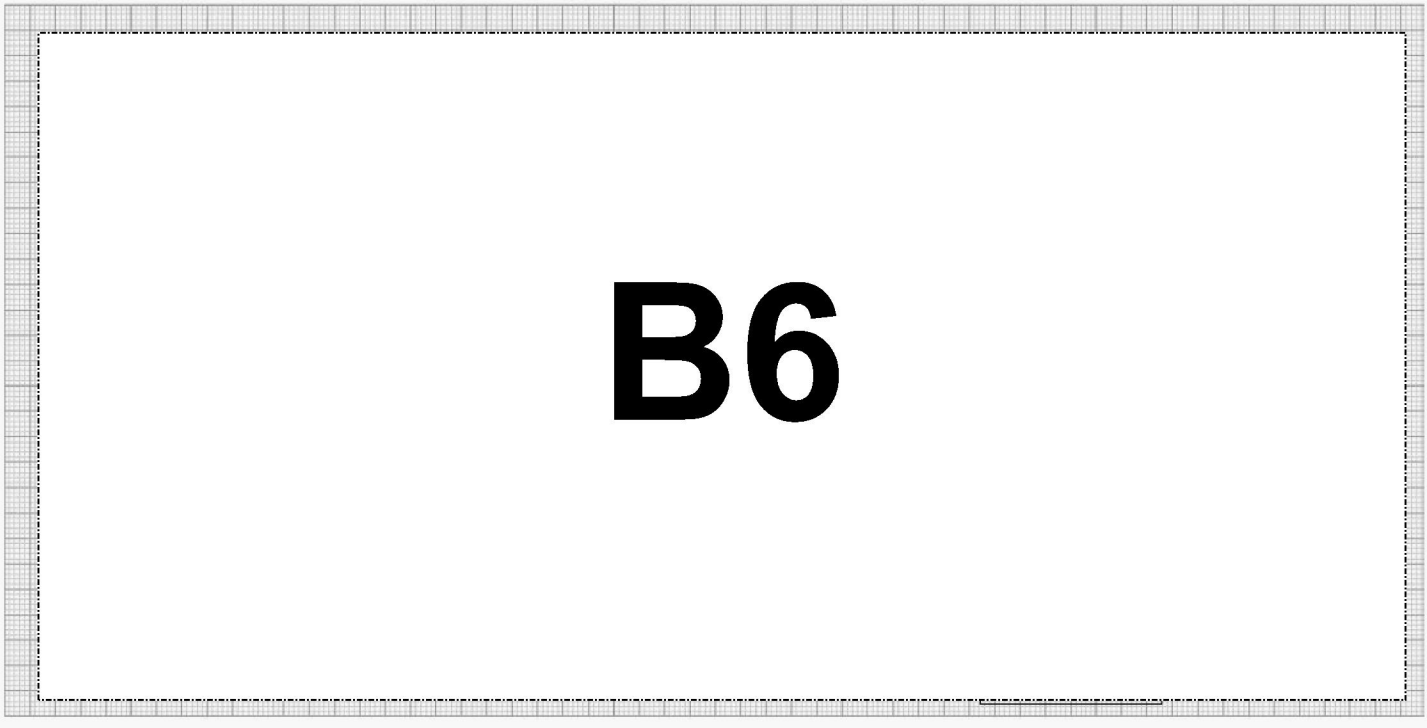


FDA-CVM-FOIA-2019-1704-010601

Client: B6
Patient:

ECG from cardio

B6 B6 9:40:52 AM Page 2 of 2
Tufts University
Tufts Cummings School of Vet Med
Cardiology



FDA-CVM-FOIA-2019-1704-010602

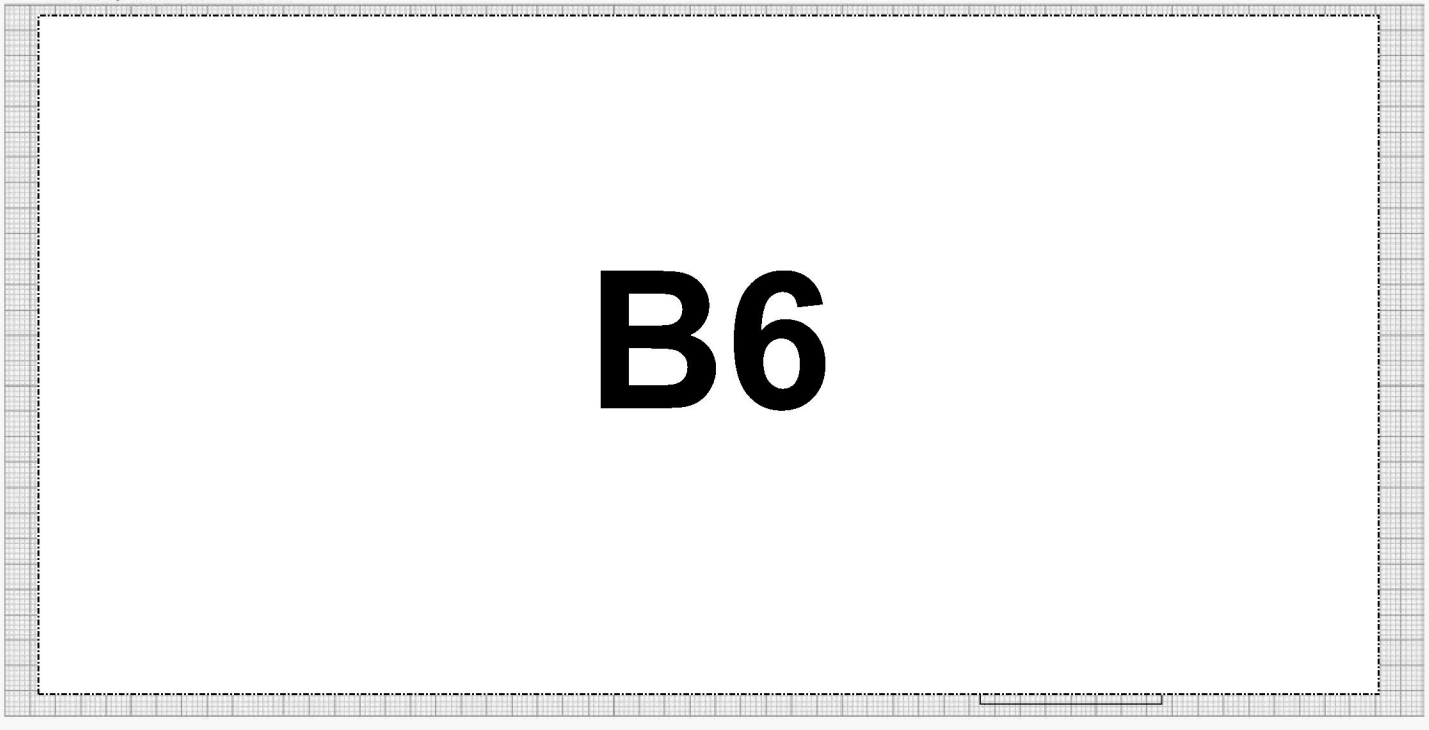
Client: B6
Patient:

ECG from cardio

B6

B6 9:41:17 AM
Tufts University
Tufts Cummings School of Vet Med
Cardiology

12 Lead; Standard Placement



FDA-CVM-FOIA-2019-1704-010603

Cummings
Veterinary Medical Center
AT TUFTS UNIVERSITY

Foster Hospital for Small Animals
55 Willard Street
North Grafton, MA 01536
Telephone (508) 839-5395
Fax (508) 839-7951
http://vetmed.tufts.edu/

Emergency & Critical Care Liaison: (508) 887 - 4745

Patient
Name: B6
Signalment: B6 Years Old White Male Boxer

Owner
Name:
Address: B6

Patient ID: B6

Emergency Clinician: B6 DVM (Emergency and Critical Care Resident)
Consulting Clinician: B6 DVM DACVECC, B6
B6 (Cardiology)

ER Supervisor:
B6

Discharge Instructions

Admit Date: B6 12:54:23 AM
Check Out Date: B6

Case Summary
Diagnosis:
1. B6
2. Dilated cardiomyopathy (DCM)
3. B6

Case Summary:
Thank you for bringing B6 to Tufts Emergency Service for evaluation of an acute onset of B6 discomfort. On presentation to the ER, B6 had an elevated heart rate and B6 B6 which was confirmed on abdominal radiographs. Point of care ultrasound identified dilated heart chambers. B6 was treated with IV fluids and pain medications prior to surgery to de-rotate the stomach. B6 B6 had low blood pressure in surgery but recovered well post-operatively. The following day, a cardiology consultation was performed which revealed dilated cardiomyopathy (DCM), which is a common heart disease of Boxer's. Bloodwork showed elevated liver enzymes, which can sometimes be seen after B6 surgery or could indicate an underlying liver issue.

B6 has continued to do very well in hospital and is now ready to be discharged home for continued supportive care, with the following instructions:

Patient Care Instructions:
1. MONITORING: Please monitor B6 closely for any vomiting, lethargy, lack of appetite or pale gums. If any of these signs are noted, please have him re-evaluated immediately.

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2. INCISION: Check the incision at least once daily to ensure that it is clean and dry with no oozing, discharge, separation of skin edges or increased redness or bruising. The sutures are absorbable, there is no need for suture removal.

3. EXERCISE & ACTIVITY: B6 must remain exercise restricted for 2 weeks after surgery. This means NO running, jumping, rough housing with other dogs or any off leash activity for 2 weeks. He may be taken outside on a leash for short walks for eliminations, but should otherwise remain indoors. No bath or swimming for 2 weeks,

4. DIET: B6 can continue his normal diet. If he is not eating at least 50% of his normal amount within 24 hours of discharge, please call for advice.

Medications:

New medications:

B6

Cardiology Summary:

B6 has been diagnosed with a primary heart muscle disease called dilated cardiomyopathy (DCM). This disease is more common in large and giant breed dogs and is characterized by thinning of the walls of the heart, reduced cardiac pump function, and enlargement of the upper chambers of the heart. Many dogs with DCM will also have significant arrhythmias which can be life-threatening and also require medical management. The heart enlargement has NOT YET progressed to the point of congestive heart failure, meaning that fluid is backing up into the lungs or belly.
Unfortunately this is a progressive disease and we cannot reverse the changes to the heart muscle, however we can use cardiac medications to improve his quality and duration of life.

Monitoring at home:

- We would like you to monitor your dog's breathing rate and effort at home, ideally during sleep or at a time of rest. The doses of drugs will be adjusted based on the breathing rate and effort.
- In general, most dogs have a breathing rate at rest of less than 35 to 40 breaths per minute. WHILE AT REST OR ASLEEP. In addition, the breathing effort, noted by the amount of belly wall motion used for each breath, is fairly minimal if heart failure is controlled.
- There are instructions for monitoring breathing, and a form to help keep track of breathing rate and drug doses, on the Tufts HeartSmart web site (http://vet.tufts.edu/heartsmart/at-home-monitoring/).
- We also want you to watch for weakness or collapse, a reduction in appetite, worsening cough, or distention of the belly as these findings indicate that we should do a recheck examination.
- If you have any concerns, please call or have your dog evaluated by a veterinarian. Our emergency clinic is open 24 hours/day.

Recheck Visits:

1) Recheck exam and bloodwork is recommended in 1-2 weeks. This can be performed with your primary care veterinarian or here at Tufts by scheduling an appointment with B6 at 508-887-4745.

2) Recheck with the Cardiology team for recheck echocardiogram is recommended in 3-6 months, or sooner if B6 develops ANY of the following symptoms: increased effort or rate of breathing at rest, cough, exercise intolerance or collapse / fainting. Cardiology recheck can be scheduled by calling 508-887-4696.

Prescription Refill Disclaimer:

For the safety and well-being of our patients, your pet must have had an examination by one of our veterinarians within the past year in order to obtain prescription medications.

FDA-CVM-FOIA-2019-1704-010605

Ordering Food:
Please check with your primary veterinarian to purchase the recommended diet(s). If you wish to purchase your food from us, please call 7-10 days in advance (508-887-4629) to ensure the food is in stock. Alternatively, veterinary diets can be ordered from online retailers with a prescription/veterinary approval.

Clinical Trials:
Clinical trials are studies in which our veterinary doctors work with you and your pet to investigate a specific disease process or a promising new test or treatment. Please see our website: vet.tufts.edu/cumc/clinical-studies

---

Case: B6 **Owner:** B6 **Discharge Instructions**

Cummings
Veterinary Medical Center
AT TUFTS UNIVERSITY
Cardiology Liaison: 508-887-4696

B6

Patient ID: B6
B6 Canine
B6 Years Old Male Boxer
White BW: Weight (kg) 36.80

Cardiology Consultation

Date: B6
Weight: Weight (kg) 36.80
Requesting Clinician: B6 DVM (Emergency and Critical Care Resident)

Attending Cardiologist:
☑ John E. Rush DVM, MS, DACVIM (Cardiology), DACVECC

B6

Cardiology Resident:

B6

Thoracic radiographs available for review?
☐ Yes - in SS
☑ Yes - in PACS
☐ No

Patient location: ICU

Presenting complaint and important concurrent diseases:
B6 <12 hours post op
No previously diagnosed heart disease or heart murmurs

Current medications and doses: B6

At-home diet: Unknown

Key indication for consultation: Concern for LV dilation and decreased contractility on TFAST, minimal ventricular ectopy intra op and none post op. Hypotensive intra op and received dobutamine, BP post op 80-110.

***STOP** - remainder of form to be filled out by Cardiology*

Physical Examination

B6

Muscle condition:

- [x] Normal
- [ ] Mild muscle loss
- [ ] Moderate cachexia
- [ ] Marked cachexia

Cardiovascular Physical Exam

Murmur Grade:

- [x] None
- [ ] I/VI
- [ ] II/VI
- [ ] III/VI
- [ ] IV/VI
- [ ] V/VI
- [ ] VI/VI

Jugular vein:

- [x] Bottom 1/3 of the neck
- [ ] Middle 1/3 of the neck
- [ ] Top 2/3 of the neck
- [ ] 1/2 way up the neck

Arterial pulses:

- [ ] Weak
- [ ] Fair
- [x] Good
- [ ] Strong
- [ ] Bounding
- [ ] Pulse deficits
- [ ] Pulsus paradoxus
- [ ] Other (describe):

Arrhythmia:

- [ ] None
- [ ] Sinus arrhythmia
- [ ] Premature beats
- [ ] Bradycardia
- [x] Tachycardia

Gallop:

- [ ] Yes
- [x] No
- [ ] Intermittent
- [ ] Pronounced
- [ ] Other:

Pulmonary assessments:

- [x] Eupneic
- [ ] Mild dyspnea
- [ ] Marked dyspnea
- [x] Normal BV sounds
- [ ] Pulmonary Crackles
- [ ] Wheezes
- [ ] Upper airway stridor
- [ ] Other auscultatory findings:

Abdominal exam:

- [x] Normal
- [ ] Hepatomegaly
- [ ] Abdominal distension
- [ ] Mild ascites

Echocardiogram Findings:

B6

Mitral inflow:

- ☑ Summated
- ☐ Normal
- ☐ Delayed relaxation
- ☐ Pseudonormal
- ☐ Restrictive

B6

Assessment and recommendations:

Echocardiogram findings are consistent with DCM-like changes. Base on the current chest radiographs the patient does not appear to be in active CHF. There is decreased contractile function which could be secondary to cardiomaphy but could also be influenced by the fact that the patient was tachycardic and had recent major surgery (inflammation/sepsis component). The degree of LAE in a dog would argue for intrinsic heart disease (DCM). We would still recommend to B6 careful with fluid administration. Differentials for the changes visualized include primary DCM vs. diet-related vs. ARVC vs. end-stage DMVD (seems less likely base on the small amount of MR and the fact that the jet was very central). Because of the breed, ARVC that would affect mainly the LV remains a differential and the patient should be on telemetry to monitor for ventricular arrhythmia. A quick recheck echocardiogram could be perform before the patient leaves the hospital to reassess the contractile function once the patient is systemically better. Full recheck echocardiogram in 4-6 months or sooner if the patient develops clinical signs consistent with worsening heart disease such as increased RR/RE, cough, exercise intolerance, or syncope.

The diet should be explored and if a grain free diet it should be reported to the FDA.

Final Diagnosis:

- DCM-like changes r/o DCM vs. diet-related vs. ARVC vs. end-stage DMVD

Heart Failure Classification Score:

ISACHC Classification:

- ☐ Ia
- ☑ Ib
- ☐ II
- ☐ IIIa
- ☐ IIIb

ACVIM CHF Classification:

- ☐ A
- ☐ B1
- ☑ B2
- ☐ C
- ☐ D

M-Mode		
IVSd	B6	cm
LVIDd		cm
LVPWd		cm
IVSs		cm
LVIDs		cm
LVPWs		cm
%FS		%
Ao Diam		cm
LA Diam		cm
LA/Ao		
Max LA		cm
TAPSE		cm
EPSS		cm
M-Mode Normalized		
IVSdN	B6	(0.29 - 0.52)
LVIDdN		(1.35 - 1.73) !
LVPWdN		(0.33 - 0.53) !
IVSsN		(0.43 - 0.71) !
LVIDsN		(0.79 - 1.14) !
LVPWsN		(0.53 - 0.78) !
Ao Diam N		(0.68 - 0.89) !
LA Diam N		(0.64 - 0.90) !
2D		
IVSd	B6	cm
LVIDd		cm
LVPWd		cm
EDV(Teich)		ml
IVSs		cm
LVIDs		cm
LVPWs		cm
ESV(Teich)		ml
EF(Teich)		%
%FS		%
SV(Teich)		ml
Doppler		
MR Vmax	B6	m/s
MR maxPG		mmHg
MV E Vel		m/s
MV DecT		ms
MV A Vel		m/s
MV E/A Ratio		
E'		m/s
A'		m/s
E/E'		
PV Vmax		m/s

PV maxPG	B6	mmHg
AV Vmax		m/s
AV maxPG		mmHg
TR Vmax		m/s
TR maxPG		mmHg

FDA-CVM-FOIA-2019-1704-010611

Cummings
Veterinary Medical Center
AT TUFTS UNIVERSITY

Foster Hospital for Small Animals
55 Willard Street
North Grafton, MA 01536
Telephone (508) 839-5395
Fax (508) 839-7951
http://vetmed.tufts.edu/

Discharge Instructions

Patient
Name: B6
Species: Canine
White Male Boxer
Birthdate: B6

Owner
Name: B6
Address: B6

Patient ID: B6

Attending Cardiologist:
☐ John E. Rush DVM, MS, DACVIM (Cardiology), DACVECC
B6

Cardiology Resident:
B6

Cardiology Technician:
B6

Date: B6

Diagnoses: Dilated cardiomyopathy (DCM)

Case summary:
Thank you for bringing B6 for evaluation of his heart. B6 has been diagnosed with a primary heart muscle disease called dilated cardiomyopathy (DCM). This disease is more common in large and giant breed dogs and is characterized by thinning of the walls of the heart, reduced cardiac pump function, and enlargement of the upper chambers of the heart. Many dogs with DCM will also have significant arrhythmias which can be life-threatening and also require medical management (so far B6 has not had this). The heart enlargement can eventually progress to the point of congestive heart failure, meaning that fluid would be backing up into the lungs or belly. Unfortunately this is typically a progressive disease and we usually cannot reverse the changes to the heart muscle. However, some dogs that have been on certain grain/gluten free diets have shown improvement in their hearts when the diet has been changed and they have received taurine supplementation.

Monitoring at home:
- We would like you to occasionally monitor your dog's breathing rate and effort at home, ideally during sleep or at a time of rest. Normal breathing rate at rest is less than 35 to 40 breaths per minute.
- We also want you to watch for weakness or collapse, a reduction in appetite, worsening cough, or distention of the belly as these findings indicate that we should do a recheck examination.
- If you have any concerns, please call or have your dog evaluated by a veterinarian. Our emergency clinic is open 24 hours/day.

Recommended Medications:
B6

FDA-CVM-FOIA-2019-1704-010612

B6

Diet suggestions:
We recommend feeding a diet formulated by a well established company since certain unique dog foods have been anecdotally associated with heart disease. Below are some dry and canned options, or if B6 does not like these foods then you could consider scheduling an appointment with our Nutrition Service (this can be done over the phone).

Dry options:
Royal Canin Early Cardiac
Royal Canin Boxer
Purina Pro Plan Adult Weight Management (not significantly calory restricted despite the name)

Canned options:
Hill's Science Diet Adult Beef and Barley Entree
Hill's Science Diet Adult 1-6 Healthy Cuisine Roasted CHicken, Carrots, and Spinach Stew
Royal Canin Mature 8+

Exercise Recommendations:
B6 can continue his walks as long as he does not lag behind or seem tired after. We generally recommend avoiding vigorous high intensity activity as this could worsen strain on the heart or cause arrhythmias.

Recheck Visits:
A recheck visit is recommended in 3 months. B6 has been enrolled in a study and this recheck along with another one in 6 months would be included in the study. We also recommend having B6 daughter B6 screened for heart disease, which may also be covered by the study. We will plan to call you to set this appointment up, but if you have not heard from us by next week then please give us a call.

Thank you for entrusting us with B6 care. He is such a good dog! Please contact our Cardiology liaison at (508)-887-4696 or email us at cardiovet@tufts.edu for scheduling and non-emergent questions or concerns.

Please visit our HeartSmart website for more information
http://vet.tufts.edu/heartsmart/

Prescription Refill Disclaimer:
For the safety and well-being of our patients, your pet must have had an examination by one of our veterinarians within the past year in order to obtain prescription medications.

Ordering Food:
Please check with your primary veterinarian to purchase the recommended diet(s). If you wish to purchase your food from us, please call 7-10 days in advance (508-887-4629) to ensure the food is in stock. Alternatively, veterinary diets can be ordered from online retailers with a prescription/veterinary approval.

Clinical Trials:
Clinical trials are studies in which our veterinary doctors work with you and your pet to investigate a specific disease process or a promising new test or treatment. Please see our website: vet.tufts.edu/cvmc/clinical-studies

---

Case: B6 Owner: B6 Discharge Instructions

Cummings
Veterinary Medical Center
AT TUFTS UNIVERSITY
Cardiology Liaison: 508-887-4696

B6

Patient ID: B6
B6 Canine
B6 Years Old Male Boxer
White

Cardiology Appointment Report

Date: B6

Attending Cardiologist:
☐ John E. Rush DVM, MS, DACVIM (Cardiology), DACVECC
B6

Cardiology Resident:
B6

Cardiology Technician:
B6

Presenting Complaint: Doing great at home since surgery. Eating and drinking normally. No V/D. Had since he was a puppy. Is on heartworm prev.

Concurrent Diseases: I B6

General Medical History: Ha B6 out 4 weeks ago. Cardio consult done at that hospitalization. No cough or trouble breathing, no exercise intolerance, goes on long walks.

Diet and Supplements:
Rachel ray super premium dry real chicken and veggie dry, purina one chicken and rice canned, Newmans own chicken and rice, hamburger and chicken and rice cooked, mixed every other day. O feels is not grain free, but it is wheat and gluten free.

Cardiovascular History:
Prior CHF diagnosis? No
Prior heart murmur? No
Prior ATE? No
Prior arrhythmia? No
Monitoring respiratory rate and effort at home?
Cough? 2 weeks before GVD had bad cough, no fine
Shortness of breath or difficulty breathing? No
Syncope or collapse? No
Sudden onset lameness? No
Exercise intolerance? No

Current Medications Pertinent to CV System:

B6

Muscle condition:

- [x] Normal
- [ ] Mild muscle loss
- [ ] Moderate cachexia
- [ ] Marked cachexia

Cardiovascular Physical Exam:

Murmur Grade:

- [x] None
- [x] I/VI +/-
- [ ] II/VI
- [ ] III/VI
- [ ] IV/VI
- [ ] V/VI
- [ ] VI/VI

Murmur location/description: systolic left apical

Jugular vein:

- [x] Bottom 1/3 of the neck
- [ ] Middle 1/3 of the neck
- [ ] 1/2 way up the neck
- [ ] Top 2/3 of the neck

Arterial pulses:

- [ ] Weak
- [ ] Fair
- [x] Good
- [ ] Strong
- [ ] Bounding
- [ ] Pulse deficits
- [ ] Pulsus paradoxus
- [ ] Other:

Arrhythmia:

- [x] None
- [ ] Sinus arrhythmia
- [ ] Premature beats
- [ ] Bradycardia
- [x] Tachycardia when more excited

Gallop:

- [ ] Yes
- [x] No
- [ ] Intermittent
- [ ] Pronounced
- [ ] Other:

Pulmonary assessments:

- [x] Eupneic
- [ ] Mild dyspnea
- [ ] Marked dyspnea
- [x] Normal BV sounds
- [ ] Pulmonary crackles
- [ ] Wheezes
- [ ] Upper airway stridor

Abdominal exam:

- [x] Normal
- [ ] Mild ascites

- ☐ Hepatomegaly
- ☐ Abdominal distension
- ☐ Marked ascites

Problems:
DCM like changes at time of B6 (r/o DCM v ARVC variant v sepsis/inflammatory related)

Diagnostic plan:
- ☑ Echocardiogram
- ☐ Chemistry profile
- ☐ ECG
- ☐ Renal profile
- ☐ Blood pressure
- ☐ Dialysis profile
- ☐ Thoracic radiographs
- ☐ NT-proBNP
- ☐ Troponin I
- ☑ Other tests: DCM study

Echocardiogram Findings:

B6

Assessment and recommendations:
Echocardiogram reveals persistent DCM like changes consistent with cardiomyopathy (primary DCM v ARVC with DCM phenotype v dietary) rather than sepsis/inflammatory induced cardiac changes. Patient was enrolled in DCM study. Recommend continuing B6 adding taurine 1000mg PO BID. Recommend diet change (list provided). Will report current diet to FDA (owner gave permission and will save bag). Recheck for study in 3 months and again in 6 months. House mate should be screened for DCM also.

Final Diagnosis:
DCM-like changes (r/o primary DCM v ARVC with DCM phenotype v dietary)

Heart Failure Classification Score:
ISACHC Classification:
- ☐ Ia
- ☑ Ib
- ☐ II
- ☐ IIIa
- ☐ IIIb

ACVIM Classification:
- ☐ A
- ☐ B1
- ☑ B2
- ☐ C
- ☐ D

M-Mode

IVSd	B6	cm
LVIDd		cm
LVPWd		cm
IVSs		cm
LVIDs		cm
LVPWs		cm
%FS		%
Ao Diam		cm
LA Diam		cm
LA/Ao		
Max LA		cm
TAPSE		cm
EPSS		cm

M-Mode Normalized

IVSdN	B6	(0.29 - 0.52)
LVIDdN		(1.35 - 1.73) !
LVPWdN		(0.33 - 0.53)
IVSsN		(0.43 - 0.71)
LVIDsN		(0.79 - 1.14) !
LVPWsN		(0.53 - 0.78) !
Ao Diam N		(0.68 - 0.89) !
LA Diam N		(0.64 - 0.90) !

2D

SA LA	B6	cm
Ao Diam		cm
SA LA / Ao Diam		
IVSd		cm
LVIDd		cm
LVPWd		cm
EDV(Teich)		ml
IVSs		cm
LVIDs		cm
LVPWs		cm
ESV(Teich)		ml
EF(Teich)		%
%FS		%
SV(Teich)		ml
LVId LAX		cm
LVAd LAX		cm
LVEDV A-L LAX		ml
LVEDV MOD LAX		ml
LVIs LAX		cm
LVAs LAX		cm
LVESV A-L LAX		ml
LVESV MOD LAX		ml

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HR	B6	BPM
EF A-L LAX		%
LVEF MOD LAX		%
SV A-L LAX		ml
SV MOD LAX		ml
CO A-L LAX		l/min
CO MOD LAX		l/min

Doppler

MV E Vel	B6	m/s
MV DecT		ms
MV A Vel		m/s
MV E/A Ratio		
E'		m/s
A'		m/s
E/E'		
PV Vmax		m/s
PV maxPG		mmHg
AV Vmax		m/s
AV maxPG		mmHg

FDA-CVM-FOIA-2019-1704-010618

Cummings
Veterinary Medical Center
AT TUFTS UNIVERSITY

B6

B6 Male
Canine Boxer White
Patient ID: B6

Outside Prescription Log

1. Date: B6

B6

2. Date:
   Clinician:
   Prescription:
   Pharmacy sent to:
   Completed by:
   Origin of request:

3. Date:
   Clinician:
   Prescription:
   Pharmacy sent to:
   Completed by:
   Origin of request:

4. Date:
   Clinician:
   Prescription:
   Pharmacy sent to:
   Completed by:
   Origin of request:

5. Date:
   Clinician:
   Prescription:
   Pharmacy sent to:
   Completed by:
   Origin of request:

6. Date:
   Clinician:
   Prescription:
   Pharmacy sent to:
   Completed by:
   Origin of request:

7. Date:

Clinician:
Prescription:
Pharmacy sent to:
Completed by:
Origin of request:

8. Date:
Clinician:
Prescription:
Pharmacy sent to:
Completed by:
Origin of request:

9. Date:
Clinician:
Prescription:
Pharmacy sent to:
Completed by:
Origin of request:

10. Date:
Clinician:
Prescription:
Pharmacy sent to:
Completed by:
Origin of request:

Cummings
Veterinary Medical Center
AT TUFTS UNIVERSITY

Foster Hospital for Small Animals
55 Willard Street
North Grafton, MA 01536
Telephone (508) 839-5395
Fax (508) 839-7951
http://vetmed.tufts.edu/

Radiology Request & Report

Patient
Name: B6
Species: Canine
White Male Boxer
Birthdate: B6

Owner
Name: B6
Address: B6

Patient ID: B6
Date of request: B6

Attending Clinician: B6 DVM (Emergency and Critical Care Resident) **Student:**

Date of exam:

Patient Location: Ward/Cage: **Weight (kg)** 36.80

- ☐ Inpatient
- ☐ Outpatient Time:
- ☐ Waiting
- ☐ Emergency

Sedation
- ☐ BAG
- ☐ OBAG
- ☐ 1/2 dose OBAG
- ☐ DexDomitor/Butorphanol
- ☐ Anesthesia to sedate/anesthetize

Examination Desired:

Presenting Complaint and Clinical Questions you wish to answer:
Emergency

Pertinent History:

Findings:

B6

THORAX, TWO VIEWS:
The cardiac silhouette is normal in size (VHS 11.5). The pulmonary vessels and caudal vena cava are small. There is a mild diffuse bronchointerstitial pattern. The trachea, diaphragm, pleural space, and mediastinum are normal.

FDA-CVM-FOIA-2019-1704-010621

There is multifocal incidental spondylosis deformans.

Conclusions:

B6

- Appearance of the pulmonary vessels and caudal vena cava suggest hypovolemia.
- Mild diffuse bronchointerstitial pattern is likely incidental. There is no evidence of pulmonary metastatic disease.

Radiologists

Primary: B6, DVM

Reviewing: B6 DVM, DACVR

Dates

Reported: B6

Finalized B6

Cummings
Veterinary Medical Center
AT TUFTS UNIVERSITY

Foster Hospital for Small Animals
55 Willard Street
North Grafton, MA 01536
Telephone (508) 839-5395
Fax (508) 839-7951
http://vetmed.tufts.edu/

Patient
Name: B6
Signalment: B6 Years Old White Male Boxer

Owner
Name:
Address: B6

Patient ID: B6

Contact Clinician: B6 DVM, PhD, DECVS,

Alternate Clinician: B6 DVM, MPH
(Ophthalmology Intern)

Student: B6 V19

Discharge Instructions

Admit Date:
Discharge Date: B6 3:00:03 PM

Diagnosis:

1. B6

B6

FDA-CVM-FOIA-2019-1704-010623

B6

Prescription Refill Disclaimer:
For the safety and well-being of our patients, your pet must have had an examination by one of our veterinarians within the past year in order to obtain prescription medications.

Ordering Food:
Please check with your primary veterinarian to purchase the recommended diet(s). If you wish to purchase your food from us, please call 7-10 days in advance (508-887-4629) to ensure the food is in stock. Alternatively, veterinary diets can be ordered from online retailers with a prescription/veterinary approval.

Clinical Trials:
Clinical trials are studies in which our veterinary doctors work with you and your pet to investigate a specific disease process or a promising new test or treatment. Please see our website: vet.tufts.edu/cvmc/clinical-studies

Case: B6 **Owner:** B6 **Discharge Instructions**

Cummings
Veterinary Medical Center
AT TUFTS UNIVERSITY
Ophthalmology Liason: 508-887-4839

Foster Hospital for Small Animals
55 Willard Street
North Grafton, MA 01536
Telephone (508) 839-5395
Fax (508) 839-7951
http://vetmed.tufts.edu/

B6

B6

Cummings
Veterinary Medical Center
AT TUFTS UNIVERSITY

B6

B6 Male
Canine Boxer White
B6

OCULAR EXAMINATION

Date: B6 3:00:03 PM

Chief complaint: B6

in June or July; meds: ABX ointment, refresh

Attending Ophthalmologist:

B6

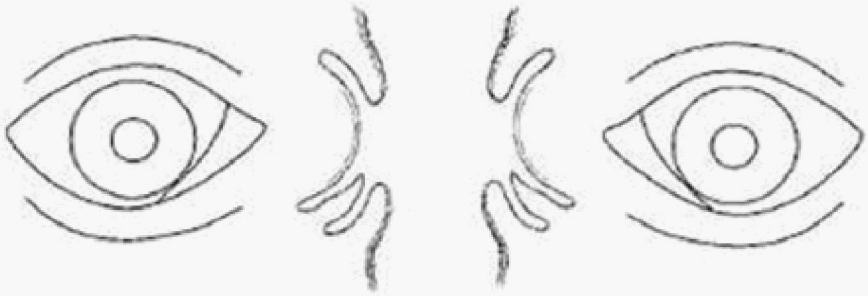
Ophthalmology Resident:

B6

B6

Membranes

Comment:	**Sclera**	**Comments:**
Comment: hyperemia	**Conjunctiva**	**Comment:**



B6

B6

OD	Exam	OS
Comment:	Vitreous	Comment:
Comment: wnl	Fundus	Comment: wnl

FDA-CVM-FOIA-2019-1704-010629

B6

Cummings
Veterinary Medical Center
AT TUFTS UNIVERSITY

Foster Hospital for Small Animals
55 Willard Street
North Grafton, MA 01536
Telephone (508) 839-5395
Fax (508) 839-7951
http://vetmed.tufts.edu/

Patient
Name: B6
Signalment: B6 Years Old White Male Boxer

Owner
Name:
Address: B6

Patient ID: B6

Contact Clinician: B6, DVM, MPH
Alternate Clinician: B6, DVM, PhD, DECVS,
Student: B6 V19

Discharge Instructions

Admit Date:
Discharge Date: B6 9:06:06 AM

B6

Thank you for entrusting us with B6 care. He is a very sweet boy!

Prescription Refill Disclaimer:
For the safety and well-being of our patients, your pet must have had an examination by one of our veterinarians within the past year in order to obtain prescription medications.

Ordering Food:
Please check with your primary veterinarian to purchase the recommended diet(s). If you wish to purchase your food from us, please call 7-10 days in advance (508-887-4629) to ensure the food is in stock. Alternatively, veterinary diets can be ordered from online retailers with a prescription/veterinary approval.

Clinical Trials:
Clinical trials are studies in which our veterinary doctors work with you and your pet to investigate a specific disease process or a promising new test or treatment. Please see our website: vet.tufts.edu/cvmc/clinical-studies

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Case: B6 **Owner:** B6 **Discharge Instructions**

Cummings
Veterinary Medical Center
AT TUFTS UNIVERSITY

B6

B6 Male
Canine Boxer White
B6

OCULAR EXAMINATION
Date B6 9:06:06 AM
Chief complaint: r B6

B6

B6

B6

B6

Cummings
Veterinary Medical Center
AT TUFTS UNIVERSITY

Foster Hospital for Small Animals
55 Willard Street
North Grafton, MA 01536
Telephone (508) 839-5395
Fax (508) 839-7951
http://vetmed.tufts.edu/

Discharge Instructions

Patient
Name: B6
Species: Canine
White Male Boxer
Birthdate: B6

Owner
Name: B6
Address: B6

Patient ID: B6

Attending Cardiologist:
☐ John E. Rush DVM, MS, DACVIM (Cardiology), DACVECC
B6

Cardiology Resident:
B6

Cardiology Technician:
B6

Student: B6, V20

Date: B6

Diagnoses:
Dilated cardiomyopathy (DCM)

Case summary:
Thank you for bringing B6 in today for re-evaluation of his heart - he is such a sweet boy! B6 's echocardiogram today showed a large left ventricle with decreased contractile function (as previously seen), and further enlargement of his left atrium, one of the upper chambers of his heart. Since B6 has some progressive heart enlargement, we are going to add a new medication and have you take another medication home to have on hand in case of trouble breathing (see below).

Monitoring at home:
- We would like you to monitor B6 's breathing rate and effort at home, ideally during sleep or at a time of rest. The doses of drugs will be adjusted based on the breathing rate and effort.
- In general, most dogs will have a breathing rate at rest of less than 35 to 40 breaths per minute.
- In the case of an increase in breathing rate or effort, you can give B6 a dose of B6 After giving the dose of B6 please call Tufts or your primary care veterinarian.
- We also want you to watch for weakness or collapse, a reduction in appetite, worsening cough, or distention of the belly as these findings indicate that we should do a recheck examination.
- If you have any concerns, please call or have your dog evaluated by a veterinarian. Our emergency clinic is open 24 hours/day.

Recommended Medications:

B6

Diet suggestions:
Please continue B6 current diet.

Exercise Recommendations:
B6 can continue his walks as long as he does not lag behind or seem tired after. We generally recommend avoiding vigorous high intensity activity as this could worsen strain on the heart or cause arrhythmias.

Recheck Visits:
Recheck blood work is recommened to check kidney values and electrolytes 2-3 weeks after starting enalapril. This can be done here as a technician appointment or at your primary care veterinarian.

A recheck with cardiology has been scheduled for B6 on B6 at 2:30 PM. This is his next appointment for the DCM study.

Please call 508-887-4745 to schedule an appointment with dermatology if B6 skin on his face does not improve. You could also try an e-collar to prevent him from scratching at his face.

Thank you for entrusting us with B6 care. He is such a good boy! Please contact our Cardiology liaison at (508)-887-4696 or email us at cardionet@tufts.edu for scheduling and non-emergent questions or concerns.

Please visit our HeartSmart website for more information
http://vet.tufts.edu/heartsmart/

Prescription Refill Disclaimer:
For the safety and well-being of our patients, your pet must have had an examination by one of our veterinarians within the past year in order to obtain prescription medications.

Ordering Food:
Please check with your primary veterinarian to purchase the recommended diet(s). If you wish to purchase your food from us, please call 7-10 days in advance (508-887-4629) to ensure the food is in stock. Alternatively, veterinary diets can be ordered from online retailers with a prescription/veterinary approval.

Clinical Trials:
Clinical trials are studies in which our veterinary doctors work with you and your pet to investigate a specific disease process or a promising new test or treatment. Please see our website: vet.tufts.edu/cvmc/clinical-studies

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FDA-CVM-FOIA-2019-1704-010638

Cummings
Veterinary Medical Center
AT TUFTS UNIVERSITY
Cardiology Liaison: 508-887-4696

B6

Patient ID: B6
B6 Canine
B6 Years Old Male Boxer
White

Cardiology Appointment Report

Date: B6

Attending Cardiologist:
☐ John E. Rush DVM, MS, DACVIM (Cardiology), DACVECC

B6

Cardiology Resident:
B6 c

Cardiology Technician:

B6

Student: B6

Presenting Complaint:
B6 presents for 4-month recheck following diagnosis of DCM following B6 correction and B6 in October. Per O is doing very well at home, no concerns related to his DCM.

Concurrent Diseases:
B6

General Medical History:

B6

Diet and Supplements:
RC dry + Hills Science Diet canned (chicken stew)
No supplements after discontinuing Taurine in October/November

Cardiovascular History:
Prior CHF diagnosis? No
Prior heart murmur? Grade I/VI
Prior ATE? No

Prior arrhythmia? No
Monitoring respiratory rate and effort at home? Yes, resting RR 25 or less
Cough? None since before the GDV sx
Shortness of breath or difficulty breathing? No
Syncope or collapse? No
Sudden onset lameness? No
Exercise intolerance? No, goes on several mile walks daily

Current Medications Pertinent to CV System:

B6

Muscle condition:
- [x] Normal
- [ ] Mild muscle loss
- [ ] Moderate cachexia
- [ ] Marked cachexia

Cardiovascular Physical Exam:

Murmur Grade:
- [x] None
- [ ] I/VI
- [ ] II/VI
- [ ] III/VI
- [ ] IV/VI
- [ ] V/VI
- [ ] VI/VI

Jugular vein:
- [x] Bottom 1/3 of the neck
- [ ] Middle 1/3 of the neck
- [ ] 1/2 way up the neck
- [ ] Top 2/3 of the neck

Arterial pulses:
- [ ] Weak
- [x] Fair
- [ ] Good
- [ ] Strong
- [ ] Bounding
- [ ] Pulse deficits
- [ ] Pulsus paradoxus
- [ ] Other:

Arrhythmia:
- [ ] None
- [ ] Bradycardia

- [ ] Sinus arrhythmia
- [ ] Premature beats
- [x] Tachycardia

Gallop:
- [ ] Yes
- [x] No
- [ ] Intermittent
- [ ] Pronounced
- [ ] Other:

Pulmonary assessments:
- [x] Eupneic
- [ ] Mild dyspnea
- [ ] Marked dyspnea
- [x] Normal BV sounds
- [ ] Pulmonary crackles
- [ ] Wheezes
- [ ] Upper airway stridor

Abdominal exam:
- [x] Normal
- [ ] Hepatomegaly
- [ ] Abdominal distension
- [ ] Mild ascites
- [ ] Marked ascites

Problems:

-DCM, r/o primary cardiomyopathy, diet induced

B6

Diagnostic plan:
- [x] Echocardiogram
- [ ] Chemistry profile
- [ ] EOG
- [ ] Renal profile
- [ ] Blood pressure
- [ ] Dialysis profile
- [ ] Thoracic radiographs
- [ ] NT-proBNP
- [ ] Troponin I
- [x] Other tests: DCM study; Recommend Derm Appt

Echocardiogram Findings:

B6

Assessment and recommendations:

Echocardiogram reveals persistent DCM changes with progression in LA size. Recommend having B6 hand in case of increased RR/RE or cough. Recommend starting B6 increase to BID if well tolerated). Recheck renal values and electrolytes 2-3 weeks after starting B6 B6 Recommend dermatology consultation for facial skin issues.

Recheck echo and blood work for study in 3 months, or sooner if clinical signs occur.

FDA-CVM-FOIA-2019-1704-010641

Final Diagnosis:
DCM-like changes (r/o primary DCM v ARVC with DCM phenotype v dietary)

Heart Failure Classification Score:
ISACHC Classification:

- ☐ Ia
- ☑ Ib
- ☐ II
- ☐ IIIa
- ☐ IIIb

ACVIM Classification:

- ☐ A
- ☐ B1
- ☑ B2
- ☐ C
- ☐ D

M-Mode		
IVSd	B6	cm
LVIDd		cm
LVPWd		cm
IVSs		cm
LVIDs		cm
LVPWs		cm
EDV(Teich)		ml
ESV(Teich)		ml
EF(Teich)		%
%FS		%
SV(Teich)		ml
Ao Diam		cm
LA Diam		cm
LA/Ao		
Max LA		cm
Ao Diam		cm
LA Diam		cm
LA/Ao		
TAPSE		cm
EPSS		cm

M-Mode Normalized		
IVSdN	B6	(0.290 - 0.520)
LVIDdN		(1.350 - 1.730) !
LVPWdN		(0.330 - 0.530)
IVSsN		(0.430 - 0.710) !
LVIDsN		(0.790 - 1.140) !
LVPWsN		(0.530 - 0.780) !
Ao Diam N		(0.680 - 0.890) !
LA Diam N		(0.640 - 0.900) !

2D		
SA LA	B6	cm

Ao Diam	B6	cm
SA LA / Ao Diam		
IVSd		cm
LVIDd		cm
LVPWd		cm
EDV(Teich)		ml
IVSs		cm
LVIDs		cm
LVPWs		cm
ESV(Teich)		ml
EF(Teich)		%
%FS		%
SV(Teich)		ml
LV Major		cm
LV Minor		cm
Sphericity Index		
LVLd LAX		cm
LVAd LAX		cm
LVEDV A-L LAX		ml
LVEDV MOD LAX		ml
LVLs LAX		cm
LVAs LAX		cm
LVESV A-L LAX		ml
LVESV MOD LAX		ml
HR		BPM
EF A-L LAX		%
LVEF MOD LAX		%
SV A-L LAX		ml
SV MOD LAX		ml
CO A-L LAX		l/min
CO MOD LAX		l/min
LVLd A4C		cm
LVEDV MOD A4C		ml
LVLs A4C		cm
LVESV MOD A4C		ml
LVEF MOD A4C		%
SV MOD A4C		ml

Doppler		
E'	B6	m/s
A'		m/s
S'		m/s
EA SUM		m/s
AV Vmax		m/s
AV maxPG		mmHg
PV Vmax		m/s
PV maxPG		mmHg

FDA-CVM-FOIA-2019-1704-010643

From:	Rotstein, David </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0A3B17EBFCF14A6CB8E94F322906BADD-DROTSTEI>
To:	Carey, Lauren; Ceric, Olgica; Glover, Mark; Jones, Jennifer L; Nemser, Sarah; Palmer, Lee Anne; Peloquin, Sarah; Queen, Jackie L; Rotstein, David
Sent:	4/2/2019 5:38:47 PM
Subject:	DCM 4/2/2019 1330
Attachments:	ACANA - Heritage Red Meat Formula Dog Food (Grain-free): B6 - EON-383914; Canidae Dog food B6 EON-383943; EON-383924 RFR Event: Honest Kitchen

For the canidae, an echocardiogram was recommended 383943; ditto for Honest Kitchen (same submitter)

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
CVM OSC/DC/CERT
7519 Standish Place
240-506-6763 (BB)

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From: PFR Event <pfreventcreation@fda.hhs.gov>

To: Cleary, Michael *; HQ Pet Food Report Notification; B6

Sent: 4/1/2019 9:48:46 PM

Subject: ACANA - Heritage Red Meat Formula Dog Food (Grain-free) B6 - EON-383914

Attachments: 2065085-report.pdf; 2065085-attachments.zip

A PFR Report has been received and PFR Event [EON-383914] has been created in the EON System.

A "PDF" report by name "2065085-report.pdf" is attached to this email notification for your reference. Please note that all documents received in the report are compressed into a zip file by name "2065085-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-383914
ICSR #: 2065085
EON Title: PFR Event created for ACANA - Heritage Red Meat Formula Dog Food (Grain-free); 2065085

AE Date	03/15/2019	**Number Fed/Exposed**	2
Best By Date		**Number Reacted**	1
Animal Species	Dog	**Outcome to Date**	Stable
Breed	Shepherd Dog - German		
Age	11.5 Years		
District Involved	PFR-New England DO		

Product information
Individual Case Safety Report Number: 2065085
Product Group: Pet Food
Product Name: ACANA - Heritage Red Meat Formula Dog Food (Grain-free)
Description: 3/15/2019 - Acute onset of difficultly breathing on walk, increased resp rate, wheezing and short of breath. Diagnosed with DCM and CHF
Submission Type: Initial
Report Type: Adverse Event (a symptom, reaction or disease associated with the product)
Outcome of reaction/event at the time of last observation: Stable

Number of Animals Treated With Product: 2
Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
ACANA - Heritage Red Meat Formula Dog Food (Grain-free)		

Sender information

B6

USA

Owner information

B6

To view this PFR Event, please click the link below:
https://eon.fda.gov/eon//browse/EON-383914

To view the PFR Event Report, please click the link below:
https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jspa?decorator=none&e=0&issueType=12&issueId=401042

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Failure to adhere to the above provisions could result in removal from the approved distribution list. If you think you received this email in error, please send an email to FDAReportableFoods@fda.hhs.gov immediately.

Report Details - EON-383914

ICSR:	2065085	
Type Of Submission:	Initial	
Report Version:	FPSR.FDA.PETF.V.V1	
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)	
Reporting Type:	Voluntary	
Report Submission Date:	2019-04-01 17:42:39 EDT	
Reported Problem:	**Problem Description:**	3/15/2019 - Acute onset of difficultly breathing on walk, increased resp rate, wheezing and short of breath. Diagnosed with DCM and CHF
	Date Problem Started:	03/15/2019
	Concurrent Medical Problem:	No
	Outcome to Date:	Stable
Product Information:	**Product Name:**	ACANA - Heritage Red Meat Formula Dog Food (Grain-free)
	Product Type:	Pet Food
	Lot Number:	
	Package Type:	BAG
	Product Use Information:	
	Manufacturer /Distributor Information:	
	Purchase Location Information:	
Animal Information:	**Name:**	
	Type Of Species:	Dog
	Type Of Breed:	Shepherd Dog - German
	Gender:	Female
	Reproductive Status:	Neutered
	Weight:	25.9 Kilogram
	Age:	11.5 Years
	Assessment of Prior Health:	Excellent
	Number of Animals Given the Product:	2
	Number of Animals Reacted:	1
	Owner Information:	**Owner Information provided:** Yes
		Contact: **Name:** B6
		Phone:
		Address: B6
		United States
	Healthcare Professional Information:	**Practice Name:** Tufts Cummings School of Veterinary Medicine
		Contact: **Name:** Lisa Freeman
		Phone: (508) 887-4523
		Email: lisa.freeman@tufts.edu
		Address: 200 Westboro Road North Grafton

FDA-CVM-FOIA-2019-1704-010647

			Massachusetts 01536 United States
		Type of Veterinarian:	Referred veterinarian
		Permission to Release Records to FDA:	Yes
Sender Information:	**Name:**		
	Address:	B6	United States
	Contact:	**Phone:**	B6
		Email:	
	Permission To Contact Sender:	Yes	
	Preferred Method Of Contact:	Email	
	Reported to Other Parties:	None	
Additional Documents:			
	Attachment:	Medical record 4-1-2019.pdf	
	Description:	Medical records	
	Type:	Medical Records	

From: PFR Event <pfreventcreation@fda.hhs.gov>

To: Cleary, Michael *; HQ Pet Food Report Notification; B6

Sent: 4/2/2019 10:48:24 AM

Subject: Canidae Dog food: B6 - EON-383943

Attachments: 2065103-report.pdf

A PFR Report has been received and PFR Event [EON-383943] has been created in the EON System.

A "PDF" report by name "2065103-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report:

EON Key: EON-383943
ICSR #: 2065103
EON Title: PFR Event created for Canidae Dog food Bison flavor grain-free:; 2065103

AE Date	03/29/2019	**Number Fed/Exposed**	
Best By Date		**Number Reacted**	1
Animal Species	Dog	**Outcome to Date**	Unknown
Breed	Bichon Frise		
Age	6.5 Months		
District Involved	PFR- B6 DO		

Product information
Individual Case Safety Report Number: 2065103
Product Group: Pet Food
Product Name: Canidae Dog food, Bison flavor, grain-free:
Description: Originally reported as RFR EON-383923. CVM resubmitting as PFR. Our canine patient, B6, a 6 and 1/2 month old neutered male Bichon Frise Mix, has been eating Canidae Bison grain-free diet long term. The dog's Cardiopet was tested on 3-29-2019 and found to be elevated: value of B6 at idexx referrence laboratory. The owner was advised to take dog to a cardiologist next for consultation and echocardiogram. B6.
B6
Submission Type: Initial
Report Type: Adverse Event (a symptom, reaction or disease associated with the product)
Outcome of reaction/event at the time of last observation: Unknown

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Canidae Dog food, Bison flavor, grain-free:		

Sender information

B6

USA

To view this PFR Event, please click the link below:
https://eon.fda.gov/eon//browse/EON-383943

To view the PFR Event Report, please click the link below:
https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jspa?decorator=none&e=0&issueType=12&issueId=401071

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Report Details - EON-383943

ICSR:	2065103	
Type Of Submission:	Initial	
Report Version:	FPSR.FDA.PETF.V.V1	
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)	
Reporting Type:	Voluntary	
Report Submission Date:	2019-04-02 06:38:41 EDT	
Reported Problem:	**Problem Description:**	Originally reported as RFR EON-383923. CVM resubmitting as PFR. Our canine patient, B6, a 6 and 1/2 month old neutered male Bichon Frise Mix, has been eating Canidae Bison grain-free diet long term. The dog's Cardiopet was tested on 3-29-2019 and found to be elevated: value of B6 at idexx referrence laboratory. The owner was advised to take dog to a cardiologist next for consultation and echocardiogram. B6 B6
	Date Problem Started:	03/29/2019
	Outcome to Date:	Unknown
Product Information:	**Product Name:**	Canidae Dog food, Bison flavor, grain-free:
	Product Type:	Pet Food
	Lot Number:	
	Possess Unopened Product:	Unknown
	Possess Opened Product:	Unknown
	Product Use Information:	
	Manufacturer /Distributor Information:	
	Purchase Location Information:	
Animal Information:	**Name:**	B6
	Type Of Species:	Dog
	Type Of Breed:	Bichon Frise
	Gender:	Male
	Reproductive Status:	Neutered
	Age:	6.5 Months
	Assessment of Prior Health:	Unknown
	Number of Animals Reacted:	1
	Owner Information:	**Owner Information provided:** No
	Healthcare Professional Information:	
Sender Information:	**Name:**	B6
	Address:	United States
	Contact:	**Phone:** **Email:** B6
	Reporter Wants to	No

FDA-CVM-FOIA-2019-1704-010651

	Remain Anonymous:	
	Permission To Contact Sender:	Yes
	Preferred Method Of Contact:	Email
	Reported to Other Parties:	Unknown
Additional Documents:		

FDA-CVM-FOIA-2019-1704-010652

From: RFR Event <rfreventcreation@fda.hhs.gov>

To: Cleary, Michael *; FDA Emergency Operations; orahqreportablefoodnotificationtriagegroup@fda.hhs.gov; B6 ORA OSPOP ENFORCEMENT Recall Operations Branch; Palmer, Lee Anne; ORA HAF WEST5 Reportable Food Notification; CFSAN Reportable Food Registry; B6

Sent: 4/2/2019 12:28:32 AM

Subject: EON-383924 RFR Event: Honest Kitchen

A RFR Report has been received and RFR Event [EON-383924] has been created in the EON System under **ICSR # 2065093**.

Reason this food is reportable: Other
Please describe Other: Cardiac disease risks of grain free diets
Health Hazard Category for Other: Biological
Product Name: Honest Kitchen, chicken grain free diet

Type of Site:	**Sender**	**Food Facility Site**
FDA Districts Impacted:	LOS	LOS
Organization Name:	B6	Honest Kitchen
Address:		111 14th Street San Diego, CA 92101 United States

Discovery Date: 2019-03-26
Product Group: Human Food
Description: Our canine patient B6 a 3 year old spayed female mixed breed dog, has been eating Honest Kitchen grain free chicken based diet exclusively for at least the last 2 years. The dog's Cardiopet was tested on 3-26-2019 and found to be elevated: value of B6 at idexx referrence laboratory. The owner was advised to take dog to a cardiologist next for consultation and echocardiogram. B6
B6
Product Recall: No
Human Symptoms Present: No
Animal Symptoms Present: Yes
Animal Symptoms Description: Our canine patient B6 a 3 year old spayed female mixed breed dog, has been eating Honest Kitchen grain free chicken based diet exclusively for at least the last 2 years. The dog's Cardiopet was tested on 3-26-2019 and found to be elevated: value of B6 at idexx referrence laboratory. The owner was advised to take dog to a cardiologist next for consultation and echocardiogram. B6
B6

Product Distribution Type: Retail
Root Cause: Unknown

Discovery Code: Self discovery

Submission Type: Initial
Reporting Type: Voluntary
EON Key: EON-383924
EON Title: RFR Event created for Honest Kitchen chicken grain free diet; 2065093

To view this RFR Event, please click the link below:
https://eon.fda.gov/eon//browse/EON-383924

To view the RFR Report, please click the link below:
https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jspa?decorator=none&e=0&issueType=9&issueId=401052

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From: Rotstein, David </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0A3B17EBFCF14A6CB8E94F322906BADD-DROTSTEI>
To: Carey, Lauren; Ceric, Olgica; Glover, Mark; Jones, Jennifer L; Nemser, Sarah; Palmer, Lee Anne; Peloquin, Sarah; Queen, Jackie L
CC: Rotstein, David
Sent: 8/22/2018 10:53:16 AM
Subject: DCM Cases 8/22/2018 7:45 AM
Attachments: Acana Free Run Poultry dry: Lisa Freeman - EON-362878; ACANA Grain Free Chicken: B6 B6 - EON-362883; ACANA singles:-Pork and Squash -Lamb and Apple: B6 - EON-362958; Fromm 4-Star Lamb & Lentil Recipe Dog Food: B6 - EON-362992; Natural Balance Salmon and Chick Pea-Natural Balance Chicken and chick pea-Both are grain free.: B6 - EON-362996; Wellness Core Ocean: B6 - EON-362997; Zignature Kangaroo Formula - EON-362940; Zignature Kangaroo Grain Free Formula: B6 B6 - EON-362973

EON-362997(2054051)-wellness core- serial Tau testing
Eon-362996(2054050)-Natural Balance-Tau; attachments included
EON-362992(2054045)-Fromm Lentil and Lamb-low Tau
EON-362973(2054024)-Zignature, NCSU case
EON-362958(2054015)-Acana, NCSU case
EON-362883(2053978)-Acana, NCSU case—this was submitted as a RFR and Lauren re-entered it
EON-362878(2053969)-Acana, Tufts

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
CVM OSC/DC/CERT
7519 Standish Place
240-506-6763 (BB)

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From: Rotstein, David </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0A3B17EBFCF14A6CB8E94F322906BADD-DROTSTEI>
To: Carey, Lauren; Ceric, Olgica; Glover, Mark; Jones, Jennifer L; Nemser, Sarah; Palmer, Lee Anne; Peloquin, Sarah; Queen, Jackie L; Rotstein, David
Sent: 8/27/2018 1:37:23 PM
Subject: DCM cases 8/27/2018 as of 9:30 AM
Attachments: Acana Meadowlands Poultry and Freshwater Fish Grain Free Dog Food: B6 - EON-363409; Acana Pork and Squash Singles: B6 - EON-363325; Fromm Beef grain free: B6 - EON-363316; Kibbles and Bits Chefs Choice Bistro AND Homestyle: B6 B6 - EON-363453; Petcurean Limited Ingredient Salmon Dry: Lisa Freeman - EON-363365

For EON-363453(2054237)—assuming "titer" for "tiger"

EON-363365 (2054221)-low taurine; boxer
EON-363325-Acana sent on Friday—person from Taurine Defic. B5
B5

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
CVM OSC/DC/CERT
7519 Standish Place
240-506-6763 (BB)

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From: PFR Event <pfreventcreation@fda.hhs.gov>

To: Cleary, Michael *; HQ Pet Food Report Notification; B6

Sent: 8/24/2018 10:20:31 PM

Subject: Petcurean Limited Ingredient Salmon Dry: Lisa Freeman - EON-363365

Attachments: 2054221-report.pdf; 2054221-attachments.zip

A PFR Report has been received and PFR Event [EON-363365] has been created in the EON System.

A "PDF" report by name "2054221-report.pdf" is attached to this email notification for your reference. Please note that all documents received in the report are compressed into a zip file by name "2054221-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-363365
ICSR #: 2054221
EON Title: PFR Event created for Petcurean Limited Ingredient Salmon Dry, Petcurean Now Fresh; 2054221

AE Date	06/19/2017	**Number Fed/Exposed**	1
Best By Date		**Number Reacted**	1
Animal Species	Dog	**Outcome to Date**	Better/Improved/Recovering
Breed	Boxer (German Boxer)		
Age	2 Years		
District Involved	PFR-New England DO		

Product information
Individual Case Safety Report Number: 2054221
Product Group: Pet Food
Product Name: Petcurean Limited Ingredient Salmon Dry, Petcurean Now Fresh
Description: Previously healthy dog. Eating Petcurean Go Limited ingredient dry primarily. Also, some Petcurean Now Fresh, Stella and Chewy Raw patties, lean treats, Wellness Core treats. Had been on Petcurean Now Fresh lg breed puppy initially. See nutrition consultation for full diet history. Dilated cardiomyopathy diagnosed with low taurine level. DCM reversed after diet change and taurine and carnitine supplementation. Note: maxed out on attachments - will send more by email. Also, I am submitting this report in collaboration with B6 I will submit a small sample of dog's food when I ship other food samples on 8/27/18

Submission Type: Initial
Report Type: Adverse Event (a symptom, reaction or disease associated with the product)
Outcome of reaction/event at the time of last observation: Better/Improved/Recovering
Number of Animals Treated With Product: 1
Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Petcurean Now Fresh		
Petcurean Limited Ingredient Salmon Dry		

Sender information
Lisa Freeman
200 Westboro Rd
North Grafton, MA 01536
USA

Owner information
B6
USA

To view this PFR Event, please click the link below:
https://eon.fda.gov/eon//browse/EON-363365

To view the PFR Event Report, please click the link below:
https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jspa?decorator=none&e=0&issueType=12&issueId=380099

==========

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Report Details - EON-363365

ICSR:	2054221	
Type Of Submission:	Initial	
Report Version:	FPSR.FDA.PETF.V.V1	
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)	
Reporting Type:	Voluntary	
Report Submission Date:	2018-08-24 18:09:51 EDT	
Reported Problem:	**Problem Description:**	Previously healthy dog. Eating Petcurean Go Limited ingredient dry primarily. Also, some Petcurean Now Fresh, Stella and Chewy Raw patties, lean treats, Wellness Core treats. Had been on Petcurean Now Fresh lg breed puppy initially. See nutrition consultation for full diet history. Dilated cardiomyopathy diagnosed with low taurine level. DCM reversed after diet change and taurine and carnitine supplementation. Note: maxed out on attachments - will send more by email. Also, I am submitting this report in collaboration with B6 I will submit a small sample of dog's food when I ship other food samples on 8/27/18
	Date Problem Started:	06/19/2017
	Concurrent Medical Problem:	No
	Outcome to Date:	Better/Improved/Recovering
Product Information:	**Product Name:**	Petcurean Now Fresh
	Product Type:	Pet Food
	Lot Number:	
	Package Type:	BAG
	Product Use Information:	
	Manufacturer /Distributor Information:	
	Purchase Location Information:	
	Product Name:	Petcurean Limited Ingredient Salmon Dry
	Product Type:	Pet Food
	Lot Number:	
	Package Type:	BAG
	Product Use Information:	**Description:** Fed daily
	Manufacturer /Distributor Information:	
	Purchase Location Information:	
Animal Information:	**Name:**	B6
	Type Of Species:	Dog
	Type Of Breed:	Boxer (German Boxer)
	Gender:	Male
	Reproductive Status:	Neutered
	Weight:	31.5 Kilogram
	Age:	2 Years
	Assessment of Prior Health:	Excellent
	Number of Animals Given the Product:	1
	Number of Animals Reacted:	1
	Owner Information:	**Owner Information** Yes

FDA-CVM-FOIA-2019-1704-010660

		provided:	
		Contact:	Name: B6 Phone: Email:
		Address:	B6 United States
	Healthcare Professional Information:	Practice Name:	Tufts Cummings School of Veterinary Medicine
		Contact:	Name: Lisa Freeman Phone: (508) 887-4523 Email: lisa.freeman@tufts.edu
		Address:	200 Westboro Rd North Grafton Massachusetts 01536 United States
		Practice Name:	B6
		Contact:	Name: Phone: B6
		Type of Veterinarian:	Referred veterinarian
		Permission to Release Records to FDA:	Yes
Sender Information:	Name:		Lisa Freeman
	Address:		200 Westboro Rd North Grafton Massachusetts 01536 United States
	Contact:	Phone:	5088874523
		Email:	lisa.freeman@tufts.edu
	Permission To Contact Sender:		Yes
	Preferred Method Of Contact:		Email
Additional Documents:			
	Attachment:		B6 echo B6 .pdf
	Description:		Echo B6
	Type:		Echocardiogram
	Attachment:		B6 rdvm records.pdf
	Description:		RDVM records
	Type:		Medical Records
	Attachment:		B6 nutrition consultation 7-7-18.pdf
	Description:		Nutrition consultation
	Type:		Other
	Attachment:		B6 echo B6 .pdf
	Description:		Echo B6
	Type:		Echocardiogram
	Attachment:		B6 diet hx form.pdf

Description:	Diet history
Type:	Other

FDA-CVM-FOIA-2019-1704-010662

Client Diet History Form

Submitted: 06/24/2017

PET INFORMATION	
Pet Name	B6
Pet Last Name	
Pet Species/Breed	B6
Pet's Color	Brindle
Pet's Birthdate	B6
Pet's Sex	Male
Spayed or Neutered?	Yes
CLIENT INFORMATION	
Client Name	B6
Client Address	
Client Phone	
Client Email	
Co-Owner Name	
Co-Owner Phone	
Co-Owner Email	
CONSULT INFORMATION	
Type of Consult	Phone
HCD Being Requested?	No
Reasons & Goals for Consult	B6 has been recently discovered to have some cardiomyopathy and low taurine levels. He has food sensitivities, so he's been on a limited ingredient diet for over a year... The cardiologist is hoping his heart presentation is mostly due to his taurine deficiency and that we can resolve it with some supplements and a balanced diet. I need help with finding a food for him that doesn't contain poultry (and possible fish).
Attachments	
PRIMARY VETERINARIAN INFORMATION	
rDVM Name	B6
rDVM Clinic	
rDVM Phone	
rDVM Fax	
rDVM Email	B6

Diet History Form

Agree to Terms

Date Submitted
06/24/2017

Information to Gather

About You, Your Veterinarian(s) and Your Pet

What type of appointment are you requesting?
Phone

Has your pet been seen at Tufts in the last 6 months?
No

About the Pet Owner

Pet owner name
B6

Pet owner email
B6

Address
B6

Preferred Phone
B6

Preferred Phone Type
Mobile

Alternate Phone

Is there another phone number you would like to give us in case we can't reach you at one of the above?
No

Spouse/partner/co-owner's name
B6

Spouse/partner/co-owner's email

Spouse/partner/co-owner's phone

Your Pet's Primary Veterinarian

Primary veterinarian
B6

Primary veterinarian's clinic name
B6

Primary veterinarian's clinic phone
B6

Primary veterinarian's clinic fax

Primary veterinarian's clinic email
B6

Is your pet currently being (or has your pet been) seen by any other veterinarians in relation to her/his current health issues or other health issues that you'd like to discuss with us?
Yes

Information About Your Second Veterinarian

Name of 2nd veterinarian
B6

Clinic name of 2nd veterinarian
B6

Phone for 2nd veterinarian's clinic
B6

Fax for 2nd veterinarian's clinic

Email for 2nd veterinarian's clinic
B6

What is this second veterinarian's role in your pet's care?
Cardiologist

Should this 2nd veterinarian receive a copy of any written reports that result from working with our service?
Yes

Is your pet being seen by a 3rd veterinarian?
No

About Your Pet

Pet's name
B6

What is your pet's species?
Dog

Breed
Boxer

Color
Brindle

Sex
Male

Spayed/neutered?
Yes

Do you know your pet's exact birthdate?
Yes

Pet's Birthdate
B6

What is your pet's current weight
69

Pounds or kilograms?
lbs

Has your pet gained or lost weight within the past 6 months?
Stayed the same

Which category best describes your pet?
ideal weight

Reason and goals for consultation
B6 has been recently discovered to have some cardiomyopathy and low taurine levels. He has food sensitivities, so he's been on a limited ingredient diet for over a year... The cardiologist is hoping his heart presentation is mostly due to his taurine deficiency and that we can resolve it with some supplements and a balanced diet. I need help with finding a food for him that doesn't contain poultry (and possible fish).

Details About Your Pet's Habits

Questions about your pet

Is your pet housed:

- Indoors

Please describe your pet's activity level:
High

Do you have any other pets?
Yes

What are your other pets?

Species	How many?
Dog	1

Do any pets have access to other pets' food?
No

How many people (including yourself) live in your household?
4

Who feeds your pet?
All of us take turns

How many times per day do you feed your pet?
Three

Does your pet finish all food that is offered?
It depends

Depends on what?
What we're offering. He won't finish Salmon - he'll walk away from it. He does like any beef/bison/venison food offered.

Does your pet have any difficulty with the following?

Does your pet have any of the following?

- Food allergies
- Environmental allergies

Please explain about your pet's conditions
B6 was on a mixed protein commercial food as a puppy. He was underweight. We saw a vet in B6 for an emergency problem when he was about 6 months old who (as an aside) suggested that he was 10-20 smaller than he should be. He suggested looking into a food that doesn't contain poultry to see if maybe he had some sort of allergy to it. We switched to a salmon limited ingredient food and he gained 10# in two months, so we stayed on that until very recently. He was fickle about eating it - I mentioned that to our trainer. She suggested that we see a kinesiologist to assess is he had developed an allergy to salmon too. She was the one who suggested we switch to food that was based in beed/bison/boar/venison (hooved animals). B6 has been on that for about 3 weeks.

He ALSO has an allergy to bees. He tends to eat them off of flowers, they sting his mouth and his face blows up like a balloon. He was on a daily dose of benadryl last spring/summer and fall. This spring, we haven't had an instances yet, but I did notice he was very affected by the pollen (runny eyes w/ discharge and lower energy)

Have you observed any changes in any of the following?

Have you made any recent changes in diet (last 4 weeks)?
Yes

Please explain the changes in your pet's diet
See above

Your Pet's Diet

Do you feed your pet DRY (e.g., kibble) pet food?
Yes

Please list each kind of DRY petfood individually

Brand or name	Amount per serving	How often given?	Fed since (mo/yr)?
Petcurean - Go! Limited ingredient	2 cups	1-3 times a day	April 2016

Brand or name	Amount per serving	How often given?	Fed since (mo/yr)?
Petcurean - Fresh Now	2 cups	1-3 times a day (we alternate)	December 2015-April 2016, and again June 2017-present
Stella & Chewy's Raw	8 oz patty	1x day (sometimes)	June 2017

Do you feed your pet WET (e.g., canned or pouched) pet food?
No

Do you feed your pet HOME-COOKED food?
No

Do you feed your pet TREATS?
Yes

Please list each kind of TREAT individually

Brand or name	Amount per serving	How often given?	Fed since (mo/yr)?
Lean Treats	1-2 chunks	1-5 times a day	December 2015
Wellness Core	2-5 pieces	1-3 times a day (Alternating with above)	June 2017

Is there any OTHER kind of food you feed your pet?
Yes

Please list each kind of OTHER petfood individually

Food, brand or name	Amount per serving	How often given?	Fed since (mo/yr)?
Bread	small piece	1x a day	April 2016
Banana	small piece	occasionally	December 2016

Do you give any dietary supplements to your pet (for example: vitamins, glucosamine, fatty acids, herbs, or any other supplements)?
Yes

Please list any dietary supplements

Product Name	Amount	Frequency
Taurine	1 gram	2-3 times a day (Started 6/19/2017)
L-Carnitine	2 grams	2-3 times a day (Started 6/19/2017)

Is your pet receiving any medications?
Yes

Please list your pet's medications

Drug Name	Dosage
B6	2x a day (started on 6/19/2017)

Do you use food (e.g., Pill Pockets, cheese, bread, peanut butter, etc.) to administer medications?
Yes

Lists foods used to administer medication

What kind?	Amount? How often?
See above - Lean treats, bread, banana	

Regarding commercial diets (pet foods and treats not made in your home) your pet may have received in the past, please select the following statement that is most accurate:
I have never fed other commercial diets to my pet

Home-cooked Diets

Is a home-cooked diet being requested? (Please note that this option is only available for phone or in-person consults, not for consults directly with veterinarians.)
No

Medical Records & Test Results

Requested Items

- Complete blood count, biochemistry profile and urinalysis
- Additional relevant diagnostics (e.g., urine culture, T4, ultrasound reports)
- Last 6 months' medical records or as appropriate (all consults)

Do you have any of the above in electronic format?
No

Would you like to upload and attach anything else to this form?

SOAP - Cardiology

Mar 01, 2018

B6 United States

Acc. No: 223669
Phone: Primary - B6

Patient: B6
Species: Canine
Breed: Boxer
Color: brindle
Doctor: B6

DOB: B6
Age:
Sex: Neutered Male
Tag:

Weight: 72.9 lbs.

Prior Medical History

As of B6
-Dilated cardiomyopathy, suspect secondary to taurine-deficiency given improvement in appearance with diet change/supplementation (currently moderate left atrial enlargement).
-Borderline pulmonary hypertension
-Mildly elevated left and right ventricular outflowtract velocities.

B6

MEDICATIONS:

B6

Presenting Complaint

Recheck echo

Current Medical History

General Complaints: Doing well at home, good energy, good appetite.
Coughing?: No
Sneezing?: No
Vomiting: No
Polyuria: No
Polydipsia: No
Diarrhea?: No
Diet?: RC Boxer
Appetite: Increased
Any collapses or seizures?: No

Current Medications

Do you need any refills today?: No
First Cardiac Evaluation?: No
Referral Radiographs?: No

Physical Exam

B6

Echocardiogram

Two Dimensional Description: B6 was very nervous and tense on the echo table- a little better when we had B6 leave the exam room. Able to do the study unsedated with two holders.

The left atrium appears mildly to moderately enlarged (appearance of enlargement and LA/Ao increased by small aortic root). The mitral valve appears normal. The left ventricular chamber appears mildly dilated with walls at lower end of normal. Wall motion appears slightly depressed (especially for such a nervous dog) and somewhat asynchronous. The aortic root appears mildly small (breed variant) with normal aortic valve. The right atrium appears mildly dilated. The tricuspid valve appears normal. The right ventricular chamber is normal. The pulmonary artery and pulmonic valve are normal.

B6

B6

ECHOCARDIOGRAPHIC DIAGNOSIS:

ECHOCARDIOGRAPHIC DIAGNOSIS:
-Hx Dilated cardiomyopathy dx B6 suspect secondary to taurine-deficiency given improvement in appearance with diet change/supplementation (currently mild to moderate left atrial enlargement, slight decreased systolic function as of B6
-Hx Borderline pulmonary hypertension
-Mildly elevated left and right ventricular outflowtract velocities.

Comparison to previous studies:
There has been continued improvement in cardiac appearance (although still not completely normal). Left atrial size nowsimilar to 2016 echo (prior to dx with DCM- when echo done for asymptomatic murmur and systolic function was normal, so this may be B6 e "normal" value).

B6

Final Assessment

Final Diagnosis:
-Hx Dilated cardiomyopathy dx B6 suspect secondary to taurine-deficiency given improvement in appearance with diet change/supplementation (currently mild to moderate left atrial enlargement, slight decreased systolic function as of B6
-Hx Borderline pulmonary hypertension
-Mildly elevated left and right ventricular outflowtract velocities.

Diagnostic Recommendations:
No further cardiac testing currently recommended.

Therapeutic Recommendations:
Continue current medications.

B6

Follow-Up:
Recheck echo scheduled for October 4th at 1:30 pm (recommended 6-9 month recheck).

Consulting Cardiologist: B6 DVM; DACVIM (cardiology)

B6

B6

Pet: B6
DOB: B6
Breed: Boxer
Sex: M
Color: brindle

Cummings Veterinary Medical Center at Tuft's University
Behavior Service
55 Willard St
North Grafton, Massachusetts, United States
01536

Visit Date: B6

Dear Drs. B6 and Freeman,

Please see the accompanying cardiology report for our mutual patient, B6. I am thrilled that B6 heart has improved since changing his diet and supplementing taurine and carnitine! He is such a nice dog with such a nice family, and it was wonderful to be able to give them some good news. Thank you for the referral and your continued support of B6 ir. Please contact me if you need any more information regarding B6

Sincerely,

B6

B6

SOAP - Cardiology

B6

B6

Acc. No: 223689
Phone: Wife cell - B6

Patient: B6
Species: Canine
Breed: Boxer
Color: brindle
Doctor: B6

DOB: B6
Age: B6
Sex: M
Tag:

Weight: 76.3 lbs

Prior Medical History

As of: B6
-Dilated cardiomyopathy (severe), r/o idiopathic, secondary to taurine-deficiency, myocarditis, other
-Borderline pulmonary hypertension
-Mildly elevated left ventricular outflow tract velocity (dx: B6
-Normal sinus arrhythmia with no ventricular ectopy

Diagnostics: B6
Taurine B6

B6

MEDICATIONS:

B6

Presenting Complaint

Recheck echo

Current Medical History

General Complaints: Doing ok at home. O is concerned that he is becoming a finicky eater again. Currently eating RC boxer and O thinks this is the longest he has gone liking/eating the same food. Will eat some treats, but is also not as interested in PB pill pockets - possibly causes stomach upset. Loose stools but not diarrhea.

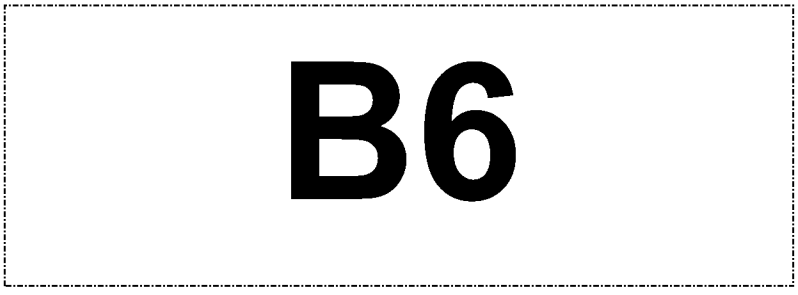
Coughing?: No
Sneezing?: No
Vomiting: No

Polyuria: No
Polydipsia: No
Diarrhea?: No
Diet?: RC Boxer (had nutrition consult with Dr. Freeman at Tufts)
Appetite: Normal
Any collapses or seizures?: No

Current Medications

Do you need any refills today?: No
First Cardiac Evaluation?: No
Referral Radiographs?: No

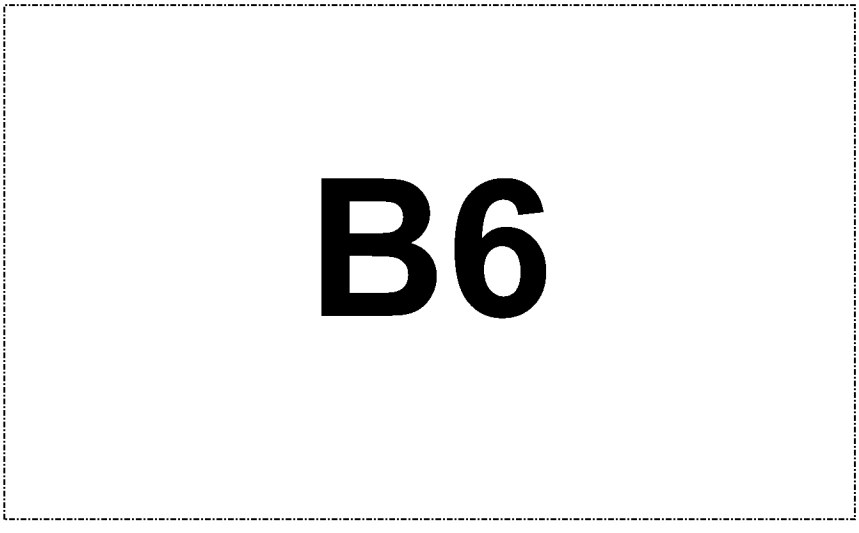
Physical Exam



Echocardiogram

Two Dimensional Description: B6 was nervous, but good on the echo table and able to do the study unsedated with two holders.

The left atrium appears moderately enlarged (appearance of enlargement and LA/Ao increased by small aortic root). The mitral valve appears normal. The left ventricular chamber is moderately dilated with mildly thin walls. Wall motion appears mildly depressed and somewhat asynchronous. The aortic root appears mildly small (breed variant) with normal aortic valve. The right atrium appears mildly dilated. The tricuspid valve appears normal. The right ventricular chamber is normal. The pulmonary artery and pulmonic valve are normal.



B6

ECHOCARDIOGRAPHIC DIAGNOSIS:

ECHOCARDIOGRAPHIC DIAGNOSIS:
-Dilated cardiomyopathy, suspect secondary to taurine-deficiency given improvement in appearance with diet change/supplementation (currently moderate left atrial enlargement).
-Borderline pulmonary hypertension
-Mildly elevated left and right ventricular outflow tract velocities

Comparison to previous studies:
There has been significant improvement in the cardiac appearance since dx with DCM 2 months ago. All chamber sizes are smaller, there is less MR and TR, and contractility appears improved. LA measurements are fairly similar to the original echo one year ago (for asymptomatic murmur).

B6

Final Assessment

Final Diagnosis:
-Dilated cardiomyopathy, suspect secondary to taurine-deficiency given improvement in appearance with diet change/supplementation (currently moderate left atrial enlargement).
-Borderline pulmonary hypertension
-Mildly elevated left and right ventricular outflow tract velocities

Diagnostic Recommendations:
No further testing currently recommended.

Therapeutic Recommendations:
B6

Follow-Up:
Recheck echo 6 months (scheduled for March 1, 2018 at 1:30 pm).

Consulting Cardiologist: B6 DVM; DACVIM (cardiology)

Clinical Nutrition Service
Foster Hospital for Small Animals
200 Westboro Road
North Grafton, MA 01536
Phone: (508) 887-4696 Attn: Nutrition Liaison
Fax: 508-887-4363
http://vetnutrition.tufts.edu/
vetnutrition@tufts.edu

Cummings Veterinary Medical Center AT TUFTS UNIVERSITY

Nutrition Consultation

Date: 7/7/17 (Phone consultation)
Pet Name: B6 (owner: B6)
Signalment: 1 ½ year old castrated male Boxer
Weight: 69 pounds (31 kg), body condition score 4/9 (ideal), muscle condition score: Normal
Diagnosis/Problems: Dilated cardiomyopathy with low taurine level; possible food sensitivities, bee and environmental allergies
Medications: B6
RDVM: B6
B6

Recommendations below are based on information obtained from owner and referring veterinarians.

Diet History:

- Current diet: Petcurean Go! Limited Ingredient dry, Petcurean Now Fresh, Stella & Chewy's raw patties, Lean Treats, Wellness Core treats; bread or banana for medication administration. Just started transitioning to Purina Pro Plan Focus Adult Sensitive Skin and Stomach salmon and rice dry based on Dr. B6 recommendations
- Petcurean Now Fresh large breed puppy dry; initially on Iams Smart Puppy Small and Toy Breed dry (8-12 weeks of age), Go Salmon (not finishing food)
- Supplements: Taurine 1000 mg 3 times daily, L-carnitine 2000 mg 2 times daily (NOW or Whole Foods)

Nutritional Goals

- Complete and balanced diet
- Adequate calorie intake to maintain ideal body weight (approximately 70 pounds)
- Reduced sodium
- Moderate protein
- Taurine and L-carnitine supplementation
- Omega-3 fatty acid supplementation

Recommendations:

- I'm happy that we were able to talk about B6 diet to ensure he's getting optimal nutrition. Nutrition is an integral part of the treatment for a dog with heart disease. This is especially important for B6 because we're suspicious of taurine and/or carnitine deficiencies playing a role in his disease. Hopefully, the taurine and carnitine supplementation and a diet we can be more confident in will be helpful for his heart!
- As we discussed, there's a lot of misinformation about pet foods so I'll only be recommending diets that meet all the criteria for being of the highest quality: http://vetnutrition.tufts.edu/2016/12/questions-you-should-be-asking-about-your-pets-food/
- My estimate of B6 daily calorie needs is approximately 1700 calories per day (based on the average of 2 cups twice daily that he was getting from the Go Fresh Now dry food). This is an initial estimate to keep him at a weight 70 pounds. However, since every dog is an individual, I'd like to have you weigh him in 2 weeks to be sure he's maintaining his weight. If he's losing weight, you should increase the amount of food and continue to weigh him and if he's gaining weight, you should reduce the amount of food and continue to weigh him. Let me know if you need help with adjusting the amounts.
- The current diet you're feeding (Purina Pro Plan Sensitive Skin and Stomach) is of excellent quality, high in omega-3 fatty acids, and not too high in sodium. Since B6 not in heart failure, the dietary sodium doesn't

need to be quite as low so I'm comfortable having him continue to eat the Pro Plan (especially since he seems to enjoy it!). However, I'm providing a few other options that are also high in omega-3 fatty acids. Please note the variable calorie density of these foods and adjust the number of cups accordingly to provide our starting point for calories of 1700 calories/day:

Dry Food	Calories/cup	Sodium (mg/100 calories)
Pro Plan Focus sensitive skin & stomach salmon & rice (dry)	447	128
Purina JM (dry)*	408	100
Purina DRM Naturals (dry)*	418	80
Royal Canin Boxer (dry)	335	73
Royal Canin Mobility Support JS (dry)*	324	70

Diets with an asterisk are ones that must be purchased from B6 or, if not available, from an online pet food store (eg, Chewy.com, Petfooddirect.com) with a prescription or approval from her. The other 2 diets are available over-the-counter

- Make all changes gradually over 5-7 days to avoid gastrointestinal upset.
- We didn't discuss this on our call but I strongly urge you to discontinue the raw patties immediately. There is no evidence of any health benefit of raw meat diets and there are many, many documented risks. In addition, raw meat diets put you, your family, and your dogs at risk for bacterial infections because of high rates of bacterial contamination of raw meat diets.

Supplements:

- Unfortunately, there is little regulation of supplements for people or animals (safety, effectiveness, and quality control do not have to be proven for them to be sold), and some of these products may be harmful rather than helpful. Therefore, I am very selective when it comes to recommending specific supplements that have undergone independent quality control testing. Looking for the USP logo or using Consumerlab.com is very helpful for finding products with independent testing of quality.
- Taurine and L-carnitine: Because of his low plasma taurine and the potential for some Boxers to have carnitine deficiency, I support B6 recommendations for supplementation. Since results of independent testing of taurine and carnitine are not available on Consumerlab, we tested a number of products in 2009. Although I don't know that the results are still true 8 years later, the products that did well in our testing were:
  - Taurine: Solgar, Twinlab, Swanson, NOW, Country Life, and GNC.
  - L-carnitine: Solgar, Country Life, Jarrow. Although we did not test the liquid L-carnitine from Solgar, I think that would be a reasonable one to try if it's easier to get him to take it as a liquid.
  - The doses that you're giving Mo are appropriate.
  - We have some additional information on these supplements on our HeartSmart website: http://vet.tufts.edu/heartsmart/diet/important-nutrients-for-pets-with-heart-disease/
- Omega-3 fatty acids: Fish oil, which is high in the omega-3 fatty acids, EPA and DHA, can have modest benefits in reducing inflammation, maintaining muscle mass, reducing abnormal heart rhythms, and improving appetite. The diets above all contain sufficient omega-3 fatty acids but if we do need to use a supplement in the future, we have brands with independent testing on our HeartSmart website: http://vet.tufts.edu/wp-content/uploads/omega-3_supplementation.pdf

Treats:

- Some good treat options
  - Hill's Ideal Balance Breakfast Medleys with Country Chicken & Egg Dog Treat
  - Hill's Ideal Balance Oven-Baked Naturals with Chicken & Apples Dog Treat
  - Science Diet Grain Free treat with Chicken & Apples Dog Treat
  - Hill's Ideal Balance Soft-Baked Naturals with Chicken & Carrots Dog Treat
  - Hill's Science Diet Baked Light Biscuits with Real Chicken Small Dog Treat
  - Royal Canin Veterinary Diets Original Dog Treats
  - Frosted Mini Wheats (original)
  - Fresh vegetables/fruit – eg, carrots, green beans, apple, orange, bananas, berries (except ones listed below)
- Avoid macadamia nuts, avocado, garlic, onions, grapes, raisins, and other foods known to be toxic to dogs.

Medication Administration

- Dog tablet sized Greenies Pill Pockets are relatively low in sodium (just be sure to avoid Duck and Pea flavor which is high in sodium) but try to limit the total to 4-5/day
- You can also insert medications into one of the following foods:
    - Low-sodium canned pet food (I can give you some specific canned foods if you want to try this option)
    - Mini marshmallows
    - Fruit such as banana, orange, melon, or berries (avoid grapes)
    - Peanut butter (labeled as "no salt added")
    - Pro Plan Additions Puree (Chicken and berries or chicken and pumpkin). This also works well for some dogs to give them pills

Follow Up:

- Monitor body weight to ensure he stays at an ideal weight of about 70 pounds (it may take some adjustment of the new food).
- Please let me know how things go at B6 recheck cardiology evaluation at the end of August. Hopefully, there will be an improvement in his heart function!

Please contact me if you have any questions abou B6 nutritional plan.

Sincerely,

Lisa M. Freeman, DVM, PhD, DACVN
Professor, Clinical Nutrition
508-887-4696 (telephone)
vetnutrition@tufts.edu (email)
www.petfoodology.org (FAQs and other resources)

From: Rotstein, David </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0a3b17ebfcf14a6cb8e94f322906badd-DRotstei>

To: Carey, Lauren; Ceric, Olgica; Glover, Mark; Jones, Jennifer L; Nemser, Sarah; Palmer, Lee Anne; Peloquin, Sarah; Queen, Jackie L; Rotstein, David

Sent: 10/9/2018 10:48:25 AM

Subject: DCM cases 10/9/18 0630

Attachments: Acana Heritage formula dog food (mostly freshwater fish: Lisa Freeman - EON-367839; Acana Singles Limited Ingredient Lamb and Apple 25 pound bag: B6 - EON-367777; Blue Buffalo Wilderness- High Protein Grain Free -Natures Evolutionary Diet- with Chicken Life Source bits- Senior: B6 - EON-367745; Core Wellness Ocean Formula: B6 B6 - EON-367873; Fromm Four Star Salmon a la Veg dog food: B6 - EON-367810; Pro Plan Savory dry - chicken: Lisa Freeman - EON-367850; Rawz meal free dry food limited recipe wild salmon dry: Lisa Freeman - EON-367845; Taste of the Wild High Forest dry: Lisa Freeman - EON-367841; Taste of the Wild Pacific Stream (dry): Lisa Freeman - EON-367849

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
CVM OSC/DC/CERT
7519 Standish Place
240-506-6763 (BB)

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From: PFR Event <pfreventcreation@fda.hhs.gov>

To: Cleary, Michael *; HQ Pet Food Report Notification; B6

Sent: 10/8/2018 5:44:37 PM

Subject: Acana Heritage formula dog food (mostly freshwater fish: Lisa Freeman - EON-367839

Attachments: 2055788-report.pdf; 2055788-attachments.zip

A PFR Report has been received and PFR Event [EON-367839] has been created in the EON System.

A "PDF" report by name "2055788-report.pdf" is attached to this email notification for your reference. Please note that all documents received in the report are compressed into a zip file by name "2055788-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-367839
ICSR #: 2055788
EON Title: PFR Event created for Acana Heritage formula dog food (mostly freshwater fish free run poultry and meats (beef pork and lamb) formulas. Also Meadowlands; 2055788

AE Date	10/04/2018	**Number Fed/Exposed**	1
Best By Date		**Number Reacted**	1
Animal Species	Dog	**Outcome to Date**	Stable
Breed	Great Dane		
Age	B6 Years		
District Involved	PFR-New England DO		

Product information
Individual Case Safety Report Number: 2055788
Product Group: Pet Food
Product Name: Acana Heritage formula dog food (mostly freshwater fish, free run poultry, and meats (beef, pork, and lamb) formulas. Also, Meadowlands
Description: Murmur identified by RDVM 7/17/18. Asymptomatic. DCM diagnosed 10/4/18. Has been eating Acana diet. Owner is happy to talk to FDA and to provide more info. Taurine levels pending. Details on diet and treats below: I can tell you, for starters, that B6 was put on a Fromm diet from July of 2015 thru about March

of 2016. Since that period, she has been eating only Acana Heritage formula dog food. This contains "0% grain, potato, gluten, meat by-products, and plant protein concentrates" as listed on their label. She has had a variety of flavors from this brand. Primarily, it has been "freshwater fish", "free run poultry", and "meats formula" (beef, pork, and lamb). B6 has also had multiple bags of Acana "meadowland" which is advertised as poultry, fish, and eggs. I have also discovered that all of her treats have been produced by Acana. One is labeled as macarel and greens, another is poultry and monkfish, and the last is lamb, liver, and tripe. I should be able to get some records from our local pet store as they have a rewards program we are part of and all of our purchases from the last three years are on our account.
Submission Type: Initial
Report Type: Adverse Event (a symptom, reaction or disease associated with the product)
Outcome of reaction/event at the time of last observation: Stable
Number of Animals Treated With Product: 1
Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Acana Heritage formula dog food (mostly freshwater fish, free run poultry, and meats (beef, pork, and lamb) formulas. Also, Meadowlands		

Sender information
Lisa Freeman
200 Westboro Rd
North Grafton, MA 01536
USA

Owner information
B6
USA

To view this PFR Event, please click the link below:
https://eon.fda.gov/eon//browse/EON-367839

To view the PFR Event Report, please click the link below:
https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jspa?decorator=none&e=0&issueType=12&issueId=384761

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Report Details - EON-367839

ICSR:	2055788	
Type Of Submission:	Initial	
Report Version:	FPSR.FDA.PETF.V.V1	
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)	
Reporting Type:	Voluntary	
Report Submission Date:	2018-10-08 13:38:04 EDT	
Reported Problem:	**Problem Description:**	Murmur identified by RDVM 7/17/18. Asymptomatic. DCM diagnosed 10/4/18. Has been eating Acana diet. Owner is happy to talk to FDA and to provide more info. Taurine levels pending. Details on diet and treats below: I can tell you, for starters, that B6 was put on a Fromm diet from July of 2015 thru about March of 2016. Since that period, she has been eating only Acana Heritage formula dog food. This contains "0% grain, potato, gluten, meat by-products, and plant protein concentrates" as listed on their label. She has had a variety of flavors from this brand. Primarily, it has been "freshwater fish", "free run poultry", and "meats formula" (beef, pork, and lamb). B6 has also had multiple bags of Acana "meadowland" which is advertised as poultry, fish, and eggs. I have also discovered that all of her treats have been produced by Acana. One is labeled as macarel and greens, another is poultry and monkfish, and the last is lamb, liver, and tripe. I should be able to get some records from our local pet store as they have a rewards program we are part of and all of our purchases from the last three years are on our account.
	Date Problem Started:	10/04/2018
	Concurrent Medical Problem:	No
	Outcome to Date:	Stable
Product Information:	**Product Name:**	Acana Heritage formula dog food (mostly freshwater fish, free run poultry, and meats (beef, pork, and lamb) formulas. Also, Meadowlands
	Product Type:	Pet Food
	Lot Number:	
	Package Type:	BAG
	Product Use Information:	**Description:** Owner can provide more details.
	Manufacturer /Distributor Information:	
	Purchase Location Information:	
Animal Information:	**Name:**	B6
	Type Of Species:	Dog
	Type Of Breed:	Great Dane
	Gender:	Female
	Reproductive Status:	Neutered
	Weight:	42.2 Kilogram
	Age:	B6 ears
	Assessment of Prior Health:	Excellent
	Number of Animals Given the Product:	1
	Number of Animals Reacted:	1
	Owner Information:	**Owner Information provided:** Yes
		Contact: Name: B6 Phone: Email:

FDA-CVM-FOIA-2019-1704-010684

		Address:	B6 United States
	Healthcare Professional Information:	**Practice Name:**	Tufts Cummings School of Veterinary Medicine
		Contact:	**Name:** Lisa Freeman **Phone:** (508) 887-4523 **Email:** lisa.freeman@tufts.edu
		Address:	200 Westboro Rd North Grafton Massachusetts 01536 United States
Sender Information:	**Name:**	Lisa Freeman	
	Address:	200 Westboro Rd North Grafton Massachusetts 01536 United States	
	Contact:	**Phone:**	5088874523
		Email:	lisa.freeman@tufts.edu
	Permission To Contact Sender:	Yes	
	Preferred Method Of Contact:	Email	
Additional Documents:			
	Attachment:	B6 compiled records.pdf	
	Description:	B6 compiled medical records	
	Type:	Medical Records	

Cummings Veterinary Medical Center
AT TUFTS UNIVERSITY

Foster Hospital for Small Animals
55 Willard Street
North Grafton, MA 01536
(508) 839-5395

All Medical Records

Client:
Address: B6

Patient: B6
Breed: Great Dane
DOB: B6

Species: Canine
Sex: Female (Spayed)

Home Phone: B6
Work Phone: ( ) -
Cell Phone: B6

Referring Information

B6

Client:
Patient: B6

Initial Complaint:
Scanned Record

Initial Complaint:
New - Rush - murmur

SOAP Text B6 **2:50PM - Rush, John**

Disposition/Recommendations

FDA-CVM-FOIA-2019-1704-010686

FDA-CVM-FOIA-2019-1704-010687

Cummings Veterinary Medical Center
AT TUFTS UNIVERSITY

Foster Hospital for Small Animals
55 Willard Street
North Grafton, MA 01536
(508) 839-5395

Client:	B6
Veterinarian:	
Patient ID:	B6
Visit ID:	

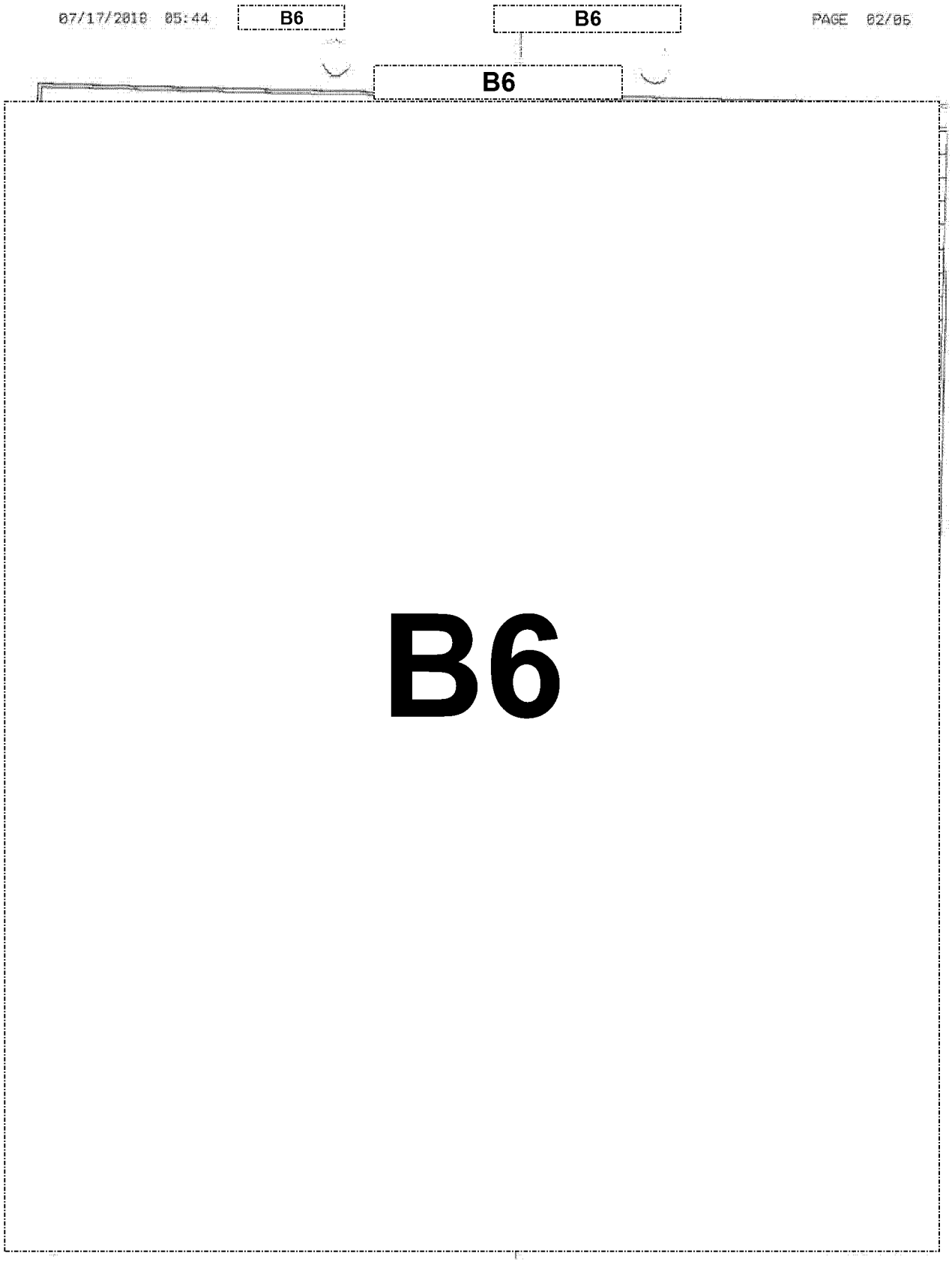
Patient:	B6
Species:	Canine
Breed:	Great Dane
Sex:	Female (Spayed)
Age:	B6 Years Old

Lab Results Report

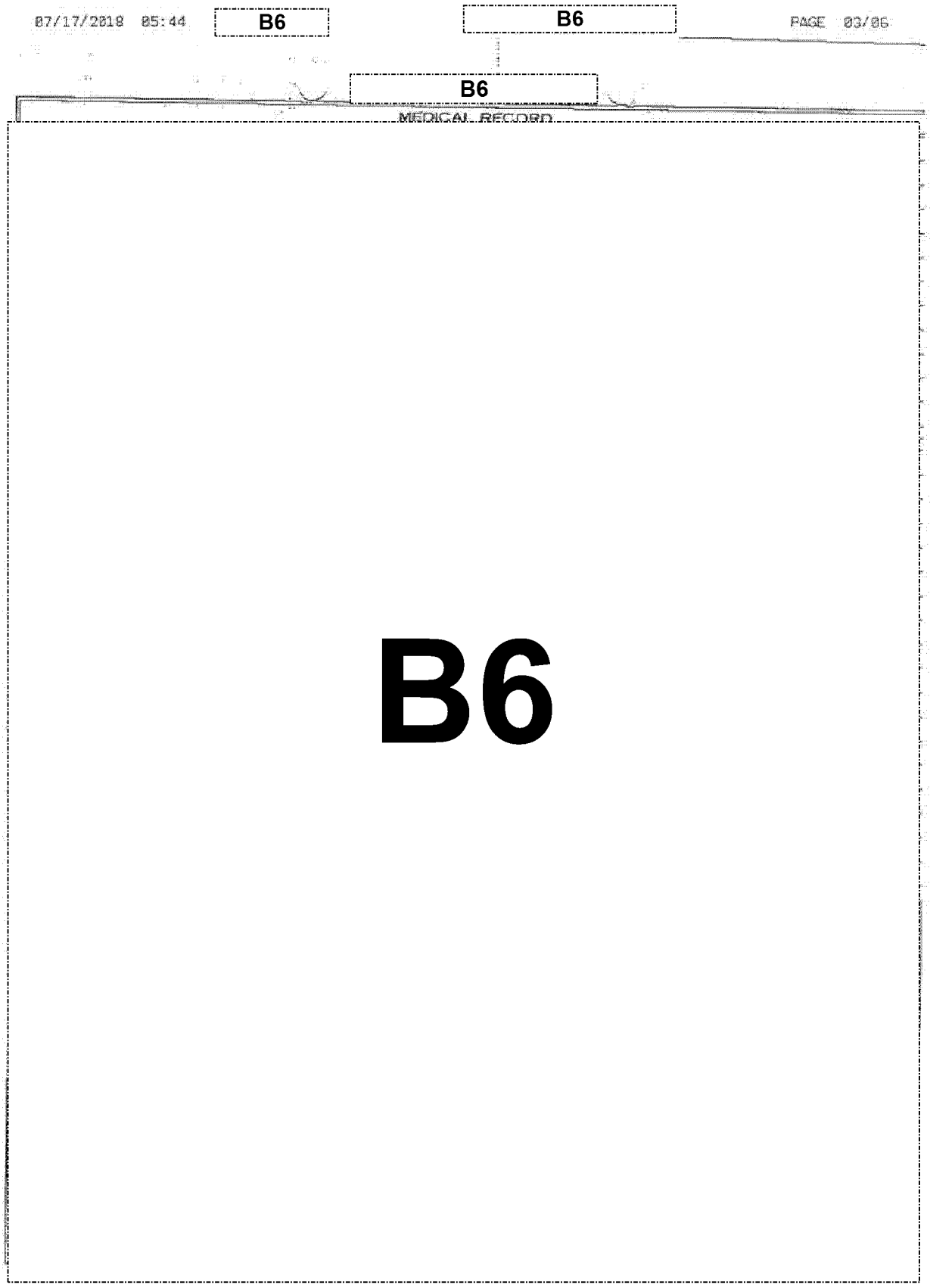
Accession ID:

Test	Results	Reference Range	Units

FDA-CVM-FOIA-2019-1704-010688



FDA-CVM-FOIA-2019-1704-010689



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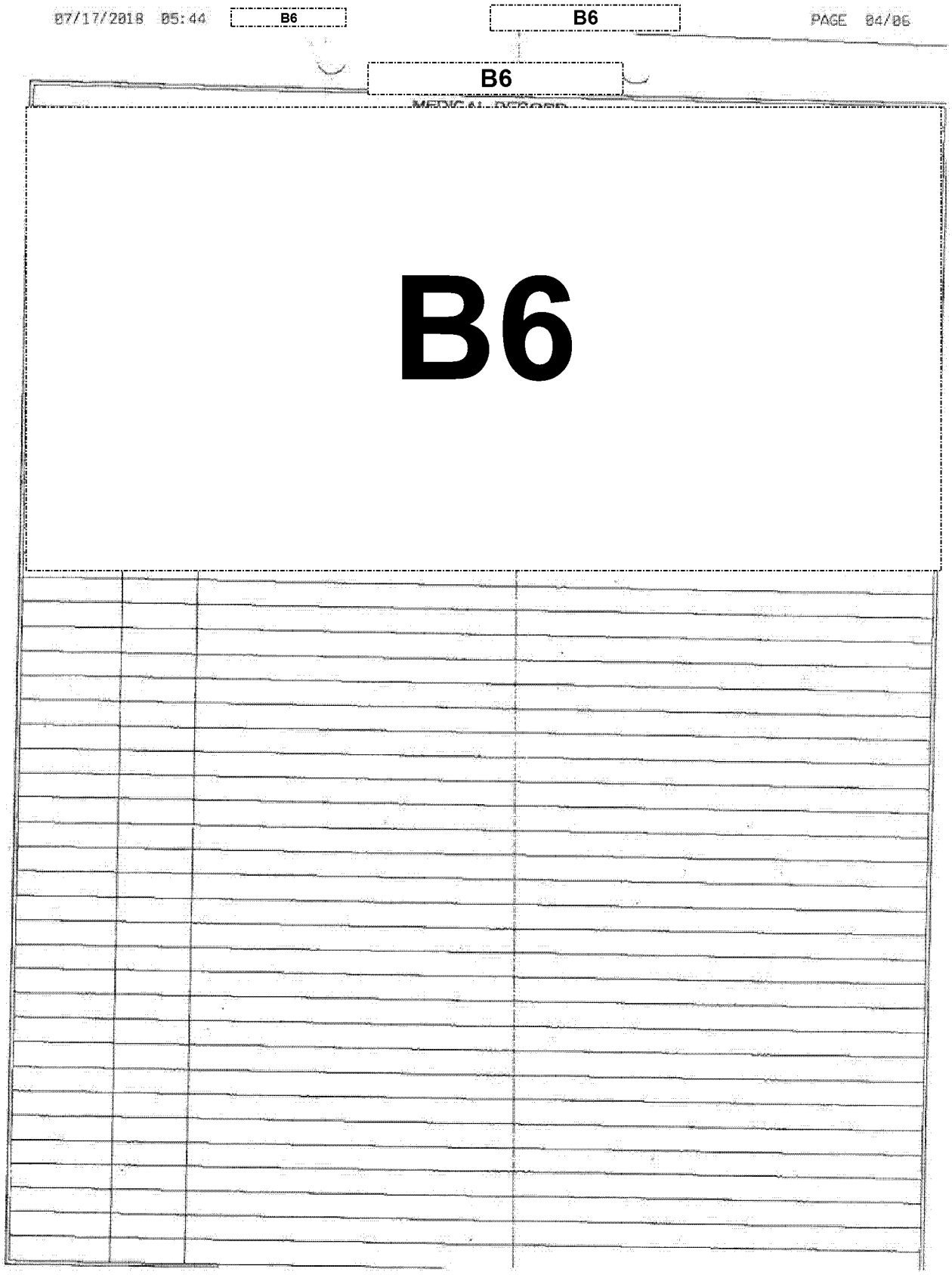

FDA-CVM-FOIA-2019-1704-010691

Client: B6
Patient:

rDVM B6 AH hx 5/21/15-7/17/18

07/17/2018 05:44 B6 B6 PAGE 05/06

Client: B6
Patient Name: B6
Species: Canine
Breed: Great Dane

Gender: Female/Spayed
Weight:
Age: 3 Years
Doctor: B6

B6

Test	Results	Reference Interval	LOW	NORMAL	HIGH	5/21/15 2:31 PM
B6						Negative
						Negative
						Negative
						Negative

Printed: July 17, 2018 3:02 PM

Page 1 of 1

B6

FDA-CVM-FOIA-2019-1704-010692

Client: B6
Patient:

rDVM B6 AH hx 5/21/15-7/17/18

07/17/2018 05:44 B6 B6 PAGE 05/06

Client: B6
Patient Name: B6
Species: Canine
Breed: Great Dane

Gender: Female Spayed
Weight:
Age: 2 Years
Doctor: B6

B6

Test	Results	Reference Interval	LOW	NORMAL	HIGH
B6					

Printed: June 21, 2017 3:31 PM

Page 1 of1

B6

FDA-CVM-FOIA-2019-1704-010693

Client: B6
Patient: B6

B6 **CARDIOPET proBNP 10/4/18**

B6

Client B6 Patient B6

B6

Client: B6
Patient: B6
Species: CANINE
Breed: GREAT_DANE
Gender: FEMALE S PAYED
Age: 3Y

Date: 10/04/2018
Requisition #: 434689
Accession # B6
Ordered by: RUSH, JOHN

TUFTS UNIVERSITY
200 WESTBORO RD
NORTH GRAFTON, Massachusetts 01536-1828
508-839-5395

Account #80735

CARDIOPET proBNP - CANINE

Test	Result	Reference Range	Low	Normal	High
CARDIOPET proBNP - CANINE	B6	0 - 900 pmol/L	HIGH	B6	

Comments:

1. Cardiopet proBNP >1800pmol/L

B6

Please note: Complete interpretive comments for all concentrations of Cardiopet proBNP are available in the online directory of services. Serum specimens received at room temperature may have decreased NT-proBNP concentrations.

Page 1 of 1

FDA-CVM-FOIA-2019-1704-010694

Client: B6
Patient:

Vitals Results

B6	2:50:15 PM	Weight (kg)	B6
	3:33:56 PM	Sedation	

Patient History

B6	03:46 PM	Appointment
	04:46 PM	Appointment
	02:28 PM	UserForm
	02:33 PM	UserForm
	02:49 PM	Purchase
	02:49 PM	Purchase
	02:50 PM	Vitals
	02:50 PM	Treatment
	02:59 PM	UserForm
	03:33 PM	Vitals
	03:34 PM	Purchase
	04:08 PM	Purchase
	04:08 PM	Purchase
	04:10 PM	Prescription
	04:10 PM	Purchase
	04:11 PM	Purchase
	04:13 PM	Purchase

B6

FDA-CVM-FOIA-2019-1704-010695

Cummings
Veterinary Medical Center
AT TUFTS UNIVERSITY

B6

B6 Female (Spayed)
Canine Great Dane Black
Patient ID: B6

STANDARD CONSENT FORM

I am the owner, or agent for the owner, of the above described animal and have the authority to execute consent. I hereby authorize the Cummings School of Veterinary Medicine at Tufts University (herein after Cummings School) to prescribe for treatment of said animal according to the following terms and conditions.

Cummings School and its officers, agents and employees will provide such veterinary medical care as they deem reasonable and appropriate under the circumstances.

Cummings School and its officers, agents, and employees will use all reasonable care in the treatment of the above mentioned animal, but will not be liable for any loss or accident that may occur or any disease that may develop as a result of the care and treatment provided.

I understand that the above identified animal may be treated by Cummings School students under the supervision and assistance of Cummings School staff members.

In executing this form, I hereby expressly acknowledge that risks, benefits and alternative forms of treatment have been explained to me. I understand said explanation, and I consent to treatment. Should any additional treatments or diagnostics be required during the continued care of my animal, I understand that I will be given the opportunity to discuss and consent to these additional procedures. I understand that further or additional treatment may be required without an opportunity for discussion and consideration by me, in the case of the development of any life-threatening emergency during the continued care of my animal and I expressly consent to all such reasonable treatment as required. I realize and understand that results cannot be guaranteed.

If any equipment is left with the animal, it will be accepted with the understanding that Cummings School assumes no responsibility for any loss of equipment that may occur.

I agree to pick up the animal when notified that it is ready for release.

In the event the animal is not picked up, and if ten (10) days have expired since a registered letter was sent to the address given above, notifying me to call for the animal, the animal may be sold or otherwise disposed of in a humane manner and the proceeds applied to the charges incurred in caring and treating the animal. Failure to remove said animal will not and does not relieve me from obligation for the costs of services rendered.

I hereby grant to the Cummings School of Veterinary Medicine at Tufts University, its officers and employees (collectively referred to herein as Cummings School), and its agents and assigns (the Grantees) the irrevocable rights to photograph / videotape the operation or procedure to be performed, including appropriate and otherwise use such photographs and images for, and in connection with, a Grantee's medical, scientific, educational, and publicity purposes, by any means, methods and media (print and electronic) now known or, in the future, developed that the Grantee deems appropriate (provided that such photographs and images may not be used in for-profit commercials, unless such commercials are publicizing educational programs at Cummings School). As medical and surgical treatment necessitates the removal of tissue, cells, fluids or body parts of my animal, I authorize the Grantees to dispose of or use these tissues, cells, fluids or body parts for scientific and educational purposes.

FDA-CVM-FOIA-2019-1704-010696

I understand that a FINANCE CHARGE will be applied to all accounts unpaid after 30 days. The FINANCE CHARGE is computed on a monthly rate of 1.33% per month, which is an annual percentage rate of 16% applied to the average daily balance outstanding, with a minimum fee of $.50.

I do further agree that should any payment, or the full amount of the sum stated above, become overdue more than 20 days from the above-agreed upon time of payment or payments, the entire balance shall be considered in default and become due and payable. I further agree to be responsible for any or all collection agency and/or attorney fees necessary to collect the full amount.

I do further agree to comply with hours of visitation in conjunction with our Hospital's policy.

I have read, understand, and agree to accept the terms and conditions herein.

Owner's name: B6 Date: B6

Owner's address: B6

B6

B6

If the individual admitting the animal is someone other than the legal owner, please complete the portion below:

The owner of the animal, B6, has granted me authority to obtain medical treatment and to bind this owner to pay the veterinary medical services provided at Cummings School pursuant to the terms and conditions described above

Authorized Agent – Please Print

Agent's Signature

Street Address

Date

Town/City State Zip

Cummings
Veterinary Medical Center
AT TUFTS UNIVERSITY

Foster Hospital for Small Animals
55 Willard Street
North Grafton, MA 01536
Telephone (508) 839-5395
Fax (508) 839-7951
http://vetmed.tufts.edu/

Discharge Instructions

Patient
Name: B6
Species: Canine
Black Female (Spayed) Great Dane
Birthdate: B6

Owner
Name: B6
Address: B6

Patient ID: B6

Attending Cardiologist:
☑ John E. Rush DVM, MS, DACVIM (Cardiology), DACVECC
B6

Cardiology Resident:
B6

Cardiology Technician:
B6

Student: B6 VM9

Admit Date: B6 2:27:50 PM
Discharge Date: B6

Diagnoses: Dilated cardiomyopathy (DCM) with mitral regurgitation

Clinical Findings:
Thank you for bringing B6 to Tufts today. On presentation B6 was bright, alert, and very nervous. We had to give some sedation to B6 for her exam today, she may be a sleepy when she gets home today. She has normal lung sounds and was panting. Her heart rate was increased (likely excitement), an extra heart sound and grade II/VI heart murmur on the left side and a grade III/VI murmur on the right was heard. On echocardiogram (ultrasound of the heart), the left ventricle is dilated with thickened walls, there is decreased ability of the heart to contract, the left atrium is moderately to markedly enlarged, and there is a moderate amount of mitral and tricuspid regurgitation. No arrhythmias were seen on ECG today.

B6 has been diagnosed with a primary heart muscle disease called dilated cardiomyopathy (DCM). This disease is more common in large and giant breed dogs and is characterized by thinning of the walls of the heart, reduced cardiac pump function, and enlargement of the upper chambers of the heart. Many dogs with DCM will also have significant arrhythmias which can be life-threatening and also require medical management. The heart enlargement can progress to the point of congestive heart failure, meaning that fluid is backing up into the lungs or belly. Unfortunately this is a progressive disease and we usually cannot reverse the changes to the heart muscle, however we can use cardiac medications and some changes to the diet to help delay the onset of heart failure

Today we performed an NT-proBNP test, BNP is produced when the heart muscles are stretched. We have also checked her taurine levels today, because of the association with the diets that she is on. These results are pending and we will give you a call when they are in. The BNP should be back in 1-2 days; the taurine often takes 10-12 days -so if you have not heard from us in about 12 days then please call.

FDA-CVM-FOIA-2019-1704-010698

Monitoring at Home:
We would like you to monitor your dog's breathing rate and effort at home, ideally during sleep or at a time of rest.

In general, most dogs have a breathing rate at rest of less than 35 breaths per minute. In addition, the breathing effort, noted by the amount of belly wall motion used for each breath, is fairly minimal. If you notice fast or labored breathing then a chest x-ray should be performed.

We want you to watch for weakness or collapse, a reduction in appetite, worsening cough, or distention of the belly as these findings indicate that we should do a recheck examination.

If you have any concerns, please call or have your dog evaluated by a veterinarian. Our emergency clinic is open 24 hours/day.

Diet Suggestions:
Today we discussed the fact that there seem to be a relationship between grain free diet, diets with exotic protein sources, and DCM. We recommend switching from a grain free diet. At this moment we are unsure of the cause of the connection, some studies have indicated low taurine levels in the food. If taurine is the cause, there is potential for some reversal of her heart disease. We have checked her taurine levels today, and results are pending. If results are low, supplementation long term may be required.

Some Diet Change Recommendations
Canned Options
- Hills Science Diet Adult Beef & Barely Entree
- Hills Science Diet Adult 1-6 Healthy Cuisine Roasted Chicken, Carrots & Spinach Stew

Dry Options
- Royal Canin Early Cardiac
- Purina Pro Plan Adult Weight Management

A sheet that has suggestions for low sodium, heart healthy, treats and diets can also be found on the HeartSmart web site (http://vet.tufts.edu/heartsmart/diet/)

Here is a link to a blog by our nutrionalist with more information about the association between diet and DCM on Petfoodology.
"A broken heart risk of heart disease in boutique or grain free diets and exotic ingredients"
http://vetnutrition.tufts.edu/2018/06/a-broken-heart-risk-of-heart-disease-in-boutique-or-grain-free-diets-and-exotic-ingredients/

If it is possible for you to bring a sample of her food to us for analyzing and reporting to the FDA.

Exercise Recommendations:
B6 can continue with her normal activity level, we recommend that she not exercise to the point of exhaustion.

Recommended Medications:

B6

Recheck Visits: A recheck echocardiogram is recommended in 3-4 months. At this time we will reasses her heart disease and changes in medication or additional medications may be required. We gave you a prescription for B6 to give before the visit - this may calm her down just a bit and we might be able to get away without sedation. Give the B6 at home on a trial at home to see the response; if good (quieter, not more excitable) then give a dose the night before and a dose (2 capsules) the morning of the next visit.

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Thank you for entrusting us with B6 care. Please contact our Cardiology liaison at (508)-887-4696 or email us at cardionet@tufts.edu for scheduling and non-emergent questions or concerns.

Please visit our HeartSmart website for more information
http://vet.tufts.edu/heartsmart/

Prescription Refill Disclaimer:
For the safety and well-being of our patients, your pet must have had an examination by one of our veterinarians within the past year in order to obtain prescription medications.

Ordering Food:
Please check with your primary veterinarian to purchase the recommended diet(s). If you wish to purchase your food from us, please call 7-10 days in advance (508-887-4629) to ensure the food is in stock. Alternatively, veterinary diets can be ordered from online retailers with a prescription/veterinary approval.

Clinical Trials:
Clinical trials are studies in which our veterinary doctors work with you and your pet to investigate a specific disease process or a promising new test or treatment. Please see our website: vet.tufts.edu/cvmc/clinical-studies

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FDA-CVM-FOIA-2019-1704-010700

Cummings
Veterinary Medical Center
AT TUFTS UNIVERSITY
Cardiology Liaison: 508-887-4696

B6

Patient ID: B6
B6 Canine
B6 Years Old Female (Spayed) Great Dane
Black

Cardiology Appointment Report

Date: B6

Attending Cardiologist:
☑ John E. Rush DVM, MS, DACVIM (Cardiology), DACVECC (primary)

B6

Cardiology Resident:
B6

Cardiology Technician:
B6

Student: B6 V19

Presenting Complaint: Murmur II/VI
First heard B6, zero change in behavior, has always been happy and healthy. No other concerns.

Concurrent Diseases: No other diseases

General Medical History:
B6

Diet and Supplements:
Acana, Fromm, dry food, Kongs with peanut butter, carrots
no supplements

Cardiovascular History:
Prior CHF diagnosis? N
Prior heart murmur? Y
Prior ATE? N
Prior arrhythmia? N
Monitoring respiratory rate and effort at home? N
Cough? N
Shortness of breath or difficulty breathing? N
Syncope or collapse? N
Sudden onset lameness? N
Exercise intolerance? N

Current Medications Pertinent to CV System:

No medications

Cardiac Physical Examination:

B6

Muscle condition:

- [x] Normal
- [ ] Mild muscle loss
- [ ] Moderate cachexia
- [ ] Marked cachexia

Cardiovaseular Physical Exam:

Murmur Grade:

- [ ] None
- [ ] I/VI
- [x] II/VI
- [x] III/VI
- [ ] IV/VI
- [ ] V/VI
- [ ] VI/VI

B6

Jugular vein:

- [x] Bottom 1/3 of the neck
- [ ] Middle 1/3 of the neck
- [ ] 1/2 way up the neck
- [ ] Top 2/3 of the neck

Arterial pulses:

- [ ] Weak
- [ ] Fair
- [x] Good
- [ ] Strong
- [ ] Bounding
- [ ] Pulse deficits
- [ ] Pulsus paradoxus
- [ ] Other:

Arrhythmia:

- [x] None
- [ ] Sinus arrhythmia
- [ ] Premature beats
- [ ] Bradycardia
- [ ] Tachycardia

Gallop:

- [x] Yes
- [ ] No
- [x] Intermittent
- [ ] Pronounced
- [ ] Other:

Pulmonary assessments:

- [ ] Eupneic
- [ ] Mild dyspnea
- [ ] Marked dyspnea
- [x] Normal BV sounds
- [ ] Pulmonary crackles
- [ ] Wheezes
- [ ] Upper airway stridor

Abdominal exam:

- [x] Normal
- [ ] Hepatomegaly
- [ ] Mild ascites
- [ ] Marked ascites

☐ Abdominal distension

Problems:
Hx: Murmur II/VI (rDVM)

Differential Diagnoses:
Valvular disease (dysplasia vs degenerative) vs pulmonic stenosis vs aortic stenosis vs DCM

Diagnostic plan:

- ☑ Echocardiogram
- ☑ Chemistry profile
- ☐ ECG
- ☐ Renal profile
- ☐ Blood pressure
- ☐ Dialysis profile
- ☐ Thoracic radiographs
- ☐ NT-proBNP
- ☐ Troponin I
- ☐ Other tests:

Echocardiogram Findings:

B6

Assessment and recommendations:
Echocardiogram findings are consistent with dilated cardiomyopathy. The patient was very tachycardiac during the echocardiogram. Because today's findings are consistent with DCM and the patient is on a grain-free diet, the DCM protocol is recommended. Blood was pulled and submitted for a taurine level today. Disoussed with the owner that the patient should not be on a grain free diet anymore and taurine supplementation should be started while we are waiting for the result of the test. B6 PO BID should be started. Recheck echocardiogram in 3 months or sooner if the patient develops clinical signs consistent with worsening heart disease such as increased RR/RE, cough, exercise intolearnce, or syncope.

Final Diagnosis:
- Occult DCM r/o genetic vs. diet related.
- Murmur due to secondary mitral regurgitation

Heart Failure Classification Score:
ISACHC Classification:

- ☐ Ia
- ☑ Ib
- ☐ IIIa
- ☐ IIIb

☐ II

ACVIM Classification:

☐ A
☐ B1
☑ B2
☐ C
☐ D

M-Mode

IVSd	B6	cm
LVIDd		cm
LVPWd		cm
IVSs		cm
LVIDs		cm
LVPWs		cm
%FS		%
Ao Diam		cm
LA Diam		cm
LA/Ao		
Max LA		cm
EPSS		cm

M-Mode Normalized

IVSdN	B6	(0.29 - 0.52) !
LVIDdN		(1.35 - 1.73) !
LVPWdN		(0.33 - 0.53)
IVSsN		(0.43 - 0.71)
LVIDsN		(0.79 - 1.14) !
LVPWsN		(0.53 - 0.78)
Ao Diam N		(0.68 - 0.89)
LA Diam N		(0.64 - 0.90) !

2D

IVSd	B6	cm
LVIDd		cm
LVPWd		cm
EDV(Teich)		ml
IVSs		cm
LVIDs		cm
LVPWs		cm
ESV(Teich)		ml
EF(Teich)		%
%FS		%
SV(Teich)		ml
LVId LAX		cm
LVAd LAX		cm
LVEDV A-L LAX		ml
LVEDV MOD LAX		ml

LVIs LAX	B6	cm
LVAs LAX		cm
LVESV A-L LAX		ml
LVESV MOD LAX		ml
HR		BPM
EF A-L LAX		%
LVEF MOD LAX		%
SV A-L LAX		ml
SV MOD LAX		ml
CO A-L LAX		l/min
CO MOD LAX		l/min
LV Diameter		cm
LV Length		cm

Doppler

MR Vmax	B6	m/s
MR maxPG		mmHg
AV Vmax		m/s
AV maxPG		mmHg

FDA-CVM-FOIA-2019-1704-010705

Cummings
Veterinary Medical Center
AT TUFTS UNIVERSITY

Foster Hospital for Small Animals
55 Willard Street
North Grafton, MA 01536
Telephone (508) 839-5395
Fax (508) 839-7951
http://vetmed.tufts.edu/

B6

B6 Female (Spayed)
Canine Great Dane Black
B6

10/5/2018

Dear B6

Thank you for referring B6 with their pet B6

If you have any questions, or concerns, please contact us at 508-887-4988.

Thank you,

John Rush DVM, DACVIM (Cardiology), DACVECC

From: PFR Event <pfreventcreation@fda.hhs.gov>

To: Cleary, Michael *; HQ Pet Food Report Notification; B6

Sent: 10/8/2018 7:28:33 PM

Subject: Pro Plan Savory dry - chicken: Lisa Freeman - EON-367850

Attachments: 2055797-report.pdf; 2055797-attachments.zip

A PFR Report has been received and PFR Event [EON-367850] has been created in the EON System.

A "PDF" report by name "2055797-report.pdf" is attached to this email notification for your reference. Please note that all documents received in the report are compressed into a zip file by name "2055797-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-367850
ICSR #: 2055797
EON Title: PFR Event created for Pro Plan Savory dry - chicken beef or lamb (1 cup TID); 2055797

AE Date	08/24/2018	**Number Fed/Exposed**	1
Best By Date		**Number Reacted**	1
Animal Species	Dog	**Outcome to Date**	Stable
Breed	Retriever - Labrador		
Age	7 Years		
District Involved	PFR-New England DO		

Product information
Individual Case Safety Report Number: 2055797
Product Group: Pet Food
Product Name: Pro Plan Savory dry - chicken, beef, or lamb (1 cup TID)
Description: Presented to ER on B6 for CHF and DCM (had rads at RDVM for cough). Full echo on 8/28/18. Unlikely to be associated with diet but reporting because he is sometimes fed the lamb formula Pro Plan. Taurine WNL
Submission Type: Initial
Report Type: Adverse Event (a symptom, reaction or disease associated with the product)
Outcome of reaction/event at the time of last observation: Stable

Number of Animals Treated With Product: 1
Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Pro Plan Savory dry - chicken, beef, or lamb (1 cup TID)		

Sender information
Lisa Freeman
200 Westboro Rd
North Grafton, MA 01536
USA

Owner information
B6
USA

To view this PFR Event, please click the link below:
https://eon.fda.gov/eon//browse/EON-367850

To view the PFR Event Report, please click the link below:
https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jspa?decorator=none&e=0&issueType=12&issueId=384772

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Report Details - EON-367850

ICSR:	2055797	
Type Of Submission:	Initial	
Report Version:	FPSR.FDA.PETF.V.V1	
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)	
Reporting Type:	Voluntary	
Report Submission Date:	2018-10-08 15:17:24 EDT	
Reported Problem:	**Problem Description:**	Presented to ER on B6 for CHF and DCM (had rads at RDVM for cough). Full echo on 8/28/18. Unlikely to be associated with diet but reporting because he is sometimes fed the lamb formula Pro Plan. Taurine WNL
	Date Problem Started:	08/24/2018
	Concurrent Medical Problem:	Yes
	Pre Existing Conditions:	B6
	Outcome to Date:	Stable
Product Information:	**Product Name:**	Pro Plan Savory dry - chicken, beef, or lamb (1 cup TID)
	Product Type:	Pet Food
	Lot Number:	
	Package Type:	BAG
	Product Use Information:	
	Manufacturer /Distributor Information:	
	Purchase Location Information:	
Animal Information:	**Name:**	B6
	Type Of Species:	Dog
	Type Of Breed:	Retriever - Labrador
	Gender:	Male
	Reproductive Status:	Neutered
	Weight:	37.7 Kilogram
	Age:	7 Years
	Assessment of Prior Health:	Good
	Number of Animals Given the Product:	1
	Number of Animals Reacted:	1
	Owner Information:	**Owner Information provided:** Yes
		Contact: **Name:** B6 **Phone:** **Email:**
		Address: B6 United States
	Healthcare Professional Information:	**Practice Name:** Tufts Cummings School of Veterinary Medicine
		Contact: **Name:** Lisa Freeman **Phone:** (508) 887-4523

FDA-CVM-FOIA-2019-1704-010709

		Email:	lisa.freeman@tufts.edu
		Address:	200 Westboro Rd North Grafton Massachusetts 01536 United States

Sender Information:	**Name:**	Lisa Freeman	
	Address:	200 Westboro Rd North Grafton Massachusetts 01536 United States	
	Contact:	**Phone:**	5088874523
		Email:	lisa.freeman@tufts.edu
	Permission To Contact Sender:	Yes	
	Preferred Method Of Contact:	Email	

Additional Documents:		
	Attachment:	compiled medical records **B6** pdf
	Description:	Compiled medical records
	Type:	Medical Records

Cummings Veterinary Medical Center
AT TUFTS UNIVERSITY

Foster Hospital for Small Animals
55 Willard Street
North Grafton, MA 01536
(508) 839-5395

All Medical Records

Client: B6
Address:

Patient: B6
Breed: Labrador Retriever
DOB: B6

Species: Canine
Sex: Male (Neutered)

Home Phone: B6
Work Phone: ( ) -
Cell Phone: B6

Referring Information

B6

Client: B6
Patient:

Initial Complaint:
Emergency

SOAP Text B6 **6:54PM - Clinician, Unassigned FHSA**

NEW VISIT (ER)

Doctor: B6
Presenting complaint: cardiomegaly
Referral visit? yes
Diagnostics completed prior to visit: CXR (on disk), cardiomegaly, perihilar interstitial pattern

HISTORY:

Signalment: 7yo NM lab
Current history: Presented for cardiomegaly diagnosed at rDVM. Developed cough and went to rDVM on Tuesday, where was put on B6 with presumtive diagnosis of kennel cough (was boarded last week). Better for about a day. However, last night was coughing a lot and seemed uncomfortable. Restless last night and this morning. Seems to have increased effort breathing. Productive cough this am. Took to rDVM this am where they took chest rads and saw cardiogenic pulmonary edema and cardiomegaly. Non-febrile at that time. Was coughing quite a bit previously at rDVM. No prior c/s/v/d/PU/PD. This past week had decreased appetite and lethargic.
Prior medical history: Hx of kennel cough last year. Was boarded again last week. Other dog doesnt show any signs. Hx of skin allergies. Takes B6 from June throuhout summer. B6
Current medications: B6
Diet: Purina ProPlan.
Vaccination status/flea & tick preventative use: UTD. Flea/tick and heartworm preventative. Just had heartworm test

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(negative)
Travel history: None

EXAM:

B6

C/V: grade IV-V/VI L systolic heart murmur, thready pulse quality, no arrythmia ausculted

B6

ASSESSMENT:
A1: Heart murmur, cardiomegaly, r/o DCM, CHF
A2:
A3: B6

PLAN:
TFAST: poor contractility, no pce, 2-3 Blines bilaterally

B6

Diagnostics completed: NOVA

Diagnostics pending: CBC/Chem, cardio consult

Client communication:
Told O that gave B6 Also told them that he had significant heart murmur today. On rads he has enlarged heart and pulmonary edema. Gave B6 o draw fluid out of lungs. On triage US also has decreased contractility. This is seen with DCM, which can be seen with genetics and age. Gave B6 because heart is being inefficient and have fluid back-up into lungs. Told O that should be admitted to hospital, get recheck rads tomorrow, and likely will need repeat o B6 Needs cardio consult and an echo-likely wont get until Monday. Also may need oxygen supplementation. O asked if common to see acute signs with DCM. Told O that likely had minor progreesive changes culminating in breathing difficulty. O asked if fluid could be related to pneumonia. Told O that unlikely, but also why we do recheck rads (looking to see improvement with B6 f it is CHF). O asked about treatment for DCM. Informed O that will be B6 to make them urinate out his retained fluid. O asked if will drink more. Told will need free choice water while o B6 O asked what other drugs he might be on. Discussed B6 which will help

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with contractility. Also informed O that with DCM are at risk for arrhythmia, which we havent noticed yet but he may need medication for if he develops it. O asked if drugs might shrink his heart. Told it likely won't make a significant difference in heart size. However, may shrink heart enough to relieve any compression on trachea and may help with relieving cough. rDVM was worried that cardiomegaly was contributing to his coughing. Told O that coughing is likely related to pulmonary edema. O asked about prognosis and told them that the goal is 6 months without another episode of failure. Some dogs may live longer than that, but on average they generally come back in failure in 6 months. O asked when they might be able to take him home, told them likely Monday. O was very distressed about 6 month timeline, was very surpirsed and upset. Told O that we frequently have dogs live past the 6 months, but it is hard for us to tell beyond that. Told O that he will need to be on medications and have follow-up with Cardio. O asked if he can go back to his normal acitivty levels. Told O that he will need to have pretty strict exercise restriction and that Cardio will guide them further.

Deposit & estimate status: B6

Resuscitation code (if admitting to ICU): B6

SOAP approved (DVM to sign): B6, DVM ECC Resident

SOAP Text B6 9:40AM B6

7 yo MN LRT
- Presented B6 for cardiomegally and suspected cardiogenic edema (rDVM rads)
- Coughing since start of the week, initially received doxy b/c boareded at week; not febrile at rDVM

Subjective:
- BAR, friendly, lovely dog

Objective:

B6

Assessment:
1. CHF, suspected secondary to DCM

Plan:
1.
2.
3.
4.
5.

B6

FDA-CVM-FOIA-2019-1704-010713

Client: B6
Patient:

B6

Initial Complaint:
New - B6 - presumed DCM from ICU

SOAP Text B6 **5:23PM -** B6

Disposition/Recommendations

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FDA-CVM-FOIA-2019-1704-010715

Cummings Veterinary Medical Center
AT TUFTS UNIVERSITY

Foster Hospital for Small Animals
55 Willard Street
North Grafton, MA 01536
(508) 839-5395

Client:	B6
Veterinarian:	
Patient ID:	B6
Visit ID:	

Patient:	B6
Species:	Canine
Breed:	Labrador Retriever
Sex:	Male (Neutered)
Age:	B6 Years Old

Lab Results Report

Nova Full Panel-ICU B6 **58:25 PM** **Accession ID:** B6

Test	Results	Reference Range	Units
SO2%	B6	94 - 100	%
HCT (POC)		38 - 48	%
HB (POC)		12.6 - 16	g/dL
NA (POC)		140 - 154	mmol/L
K (POC)		3.6 - 4.8	mmol/L
CL(POC)		109 - 120	mmol/L
CA (ionized)		1.17 - 1.38	mmol/L
MG (POC)		0.1 - 0.4	mmol/L
GLUCOSE (POC)		80 - 120	mg/dL
LACTATE		0 - 2	mmol/L
BUN (POC)		12 - 28	mg/dL
CREAT (POC)		0.2 - 2.1	mg/dL
TCO2 (POC)		0 - 0	mmol/L
nCA		0 - 0	mmol/L
nMG		0 - 0	mmol/L
GAP		0 - 0	mmol/L
CA/MG		0 - 0	mol/mol
BEecf		0 - 0	mmol/L
BEb		0 - 0	mmol/L
A		0 - 0	mmHg
NOVA SAMPLE		0 - 0	

FDA-CVM-FOIA-2019-1704-010716

Client:
Patient: B6

FiO2	B6	0 - 0	%
PCO2		36 - 44	mmHg
PO2		80 - 100	mmHg
PH		7.337 - 7.467	
PCO2		36 - 44	mmHg
PO2		80 - 100	mmHg
HCO3		18 - 24	mmol/L

Nova Full Panel-ICU B6 **10:02:12 PM** **Accession ID:** B6

Test	Results	Reference Range	Units
WBC (ADVIA)	B6	4.4 - 15.1	K/uL
RBC(ADVIA)		5.8 - 8.5	M/uL
HGB(ADVIA)		13.3 - 20.5	g/dL
HCT(ADVIA)		39 - 55	%
MCV(ADVIA)		64.5 - 77.5	fL
MCH(ADVIA)		21.3 - 25.9	pg
MCHC(ADVIA)		31.9 - 34.3	g/dL
RDW (ADVIA)		11.9 - 15.2	
PLT(ADVIA)		173 - 486	K/uL
MPV (ADVIA)		8.29 - 13.2	fl
PLTCRT		0.129 - 0.403	%
RETIC(ADVIA)		0.2 - 1.6	%
RETICS (ABS) ADVIA		14.7 - 113.7	K/uL

Nova Full Panel-ICU B6 **10:02:28 PM** **Accession ID:** B6

Test	Results	Reference Range	Units
GLUCOSE	B6	67 - 135	mg/dL
UREA		8 - 30	mg/dL
CREATININE		0.6 - 2	mg/dL
PHOSPHORUS		2.6 - 7.2	mg/dL
CALCIUM2		9.4 - 11.3	mg/dL
MAGNESIUM 2+		1.8 - 3	mEq/L
T. PROTEIN		5.5 - 7.8	g/dL
ALBUMIN		2.8 - 4	g/dL
GLOBULINS		2.3 - 4.2	g/dL
A/G RATIO		0.7 - 1.6	
SODIUM		140 - 150	mEq/L
CHLORIDE		106 - 116	mEq/L
POTASSIUM		3.7 - 5.4	mEq/L
tCO2 (BICARB)		14 - 28	mEq/L
AGAP		8 - 19	
NA/K		29 - 40	

FDA-CVM-FOIA-2019-1704-010717

Client:
Patient: B6

T BILIRUBIN	B6	0.1 - 0.3	mg/dL
D.BILIRUBIN		0 - 0.1	mg/dL
I BILIRUBIN		0 - 0.2	mg/dL
ALK PHOS		12 - 127	U/L
GGT		0 - 10	U/L
ALT		14 - 86	U/L
AST		9 - 54	U/L
CK		22 - 422	U/L
CHOLESTEROL		82 - 355	mg/dL
TRIGLYCERIDES		30 - 338	mg/dl
AMYLASE		409 - 1250	U/L
OSMOLALITY (CALCULATED)		291 - 315	mmol/L
COMMENTS (CHEMISTRY)		0 - 0	

Nova Full Panel-ICU B6 **10:02:07 PM** **Accession ID:** B6

Test	Results	Reference Range	Units
SEGS%	B6	43 - 86	%
LYMPHS%		7 - 47	%
MONOS%		1 - 15	%
SEGS (AB)ADVIA		2.8 - 11.5	K/ul
LYMPHS (ABS)ADVIA		1 - 4.8	K/uL
MONOS (ABS)ADVIA		0.1 - 1.5	K/uL
WBC MORPHOLOGY		0 - 0	
No Morphologic Abnormalities			
RBC MORPHOLOGY		0 - 0	
No morphologic abnormalities			

Nova Full Panel-ICU B6 **0:49:36 PM** **Accession ID:** B6

Test	Results	Reference Range	Units
TS (FHSA)	B6	0 - 0	g/dl
PCV **		0 - 0	%
TS (FHSA)		0 - 0	g/dl

Nova Full Panel-ICU B6 **11:42:25 AM** **Accession ID:** B6

Test	Results	Reference Range	Units
SO2%	B6	94 - 100	%
HCT (POC)		38 - 48	%
HB (POC)		12.6 - 16	g/dL
NA (POC)		140 - 154	mmol/L
K (POC)		3.6 - 4.8	mmol/L
CL(POC)		109 - 120	mmol/L
CA (ionized)		1.17 - 1.38	mmol/L
MG (POC)		0.1 - 0.4	mmol/L

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Client:
Patient: B6

GLUCOSE (POC)	B6	80 - 120	mg/dL
LACTATE		0 - 2	mmol/L
BUN (POC)		12 - 28	mg/dL
CREAT (POC)		0.2 - 2.1	mg/dL
TCO2 (POC)		0 - 0	mmol/L
nCA		0 - 0	mmol/L
nMG		0 - 0	mmol/L
GAP		0 - 0	mmol/L
CA/MG		0 - 0	mol/mol
BEecf		0 - 0	mmol/L
BEb		0 - 0	mmol/L
A		0 - 0	mmHg
NOVA SAMPLE		0 - 0	
FiO2		0 - 0	%
PCO2		36 - 44	mmHg
PO2		80 - 100	mmHg
PH		7.337 - 7.467	
PCO2		36 - 44	mmHg
PO2		80 - 100	mmHg
HCO3		18 - 24	mmol/L

Nova Full Panel-ICU B6 **11:47:47 AM** **Accession ID:** B6

Test	Results	Reference Range	Units
TS (FHSA)	B6	0 - 0	g/dl
PCV **		0 - 0	%
TS (FHSA)		0 - 0	g/dl

Nova Full Panel-ICU B6 **5:24:21 PM** **Accession ID:** B6

Test	Results	Reference Range	Units
GLUCOSE	B6	67 - 135	mg/dL
UREA		8 - 30	mg/dL
CREATININE		0.6 - 2	mg/dL
PHOSPHORUS		2.6 - 7.2	mg/dL
CALCIUM2		9.4 - 11.3	mg/dL
T. PROTEIN		5.5 - 7.8	g/dL
ALBUMIN		2.8 - 4	g/dL
GLOBULINS		2.3 - 4.2	g/dL
A/G RATIO		0.7 - 1.6	
SODIUM		140 - 150	mEq/L
CHLORIDE		106 - 116	mEq/L
POTASSIUM		3.7 - 5.4	mEq/L
NA/K		29 - 40	

FDA-CVM-FOIA-2019-1704-010719

Client:
Patient: B6

T BILIRUBIN	B6	0.1 - 0.3	mg/dL
D.BILIRUBIN		0 - 0.1	mg/dL
I BILIRUBIN		0 - 0.2	mg/dL
ALK PHOS		12 - 127	U/L
ALT		14 - 86	U/L
AST		9 - 54	U/L
CHOLESTEROL		82 - 355	mg/dL
OSMOLALITY (CALCULATED)		291 - 315	mmol/L
COMMENTS (CHEMISTRY)		0 - 0	

Slight hemolysis; Slight lipemia

Nova Full Panel-ICU B6 **5:27:40 PM** **Accession ID:** B6

Test	Results	Reference Range	Units
TS (FHSA)		0 - 0	g/dl
PCV **	B6	0 - 0	%
TS (FHSA)		0 - 0	g/dl

10/27 B6

stringsoft

Printed Monday, October 08, 2018

FDA-CVM-FOIA-2019-1704-010720

Client: B6
Patient:

RDVM B6 animal Hosp referral B6

REFERRAL FORM

TUFTS UNIVERSITY
Cummings School of Veterinary Medicine
Henry and Lois Foster Hospital for Small Animals
Hospital for Large Animals
200 Westboro Road, Route 30
North Grafton, MA 01536
508-839-5395

Service to Which Referred: Cardiology Appointment Date: _____ Time: _____

OWNER INFORMATION:

Name: B6 Daytime Phone: B6 Evening Phone: ( ) _____

Address: B6 City: B6 State: B6 Zip Code: B6

PATIENT INFORMATION:

Registered Name/ID: B6

Species: Dog Breed: [illegible] Sex: M Age: 7

CASE HISTORY:

Chief Concern/Tentative Diagnosis: [illegible]

Vaccination History: Current — [illegible]

Other History: [illegible]

Diagnostic Test Results (if possible, please attach results): [illegible]

Are Radiographs enclosed? Yes

Current Therapy & Medications (include dosages): B6

Special Comments/Requests: Please fax [illegible]

REFERRING VETERINARIAN INFORMATION

Name: B6 Clinic/Hospital: B6

Phone: ( ) Fax: ( ) _____

Address: _____ City: _____ State: _____ Zip Code: _____

If an animal is being referred which has had lab work done at TVDL, please include copies of the lab results or the TVDL accession number. If you are faxing us information about a clinical case which has been referred, please use fax number (508) 839-7951.

FDA-CVM-FOIA-2019-1704-010721

Client: B6
Patient:

Taurine Level

B6

Sample Submission Form

UC CUSTOMERS ONLY:
Non-federal funds ID/Account Number
to bill:_____

Amino Acid Laboratory
University of California, Davis
1020 Vet Med 3B
1089 Veterinary Medicine Drive
Davis, CA 95616
Tel: (530)752-5058, Fax: (530)752-4698

http://www.vetmed.ucdavis.edu/vmb/aal/aal.html

Vet/Tech Contact: B6
Company Name: Tufts Cummings School of Vet Med - Clinical Pathology Laboratory
Address: 200 Westboro Road
North Grafton, MA 01536

Email: clinpath@tufts.edu; cardover@tufts.edu
Tel: 508-887-4660 Fax: 508-839-7936

Billing Contact: B6 TAX ID:
Email: B6 Tel: B6

Patient Name: B6
Species: canine B6
Owner's Name: B6

Sample Type: ☐ Plasma ☑ Whole Blood ☐ Urine ☐ Food ☐ Other:_____
Test Items: ☑ Taurine ☐ Complete Amino Acid ☐ Other:_____

Taurine Results (nmol/ml)

Plasma:_____ Whole Blood: B6 Urine:_____ Food:_____

Reference Ranges (nmol/ml)

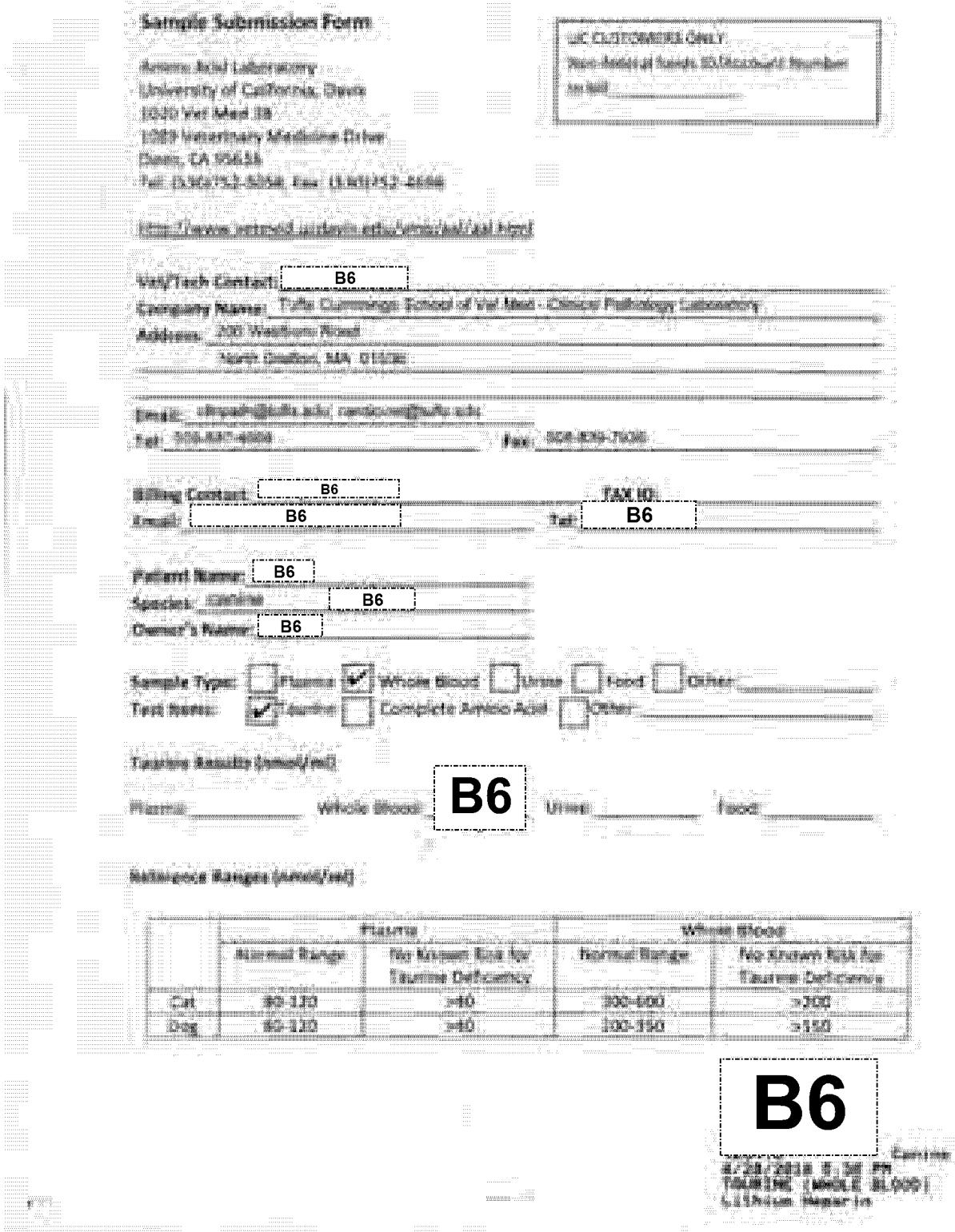
	Plasma		Whole Blood	
	Normal Range	No Known Risk for Taurine Deficiency	Normal Range	No Known Risk for Taurine Deficiency
Cat	80-120	>40	300-600	>200
Dog	60-120	>40	200-350	>150

FDA-CVM-FOIA-2019-1704-010722

Client: B6
Patient:

Amino Acid Labs Taurine results B6

B6



Sample Submission Form

Amino Acid Laboratory
University of California, Davis
[illegible]
[illegible]
[illegible]
[illegible]

UC CUSTOMERS ONLY
[illegible]

Vet/Tech Contact: B6
Company Name: Tufts Cummings School of Vet Med - Clinical Pathology Laboratory
Address: 200 Westboro Road
North Grafton, MA 01536
Email: [illegible]
Tel: [illegible] Fax: [illegible]

Billing Contact: B6 TAX ID:
Email: B6 Tel: B6

Patient Name: B6
Species: Canine B6
Owner's Name: B6

Sample Type: ☐ Plasma ☑ Whole Blood ☐ Urine ☐ Food ☐ Other
Test Items: ☑ Taurine ☐ Complete Amino Acid ☐ Other

Taurine Results (nmol/ml)

Plasma: B6 Whole Blood: B6 Urine: Food:

Reference Ranges (nmol/ml)

	Plasma		Whole Blood	
	Normal Range	No Known Risk for Taurine Deficiency	Normal Range	No Known Risk for Taurine Deficiency
Cat	60-120	>40	300-600	>200
Dog	60-120	>40	100-150	>150

B6

Canine
[illegible]
[illegible]
[illegible]

FDA-CVM-FOIA-2019-1704-010723

Client: B6
Patient:

Amino Acid Labs Taurine results 8/28/18

UNIVERSITY OF CALIFORNIA, DAVIS

STERN CARDIAC GENETICS LABORATORY
JOSHUA A. STERN, DVM, PHD, DACVIM (CARDIOLOGY)
August 9, 2018

FREQUENTLY REQUESTED INFORMATION REGARDING TAURINE & DILATED CARDIOMYOPATHY IN GOLDEN RETRIEVERS

Taurine reference ranges for Golden Retrievers: The Stern Lab suggests that the following clinical reference ranges be used for Golden Retrievers and be considered for other known taurine-sensitive breeds such as Newfoundlands or American Cocker Spaniels. This is primarily based on 3 observations:
1. Golden Retrievers with marginal taurine levels (defined below) have been diagnosed with dilated cardiomyopathy and have documented disease reversal after taurine supplementation and diet change.
2. Previously published work documents taurine sensitivity in Golden Retrievers.
3. The most recently published reference on normal blood taurine values shows higher levels than previously reported.

- Normal whole blood taurine: >250nmol/mL
- Normal plasma taurine: >70nmol/mL

- Marginal whole blood taurine: 200-250nmol/mL
- Marginal plasma taurine: 60-70nmol/mL

- Low whole Blood taurine: <200nmol/mL
- Low plasma taurine: <60nmol/mL

References:

Plasma vs. whole blood taurine testing:
If at all possible, we recommend that paired (plasma and whole blood) taurine samples be submitted for analysis. A low value on either or both tests is clinically relevant. If your dog is diagnosed with DCM, submitting paired taurine samples (plasma and whole blood) is imperative. We recommend that the UC Davis Amino Acid Laboratory be used for taurine testing, as this is where the literature utilized for our reference ranges was generated: https://www.vetmed.ucdavis.edu/labs/amino-acid-assessment. If a single test is submitted the Stern Lab recommends that whole blood be submitted preferentially. This is due to the false elevation of taurine levels that is possible in plasma samples due to sample handling issues. This is an area of some debate between clinicians and conflicting information on preference for plasma vs. whole blood exists. This underscores the value of paired sampling.

Page 1 of 3

FDA-CVM-FOIA-2019-1704-010724

Amino Acid Labs Taurine results 8/28/18

[redacted]

FDA-CVM-FOIA-2019-1704-010725

Client: B6
Patient:

Amino Acid Labs Taurine results 8/28/18

Facts of Concern & Choosing a Diet

The FDA alert called attention to several dietary ingredients that should be considered when evaluating whether your pet is at risk (for example legumes like peas and lentils, potatoes, tapioca). These findings were largely extrapolated to our current study of Golden Retrievers with low taurine levels and DCM. Our lab considers these ingredients to be of greatest concern when present within the first 5 listed ingredients on the dog food bag. Additionally, we noted a high percent of diets in our study were using protein sources other than chicken or beef and labeled as grain-free.

Factors to consider when making a diet change:

- Choose a diet that does not contain the concerning components listed above
- Choose a diet that meets the WSAVA Global Nutrition Assessment Guidelines published in conjunction by veterinary nutritionists from around the world:
  - https://www.wsava.org/WSAVA/media/Arpita-and-Emma-editorial/Assessing-the-Best-Food-for-your-Pet.pdf
- FDA alert found here:
  - https://www.fda.gov/AnimalVeterinary/NewsEvents/CVMUpdates/ucm449070.htm

Choosing a taurine or l-carnitine supplement:

Selecting supplements should be performed based upon those that meet their stated amounts and are readily available for dosing/use. Lately a previous publication used multiple taurine and l-carnitine supplements. Based upon this publication our laboratory recommends the following supplements as those meeting our quality criteria. (Braga et al. 2005 | Am Vet Med Assoc. 234[1])

Taurine supplements that test within 5% of stated contents and if applicable disintegrated within 30 minutes:

- Mega taurine caps by Twinlab [1000 mg/pill]
- Taurine by Swanson Health Products [500mg caplets]
- Taurine by NOW foods [500mg capsule]
- Taurine 500 by GNC [500mg tablet]

Tested L-carnitine supplements that test within 5% of stated contents and if applicable disintegrated within 30 minutes:

- L-carnitine 500 by Jarrow Formulas [500mg capsule]
- L-carnitine caps by Country Life [500mg capsule]
- Maxi L-carnitine by Solgar Vitamin and Herb [500mg tablet]
- L-carnitine by Puritan's Pride [500mg tablet]

The Davis lab does not recommend the empirical supplementation of taurine or l-carnitine to dogs without evidence of DCM and/or appropriate deficiency. If DCM is diagnosed we typically recommend dogs over 50lbs receive 1,000mg of taurine every 12hrs and dogs under 50lbs receive 500mg of taurine every 12hours. We recommend L-carnitine at a dose of ~50mg/kg orally with food every 8hrs. Your veterinary cardiologist or family veterinarian should be consulted for prescribing the best dose for your dog.

Reporting to the FDA:

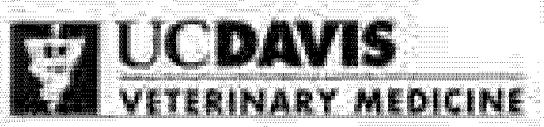
Understanding the scope of this condition requires a great deal of research and investigation. Clients with affected dogs can contribute their data to help propel this research forward. You can report cases of taurine deficiency, dilated cardiomyopathy, sudden cardiac death or any combination of these events to the FDA by following the information found here:

https://www.fda.gov/AnimalVeterinary/SafetyHealth/ReportaProblem/ucm284030.htm

Additional questions or comments:
(myvetmed@ucdavis.edu)
This document last updated: Aug. 30, 2018
Page 1 of 1

FDA-CVM-FOIA-2019-1704-010726

Amino Acid Labs Taurine results 8/28/18



CARDIOLOGY SERVICE UPDATE 2: DCM FOCUS & DILATED CARDIOMYOPATHY

The Cardiology Service has developed this document in response to the alerts from the FDA. These alerts identify an association with canine grain free diets containing certain ingredients (legumes like peas, pea components, lentils, other legumes, sweet potatoes) and a diagnosis of dilated cardiomyopathy (DCM). The links provided throughout this document can be copied and pasted to obtain additional information.

FDA Alerts found here:
https://www.fda.gov/AnimalVeterinary/NewsEvents/CVMUpdates/ucm613284.htm
https://www.fda.gov/AnimalVeterinary/NewsEvents/CVMUpdates/ucm615017.htm

What is Dilated Cardiomyopathy (DCM)?
DCM is a heart muscle disease that results in a weak pump function and heart chamber enlargement. In the early stages of the disease pets may appear totally healthy with no apparent clinical signs. Later in the course of the disease, dogs may have a heart murmur, an arrhythmia (irregular heart beat), collapse episodes, weakness or tiredness with exercise, and even suffer breathing from congestive heart failure. While there are some breeds of dogs (like Dobermans) that have a genetic predisposition to development of DCM, there are also nutritional factors that may result in this disease.

What should I do?
If you are feeding a diet of concern based upon the FDA alert we recommend that you consult with your veterinarian or veterinary cardiologist. We provide 4 general points for guidance below.

1. At most vets is to consider **whether you are willing or interested in performing additional testing** to assess whether your pet is affected with DCM. If you believe your dog is at risk, showing any of the aforementioned clinical signs or would prefer to simply rule out any heart disease, we recommend that you first have your pet's taurine levels tested (both whole blood and plasma levels) as well as have an echocardiogram by a board certified veterinary cardiologist. Low taurine levels are associated with development of DCM in dogs and are sometimes a component of this current issue.

Information on taurine testing can be found here: https://www.vetmed.ucdavis.edu/vdl/services/amino_acid.html

2. At this time, **diet change is recommended when possible** and should be considered regardless of the results obtained from any testing. You can consult with your veterinarian in selecting a new diet that avoids the ingredients of concern listed by the FDA. When selecting this diet, we recommend that you choose a diet that is manufactured with rigorous quality control measures and research behind the formulations. A way to ensure that your diet meets these recommendations is to follow the following guidelines that were generated by a large number of the world's leading experts in veterinary nutrition.

Food selection guidelines found here:
https://www.wsava.org/WSAVA/media/Arquivos/Documents/Nutritional-Guidelines-Best-Food-for-your-Pet.pdf

3. If your pet is identified through testing to have a low blood taurine level or evidence of DCM by echocardiogram, we urge you to report this information to the FDA.

FDA reporting guidelines found here: https://www.fda.gov/AnimalVeterinary/SafetyHealth/ReportaProblem/ucm383412.htm

4. Work with your veterinarian(s) to determine the best course of action and medical treatments if indicated. In the case of a DCM diagnosis, diet change alone may not be sufficient and additional medications may be prescribed.

Please continue to monitor the FDA website and the UC Davis School of Veterinary Medicine Newsfeeds for updates and recommendations regarding this issue.

FDA-CVM-FOIA-2019-1704-010727

Client: B6
Patient:

Vitals Results

B6

7:19:38 PM	Heart Rate (/min)	
7:19:39 PM	Respiratory Rate	
7:19:40 PM	Temperature (F)	
7:19:41 PM	B6 treatment note	
8:01:18 PM	Nursing note	
10:51:29 PM	Cardiac rhythm	
10:51:30 PM	Heart Rate (/min)	
10:52:15 PM	Respiratory Rate	
10:55:36 PM	B6 treatment note	
11:11:46 PM	Respiratory Rate	
11:15:36 PM	Eliminations	
11:59:29 PM	Cardiac rhythm	
11:59:30 PM	Heart Rate (/min)	
1:06:28 AM	Respiratory Rate	
1:06:38 AM	Cardiac rhythm	
1:06:39 AM	Heart Rate (/min)	
1:07:29 AM	Respiratory Rate	
1:16:20 AM	Catheter Assessment	
1:16:30 AM	Temperature (F)	
1:16:40 AM	Amount eaten	
1:24:55 AM	Eliminations	
1:59:16 AM	Cardiac rhythm	
1:59:17 AM	Heart Rate (/min)	
2:00:45 AM	Nursing note	
3:07:42 AM	Cardiac rhythm	
3:07:43 AM	Heart Rate (/min)	
3:08:14 AM	Respiratory Rate	
3:51:34 AM	Respiratory Rate	
3:51:49 AM	Cardiac rhythm	
3:51:50 AM	Heart Rate (/min)	
3:56:33 AM	Eliminations	
4:53:31 AM	Respiratory Rate	
4:53:41 AM	Cardiac rhythm	
4:53:42 AM	Heart Rate (/min)	
5:05:59 AM	Catheter Assessment	
5:47:32 AM	Cardiac rhythm	
5:47:33 AM	Heart Rate (/min)	
5:47:43 AM	Respiratory Rate	
6:58:01 AM	Cardiac rhythm	
6:58:02 AM	Heart Rate (/min)	

B6

FDA-CVM-FOIA-2019-1704-010728

Client: B6
Patient:

Vitals Results

B6

6:58:10 AM	Respiratory Rate	
7:36:37 AM	Weight (kg)	
7:36:43 AM	Eliminations	
7:36:58 AM	Respiratory Rate	
7:40:41 AM	Amount eaten	
7:40:57 AM	Cardiac rhythm	
7:40:58 AM	Heart Rate (/min)	
8:15:42 AM	B6 eatment note	
8:57:02 AM	Cardiac rhythm	
8:57:03 AM	Heart Rate (/min)	
8:57:12 AM	Respiratory Rate	
9:02:45 AM	Catheter Assessment	
9:02:59 AM	Eliminations	
9:58:29 AM	Respiratory Rate	
11:03:50 AM	Respiratory Rate	
11:36:45 AM	Respiratory Rate	
11:36:53 AM	Heart Rate (/min)	
11:42:00 AM	Eliminations	
12:53:35 PM	Respiratory Rate	
1:51:27 PM	Amount eaten	
2:11:08 PM	Respiratory Rate	
2:32:31 PM	B6 reatment note	
2:32:41 PM	Catheter Assessment	
2:46:00 PM	Respiratory Rate	
2:50:43 PM	Eliminations	
4:29:41 PM	Weight (kg)	

FDA-CVM-FOIA-2019-1704-010729

Client: B6
Patient:

RDVM B6 Center Rads B6

FDA-CVM-FOIA-2019-1704-010730

B6

FDA-CVM-FOIA-2019-1704-010731

Client: B6
Patient:

RDVM B6 Center Rads B6

B6

FDA-CVM-FOIA-2019-1704-010732

Patient History

B6

06:37 PM	UserForm
07:19 PM	Vitals
07:19 PM	Vitals
07:19 PM	Vitals
07:19 PM	Vitals
07:19 PM	Vitals
08:01 PM	Vitals
08:13 PM	Prescription
09:00 PM	UserForm
09:24 PM	Purchase
09:24 PM	Purchase
09:25 PM	Purchase
09:25 PM	Purchase
09:25 PM	Purchase
09:58 PM	Purchase
10:02 PM	Purchase
10:02 PM	Purchase
10:06 PM	Purchase
10:06 PM	Purchase
10:49 PM	Labwork
10:51 PM	Treatment
10:51 PM	Vitals
10:51 PM	Vitals
10:52 PM	Treatment
10:52 PM	Vitals
10:55 PM	Vitals
10:55 PM	Treatment
11:11 PM	Treatment
11:11 PM	Vitals
11:11 PM	Treatment
11:15 PM	Treatment
11:15 PM	Vitals
11:59 PM	Treatment
11:59 PM	Vitals
11:59 PM	Vitals
01:06 AM	Treatment
01:06 AM	Vitals
01:06 AM	Treatment
01:06 AM	Vitals
01:06 AM	Vitals
01:07 AM	Treatment
01:07 AM	Vitals
01:16 AM	Treatment
01:16 AM	Vitals

B6

FDA-CVM-FOIA-2019-1704-010733

Client: B6
Patient:

Patient History

01:16 AM	Treatment
01:16 AM	Vitals
01:16 AM	Treatment
01:16 AM	Vitals
01:24 AM	Treatment
01:24 AM	Vitals
01:59 AM	Treatment
01:59 AM	Vitals
01:59 AM	Vitals
02:00 AM	Vitals
03:07 AM	Treatment
03:07 AM	Vitals
03:07 AM	Vitals
03:08 AM	Treatment
03:08 AM	Vitals
03:51 AM	Treatment
03:51 AM	Vitals
03:51 AM	Treatment
03:51 AM	Vitals
03:51 AM	Vitals
03:56 AM	Treatment
03:56 AM	Vitals
04:53 AM	Treatment
04:53 AM	Vitals
04:53 AM	Treatment
04:53 AM	Vitals
04:53 AM	Vitals
05:05 AM	Treatment
05:05 AM	Vitals
05:06 AM	Treatment
05:47 AM	Treatment
05:47 AM	Vitals
05:47 AM	Vitals
05:47 AM	Treatment
05:47 AM	Vitals
06:58 AM	Treatment
06:58 AM	Vitals
06:58 AM	Vitals
06:58 AM	Treatment
06:58 AM	Vitals
07:36 AM	Treatment
07:36 AM	Vitals
07:36 AM	Treatment

B6

B6

FDA-CVM-FOIA-2019-1704-010734

Client: B6
Patient:

Patient History

B6

07:36 AM	Vitals
07:36 AM	Treatment
07:36 AM	Vitals
07:40 AM	Treatment
07:40 AM	Treatment
07:40 AM	Vitals
07:40 AM	Treatment
07:40 AM	Vitals
07:40 AM	Vitals
08:15 AM	Vitals
08:16 AM	Treatment
08:57 AM	Treatment
08:57 AM	Vitals
08:57 AM	Vitals
08:57 AM	Treatment
08:57 AM	Vitals
09:02 AM	Treatment
09:02 AM	Vitals
09:02 AM	Treatment
09:02 AM	Vitals
09:11 AM	Purchase
09:22 AM	Purchase
09:52 AM	UserForm
09:58 AM	Treatment
09:58 AM	Treatment
09:58 AM	Vitals
10:04 AM	Deleted Reason
11:03 AM	Treatment
11:03 AM	Vitals
11:29 AM	Treatment
11:31 AM	Purchase
11:36 AM	Treatment
11:36 AM	Vitals
11:36 AM	Treatment
11:36 AM	Vitals
11:42 AM	Treatment
11:42 AM	Vitals
11:42 AM	Treatment
11:42 AM	Purchase
11:47 AM	Labwork
12:53 PM	Treatment

B6

FDA-CVM-FOIA-2019-1704-010735

Client: B6
Patient:

Patient History

B6

12:53 PM	Vitals
01:51 PM	Treatment
01:51 PM	Treatment
01:51 PM	Vitals
02:11 PM	Treatment
02:11 PM	Vitals
02:30 PM	Prescription
02:31 PM	Prescription
02:32 PM	Vitals
02:32 PM	Treatment
02:32 PM	Treatment
02:32 PM	Vitals
02:34 PM	Purchase
02:46 PM	Treatment
02:46 PM	Vitals
02:50 PM	Treatment
02:50 PM	Vitals
03:05 PM	UserForm
12:25 PM	Appointment
04:00 PM	UserForm
04:00 PM	Purchase
04:04 PM	Treatment
04:29 PM	Vitals
04:49 PM	Purchase
05:24 PM	Purchase
05:27 PM	Labwork
06:02 PM	UserForm
06:17 PM	Prescription
06:19 PM	Purchase
09:54 AM	Prescription
09:54 AM	Purchase

B6

B6

FDA-CVM-FOIA-2019-1704-010736

FDA-CVM-FOIA-2019-1704-010737

From: PFR Event <pfreventcreation@fda.hhs.gov>

To: Cleary, Michael *; HQ Pet Food Report Notification; B6

Sent: 10/8/2018 6:44:41 PM

Subject: Rawz meal free dry food limited recipe wild salmon dry: Lisa Freeman - EON-367845

Attachments: 2055793-report.pdf; 2055793-attachments.zip

A PFR Report has been received and PFR Event [EON-367845] has been created in the EON System.

A "PDF" report by name "2055793-report.pdf" is attached to this email notification for your reference. Please note that all documents received in the report are compressed into a zip file by name "2055793-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-367845
ICSR #: 2055793
EON Title: PFR Event created for Rawz meal free dry food limited recipe wild salmon dry; 2055793

AE Date	10/04/2018	**Number Fed/Exposed**	1
Best By Date		**Number Reacted**	1
Animal Species	Dog	**Outcome to Date**	Stable
Breed	Mixed (Dog)		
Age	10 Years		
District Involved	PFR-New England DO		

Product information
Individual Case Safety Report Number: 2055793
Product Group: Pet Food
Product Name: Rawz meal free dry food limited recipe wild salmon dry
Description: DCM and atrial fibrillation diagnosed 10/5/18
Submission Type: Initial
Report Type: Adverse Event (a symptom, reaction or disease associated with the product)
Outcome of reaction/event at the time of last observation: Stable
Number of Animals Treated With Product: 1

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Rawz meal free dry food limited recipe wild salmon dry		

Sender information

Lisa Freeman
200 Westboro Rd
North Grafton, MA 01536
USA

Owner information

B6 USA

To view this PFR Event, please click the link below:
https://eon.fda.gov/eon//browse/EON-367845

To view the PFR Event Report, please click the link below:
https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jspa?decorator=none&e=0&issueType=12&issueId=384767

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Report Details - EON-367845

ICSR:	2055793	
Type Of Submission:	Initial	
Report Version:	FPSR.FDA.PETF.V.V1	
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)	
Reporting Type:	Voluntary	
Report Submission Date:	2018-10-08 14:34:26 EDT	
Reported Problem:	**Problem Description:**	DCM and atrial fibrillation diagnosed 10/5/18
	Date Problem Started:	10/04/2018
	Concurrent Medical Problem:	Yes
	Pre Existing Conditions:	B6
	Outcome to Date:	Stable
Product Information:	**Product Name:**	Rawz meal free dry food limited recipe wild salmon dry
	Product Type:	Pet Food
	Lot Number:	
	Package Type:	BAG
	Product Use Information:	
	Manufacturer /Distributor Information:	
	Purchase Location Information:	
Animal Information:	**Name:**	B6
	Type Of Species:	Dog
	Type Of Breed:	Mixed (Dog)
	Gender:	Male
	Reproductive Status:	Neutered
	Weight:	33.2 Kilogram
	Age:	10 Years
	Assessment of Prior Health:	Excellent
	Number of Animals Given the Product:	1
	Number of Animals Reacted:	1
	Owner Information:	**Owner Information provided:** Yes
		Contact: **Name:** B6
		Phone:
		Email:
		Address: B6 United States
	Healthcare Professional Information:	**Practice Name:** Tufts Cummings School of Veterinary Medicine
		Contact: **Name:** Lisa Freeman
		Phone: (508) 887-4523
		Email: lisa.freeman@tufts.edu
		Address: 200 Westboro Rd

FDA-CVM-FOIA-2019-1704-010740

			North Grafton Massachusetts 01536 United States
Sender Information:	**Name:**	Lisa Freeman	
	Address:	200 Westboro Rd North Grafton Massachusetts 01536 United States	
	Contact:	**Phone:**	5088874523
		Email:	lisa.freeman@tufts.edu
	Permission To Contact Sender:	Yes	
	Preferred Method Of Contact:	Email	
Additional Documents:			
	Attachment:	B6 compiled records B6 pdf	
	Description:	Compiled records	
	Type:	Medical Records	

Cummings Veterinary Medical Center
AT TUFTS UNIVERSITY

Foster Hospital for Small Animals
55 Willard Street
North Grafton, MA 01536
(508) 839-5395

All Medical Records

Client: B6
Address: B6

Patient: B6
Breed: Bulldog Cross
DOB: B6

Species: Canine
Sex: Male (Neutered)

Home Phone: (B6
Work Phone: ( ) -
Cell Phone: B6

Referring Information

B6

Client:
Patient: B6

Initial Complaint:
Emergency

SOAP Text B6 6:17PM - B6

NEW VISIT (ER) - B6

Doctor: B6, DVM
Student: B6 V'19
Presenting complaint: B6
Referral visit? Yes
Diagnostics completed prior to visit (approximately 2 PM on B6):

B6

HISTORY
Signalment: 10 yr. M/C Bulldog mix

B6

FDA-CVM-FOIA-2019-1704-010742

Client: B6
Patient:

Current medications: B6
Diet: Raw Limited Ingredient Salmon

EXAM

B6

C/V: No heart murmur heard on auscultation; irregularly irregular rhythm noted. Femoral pulses strong and synchronous.

B6

ASSESSMENT

A1: Arrhythmia - suspect atrial fibrillation secondary to enlarged left atrium
A2: B6

PLAN

(1) Diagnostic plan:

B6

(3) Client communication:

(A) Discussed with owner that patient may have two separate issues (GI and heart), but that it is possible for the two to be related. Based on rDVM rads that were taken at 2 PM today I do not see overt evidence of mechanical obstruction. B6

B6

Deposit & estimate status: B6

FDA-CVM-FOIA-2019-1704-010743

Client: B6
Patient:

Resuscitation code (if admitting to ICU) B6

SOAP approved (DVM to sign): B6 DVM

SOAP Text B6 **6:11AM -** B6

Day 2 Hospitalization

Presenting complaint: vomiting, anorexia
Referral visit? Yes
Diagnostics completed prior to visit (approximately 2 PM on B6):

B6

HISTORY

Signalment: 10 yr. M/C Bulldog mix

B6

Diet: Raw Limited Ingredient Salmon - Rawz for about 1.5-2 years, but been on grain free for a long time
Might have tried hydrolyzed food in the past but unsure

EXAM

B6

C/V: No heart murmur heard on auscultation; irregularly irregular rhythm noted. Femoral pulses strong and synchronous.

B6

ASSESSMENT

A1: Arrhythmia - suspect atrial fibrillation secondary to enlarged left atrium
A2: B6

FDA-CVM-FOIA-2019-1704-010744

Client: B6
Patient:

PLAN

B6

Deposit & estimate status B6
Resuscitation code (if admitting to ICU) B6

SOAP approved (DVM to sign): B6 DVM

Disposition/Recommendations

FDA-CVM-FOIA-2019-1704-010745

FDA-CVM-FOIA-2019-1704-010746

Cummings Veterinary Medical Center
AT TUFTS UNIVERSITY

Foster Hospital for Small Animals
55 Willard Street
North Grafton, MA 01536
(508) 839-5395

Client:	B6
Veterinarian:	
Patient ID:	B6
Visit ID:	

Patient:	B6
Species:	Canine
Breed:	Bulldog Cross
Sex:	Male (Neutered)
Age:	B6 Years Old

Lab Results Report

Nova Full Panel-ICU B6 **8:52:25 PM** **Accession ID:** B6

Test	Results	Reference Range	Units
SO2%	B6	94 - 100	%
HCT (POC)		38 - 48	%
HB (POC)		12.6 - 16	g/dL
NA (POC)		140 - 154	mmol/L
K (POC)		3.6 - 4.8	mmol/L
CL(POC)		109 - 120	mmol/L
CA (ionized)		1.17 - 1.38	mmol/L
MG (POC)		0.1 - 0.4	mmol/L
GLUCOSE (POC)		80 - 120	mg/dL
LACTATE		0 - 2	mmol/L
BUN (POC)		12 - 28	mg/dL
CREAT (POC)		0.2 - 2.1	mg/dL
TCO2 (POC)		0 - 0	mmol/L
nCA		0 - 0	mmol/L
nMG		0 - 0	mmol/L
GAP		0 - 0	mmol/L
CA/MG		0 - 0	mol/mol
BEecf		0 - 0	mmol/L
BEb		0 - 0	mmol/L
A		0 - 0	mmHg
NOVA SAMPLE		0 - 0	

FDA-CVM-FOIA-2019-1704-010747

Client: B6
Patient:

FiO2	B6	0 - 0	%
PCO2		36 - 44	mmHg
PO2		80 - 100	mmHg
PH		7.337 - 7.467	
PCO2		36 - 44	mmHg
PO2		80 - 100	mmHg
HCO3		18 - 24	mmol/L

Nova Full Panel-ICU B6 **8:54:03 PM** **Accession ID:** B6

Test	Results	Reference Range	Units
HW ANTIGEN-CANINE	B6	0 - 0	
LYME C6		0 - 0	
A.PHAGO/PLATYS		0 - 0	
E CANIS/EWINGI		0 - 0	

Nova Full Panel-ICU B6 **8:54:13 PM** **Accession ID:** B6

Test	Results	Reference Range	Units
WBC (ADVIA)	B6	4.4 - 15.1	K/uL
RBC(ADVIA)		5.8 - 8.5	M/uL
HGB(ADVIA)		13.3 - 20.5	g/dL
HCT(ADVIA)		39 - 55	%
MCV(ADVIA)		64.5 - 77.5	fL
MCH(ADVIA)		21.3 - 25.9	pg
MCHC(ADVIA)		31.9 - 34.3	g/dL
RDW (ADVIA)		11.9 - 15.2	
PLT(ADVIA)		173 - 486	K/uL
MPV (ADVIA)		8.29 - 13.2	fl
PLTCRT		0.129 - 0.403	%
RETIC(ADVIA)		0.2 - 1.6	%
RETICS (ABS) ADVIA		14.7 - 113.7	K/uL
COMMENTS (HEMATOLOGY)		0 - 0	

Nova Full Panel-ICU B6 **8:54:27 PM** **Accession ID:** B6

Test	Results	Reference Range	Units
GLUCOSE	B6	67 - 135	mg/dL
UREA		8 - 30	mg/dL
CREATININE		0.6 - 2	mg/dL
PHOSPHORUS		2.6 - 7.2	mg/dL
CALCIUM2		9.4 - 11.3	mg/dL
MAGNESIUM 2+		1.8 - 3	mEq/L
T. PROTEIN		5.5 - 7.8	g/dL
ALBUMIN		2.8 - 4	g/dL
GLOBULINS		2.3 - 4.2	g/dL

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A/G RATIO		0.7 - 1.6	
SODIUM		140 - 150	mEq/L
CHLORIDE		106 - 116	mEq/L
POTASSIUM		3.7 - 5.4	mEq/L
tCO2 (BICARB)		14 - 28	mEq/L
AGAP		8 - 19	
NA/K	B6	29 - 40	
T BILIRUBIN		0.1 - 0.3	mg/dL
D.BILIRUBIN		0 - 0.1	mg/dL
I BILIRUBIN		0 - 0.2	mg/dL
ALK PHOS		12 - 127	U/L
GGT		0 - 10	U/L
ALT		14 - 86	U/L
AST		9 - 54	U/L
CK		22 - 422	U/L
6068 Result(s) verified			
CHOLESTEROL		82 - 355	mg/dL
TRIGLYCERIDES	B6	30 - 338	mg/dl
AMYLASE		409 - 1250	U/L
OSMOLALITY (CALCULATED)		291 - 315	mmol/L

Nova Full Panel-ICU B6 8:54:11 PM **Accession ID:** B6

Test	Results	Reference Range	Units
SEGS%		43 - 86	%
LYMPHS%		7 - 47	%
MONOS%		1 - 15	%
SEGS (AB)ADVIA		2.8 - 11.5	K/ul
LYMPHS (ABS)ADVIA		1 - 4.8	K/uL
MONOS (ABS)ADVIA		0.1 - 1.5	K/uL
WBC MORPHOLOGY	B6	0 - 0	
Occasional reactive lymphocytes			
ACANTHOCYTES		0 - 0	
KERATOCYTES/BLISTER CELLS		0 - 0	
POIKILOCYTOSIS		0 - 0	
SCHISTOCYTES		0 - 0	
SPHEROCYTES		0 - 0	

Nova Full Panel-ICU B6 8:54:00 PM **Accession ID:** B6

Test	Results	Reference Range	Units
CBC Review		0 - 0	
See comment.			

B6

FDA-CVM-FOIA-2019-1704-010749

Client: B6
Patient:

finding: B6 DVM PhD DACVP

Nova Full Panel-ICU	B6 8:54:00 PM	Accession ID: B6	
Test	Results	Reference Range	Units
T4/TOSOH	B6	1 - 4.1	ug/dl

Nova Full Panel-ICU	B6 8:58:31 PM	Accession ID: B6	
Test	Results	Reference Range	Units
TS (FHSA)		0 - 0	g/dl
PCV **	B6	0 - 0	%
TS (FHSA)		0 - 0	g/dl

FDA-CVM-FOIA-2019-1704-010750

B6

Patient ID: B6
Name: B6

Species: CANINE
Breed: BULLDOG/MIX
Color: WHITE/YELLOW
Birth Date: B6

Email Addres: B6

Microchip:
Sex: Male Neutered

Client Education

Puppy/Kitten		Lyme		Senior Wellness	
Deference		Rabies		Dental Disease	
Basic Training		Flea & Tick		FUS	
Aggression		Obesity		Elim. Disorder	
Heartworm		Osteoarthritis			
Leptospirosis					

Immunization Record

B6

U/S 6/18/18

Superficial wounds
Ceptroline batter

FDA-CVM-FOIA-2019-1704-010751

PAGE:

PATIENT NAME		OWNER'S NAME

DATE MO.	DATE DAY	YR.	PROB. NO.	SOAP	MEDICAL RECORD

B6

FDA-CVM-FOIA-2019-1704-010752

PAGE:

PATIENT NAME		OWNER'S NAME

DATE MO.	DAY	YR.	PROB. NO.	SOAP	MEDICAL RECORD

B6

FDA-CVM-FOIA-2019-1704-010753

PAGE:

PATIENT NAME		OWNER'S NAME

DATE MO.	DAY	YR.	PROB. NO.	SOAP	MEDICAL RECORD

B6

FDA-CVM-FOIA-2019-1704-010754

PAGE:

PATIENT NAME | OWNER'S NAME

DATE MO.	DAY	YR.	PROB. NO.	SOAP	MEDICAL RECORD

B6

FDA-CVM-FOIA-2019-1704-010755

PAGE:

PATIENT NAME | OWNER'S NAME

DATE MO.	DATE DAY	DATE YR.	PROB. NO.	SOAP	MEDICAL RECORD

B6

FDA-CVM-FOIA-2019-1704-010756

PAGE:

PATIENT NAME		OWNER'S NAME

DATE MO.	DAY	YR.	PROB. NO.	SOAP	MEDICAL RECORD

B6

FDA-CVM-FOIA-2019-1704-010757

PAGE:

PATIENT NAME		OWNER'S NAME

DATE MO.	DAY	YR.	PROB. NO.	SOAP	MEDICAL RECORD

B6

Referral to Vets Thrust

FDA-CVM-FOIA-2019-1704-010758

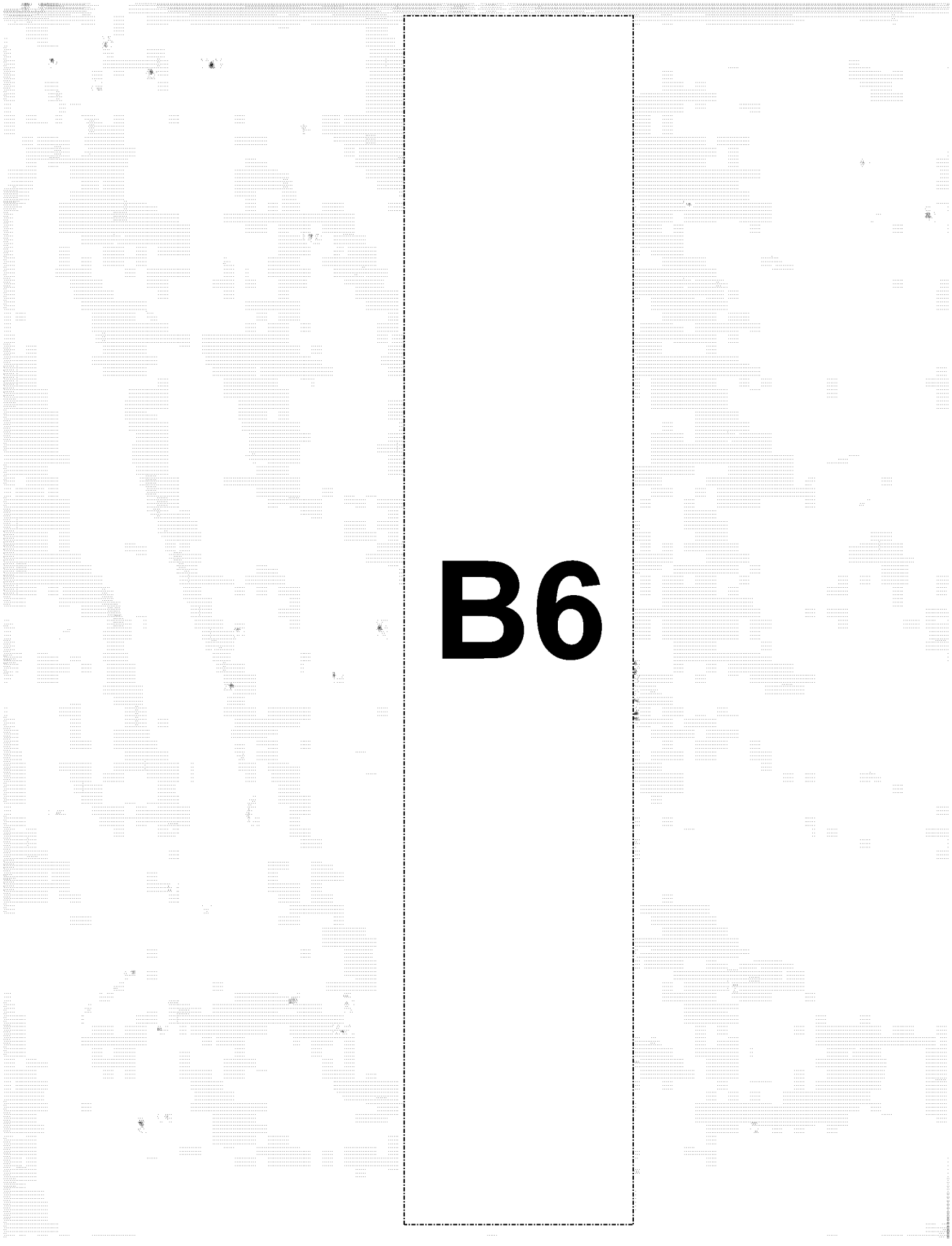
PAGE:

PATIENT NAME		OWNER'S NAME

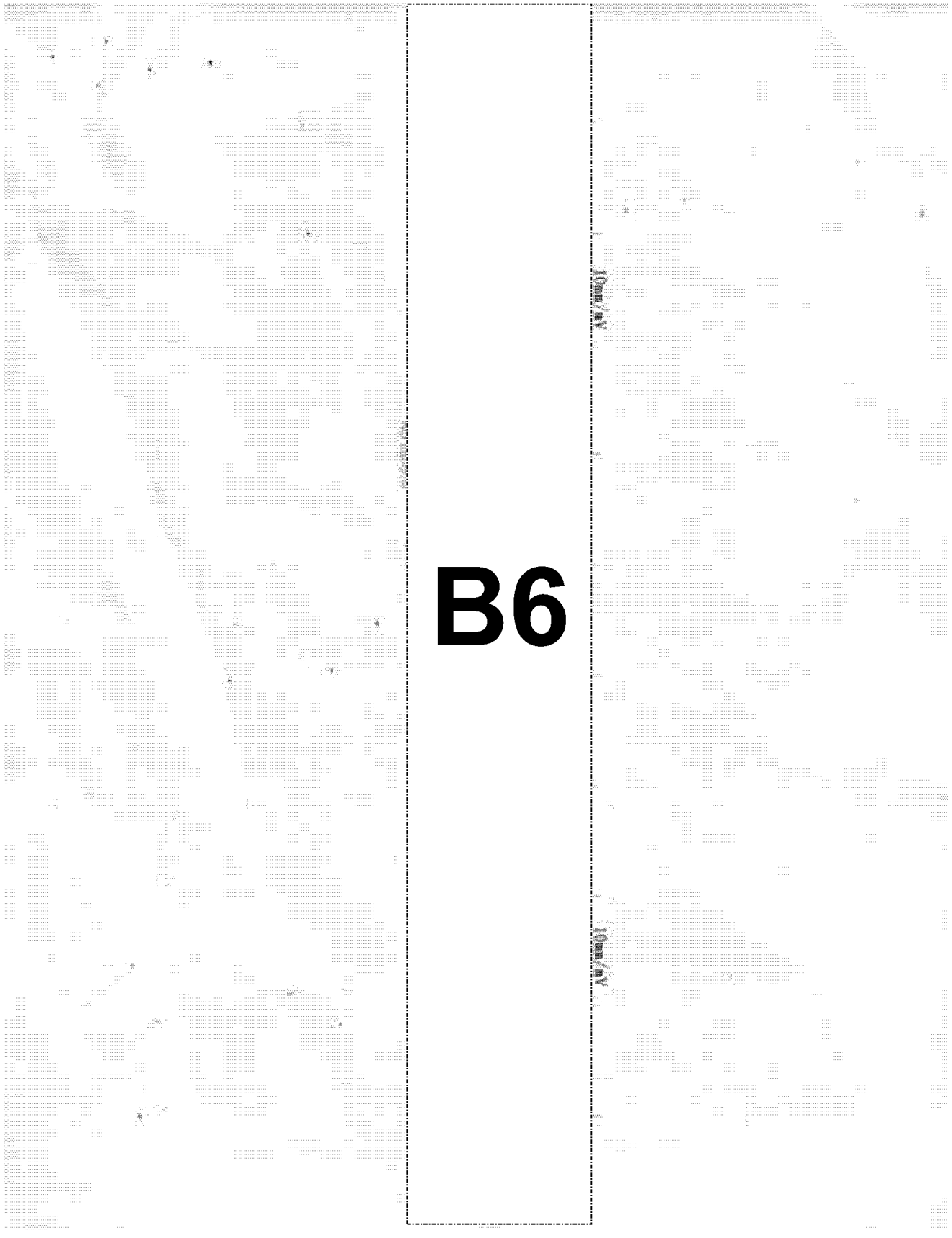
DATE MO.	DATE DAY	DATE YR.	PROB. NO.	SOAP	MEDICAL RECORD
					Emergency.

B6

FDA-CVM-FOIA-2019-1704-010759



FDA-CVM-FOIA-2019-1704-010760



FDA-CVM-FOIA-2019-1704-010761

B6

FDA-CVM-FOIA-2019-1704-010762

Client: B6
(11004)
Patient Name: B6
Species: Canine
Breed:

Gender: Male/Castrated
Weight: 70.40 lbs
Age: 10 Years
Doctor: B6 DVM

Test	Results	Reference Interval	LOW	NORMAL	HIGH
ProCyte Dx (B6 1:24 PM)					
RBC	B6	5.65 - 8.87			
HCT		37.3 - 61.7	LOW		
HGB		13.1 - 20.5			
MCV		61.6 - 73.5	LOW		
MCH		21.2 - 25.9			
MCHC		32.0 - 37.9			
RDW		13.6 - 21.7			
%RETIC					
RETIC		10.0 - 110.0			
RETIC-HGB		22.3 - 29.6			
WBC		5.05 - 16.76			
%NEU					
%LYM					
%MONO					
%EOS					
%BASO					
NEU		2.95 - 11.64			
LYM		1.05 - 5.10	LOW		
MONO		0.16 - 1.12			
EOS		0.38 - 1.35	LOW		
BASO		0.00 - 0.10			
PLT		148 - 484			
MPV		8.7 - 13.2			
PDW		9.1 - 19.4			
PCT		0.14 - 0.46			

B6 (9:37 AM)

RBC Run

WBC Run

Size

B6

B6

B6

B6

Printed: B6 1:32 PM

Page 1 of 2

FDA-CVM-FOIA-2019-1704-010763

Client: B6
(11004)
Patient Name: B6
Species: Canine
Breed:

Gender: Male/Castrated
Weight: 70.40 lbs
Age: 10 Years
Doctor: B6 , DVM

Test	Results	Reference Interval	LOW	NORMAL	HIGH
Catalyst One	B6	1:32 PM)			B6 9:53 AM
GLU	B6	70 - 143		B6	B6
CREA		0.5 - 1.8			
BUN		7 - 27			
BUN/CREA					
PHOS		2.5 - 6.8			
CA		7.9 - 12.0			
TP		5.2 - 8.2			
ALB		2.2 - 3.9			
GLOB		2.5 - 4.5			
ALB/GLOB					
ALT		10 - 125			HIGH
ALKP		23 - 212			
GGT		0 - 11			
TBIL		0.0 - 0.9			
CHOL		110 - 320			
AMYL		500 - 1500			LOW
LIPA		200 - 1800			
Na		144 - 160			
K		3.5 - 5.8			
Na/K					
Cl		109 - 122			
Osm Calc					

Printed: B6 1:32 PM Page 2 of2 B6

FDA-CVM-FOIA-2019-1704-010764

Client: B6
Patient:

RDVM B6 animal hosp allergy test results B6

B6 17:46 B6 B6 PAGE 02/03
B6

B6

Diets Recommended

· Iams - Skin & Coat Plus Response FP: Potato, herring meal, catfish, animal fat, beet pulp, fish digest (Dry)
· FirstMate - Grain Free Wild Tuna Formula: Tuna, water, potato, kale (Can)
· FirstMate - Grain Free Salmon Formula: Wild boneless/skinless salmon, water, potato, kale (Can)
· Hill's - d/d Canine Salmon Formula: Water, salmon, potato, potato starch, potato protein, soybean oil, fish oil, powdered cellulose (Can)
· Brothers Complete - Bare Bites: Beef liver (Treat)
· Canine Caviar - Turkey: Turkey, water, turkey liver, guar gum (Can); Can be mixed with potato
· Canine Caviar - Duck: Duck, duck liver, sweet potatoes, water, guar gum (Can)
· Hill's - d/d Canine Duck Formula: Water, duck, potato, duck liver, potato starch, soybean oil, powdered cellulose, fish oil (Can)
· Hill's - d/d Canine Venison Formula: Water, venison, potatoes, potato starch, potato protein, soybean oil, powdered cellulose, fish oil (Can)
· Canine Caviar - Venison: Venison, water, venison tripe, venison liver, guar gum (Can); Can be mixed with potato
· Iams - Response KO: Oat flour, kangaroo, canola meal, animal fat, beet pulp, fish oil (Dry)
· Canine Caviar - Beaver: Beaver, water, guar gum (Can)
· Canine Caviar - Buffalo: Buffalo, water, guar gum (Can)

FDA-CVM-FOIA-2019-1704-010765

Client: B6
Patient:

RDVM B6 animal hosp allergy test results B6

B6 17:46 B6 B6 PAGE 03/03

B6

B6

B6

PRIMARY FOODS

Allergen	Class Score	Allergen	Class Score
Egg		Milk	
Salmon		Wheat	
Corn		Rice	
Soybean		Pork	
Beef		Turkey	
Chicken		Lamb	

EXTENDED FOODS

Allergen	Class Score	Allergen	Class Score
Egg	2	Milk	1
Salmon	0	Wheat	0
Corn	0	Rice	3
Soybean	1	Pork	0
Beef	1	Turkey	0
Chicken	2	Lamb	3
Duck	0	Potato	0
Rabbit	0	Venison	0
Yeast	0	Pea	0
Oat	0	Barley	0

MOLD SPECIAL PANEL

Allergen	Class Score	Allergen	Class Score
Penicillium		Cladosporium	
Aspergillus		Mucor	
Alternaria		Helminthosprium	
Fusarium		Stemphylium	
Rhizopus		Aureobasidium	
Phoma		Epicoccum	

Explanation of Results:

Classes 1, 2, 3, 4, 5 and 6 represent levels of IgE antibody specific for the respective allergen. Consider Class 2 level and greater for allergen immunotherapy.

Class 6- Ultra high level
Class 5- Ultra high level
Class 4- Very high level
Class 3- High level
Class 2- Low level
Class 1- Very low level
Class 0- Absent or undetectable

** VERY IMPORTANT** Please read

IF REQUESTED
FOODS AND SPECIAL PANELS ON THIS PAGE

Flea hypersensitivity is a multi-component disease. It is not always totally IgE antibody-mediated. Negative in vitro test probably indicates a Type IV Cell-mediated (Delayed-type Hypersensitivity)

VETERINARIAN

FDA-CVM-FOIA-2019-1704-010766

Client: B6
Patient:

Vitals Results

B6	4:57:35 PM	Heart Rate (/min)	B6
	4:57:36 PM	Respiratory Rate	
	4:57:37 PM	Temperature (F)	
	4:57:38 PM	Weight (kg)	
	7:23:44 PM	Heart Rate (/min)	
	7:23:45 PM	Temperature (F)	
	7:23:46 PM	Respiratory Rate	
	9:34:16 PM	Amount eaten	
	10:12:31 PM	Cardiac rhythm	
	10:12:32 PM	Heart Rate (/min)	
	10:12:52 PM	Respiratory Rate	
	11:52:54 PM	Cardiac rhythm	
	11:52:55 PM	Heart Rate (/min)	
	11:53:07 PM	Eliminations	
	11:53:16 PM	Respiratory Rate	
	1:00:47 AM	Cardiac rhythm	
	1:00:48 AM	Heart Rate (/min)	
	1:37:16 AM	Catheter Assessment	
	1:38:12 AM	Respiratory Rate	
	1:50:37 AM	Cardiac rhythm	
	1:50:38 AM	Heart Rate (/min)	
	2:49:03 AM	Cardiac rhythm	
	2:49:04 AM	Heart Rate (/min)	
	3:35:48 AM	Respiratory Rate	
	3:36:03 AM	Cardiac rhythm	
	3:36:04 AM	Heart Rate (/min)	
	4:44:11 AM	Cardiac rhythm	
	4:44:12 AM	Heart Rate (/min)	
	5:37:23 AM	Weight (kg)	
	5:37:33 AM	Eliminations	
	5:38:50 AM	Respiratory Rate	
	5:39:04 AM	Catheter Assessment	
	5:39:36 AM	Temperature (F)	
	6:30:19 AM	Cardiac rhythm	
	6:30:20 AM	Heart Rate (/min)	
	7:28:56 AM	Respiratory Rate	
	8:01:55 AM	Cardiac rhythm	
	8:01:56 AM	Heart Rate (/min)	
	8:55:50 AM	Cardiac rhythm	

FDA-CVM-FOIA-2019-1704-010767

Client: B6
Patient:

Vitals Results

B6	8:55:51 AM	Heart Rate (/min)	B6
	8:56:45 AM	Catheter Assessment	
	10:04:36 AM	Cardiac rhythm	
	10:04:37 AM	Heart Rate (/min)	
	10:05:26 AM	Respiratory Rate	
	11:07:25 AM	Cardiac rhythm	
	11:07:26 AM	Heart Rate (/min)	
	11:12:49 AM	Respiratory Rate	
	11:13:11 AM	Eliminations	
	12:20:08 PM	Blood Pressure (mmHg)	
	12:28:05 PM	Cardiac rhythm	
	12:28:06 PM	Heart Rate (/min)	
	12:55:30 PM	Cardiac rhythm	
	12:55:31 PM	Heart Rate (/min)	
	1:40:43 PM	Cardiac rhythm	
	1:40:44 PM	Heart Rate (/min)	
	1:42:42 PM	Respiratory Rate	
	1:42:50 PM	Catheter Assessment	
	2:56:24 PM	Cardiac rhythm	
	2:56:25 PM	Heart Rate (/min)	
	3:50:38 PM	Cardiac rhythm	
	3:50:39 PM	Heart Rate (/min)	
	3:51:17 PM	Respiratory Rate	
	4:53:34 PM	Cardiac rhythm	
	4:53:35 PM	Heart Rate (/min)	
	5:26:51 PM	Weight (kg)	
	5:27:11 PM	Catheter Assessment	
	5:27:40 PM	Eliminations	
	5:28:37 PM	Cardiac rhythm	
	5:28:38 PM	Heart Rate (/min)	
	5:31:07 PM	Respiratory Rate	
	5:31:19 PM	Temperature (F)	
	5:42:41 PM	Amount eaten	
	6:26:38 PM	Cardiac rhythm	
	6:26:39 PM	Heart Rate (/min)	
	7:11:26 PM	Respiratory Rate	
	7:33:30 PM	Cardiac rhythm	
	7:33:31 PM	Heart Rate (/min)	
	8:37:08 PM	Cardiac rhythm	
	8:37:09 PM	Heart Rate (/min)	
	9:04:40 PM	Catheter Assessment	

FDA-CVM-FOIA-2019-1704-010768

Client: B6
Patient:

Vitals Results

B6	9:04:48 PM	Respiratory Rate	B6
	10:11:22 PM	Cardiac rhythm	
	10:11:23 PM	Heart Rate (/min)	
	10:36:23 PM	Cardiac rhythm	
	10:36:24 PM	Heart Rate (/min)	
	11:20:49 PM	Eliminations	
	11:20:56 PM	Respiratory Rate	
	11:21:56 PM	Cardiac rhythm	
	11:21:57 PM	Heart Rate (/min)	
	1:40:01 AM	Catheter Assessment	
	1:40:50 AM	Cardiac rhythm	
	1:40:51 AM	Heart Rate (/min)	
	1:41:04 AM	Respiratory Rate	
	3:26:17 AM	Cardiac rhythm	
	3:26:18 AM	Heart Rate (/min)	
	3:26:43 AM	Respiratory Rate	
	3:30:08 AM	Cardiac rhythm	
	3:30:09 AM	Heart Rate (/min)	
	4:27:51 AM	Cardiac rhythm	
	4:27:52 AM	Heart Rate (/min)	
	5:53:01 AM	Cardiac rhythm	
	5:53:02 AM	Heart Rate (/min)	
	5:55:46 AM	Catheter Assessment	
	5:55:59 AM	Amount eaten	
	5:56:30 AM	Respiratory Rate	
	6:00:21 AM	Weight (kg)	
	6:00:27 AM	Eliminations	
	6:00:34 AM	Temperature (F)	
	6:41:18 AM	Cardiac rhythm	
	6:41:19 AM	Heart Rate (/min)	
	7:34:31 AM	Blood Pressure (mmHg)	
	7:35:00 AM	Cardiac rhythm	
	7:35:01 AM	Heart Rate (/min)	
	7:35:25 AM	Respiratory Rate	
	8:37:50 AM	Cardiac rhythm	
	8:37:51 AM	Heart Rate (/min)	
	9:59:36 AM	Cardiac rhythm	
	9:59:37 AM	Heart Rate (/min)	
	10:02:17 AM	Respiratory Rate	
	10:02:31 AM	Catheter Assessment	
	10:50:27 AM	Cardiac rhythm	

FDA-CVM-FOIA-2019-1704-010769

Client: B6
Patient:

Vitals Results

B6	0:50:28 AM	Heart Rate (/min)	B6
	1:29:06 AM	Eliminations	
	1:55:39 AM	Cardiac rhythm	
	1:55:40 AM	Heart Rate (/min)	
	1:55:49 AM	Respiratory Rate	
	2:45:30 PM	Cardiac rhythm	
	2:45:31 PM	Heart Rate (/min)	
	:44:51 PM	Cardiac rhythm	
	:44:52 PM	Heart Rate (/min)	
	:07:26 PM	Respiratory Rate	
	:07:35 PM	Catheter Assessment	
	:57:59 PM	Cardiac rhythm	
	:58:00 PM	Heart Rate (/min)	

FDA-CVM-FOIA-2019-1704-010770

Client: B6
Patient:

ECG from Cardio

B6

B6 11:54:36 AM
Tufts University
Tufts Cummings School of Vet Med
Cardiology

12 Lead: Standard Placement

FDA-CVM-FOIA-2019-1704-010771

Client: B6
Patient:

ECG from Cardio

B6

B6 11:54:52 AM
Tufts University
Tufts Cummings School of Vet Med
Cardiology

12 Lead: Standard Placement

FDA-CVM-FOIA-2019-1704-010772

Client: B6
Patient:

Patient History

B6

04:57 PM	Vitals
04:57 PM	Vitals
04:57 PM	Vitals
04:57 PM	Vitals
05:05 PM	UserForm
05:06 PM	UserForm
07:23 PM	Vitals
07:23 PM	Vitals
07:23 PM	Vitals
07:23 PM	Vitals
08:13 PM	UserForm
08:52 PM	Purchase
08:53 PM	Purchase
08:53 PM	Purchase
08:55 PM	Purchase
08:58 PM	Labwork
09:08 PM	Treatment
09:28 PM	Purchase
09:28 PM	Purchase
09:33 PM	Treatment
09:34 PM	Treatment
09:34 PM	Vitals
10:12 PM	Treatment
10:12 PM	Treatment
10:12 PM	Vitals
10:12 PM	Vitals
10:12 PM	Treatment
10:12 PM	Vitals
10:46 PM	Purchase
10:46 PM	Purchase
10:46 PM	Purchase
11:52 PM	Treatment
11:52 PM	Treatment
11:52 PM	Vitals
11:52 PM	Vitals
11:53 PM	Treatment
11:53 PM	Vitals
11:53 PM	Treatment
11:53 PM	Vitals
01:00 AM	Treatment
01:00 AM	Vitals
01:00 AM	Vitals

B6

FDA-CVM-FOIA-2019-1704-010773

Client: B6
Patient:

Patient History

	01:33 AM	Treatment
	01:37 AM	Treatment
	01:37 AM	Vitals
	01:38 AM	Treatment
	01:38 AM	Vitals
	01:50 AM	Treatment
	01:50 AM	Vitals
	01:50 AM	Vitals
	02:49 AM	Treatment
	02:49 AM	Vitals
	02:49 AM	Vitals
	03:35 AM	Treatment
	03:35 AM	Vitals
	03:36 AM	Treatment
	03:36 AM	Vitals
	03:36 AM	Vitals
	04:03 AM	Prescription
	04:44 AM	Treatment
B6	04:44 AM	Vitals
	04:44 AM	Vitals
	05:30 AM	Treatment
	05:37 AM	Treatment
	05:37 AM	Treatment
	05:37 AM	Vitals
	05:37 AM	Treatment
	05:37 AM	Vitals
	05:38 AM	Treatment
	05:38 AM	Vitals
	05:39 AM	Treatment
	05:39 AM	Vitals
	05:39 AM	Treatment
	05:39 AM	Vitals
	06:30 AM	Treatment
	06:30 AM	Treatment
	06:30 AM	Vitals
	06:30 AM	Vitals
	06:30 AM	Vitals
	07:28 AM	Treatment
	07:28 AM	Vitals
	07:56 AM	Purchase
	08:01 AM	Treatment

B6

FDA-CVM-FOIA-2019-1704-010774

Client: B6
Patient:

Patient History

	08:01 AM	Vitals
	08:01 AM	Vitals
	08:23 AM	Purchase
	08:55 AM	Treatment
	08:55 AM	Vitals
	08:55 AM	Vitals
	08:56 AM	Treatment
	08:56 AM	Treatment
	08:56 AM	Vitals
	09:09 AM	Purchase
	09:11 AM	Purchase
	10:04 AM	Vitals
	10:04 AM	Vitals
	10:05 AM	Vitals
	10:24 AM	Treatment
	10:25 AM	Treatment
	10:40 AM	UserForm
	11:07 AM	Treatment
	11:07 AM	Vitals
	11:07 AM	Vitals
B6	11:12 AM	Treatment
	11:12 AM	Vitals
	11:13 AM	Treatment
	11:13 AM	Vitals
	11:13 AM	Purchase
	11:58 AM	Treatment
	11:59 AM	Purchase
	11:59 AM	Purchase
	12:08 PM	Purchase
	12:20 PM	Vitals
	12:20 PM	Purchase
	12:28 PM	Treatment
	12:28 PM	Vitals
	12:28 PM	Vitals
	12:55 PM	Treatment
	12:55 PM	Vitals
	12:55 PM	Vitals
	01:40 PM	Treatment
	01:40 PM	Vitals
	01:40 PM	Vitals
	01:42 PM	Treatment
	01:42 PM	Treatment

B6

FDA-CVM-FOIA-2019-1704-010775

Client: B6
Patient:

Patient History

	01:42 PM	Vitals
	01:42 PM	Treatment
	01:42 PM	Vitals
	02:12 PM	Prescription
	02:13 PM	Purchase
	02:42 PM	Purchase
	02:48 PM	Treatment
	02:56 PM	Treatment
	02:56 PM	Vitals
	02:56 PM	Vitals
	02:57 PM	Treatment
	03:50 PM	Treatment
	03:50 PM	Vitals
	03:50 PM	Vitals
	03:51 PM	Treatment
	03:51 PM	Vitals
	04:53 PM	Treatment
	04:53 PM	Vitals
	04:53 PM	Vitals
B6	05:26 PM	Treatment
	05:26 PM	Vitals
	05:27 PM	Treatment
	05:27 PM	Treatment
	05:27 PM	Vitals
	05:27 PM	Treatment
	05:27 PM	Vitals
	05:28 PM	Treatment
	05:28 PM	Vitals
	05:28 PM	Vitals
	05:31 PM	Treatment
	05:31 PM	Vitals
	05:31 PM	Treatment
	05:31 PM	Vitals
	05:32 PM	Prescription
	05:42 PM	Treatment
	05:42 PM	Vitals
	05:49 PM	Prescription
	06:24 PM	Treatment
	06:24 PM	Treatment
	06:26 PM	Treatment
	06:26 PM	Vitals

B6

FDA-CVM-FOIA-2019-1704-010776

Client: B6
Patient:

Patient History

	06:26 PM	Vitals
	07:11 PM	Treatment
	07:11 PM	Vitals
	07:33 PM	Treatment
	07:33 PM	Vitals
	07:33 PM	Vitals
	08:37 PM	Treatment
	08:37 PM	Vitals
	08:37 PM	Vitals
	08:59 PM	Treatment
	09:04 PM	Treatment
	09:04 PM	Treatment
	09:04 PM	Vitals
	09:04 PM	Treatment
	09:04 PM	Vitals
	09:13 PM	Purchase
	09:13 PM	Purchase
	10:11 PM	Treatment
	10:11 PM	Vitals
	10:11 PM	Vitals
B6	10:36 PM	Treatment
	10:36 PM	Vitals
	10:36 PM	Vitals
	10:38 PM	Treatment
	11:20 PM	Treatment
	11:20 PM	Vitals
	11:20 PM	Treatment
	11:20 PM	Vitals
	11:21 PM	Treatment
	11:21 PM	Vitals
	11:21 PM	Vitals
	01:39 AM	Treatment
	01:40 AM	Treatment
	01:40 AM	Vitals
	01:40 AM	Treatment
	01:40 AM	Vitals
	01:40 AM	Vitals
	01:41 AM	Treatment
	01:41 AM	Vitals
	03:26 AM	Treatment
	03:26 AM	Vitals

B6

FDA-CVM-FOIA-2019-1704-010777

Client: B6
Patient:

Patient History

B6

03:26 AM	Vitals
03:26 AM	Treatment
03:26 AM	Vitals
03:30 AM	Treatment
03:30 AM	Vitals
03:30 AM	Vitals
04:27 AM	Treatment
04:27 AM	Vitals
04:27 AM	Vitals
05:52 AM	Treatment
05:53 AM	Treatment
05:53 AM	Vitals
05:53 AM	Vitals
05:55 AM	Treatment
05:55 AM	Vitals
05:55 AM	Treatment
05:55 AM	Vitals
05:56 AM	Treatment
05:56 AM	Treatment
05:56 AM	Vitals
06:00 AM	Treatment
06:00 AM	Vitals
06:00 AM	Treatment
06:00 AM	Vitals
06:00 AM	Treatment
06:00 AM	Vitals
06:41 AM	Treatment
06:41 AM	Vitals
06:41 AM	Vitals
07:24 AM	Treatment
07:34 AM	Vitals
07:34 AM	Treatment
07:35 AM	Treatment
07:35 AM	Vitals
07:35 AM	Vitals
07:35 AM	Treatment
07:35 AM	Vitals
08:37 AM	Treatment
08:37 AM	Vitals
08:37 AM	Vitals
09:11 AM	Purchase

B6

FDA-CVM-FOIA-2019-1704-010778

Client: B6
Patient:

Patient History

	09:59 AM	Treatment
	09:59 AM	Vitals
	09:59 AM	Vitals
	10:02 AM	Treatment
	10:02 AM	Vitals
	10:02 AM	Treatment
	10:02 AM	Treatment
	10:02 AM	Vitals
	10:33 AM	UserForm
	10:50 AM	Treatment
	10:50 AM	Vitals
	10:50 AM	Vitals
	11:29 AM	Treatment
	11:29 AM	Vitals
	11:47 AM	Deleted Reason
	11:55 AM	Treatment
	11:55 AM	Vitals
B6	11:55 AM	Vitals
	11:55 AM	Treatment
	11:55 AM	Vitals
	11:57 AM	Purchase
	12:05 PM	Prescription
	12:05 PM	Prescription
	12:06 PM	Purchase
	12:45 PM	Treatment
	12:45 PM	Vitals
	12:45 PM	Vitals
	01:43 PM	Treatment
	01:44 PM	Treatment
	01:44 PM	Vitals
	01:44 PM	Vitals
	02:07 PM	Treatment
	02:07 PM	Vitals
	02:07 PM	Treatment
	02:07 PM	Vitals
	02:57 PM	Treatment
	02:57 PM	Vitals
	02:57 PM	Vitals
	02:59 PM	Treatment

B6

FDA-CVM-FOIA-2019-1704-010779

FDA-CVM-FOIA-2019-1704-010780

Cummings
Veterinary Medical Center
AT TUFTS UNIVERSITY

B6

B6 Male (Neutered)
Canine Bulldog Cross White/Yellow
Patient ID: B6

STANDARD CONSENT FORM

I am the owner, or agent for the owner, of the above described animal and have the authority to execute consent. I hereby authorize the Cummings School of Veterinary Medicine at Tufts University (herein after Cummings School) to prescribe for treatment of said animal according to the following terms and conditions.

Cummings School and its officers, agents and employees will provide such veterinary medical care as they deem reasonable and appropriate under the circumstances.

Cummings School and its officers, agents, and employees will use all reasonable care in the treatment of the above mentioned animal, but will not be liable for any loss or accident that may occur or any disease that may develop as a result of the care and treatment provided.

I understand that the above identified animal may be treated by Cummings School students under the supervision and assistance of Cummings School staff members.

In executing this form, I hereby expressly acknowledge that risks, benefits and alternative forms of treatment have been explained to me. I understand said explanation, and I consent to treatment. Should any additional treatments or diagnostics be required during the continued care of my animal, I understand that I will be given the opportunity to discuss and consent to these additional procedures. I understand that further or additional treatment may be required without an opportunity for discussion and consideration by me, in the case of the development of any life-threatening emergency during the continued care of my animal and I expressly consent to all such reasonable treatment as required. I realize and understand that results cannot be guaranteed.

If any equipment is left with the animal, it will be accepted with the understanding that Cummings School assumes no responsibility for any loss of equipment that may occur.

I agree to pick up the animal when notified that it is ready for release.

In the event the animal is not picked up, and if ten (10) days have expired since a registered letter was sent to the address given above, notifying me to call for the animal, the animal may be sold or otherwise disposed of in a humane manner and the proceeds applied to the charges incurred in caring and treating the animal. Failure to remove said animal will not and does not relieve me from obligation for the costs of services rendered.

I hereby grant to the Cummings School of Veterinary Medicine at Tufts University, its officers and employees (collectively referred to herein as Cummings School), and its agents and assigns (the Grantees) the irrevocable rights to photograph / videotape the operation or procedure to be performed, including appropriate and otherwise use such photographs and images for, and in connection with, a Grantee's medical, scientific, educational, and publicity purposes, by any means, methods and media (print and electronic) now known or, in the future, developed that the Grantee deems appropriate (provided that such photographs and images may not be used in for-profit commercials, unless such commercials are publicizing educational programs at Cummings School). As medical and surgical treatment necessitates the removal of tissue, cells, fluids or body parts of my animal, I authorize the Grantees to dispose of or use these tissues, cells, fluids or body parts for scientific and educational purposes.

I understand that a FINANCE CHARGE will be applied to all accounts unpaid after 30 days. The FINANCE CHARGE is computed on a monthly rate of 1.33% per month, which is an annual percentage rate of 16% applied to the average daily balance outstanding, with a minimum fee of $.50.

I do further agree that should any payment, or the full amount of the sum stated above, become overdue more than 20 days from the above-agreed upon time of payment or payments, the entire balance shall be considered in default and become due and payable. I further agree to be responsible for any or all collection agency and/or attorney fees necessary to collect the full amount.

I do further agree to comply with hours of visitation in conjunction with our Hospital's policy.

I have read, understand, and agree to accept the terms and conditions herein.

Owner's name: B6 Date: B6

Owner's address: B6

B6

B6

Date

If the individual admitting the animal is someone other than the legal owner, please complete the portion below:

The owner of the animal, B6 has granted me authority to obtain medical treatment and to bind this owner to pay the veterinary medical services provided at Cummings School pursuant to the terms and conditions described above

Authorized Agent – Please Print

Agent's Signature

Street Address

Date

Town/City State Zip

Cummings
Veterinary Medical Center
AT TUFTS UNIVERSITY

B6

Patient ID: B6
B6 Canine
B6 Years Old Male (Neutered) Bulldog Cross
Body Weight: Weight (kg) 0.00

Brachycephalic Consent Form

Anesthesia, Sedation and Hospitalization

Brachycephalic is a term for "short-nosed". Several dog breeds may experience difficulty breathing due to the shape of their head, muzzle and throat. Shorter nosed dogs include English Bulldogs, French Bulldogs, Pugs, Boston Terriers and many other breeds. The shorter than average nose and face in proportion to their body size can cause problems for these breeds at times. Owners with brachycephalic breeds must pay extra attention to their animals during exercise, heat and while obtaining veterinary care.

Overview

The purpose of this form is to inform you of the risks associated with anesthesia/sedation and occasionally hospitalization, which are inherent for dogs with shorter noses (brachycephalic). Not all of these problems may apply to your dog, but these are part of the brachycephalic syndrome. Please discuss any specific concerns with your attending veterinarian.

Respiratory problems

Brachycephalic dogs have a shortened skull, resulting in a compressed nasal passage and abnormal throat anatomy. The abnormal upper airway anatomy causes increased negative pressure while taking a breath, leading to inflammation, deformation of throat tissues, and obstruction of breathing. We encourage corrective surgery in moderate to severely affected dogs.

Cooling problems

As dogs cool by panting, dogs with narrowed airways may have difficulty cooling themselves. This may be made worse by anxiety or stress.

Stomach and intestinal problems

Brachycephalic dogs may swallow a lot of air which can lead to increased vomiting or regurgitation, and this could lead to pneumonia. If possible, we pre-treat brachycephalic dogs with medications to reduce stomach acids, and to promote stomach emptying.

Restraint challenges

Due to their airway, and in some bulldogs, their intrinsic personality as "tough" dogs, it may be difficult to restrain them safely. This is a particularly significant problem with more aggressive dogs. We

occasionally need to sedate them, or ask family members to help with some routine procedures to avoid unnecessary stress on the patient.

Sedation and anesthesia

While sedation and anesthesia are commonly performed in brachycephalic breeds, especially bulldogs, recovery from anesthesia may be more difficult for these patients due to a narrowed airway. We have our anesthesia team very closely involved in sedation and anesthesia of brachycephalic breeds especially bulldogs. They have found that careful monitoring is essential to a good outcome. In fact, many dog owners travel some distance in order to ensure that a Tufts board-certified anesthesiologist is present during anesthesia or sedation to minimize the risk of complications.

We consider brachycephalic dogs a high risk population. Please be sure you talk with your doctor about the following:

1. Any medical and/or surgical treatment alternatives for your pet
2. Sufficient details of this consent form and how they apply to your dog
3. How fully your pet might respond or recover and how long it could take
4. The most common complications and how serious they might be

I grant permission for my pet to undergo general anesthesia/sedation/hospitalization at Tufts Foster Hospital for Small Animals at the Cummings School of Veterinary Medicine.

I am aware that my pet has physical characteristics that make anesthesia and sedation more challenging and possibly more risky than for the average dog with a longer nose.

I am aware that brachycephalic breeds, such as the English and French bulldog, Boston Terrier, Pug, and Pekingese have a shortened skull, resulting in a compressed nasal passage and abnormal throat anatomy. The abnormal upper airway anatomy causes increased negative pressure while taking a breath, leading to inflammation, deformation of throat tissues, and obstruction of breathing.

I am aware that if my brachycephalic pet undergoes sedation or general anesthesia the potential complications include partial or complete airway obstruction during recovery and regurgitation/vomiting which could lead to aspiration pneumonia/respiratory distress. With airway surgery, death has been reported as a rare complication in <3% of cases.

I am aware that anesthetizing or sedating a brachycephalic animal for any reason can lead to the development of significant complications as described in this document.

Please answer YES or NO to the following questions:

My pet has demonstrated difficulty breathing, exercise intolerance, and/or collapse episodes.

☐ YES ☒ NO

My pet has demonstrated difficulty eating, such as gagging, vomiting, and regurgitation.

☑ YES ☐ NO

My pet is receiving or has recently received a non-steroidal anti-inflammatory drug (e.g., Rimadyl)

☐ YES ☑ NO

Your signature indicates that you have read and understand the above information and give your

consent for treatment

Owner signature: B6

Date: B6

Cummings Veterinary Medical Center
AT TUFTS UNIVERSITY

Treatment Plan

Estimated Charges
10/04/2018

Foster Hospital for Small Animals
55 Willard Street
North Grafton MA 01536
(508) 839-5395
http://vetmed.tufts.edu/

B6

This estimate is based upon our preliminary examination. This is an estimate and is not the final bill. Every effort will be made to keep you informed of the current status of your bill throughout your animal's hospitalization. The final fee may vary considerably from this estimated cost.

Patient	Description	Low Qty	Low Extended	High Qty	High Extended
B6	This estimate includes hospitalization, medication, cardiology consult, bloodwork. It does not include surgery, if indicated.	1.00	B6	1.00	B6

B6

Doctor of Record: B6

Client Signature

I understand that no guarantee of successful treatment is made. I certify that I have read and fully understand the authorization for medical and/or surgical treatment, the reason for why such medical and/or surgical treatment is considered necessary, as well as its advantages and possible complications, if any. I also assume financial responsibility for all charges incurred to this patient(s). I agree to pay 75% of the estimated cost at the time of admission. Additional deposits will be required if additional care or procedures are required. I further agree to pay the balance of the charges when this patient(s) is released.
Procedural billing is inclusive up to and including the estimated duration of hospitalization. There will be additional expenses if hospitalization extends beyond the specified duration.
I have read, understand, and agree to accept the conditions of this treatment plan.

Thank you for entrusting us with your pets care.

High Total	
Low Total	
75% Deposit	

B6

Printed Thursday B6

FDA-CVM-FOIA-2019-1704-010786

Cummings
Veterinary Medical Center
AT TUFTS UNIVERSITY
Cardiology Liaison: 508-887-4696

B6

Patient ID: B6
B6 Canine
B6 Years Old Male (Neutered) Bulldog
Cross
White/Yellow BW: Weight (kg) 32.00

Cardiology Consultation

Date: B6
Weight: Weight (kg) 32.00
Requesting Clinician: B6 DVM (Emergency & Critical Care Resident)

Attending Cardiologist:

- ☐ John E. Rush DVM, MS, DACVIM (Cardiology), DACVECC

B6

Cardiology Resident:

B6

Thoracic radiographs available for review?

- ☐ Yes - in SS
- ☐ Yes - in PACS
- ☐ No

Patient location:
ICU Run

Presenting complaint and important concurrent diseases:

B6

Current medications and doses:

B6

At-home diet: (name, form, amount, frequency)
Rawz limited ingredient wild salmon

Key indication for consultation: (murmur, arrhythmia, needs fluids, etc.)

B6

Suspect DCM based on TFAST

Questions to be answered: Cause of arrhythmia

Is your consult time-sensitive? (e.g., anesthesia today, owner waiting, trying to get biopsy today)

☐ Yes (explain):
☑ No

STOP - remainder of form to be filled out by Cardiology

Physical Examination

B6

Muscle condition:

☐ Normal	☐ Moderate cachexia
☑ Mild muscle loss	☐ Marked cachexia

Cardiovascular Physical Exam

Murmur Grade:

☐ None	☐ IV/VI
☑ I/VI	☐ V/VI
☑ II/VI	☐ VI/VI
☐ III/VI	

Murmur location/description: left systolic apical

Jugular vein:

☑ Bottom 1/3 of the neck	☐ Top 2/3 of the neck
☐ Middle 1/3 of the neck	☐ 1/2 way up the neck

Arterial pulses:

☐ Weak	☐ Bounding
☑ Fair	☐ Pulse deficits
☐ Good	☐ Pulsus paradoxus
☐ Strong	☐ Other (describe):

Arrhythmia: irregularly irregular

☐ None	☐ Bradycardia
☐ Sinus arrhythmia	☐ Tachycardia
☐ Premature beats	

Gallop:

☑ Yes	☐ Pronounced
☐ No	☐ Other:
☐ Intermittent	

Pulmonary assessments:

☑ Eupneic	☐ Pulmonary Crackles
☐ Mild dyspnea	☐ Wheezes
☐ Marked dyspnea	☐ Upper airway stridor
☑ Normal BV sounds	☐ Other auscultatory findings:

Abdominal exam:

☑ Normal	☐ Abdominal distension

☐ Hepatomegaly ☐ Mild ascites

Echocardiogram Findings:

B6

Assessment and recommendations:

DCM with atrial fibrillation and hypotension. The radiographics and physical exam does not suggest that the patient is currently in CHF, but the LA is enlarged enough that I would be worried that he could go into CHF shortly. The patient is also hypotensive. Recommend starting B6 TID, recheck BP tonight to see BP is improved and if dose needs to be increased. Also recheck T4 level. Ideally we can get a taurine level (Whole blood). Start taurine supplementation 1000mg BID. Change diet to non-grain free. Monitor RR/RE at home. Because of the hypotension, I hesitate to start B6 at this time. The dog's HR is not that high at this time, so we can wait until BP is improved become considering B6 Recheck ECG and BP 1 week after discharge.

Final Diagnosis:

DCM, atrial fibrillation

Heart Failure Classification Score:

ISACHC Classification:

☐ Ia ☐ IIIa
☑ Ib ☐ IIIb
☐ II

ACVIM CHF Classification:

☐ A ☐ C
☐ B1 ☐ D
☑ B2

FDA-CVM-FOIA-2019-1704-010789

M-Mode		
IVSd	B6	cm
LVIDd		cm
LVPWd		cm
IVSs		cm
LVIDs		cm
LVPWs		cm
%FS		%
Ao Diam		cm
LA Diam		cm
LA/Ao		
Max LA		cm
EPSS		cm

M-Mode Normalized		
IVSdN	B6	(0.29 - 0.52)
LVIDdN		(1.35 - 1.73) !
LVPWdN		(0.33 - 0.53) !
IVSsN		(0.43 - 0.71) !
LVIDsN		(0.79 - 1.14) !
LVPWsN		(0.53 - 0.78) !
Ao Diam N		(0.68 - 0.89) !
LA Diam N		(0.64 - 0.90) !

2D		
SA LA	B6	cm
Ao Diam		cm
SA LA / Ao Diam		
LVLd A4C		cm
LVEDV MOD A4C		ml
LVLs A4C		cm
LVESV MOD A4C		ml
LVEF MOD A4C		%
SV MOD A4C		ml

Doppler		
MR Vmax	B6	m/s
MR maxPG		mmHg
MV E Vel		m/s
PV Vmax		m/s
PV maxPG		mmHg
AV Vmax		m/s
AV maxPG		mmHg

FDA-CVM-FOIA-2019-1704-010790

Cummings
Veterinary Medical Center
AT TUFTS UNIVERSITY

Foster Hospital for Small Animals
55 Willard Street
North Grafton, MA 01536
Telephone (508) 839-5395
Fax (508) 839-7951
http://vetmed.tufts.edu/

Emergency & Critical Care Liaison: (508) 887 - 4745

Patient Name: B6
Signalment: B6 Years Old White/Yellow Male (Neutered) Bulldog Cross

Owner Name:
Address: B6

Patient ID: B6

Emergency Clinician: B6 DVM (Resident - Cardiology)
Consulting Clinician:

ER Supervisor:

B6

Discharge Instructions

Admit Date: B6 4:55:40 PM
Check Out Date: B6

Case Summary

Thank you for bringing B6 to Tufts, he is such a lovely dog! B6 has been eating random things out of the garbage (dietary indiscretion) but only became anorexic few days ago with some episodes of vomit. Abdominal radiographs performed by your primary veterinarian did not reveal findings consistent with intestinal obstruction or foreign body.

At the presentation, he was alert and responsive but an arrhythymia was noticed and cardiology consult showed that he has a heart disease (dilated cardiomyopathy). This disease is more common in large and giant breed dogs and is characterized by thinning of the walls of the heart, reduced cardiac pump function, and enlargement of the upper chambers of the heart. Many dogs with DCM will also have significant arrhythmias which can be life-threatening and also require medical management. Unfortunately this is a progressive disease and we cannot reverse the changes to the heart muscle, however we can use cardiac medications and some changes to the diet to make your dog comfortable and have him breathing easier.

Also he has been on a diet (grain free) that unfortunately can be associated to cardiac disease and might contribute to worsening of his cardiac function. For this reason, we highly suggest to change his diet and he has been eating and hydrolized diet in the hospital (which we would like to keep him on at home) with good appetite. We also can not rule out that the reason for his dietary indiscretion could be related to some nutritional defficiency. We hope he will respond well to the diet change.

Blood work did not reveal any significant abnormality and B6 has been on anti-nausea medication and responded

well, as his appetite is back and he has not vomited anymore.

Diagnostic test results and findings:

Chest radiograph (x-ray) findings: The heart is enlarged but there is no fluid in the lungs (heart failure)
Echocardiogram findings: All chambers of the heart are enlarged and there is a leak at the mitral valve
ECG findings: The ECG showed a persistent arrhythmia (atrial fibrillation)
Blood pressure findings: The blood pressure is slightly lower than we would like it (80-100mmHg)
Labwork findings: The kidney values are normal.

Monitoring at home:

- We would like you to monitor your dog's breathing rate and effort at home, ideally during sleep or at a time of rest. The doses of drugs will be adjusted based on the breathing rate and effort.
- In general, most dogs with heart failure that is well controlled have a breathing rate at rest of less than 35 to 40 breaths per minute. In addition, the breathing effort, noted by the amount of belly wall motion used for each breath, is fairly minimal if heart failure is controlled.
- An increase in breathing rate or effort will usually mean that you should give an extra dose of B6 B6 if difficulty breathing is not improved by within 30-60 minutes after giving extra B6 then we recommend that a recheck exam be scheduled and/or that your dog be evaluated by an emergency clinic.
- There are instructions for monitoring breathing, and a form to help keep track of breathing rate and drug doses, on the Tufts HeartSmart web site (http://vet.tufts.edu/heartsmart/at-home-monitoring/).
- We also want you to watch for weakness or collapse, a reduction in appetite, worsening cough, or distention of the belly as these findings indicate that we should do a recheck examination.
- If you have any concerns, please call or have your dog evaluated by a veterinarian. Our emergency clinic is open 24 hours/day.

Recommended Medications:

B6

Diet suggestions:

Dogs with heart failure accumulate more fluid in their body if they eat large amounts of sodium (salt). Sodium can be found in all foods, but some foods are lower in sodium than others. Many pet treats, people foods, and supplements used to give pills often have more sodium than is desirable - a sheet that has suggestions for low sodium treats can be found on the HeartSmart web site (http://vet.tufts.edu/heartsmart/diet/).

Exercise Recommendations:

For the first 7 to 10 days after starting medications for heart failure we recommend very limited activity. Leash walking only is ideal, and short walks to start. Once the heart failure is better controlled, then slightly longer walks are acceptable. However, if you find that B6 is lagging behind or needs to stop on a walk then this was too long a walk and shorter walks are advised in the future. Repetitive or strenuous high energy activities (repetitive ball chasing, running fast off-leash, etc.) are generally not advised at this stage of heart failure.

Recheck Visits:

A recheck visit is recommended in 1-2 weeks after any medication adjustments are made. At this visit we will check your dog's breathing effort and heart function, do a blood test to recheck kidney values, and probably recheck a blood pressure. A recheck echocardiogram is recommended in 3-4 months.

Thank you for entrusting us with B6 care. Please contact our Cardiology liaison at (508)-887-4696 or email us at cardiovet@tufts.edu for scheduling and non-emergent questions or concerns.

Please visit our HeartSmart website for more information
http://vet.tufts.edu/heartsmart/

Prescription Refill Disclaimer:
For the safety and well-being of our patients, your pet must have had an examination by one of our veterinarians within the past year in order to obtain prescription medications.

Ordering Food:
Please check with your primary veterinarian to purchase the recommended diet(s). If you wish to purchase your food from us, please call 7-10 days in advance (508-887-4629) to ensure the food is in stock. Alternatively, veterinary diets can be ordered from online retailers with a prescription/veterinary approval.

Clinical Trials:
Clinical trials are studies in which our veterinary doctors work with you and your pet to investigate a specific disease process or a promising new test or treatment. Please see our website: vet.tufts.edu/cvmc/clinical-studies

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Case B6 Owner B6 **Discharge Instructions**

From: PFR Event <pfreventcreation@fda.hhs.gov>

To: Cleary, Michael *; HQ Pet Food Report Notification; B6

Sent: 10/8/2018 6:20:46 PM

Subject: Taste of the Wild High Forest dry: Lisa Freeman - EON-367841

Attachments: 2055791-report.pdf; 2055791-attachments.zip

A PFR Report has been received and PFR Event [EON-367841] has been created in the EON System.

A "PDF" report by name "2055791-report.pdf" is attached to this email notification for your reference. Please note that all documents received in the report are compressed into a zip file by name "2055791-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-367841
ICSR #: 2055791
EON Title: PFR Event created for Taste of the Wild High Forest dry; 2055791

AE Date	01/25/2018	**Number Fed/Exposed**	1
Best By Date		**Number Reacted**	1
Animal Species	Dog	**Outcome to Date**	Stable
Breed	Mixed (Dog)		
Age	B6 Years		
District Involved	PFR-New England DO		

Product information
Individual Case Safety Report Number: 2055791
Product Group: Pet Food
Product Name: Taste of the Wild High Forest dry
Description: Feeding Taste of the Wild High Prairie Grain Free (Pine Forest before that). Diagnosed with DCM and CHF this past winter. Owner willing to provide additional information. Our records do not include echo from B6 from Feb, 2018. They also ran taurine at UCD which was reported to be normal. I am getting those records from B6 and will submit as soon as I have them.
Submission Type: Initial
Report Type: Adverse Event (a symptom, reaction or disease associated with the product)

Outcome of reaction/event at the time of last observation: Stable
Number of Animals Treated With Product: 1
Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Taste of the Wild High Forest dry		

Sender information
Lisa Freeman
200 Westboro Rd
North Grafton, MA 01536
USA

Owner information
B6
USA

To view this PFR Event, please click the link below:
https://eon.fda.gov/eon//browse/EON-367841

To view the PFR Event Report, please click the link below:
https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jspa?decorator=none&e=0&issueType=12&issueId=384763

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This email and attached document are being provided to you in your capacity as a Commissioned Official with the U.S. Department of Health and Human Services as authorized by law. You are being provided with this information pursuant to your signed Acceptance of Commission.

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Failure to adhere to the above provisions could result in removal from the approved distribution list. If you think you received this email in error, please send an email to FDAReportableFoods@fda.hhs.gov immediately.

Report Details - EON-367841

ICSR:	2055791		
Type Of Submission:	Initial		
Report Version:	FPSR.FDA.PETF.V.V1		
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)		
Reporting Type:	Voluntary		
Report Submission Date:	2018-10-08 14:14:30 EDT		
Reported Problem:	**Problem Description:**	Feeding Taste of the Wild High Prairie Grain Free (Pine Forest before that). Diagnosed with DCM and CHF this past winter. Owner willing to provide additional information. Our records do not include echo from B6 B6 from Feb, 2018. They also ran taurine at UCD which was reported to be normal. I am getting those records from B6 and will submit as soon as I have them.	
	Date Problem Started:	01/25/2018	
	Concurrent Medical Problem:	No	
	Outcome to Date:	Stable	
Product Information:	**Product Name:**	Taste of the Wild High Forest dry	
	Product Type:	Pet Food	
	Lot Number:		
	Package Type:	BAG	
	Product Use Information:	**Description:**	See diet history in medical records. Owner can provide additional info
		First Exposure Date:	12/01/2017
	Manufacturer /Distributor Information:		
	Purchase Location Information:		
Animal Information:	**Name:**	B6	
	Type Of Species:	Dog	
	Type Of Breed:	Mixed (Dog)	
	Gender:	Female	
	Reproductive Status:	Neutered	
	Weight:	34.1 Kilogram	
	Age:	B6 Years	
	Assessment of Prior Health:	Excellent	
	Number of Animals Given the Product:	1	
	Number of Animals Reacted:	1	
	Owner Information:	**Owner Information provided:**	Yes
		Contact:	**Name:** B6 **Phone:** **Email:**
		Address:	B6 United States
	Healthcare Professional		

FDA-CVM-FOIA-2019-1704-010796

	Information:	**Practice Name:**	Tufts Cummings School of Veterinary Medicine
		Contact:	**Name:** Lisa Freeman
			Phone: (508) 887-4523
			Email: lisa.freeman@tufts.edu
		Address:	200 Westboro Rd North Grafton Massachusetts 01536 United States
Sender Information:	**Name:**		Lisa Freeman
	Address:		200 Westboro Rd North Grafton Massachusetts 01536 United States
	Contact:	**Phone:**	5088874523
		Email:	lisa.freeman@tufts.edu
	Permission To Contact Sender:		Yes
	Preferred Method Of Contact:		Email
Additional Documents:			
	Attachment:		B6 compiled medical records.pdf
	Description:		Compiled medical records
	Type:		Medical Records

FDA-CVM-FOIA-2019-1704-010797

Cummings Veterinary Medical Center
AT TUFTS UNIVERSITY

Foster Hospital for Small Animals
55 Willard Street
North Grafton, MA 01536
(508) 839-5395

All Medical Records

Client:
Address: **B6**

Patient: **B6**
Breed: Hound Cross
DOB: **B6**

Species: Canine
Sex: Female (Spayed)

Home Phone: **B6**
Work Phone: ( ) -
Cell Phone: **B6**

Referring Information

UNKNOWN RDVM **UNKNOWN RDVM** ,
UNKNOWN RDVM **UNKNOWN RDVM** ,

Client:
Patient: **B6**

Initial Complaint:
Scanned Record

Initial Complaint:
Nutrition Phone/In person

SOAP Text Oct 2 2018 5:09PM - Freeman, Lisa

Subjective
Nutrition Phone Consult Notes
PHONE CONSULTATION - NO EXAM PERFORMED

(See Diet History Form and information from referring veterinarian in Documents for additional details)

History: DCM and CHF diagnosed Jan, 2018; history of environmental allergies (ears/skin). Taurine WNL.

Meds: **B6**

Current Diet: (See Diet History Form in Documents and comm log for additional information)

- Current diet: Taste of the Wild High Prairie dry (1 ¾ cup [10 oz cup] or 17.5 oz twice daily). Occasional canned (I and love and you Clucking Good Stew or Wellness Beef Stew)

FDA-CVM-FOIA-2019-1704-010798

- Previous: Taste of the Wild Pine Forest dry (20 oz twice daily)
- Treats/human foods: Homemade dried cooked beef liver or kidneys (dried in oven – keep in freezer); Occasional "I and love and you" jerky treats – venison and lamb but none recently.
- Medication administration: Galbani ricotta cheese ½ teaspoon twice daily

Supplements:

- Supplements: Taurine (Nutricost) – 1000 mg twice daily

Owner Goals:
Diet to help with DCM

Assessment: Possible diet-associated DCM and CHF

Plan: Change diet

- Avoid BEG diets (boutique, exotic ingredient, or grain-free)
- Adequate calories to maintain body weight at 75 pounds
- Reduced sodium from all sources (diet, treats, table food)
- Moderate protein to help maintain muscle mass
- Supplements: Taurine, omega-3 fatty acids
- Owner is ok to have me report to FDA and willing to answer their questions

PHONE CONSULTATION - NO EXAM PERFORMED

Disposition/Recommendations

FDA-CVM-FOIA-2019-1704-010799

FDA-CVM-FOIA-2019-1704-010800

Cummings Veterinary Medical Center
AT TUFTS UNIVERSITY

Foster Hospital for Small Animals
55 Willard Street
North Grafton, MA 01536
(508) 839-5395

Client:	B6
Veterinarian:	
Patient ID:	B6
Visit ID:	

Patient:	B6
Species:	Canine
Breed:	Hound Cross
Sex:	Female (Spayed)
Age:	B6 Years Old

Lab Results Report

Accession ID:

Test	Results	Reference Range	Units

FDA-CVM-FOIA-2019-1704-010801

Client Diet History Form

Submitted: 09/04/2018

PET INFORMATION	
Pet Name	B6
Pet Last Name	
Pet Species/Breed	Dog / Hound (Bloodhound Redbone mix)
Pet's Color	Tan
Pet's Age (Best Guess)	Probably born B6
Pet's Sex	Female
Spayed or Neutered?	Yes
CLIENT INFORMATION	
Client Name	B6
Client Address	
Client Phone	
Client Email	
Co-Owner Name	
Co-Owner Phone	
Co-Owner Email	
CONSULT INFORMATION	
Type of Consult	Phone
HCD Being Requested?	No
Reasons & Goals for Consult	On B6 B6 was diagnosed with DCM. I read the "A broken heart" article about the possible association between grain-free diet and DCM. B6 has been on a gain-free diet, and I'm hoping that a change of diet will help with her condition. As of her weight, she might be just a tad overweight but most likely not by much, perhaps a pound or two.
Attachments	Additional relevant diagnostics IMG_4818.jpeg
PRIMARY VETERINARIAN INFORMATION	
rDVM Name	B6
rDVM Clinic	
rDVM Phone	
rDVM Fax	
rDVM Email	

FDA-CVM-FOIA-2019-1704-010802

Diet History Form - updated

Agree to Terms

Date Submitted
09/04/2018

Information to Gather

About You, Your Veterinarian(s) and Your Pet

What type of appointment are you requesting?
Phone

Has your pet been seen at Tufts in the last 6 months?
No

About the Pet Owner

Pet owner name
B6

Pet owner email
B6

Address
B6
United States

Preferred Phone
B6

Preferred Phone Type
Mobile

Alternate Phone

Is there another phone number you would like to give us in case we can't reach you at one of the above?
No

Spouse/partner/co-owner's name
B6

Spouse/partner/co-owner's email
B6

Spouse/partner/co-owner's phone
(B6

How did you hear about our service?

- Media - interview, article, etc

FDA-CVM-FOIA-2019-1704-010803

Nutrition Diet Hx Form

Your Pet's Primary Veterinarian

Primary veterinarian
B6

Primary veterinarian's clinic name
B6

Primary veterinarian's clinic phone
B6

Primary veterinarian's clinic fax
B6

Primary veterinarian's clinic email
B6

Is your pet currently being (or has your pet been) seen by any other veterinarians in relation to her/his current health issues or other health issues that you'd like to discuss with us?
Yes

Information About Your Second Veterinarian

Name of 2nd veterinarian
B6

Clinic name of 2nd veterinarian
B6

Phone for 2nd veterinarian's clinic
B6

Fax for 2nd veterinarian's clinic
B6

Email for 2nd veterinarian's clinic
B6

What is this second veterinarian's role in your pet's care?
To get an expert opinion on B6 treatment

Should this 2nd veterinarian receive a copy of any written reports that result from working with our service?
No

Is your pet being seen by a 3rd veterinarian?
No

About Your Pet

Pet's name
B6

What is your pet's species?
Dog

FDA-CVM-FOIA-2019-1704-010804

Nutrition Diet Hx Form

Breed
Hound (Bloodhound Redbone mix)

Color
Tan

Sex
Female

Spayed/neutered?
Yes

Do you know your pet's exact birthdate?
No

Pet's Age
Probably born B6

What is your pet's current weight
75

Pounds or kilograms?
lbs

Has your pet gained or lost weight within the past 6 months?
Stayed the same

Which category best describes your pet?
ideal weight

Reason and goals for consultation
On B6 B6 was diagnosed with DCM. I read the "A broken heart" article about the possible association between grain-free diet and DCM. B6 has been on a gain-free diet, and I'm hoping that a change of diet will help with her condition.
As of her weight, she might be just a tad overweight but most likely not by much, perhaps a pound or two.

Details About Your Pet's Habits

Questions about your pet

Is your pet housed:

- Indoors

Please describe your pet's activity level:
Moderate

Do you have any other pets?
Yes

What are your other pets?

Species	How many?
Dogs	two additional dogs

FDA-CVM-FOIA-2019-1704-010805

Nutrition Diet Hx Form

Do any pets have access to other pets' food?
No

How many people (including yourself) live in your household?
3

Who feeds your pet?
Me

How many times per day do you feed your pet?
Twice

Does your pet finish all food that is offered?
Yes

Does your pet have any difficulty with the following?

Does your pet have any of the following?

- Environmental allergies

Please explain about your pet's conditions
Seasonal allergies only. Her underbelly gets dark, and she gets ear infections.

Have you observed any changes in any of the following?

Have you made any recent changes in diet (last 4 weeks)?
No

Your Pet's Diet

Do you feed your pet DRY (e.g., kibble) pet food?
Yes

Please list each kind of DRY petfood individually

Brand or name	Amount per serving	How often given?	Fed since (mo/yr)?
Taste of the Wild High Prairie Grain-Free	1 ¾ cup (cup size 10 oz)	2x/day	Dec 2017
Taste of the Wild Pine Forest Grain-Free	2 cups (cup size 10 oz)	2x/day	Feb 2016

Do you feed your pet WET (e.g., canned or pouched) pet food?
Yes

Please list each kind of WET (e.g., canned or pouched) petfood individually

Brand or name	Amount per serving	How often given?	Fed since (mo/yr)?
"I and love and you" Clucking' Good Stew	Perhaps ½ can	Rarely	Several cans at most since late 2016
Wellness Beef Stew	Perhaps ½ can	Rarely	Several cans at most since late 2016

Do you feed your pet HOME-COOKED food?
No

FDA-CVM-FOIA-2019-1704-010806

Client:
Patient: B6

Nutrition Diet Hx Form

Do you feed your pet TREATS?
Yes

Please list each kind of TREAT individually

Brand or name	Amount per serving	How often given?	Fed since (mo/yr)?
Homemade dried beef liver and kidneys	2-3 small pieces	Perhaps 4 times a week, if that	Not sure, probably less than a year
"I and love and you", Natural Jerky Dog Treats, Venison & Lamb	Small pieces	Not sure, infrequently	Not sure, probably several bags since early 2016
Happy Howie's Premium Turkey Roll	Tiny pieces	Infrequent, a 2 bl log lasted a long time	May 2017 only
Merrick Texas Hold'ems Premium Lamb (or beef) Lung Filets Dog Treats	A little bit, not sure	Infrequently, 2-3 8 oz bag lasted several months	Mid 2016 to early 2017 only
Merrick Lamb Lung Training Dog Treats	A little bit, not sure	Infrequently, the 5 oz bag lasted a while	June-July 2016 only
Stewart Pro-Treat Beef Liver Freeze-Dried Dog Treats	A little bit, not sure	Infrequently, the 21 oz tub lasted a good few months	June-July 2016 only
Beef Marrow Bone Dog Treat & Beef Knee Caps Dog Treats	One piece	Once a month	March & April 2017 only

Is there any OTHER kind of food you feed your pet?
No

Do you give any dietary supplements to your pet (for example: vitamins, glucosamine, fatty acids, herbs, or any other supplements)?
Yes

Please list any dietary supplements

Product Name	Amount	Frequency
Nutricost Taurine 1000mg	2x	daily

Is your pet receiving any medications?
Yes

Please list your pet's medications

Drug Name	Dosage

B6

Do you use food (e.g., Pill Pockets, cheese, bread, peanut butter, etc.) to administer medications?
Yes

Lists foods used to administer medication

What kind?	Amount?	How often?
Ricotta cheese	½ teaspoon	2x daily

Regarding commercial diets (pet foods and treats not made in your home) your pet may have received

FDA-CVM-FOIA-2019-1704-010807

Nutrition Diet Hx Form

in the past, please select the following statement that is most accurate:
I have never fed other commercial diets to my pet

Home-cooked Diets

Is a home-cooked diet being requested? (Please note that this option is only available for phone or in-person consults, not for consults directly with veterinarians.)
No

Medical Records & Test Results

Requested Items

- Additional relevant diagnostics (e.g., urine culture, T4, ultrasound reports)
- Last 6 months' medical records or as appropriate (all consults)

Do you have any of the above in electronic format?
Yes

Additional relevant diagnostics

- Archive.zip

Last 6 months' medical records

Would you like to upload and attach anything else to this form?

- IMG_4818.jpeg

FDA-CVM-FOIA-2019-1704-010808

B6

Patient Chart

Printed: 09-05-18 at 6:47p

CLIENT INFORMATION

Name B6
Address

Spouse B6

PATIENT INFORMATION

Name	B6 (Record - 18741)	**Species**	Canine
Sex	Female, Spayed	**Breed**	Bloodhound Mix
Birthday	B6	**Age**	3y
ID		**Rabies**	011425
Color	Red	**Weight**	75.00 lbs
Reminded	10-01-16	**Codes**	

Reminders for B6

	Last done
02/21	02-21-18
11/19	11-21-16
02/19	02-21-18
02/19	02-21-18
01/19	01-25-18
03/18	**09-27-17**

B6

HEALTH HISTORY SUMMARY

Date	Diagnosis
02-22-18	-Spoke to owner
11-21-16	-Spoke to owner

B6 **Weight history** (in lbs)

02-21-18	75.00
01-22-18	75.30
01-12-18	74.00
12-23-17	71.60
11-30-17	70.90
09-27-17	76.00
05-25-17	68.50
03-23-17	65.60
02-01-17	73.00
12-07-16	64.60
11-21-16	66.10
09-01-16	62.50
08-30-16	62.80
08-23-16	62.20
08-10-16	59.00
05-25-16	58.30
05-04-16	55.10
04-19-16	56.90
02-08-16	52.10

MEDICAL HISTORY

FDA-CVM-FOIA-2019-1704-010809

B6

Patient Chart for B6
Date: 09-05-18, Time: 6:47p

Client B6
Page: 2

Date	By	Code	Description	Qty (Variance)

B6

FDA-CVM-FOIA-2019-1704-010810

B6

Patient Chart for B6 Client B6
Date: 09-05-18, Time: 6:47p Page: 3

Date	By	Code	Description	Qty (Variance)

B6

FDA-CVM-FOIA-2019-1704-010811

B6

Patient Chart fo B6
Date: 09-05-18, Time: 6:47p

Client: B6
Page: 4

Date	By	Code	Description	Qty (Variance)

B6

FDA-CVM-FOIA-2019-1704-010812

B6

Patient Chart for B6 Client: B6
Date: 09-05-18, Time: 6:47p Page: 5

Date	By	Code	Description	Qty (Variance)

B6

FDA-CVM-FOIA-2019-1704-010813

B6

Patient Chart for B6 Client: B6
Date: 09-05-18, Time: 6:47p Page: 6

Date	By	Code	Description	Qty (Variance)

Age: 2y

02-05-18 B6 FNOTE$ By: B6 Rx request
B6 02-05-18 at 2:45p: O is requesting 2 pills of B6 10mg and B6 25mg. Does not want the B6 10mg tablets anymore
B6 02-05-18 at 4:02p: filled. please print the labels.
B6 02-05-18 at 5:11p: labels printed, O will pick up tonight

02-03-18 B6 FNOTE$ By: B6 Update/New Records
B6 02-03-18 at 8:39a: B6 Cardiology Report Attached

FNOTE$ By: B6 P Update
B6 01-31-18 at 9:34a: O emailed yesterday

We met with B6 today. He ran another echo. According to him, the prognosis is terrible and the upcoming week is critical. He'll talk with B6 and will send a written report.

He modified some of the doses:

B6

The other two meds he left the doses the same.

He sent blood work to see her taurine levels.

I placed an order with B6 for all the meds. Can you please let me know when you send them the prescription? I don't want to run out of the meds.

A few questions:

1. When should we bring B6 for blood work? B6 mentioned that we should do a blood test in a week or so to test for kidney issues.
2. Given that B6 has a heart murmur, are there any preventative measures we can take? For example, to give him this supplement or something like it (which also includes Taurine and L-Carnitine)?
https://www.amazon.com/VetriScience-Laboratories-Cardiovascular-Circulatory-Supplement/dp/B0015IO8TA

B6 02-02-18 at 5:50p: O came in to P/U meds and asked when he should Bring in P for renal panel?
B6 02-03-18 at 5:53p: One week after starting medications.

OUTRCD Outside Records
B6 02-03-18 at 8:38a: B6 Cardiology Report Attached

02-02-18 B6 FNOTE$ By: B6 Rx Request
B6 02-02-18 at 10:54a: O emailed that they need 18 pills of the B6 (2 day supply) until their meds arrive from B6 Let O know we will let them know when its ready
B6 02-02-18 at 1:03p: O emailed again asking to Pick up meds at 5:30pm, Let O know again that

FDA-CVM-FOIA-2019-1704-010814

B6

Patient Chart for B6 Client: B6
Date: 09-05-18, Time: 6:47p Page: 7

Date	By	Code	Description	Qty (Variance)

we will let him know when its ready and you are currently in procedures.
B6: 02-02-18 at 3:59p: we can only give the full bottle of B6 will rx that.
B6: 02-02-18 at 4:03p: Sent Email to O that meds are ready for P/U

02-02-18 B6 Tablets 50 count
Please give as directed by: B6

02-01-18 B6 FNOTE$ By: B6 Rx request
B6: 02-01-18 at 6:16p: In your bin, B6 forgot his signature
B6: 02-01-18 at 6:40p: signed
B6: 02-01-18 at 6:56p: attached and faxed

02-01-18 B6 03061 B6 Tablets 18
Give two tablets every eight hours. Once coughing subsides and she is breathing easier, reduce dose to one tablet every eight hours. We will gradually lower dose to lowest effective dose.

FNOTE$ By: B6 Rx form
B6: 01-30-18 at 7:49p: forms for 4 different prescriptions are in your bin
B6: 01-31-18 at 7:46p: O called and asked if we can do the RX forms, informed o that RX time is usually within 24hrs
B6: 01-31-18 at 8:38p: Send it out
B6: 02-01-18 at 8:58a: sent via fax

01-30-18 EM FNOTE$ By: B6 client communication
B6: 01-30-18 at 8:46p: new client communication in chart, most of it regarding Rx form requests in separate follow up

CALL Client Communication
B6: 01-30-18 at 8:38p: O emailed the following message:
"We met with B6 today. He ran another echo. According to him, the prognosis is terrible and the upcoming week is critical. He'll talk with B6 and will send a written report.

He modified some of the doses:

B6

- He added Taurine 2g every 8 hours,
The other two meds he left the doses the same.
He sent blood work to see her taurine levels.

I placed an order with B6 for all the meds. Can you please let me know when you send them the prescription? I don't want to run out of the meds.
A few questions:

1. When should we bring B6 for blood work? B6 mentioned that we should do a blood test in a week or so to test for kidney issues.

FNOTE$ By: B6 Call back/Outside Dr
B6: 01-30-18 at 4:32p: B6 called for you and wanted to discuss his finding for this P. He is only

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B6

Patient Chart for B6 Client B6
Date: 09-05-18, Time: 6:47p Page: 8

Date	By	Code	Description	Qty (Variance)
	available to speak over the phone until 6pm B6			
01-30-18	B6	FNOTE$	By: B6 Update/New Records	
	B6 01-30-18 at 6:09p: echo report and letter attached			
		OUTRECD	Outside Records	
	B6 01-30-18 at 6:10p: echo report and letter attached			
01-27-18	B6	FNOTE$	By: B6 Records request	
	B6 01-27-18 at 8:13a: O need records and rads to be emailed to him,P has appt with B6 on Tuesday. okay to send?			
	B6 01-27-18 at 10:22a: ok to send. make sure the x-rays from Thursday get sent and there were xrays taken in november too (there is one of the heart).			
	B6 01-27-18 at 10:46a: Emailed O records, echo report and all rads			
	01-30-18 at 12:42p: sent via email to B6			
01-26-18	B6	FNOTE$	By: B6 Echocardiogram	
	B6 01-26-18 at 8:22a: Echo Report Attached			
	B6 01-26-18 at 5:07p: O called for Results, O is worried			
	01-26-18 at 5:52p: swo about report. rec cardiologist consult if o is interested. will fill meds.			
	can you email o the report and let him know that B6 rec cardiologist B6 at the B6 B6 and text him when the meds are filled?			
	and can you print the labels?			
	B6 : 01-26-18 at 5:59p: Printed Labels and emailed O			
	: 01-26-18 at 7:50p: O came in to pick up meds			
		1002	B6	30
	Please give 1.5 tablets by mouth twice daily.			
		10101	B6	2
	Please give 1.5 tablet twice daily.			
			B6	
	Please give 2 tablets by mouth twice daily.			
01-25-18	B6	111	Transaction Complete	
01-25-18			B6	3 30
	Give two tablets every eight hours. Once coughing subsides and she is breathing easier, reduce dose to one tablet every eight hours. We will gradually lower dose to lowest effective dose.			
		RAD	Radiographic Series	
	B6 01-26-18 at 8:30a: RADS Attached			
		2313	Office Exam, Recheck	

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B6

Patient Chart for: B6
Date: 09-05-18, Time: 6:47p

Client: B6
Page: 9

Date	By	Code	Description	Qty (Variance)
01-25-18	B6	601	Echocardiogram	
		OD: 01-26-18 at 8:22a: Echo Report Attached		
		2002	Blood Pressure	
		VISIT	Patient check-in	

Drop off for rads
B6 cough hasn't improved. She coughed all night and hardly slept. Yesterday morning she refused to eat, last night she ate a bit of her food and some leftover rice and chicken. This morning she hasn't eaten again and vomited yellow bile. She drinks normally, but behaves weird - staring at us and occasionally panting.

Age: 2y

SUBJECTIVE SECTION

Coughing getting worse. Seems lethargic today

OBJECTIVE SECTION

BARH
Very pronounced cough.

ABNORMALITIES
Heart/Lungs
Gallop arrhythmia -

Normal Systems: Coat, Skin, Vital Signs, Extremities, Urinary/Genital, Gait, Mouth/Teeth, Lymph Nodes, Eyes/Ears/Nose/Throat, Abdomen/GI

ASSESSMENT SECTION

NOTES

Gallop arrhythmia, cardiomegaly on radiograph. Possible pulmonary effusion

PLAN SECTION

NOTES

Spoke with owner. Need echocardiogram.

DIAGNOSTIC PLAN
Blood Pressure
Echocardiogram
Radiographic Series
Office Exam, Recheck

01-22-18	B6	111	Transaction Complete
01-22-18		6019	Office Exam

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B6

Patient Chart for B6 Client: B6
Date: 09-05-18, Time: 6:47p Page: 10

Date	By	Code	Description	Qty (Variance)
01-22-18	B6	B6	mg	2
	Give two tablets twice daily until finished.			
		VISIT	Patient check-in	
	Still Coughing			

Age: 2y **Weight:** 75.30

SUBJECTIVE SECTION

GS2: 01-22-18 at 6:34p: still coughing and panting since the last visit - sent videos through email

Verify Address and Phone Number: same
Verify E-Mail: same
Diet (brand, frequency, amount):
Appetite: eats slower
Drinking: normal
Energy: normal
Urination:normal
Defecation: normal
C/S/V/D: coughing - sometimes tries to vomit but doesn't actually vomit
Medications (type, frequency, dose): none
Vaccine Status: due for da2p & cpv
Lyme (dog only)? never had
Bordetella (dog only)?has had
Influenza (dog only)?has had
Lepto (dog only)?doesn't need
Senior Wellness (>7 yrs): doesn't need yet
Heartworm Status (year round or seasonal?): already has
Flea/Tick preventative (refills needed?): already has
Indoor/Outdoor: both
Other Pets: yes
Microchip: no
Tech discussed:

OBJECTIVE SECTION

BARH

ABNORMALITIES
Normal Systems: Coat, Heart/Lungs, Skin, Vital Signs, Extremities, Urinary/Genital, Gait, Mouth/Teeth, Lymph Nodes, Eyes/Ears/Nose/Throat, Abdomen/GI

ASSESSMENT SECTION

NOTES

Prominent tracheal cough. Lungs sound clear

PLAN SECTION

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B6

Patient Chart for B6 Client B6
Date: 09-05-18, Time: 6:47p Page: 11

Date	By	Code	Description	Qty (Variance)

NOTES

Consider radiographs

TREATMENT PLAN
B6 mg
Give two tablets twice daily until finished.

Office Visit
01-22-18 B6 VISIT Patient check-in
still coughing

01-21-18 EM FNOTE$ By: B6 O question
B6 01-21-18 at 2:35p: O wants to know if it is okay to give flea and tick while P is taking meds for kennel cough
B6 01-21-18 at 2:51p: Yes that would be ok
01-21-18 at 2:59p: emailed O, said giving f&t meds is fine

01-12-18 111 Transaction Complete

B6

B6

SUBJECTIVE SECTION

cough started yesterday, all night mucous noted in am several spots on floor
patient goes to park in am (during off leash hours)
hx of kennel cough end of Nov 2017, pt given ab's - finshed

Verify Address and Phone Number: verified
Verify E-Mail: verified

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B6

Patient Chart for B6 Client: B6
Date: 09-05-18, Time: 6:47p Page: 12

Date	By	Code	Description	Qty (Variance)

Diet (brand, frequency, amount): dry, owner unsure of brand
Appetite: WNL
Drinking: WNL
Energy: WNL, no lethargy noted
Urination: WNL
Defecation: WNL
C/S/V/D: No s, d, v
Medications (type, frequency, dose): none
Vaccine Status: informed of distemper vaccine
Lyme (dog only)? NA
Bordetella (dog only)? up to date
Influenza (dog only)? up to date
Lepto (dog only)? NA
Senior Wellness (>7 yrs):
Heartworm Status (year round or seasonal?): up to date
Flea/Tick preventative (refills needed?):
Indoor/Outdoor: both
Other Pets: 2 other dogs at home
Microchip:
Tech discussed: ear cytology

OBJECTIVE SECTION

ABNORMALITIES
Heart/Lungs
cough on tracheal palp

Eyes/Ears/Nose/Throat
mod brown debris AU

Normal Systems: Coat, Skin, Vital Signs, Extremities, Urinary/Genital, Gait, Mouth/Teeth, Lymph Nodes, Abdomen/GI

ASSESSMENT SECTION

NOTES

mild otitis externa AU
r/o kennel cough vs other

PLAN SECTION

B6

FDA-CVM-FOIA-2019-1704-010820

B6

Patient Chart for B6 Client B6
Date: 09-05-18, Time: 6:47p Page: 13

Date	By	Code	Description	Qty (Variance)

B6

FDA-CVM-FOIA-2019-1704-010821

B6

Patient Chart for B6
Date: 09-05-18, Time: 6:47p

Client: B6
Page: 14

Date	By	Code	Description	Qty (Variance)
			Discussed coag profile, radiogrpaphs. Owner wants to give it a day and see how she does. She ate treats readily in exam room	
			DIAGNOSTIC PLAN	
			Office Visit	
11-30-17	B6	111	Transaction Complete	
11-30-17		6024	Office Visit, Brief	
		VISIT	Patient check-in	
			still coughing	

Age: 2y **Weight:** 70.90

B6

FDA-CVM-FOIA-2019-1704-010822

B6

Patient Chart for B6 Client: B6
Date: 09-05-18, Time: 6:47p Page: 15

Date	By	Code	Description	Qty (Variance)

NOTES

B6 (per o ~90% better)

PLAN SECTION

NOTES

disc cough can take weeks to go away but as long as p continues to improve no need to add in more abx. if p gets worse o to update us, and rec slowly returning to normal activity.

TREATMENT PLAN

Office Visit

11-19-17	B6	111	Transaction Complete	
11-19-17		B6		20

Give one capsule with food twice daily until finished.

6019 Office Exam
VISIT Patient check-in

Coughing, wants to give vx only if doctor thinks P is well enough

Age: 2y

SUBJECTIVE SECTION

11-19-17 at 1:41p: Coughing for about 2 days and has been sneezing But O wants ti vaccinate if the doctor thinks B6 is well enough might have ear infection right ear was scratching at it may have been bite.

B6

FDA-CVM-FOIA-2019-1704-010823

B6

Patient Chart for B6 Client: B6
Date: 09-05-18, Time: 6:47p Page: 16

Date	By	Code	Description	Qty (Variance)

OBJECTIVE SECTION

B6

SUBJECTIVE SECTION

B6

FDA-CVM-FOIA-2019-1704-010824

B6

Patient Chart for B6 Client: B6
Date: 09-05-18, Time: 6:47p Page: 17

Date	By	Code	Description	Qty (Variance)

ASSESSMENT SECTION

B6

FDA-CVM-FOIA-2019-1704-010825

B6

Patient Chart for B6 Client: B6
Date: 09-05-18, Time: 6:47p Page: 18

Date	By	Code	Description	Qty (Variance)

B6

FDA-CVM-FOIA-2019-1704-010826

B6

Patient Chart for: B6
Date: 09-05-18, Time: 6:47p

Client: B6
Page: 19

Date	By	Code	Description	Qty (Variance)

B6

FDA-CVM-FOIA-2019-1704-010827

B6

Patient Chart for B6 Client: B6
Date: 09-05-18, Time: 6:47p Page: 20

Date	By	Code	Description	Qty (Variance)

B6

FDA-CVM-FOIA-2019-1704-010828

B6

Patient Chart for B6 Client: B6
Date: 09-05-18, Time: 6:47p Page: 21

Date	By	Code	Description	Qty (Variance)

PLAN SECTION

B6

FDA-CVM-FOIA-2019-1704-010829

B6

Patient Chart for B6 Client B6
Date: 09-05-18, Time: 6:47p Page: 22

Date	By	Code	Description	Qty (Variance)

B6

FDA-CVM-FOIA-2019-1704-010830

B6

Patient Chart for: B6
Date: 09-05-18, Time: 6:47p

Client: B6
Page: 23

Date	By	Code	Description	Qty (Variance)

B6

FDA-CVM-FOIA-2019-1704-010831

B6

Patient Chart for B6 Client: B6
Date: 09-05-18, Time: 6:47p Page: 24

Date	By	Code	Description	Qty (Variance)

B6

FDA-CVM-FOIA-2019-1704-010832

B6

Patient Chart fo B6
Date: 09-05-18, Time: 6:47p

Client: B6
Page: 25

Date	By	Code	Description	Qty (Variance)

B6

FDA-CVM-FOIA-2019-1704-010833

B6

Patient Chart for B6 Client: B6
Date: 09-05-18, Time: 6:47p Page: 26

Date	By	Code	Description	Qty (Variance)

B6

FDA-CVM-FOIA-2019-1704-010834

B6

Patient Chart for B6 Client: B6
Date: 09-05-18, Time: 6.47p Page: 27

Date	By	Code	Description	Qty (Variance)

B6

FDA-CVM-FOIA-2019-1704-010835

B6

Patient Chart for B6 Client: B6
Date: 09-05-18, Time: 6:47p Page: 28

Date	By	Code	Description	Qty (Variance)

B6

FDA-CVM-FOIA-2019-1704-010836

B6

Patient Chart for B6
Date: 09-05-18, Time: 6:47p

Client B6
Page: 29

Date	By	Code	Description	Qty (Variance)

B6

FDA-CVM-FOIA-2019-1704-010837

B6

Patient Chart for B6 Client B6
Date: 09-05-18, Time: 6:47p Page: 30

Date	By	Code	Description	Qty (Variance)

B6

FDA-CVM-FOIA-2019-1704-010838

B6

Patient Chart for B6 Client: B6
Date: 09-05-18, Time: 6:47p Page: 31

Date	By	Code	Description	Qty (Variance)

B6

FDA-CVM-FOIA-2019-1704-010839

B6

Patient Chart for B6 Client: B6
Date: 09-05-18, Time: 6:47p Page: 32

Date	By	Code	Description	Qty (Variance)

B6

FDA-CVM-FOIA-2019-1704-010840

B6

Patient Chart for B6 Client: B6
Date: 09-05-18, Time: 6:47p Page: 33

Date	By	Code	Description	Qty (Variance)

B6

FDA-CVM-FOIA-2019-1704-010841

B6

Patient Chart for B6
Date: 09-05-18, Time: 6:47p

Client B6
Page: 34

Date	By	Code	Description	Qty (Variance)

B6

FDA-CVM-FOIA-2019-1704-010842

B6

Patient Chart for B6 Client: B6
Date: 09-05-18, Time: 6:47p Page: 35

Date	By	Code	Description	Qty (Variance)

B6

FDA-CVM-FOIA-2019-1704-010843

B6

Patient Chart for B6
Date: 09-05-18, Time: 6:47p

Client: B6
Page: 36

Date	By	Code	Description	Qty (Variance)

B6

FDA-CVM-FOIA-2019-1704-010844

B6

Patient Chart for B6
Date: 09-05-18, Time: 6:47p

Client B6
Page: 37

Date	By	Code	Description	Qty (Variance)

B6

FDA-CVM-FOIA-2019-1704-010845

B6

Patient Chart for B6 Client B6
Date: 09-05-18, Time: 6:47p Page: 38

Date	By	Code	Description	Qty (Variance)

B6

FDA-CVM-FOIA-2019-1704-010846

B6

Patient Chart for: B6
Date: 09-05-18, Time: 6:47p

Client: B6
Page: 39

Date	By	Code	Description	Qty (Variance)

B6

FDA-CVM-FOIA-2019-1704-010847

B6

Patient Chart fo B6
Date: 09-05-18, Time: 6:47p

Client B6
Page: 40

Date	By	Code	Description	Qty (Variance)

NOTES

B6

FDA-CVM-FOIA-2019-1704-010848

B6

Patient Chart for B6 Client B6
Date: 09-05-18, Time: 6:47p Page: 41

Date	By	Code	Description	Qty (Variance)

B6

FDA-CVM-FOIA-2019-1704-010849

Client: B6
Patient:

RDVM B6 **Care echo results 5/2/18**

B6

REFERRING DOCTOR / HOSPITAL: B6

PATIENT INFORMATION

PATIENT'S NAME: B6
RECORD #: B6
DATE OF EXAM: Wednesday, B6
HISTORY: severe DCM

SIGNALMENT B6 FS, mixed breed [canine]
WEIGHT: 75 pounds; [34.1 kg]

ECHOCARDIOGRAM

Left Inflow The left atrium was dilated. LAmax=5.4cm; normally (1.99 - 3.28). LA:Ao=1.5; normally < 1.3. Mitral insufficiency was not detected.

Right Inflow The right atrium was not dilated. Tricuspid insufficiency was not detected.

Left Outflow The left ventricular walls were of appropriate thicknesses. The left ventricle was dilated during diastole suggesting volume overload. Fractional shortening was reduced at 8.6%; normally (33.7 - 45.9%). Aortic velocity (1.6m/s) was wnl and showed laminar flow on PW. Aortic insufficiency was not detected. The left ventricle was dilated in systole at 6.5cm; normally (2.16 - 3.83cm), suggesting reduced systolic function. EPSS (1.8cm; normally < 0.77cm), was increased, suggesting reduced systolic function. HR=152bpm.

Right Outflow Pulmonary arterial velocity (1.3m/s) was wnl and showed laminar flow on PW. Trivial pulmonic insufficiency (1.7m/s; 12mmHg) was detected.

Echo Summary Diastolic LV Dilation; Systolic LV Dilation; LA enlargement; Systolic dysfunction; Trivial pulmonic insufficiency;

Echo Discussion Severe dilated cardiomyopathy persists. Continue medication as prescribed. Monitor EKG for development of atrial fibrillation.

FDA-CVM-FOIA-2019-1704-010850

Client: B6
Patient:

RDVM B6 **Care echo results 5/2/18**

B6

PATIENT'S NAME: B6

GROSS ECHO MEASUREMENTS

		normal range
IVSd		(0.68 - 1.38 cm)
LVIDd	HIGH	(3.58 - 5.22cm)
LVPWd		(0.66 - 1.36cm)
IVSs		(1 - 1.84cm)
LVIDs	HIGH	(2.16 - 3.83cm)
LVPWs		(1.05 - 1.9cm)
%FS	LOW	(33.7 - 45.9%)
HR		
LAmax	HIGH	(1.99 - 3.28)
LA/Ao (boon)	HIGH	< 1.3
TRmax (m/s)		
TRmax (mmHg)		
MRmax (m/s)		
MRmax (mmHg)		
PA max (m/s)		(<2.5m/s)
Pi max (m/s)	see discussion	
AOmax (m/s)		(<2.5m/s)
Ai max (m/s)		

B6

B6 *DVM*
Clinical Sonographer

FDA-CVM-FOIA-2019-1704-010851

Nutrition RDVM Consult Request Form

Referring Veterinarian Nutrition Consult Form - Updated

Date Submitted
09/29/2018

Veterinarian's Name
B6

Practice Name
B6

Practice Address
B6
United States

Email
B6

Phone
B6

Fax
B6

Preferred Method of Contact
Email

How did you hear about our service?

- Your client

Client Name
B6

Client Email
B6

Pet Name
B6

Pet Species
Dog

Pet weight
75

Pounds or kilograms
lbs

Body condition score
5

FDA-CVM-FOIA-2019-1704-010852

Nutrition RDVM Consult Request Form

On what scale?
out of 9

Does this pet have any generalized muscle loss?
No

Type of consult
Client consultation or appointment

Reason for consult
See attached B6 report

Is a home-cooked diet recipe being requested?
No

Current medical concerns
See attached B6 report

Is this pet currently on medication?
Yes

Current medications

Drug	Route	Dose	Frequency
B6	Oral	37.5mg	Every 12 hours
	Oral	15mg	Every 12 hours
	Oral	15mg	Every 8 hours
B6	Oral	60mg	Every 12 hours

Previous medical history
Diagnosed January 2018. Initially brought in for coughing. Owner was feeding Taste of the Wild Bison Formula.

Medical Records

How will you provide the required records?

- I will upload now via this form

File(s)

- 4172_1881_6_s0.jpg
- 4172_1881_7_s0.jpg
- 4172_1881_8_s0.jpg
- 4172_1881_9_s0.jpg
- B6 -Echo-report-26January18.pdf
- B6 -echo-report-letter-30Jan18.pdf
- B6 -Echocardiography-report-30Jan18.pdf
- B6 -Cardiology-Report-2Feb18.pdf
- B6 2018-02-10-0430.pdf
- 4241_1881_1_s0.jpg
- 4241_1881_2_s0.jpg
- B6 -Echo-Results-3May18.pdf
- B6 Meds-update-26Sept18.pdf
- 4172_1881_1_s0.jpg

FDA-CVM-FOIA-2019-1704-010853

- 4172_1881_2_s0.jpg
- 4172_1881_3_s0.jpg
- 4172_1881_4_s0.jpg
- 4172_1881_5_s0.jpg

Diet History

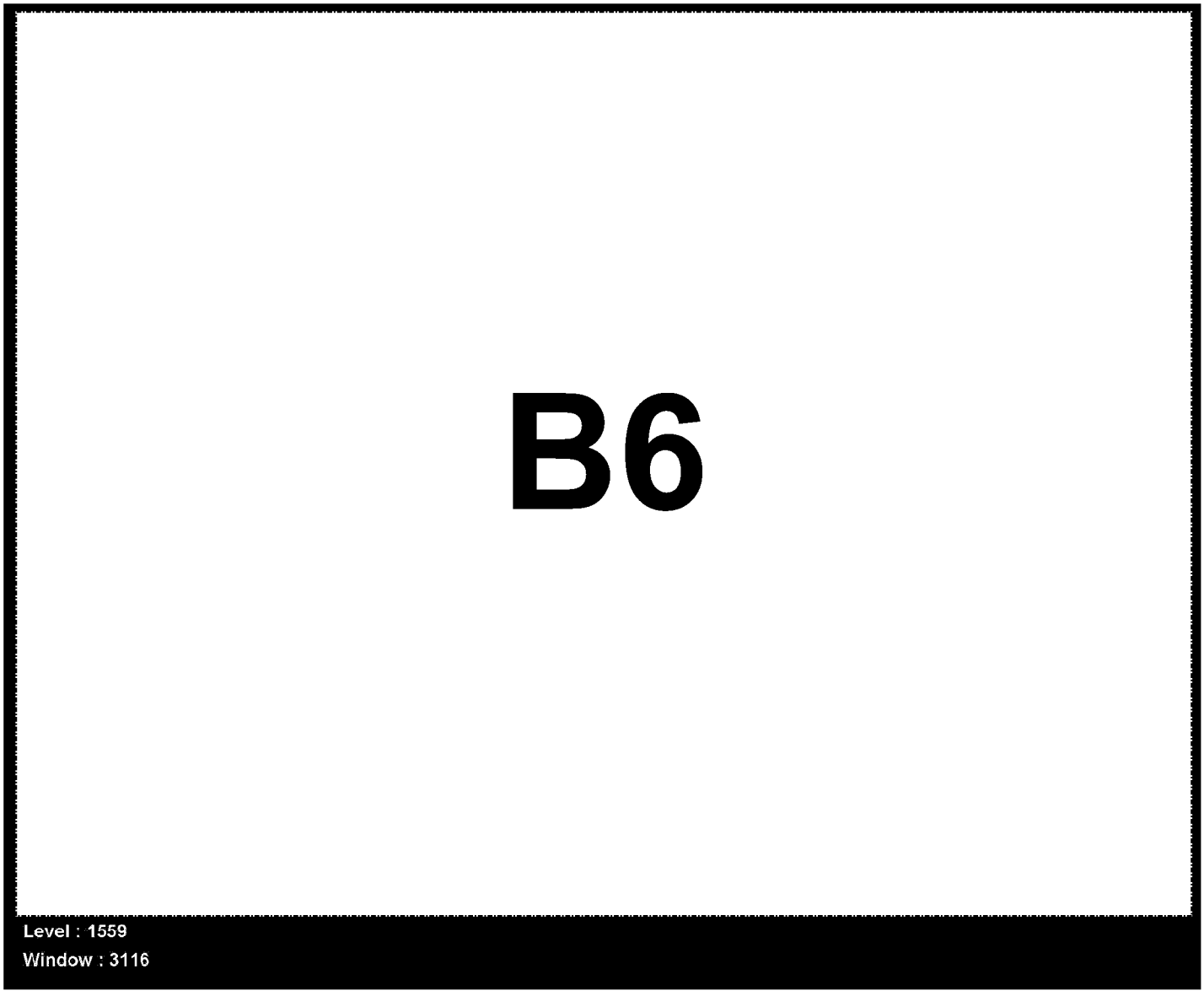
FDA-CVM-FOIA-2019-1704-010854

Client: B6
Patient:

Vitals Results

B6	5:09:37 PM	Muscle Condition Score (MCS)	B6
	5:09:38 PM	Body Condition Score (BCS)	
	5:09:39 PM	Weight (kg)	

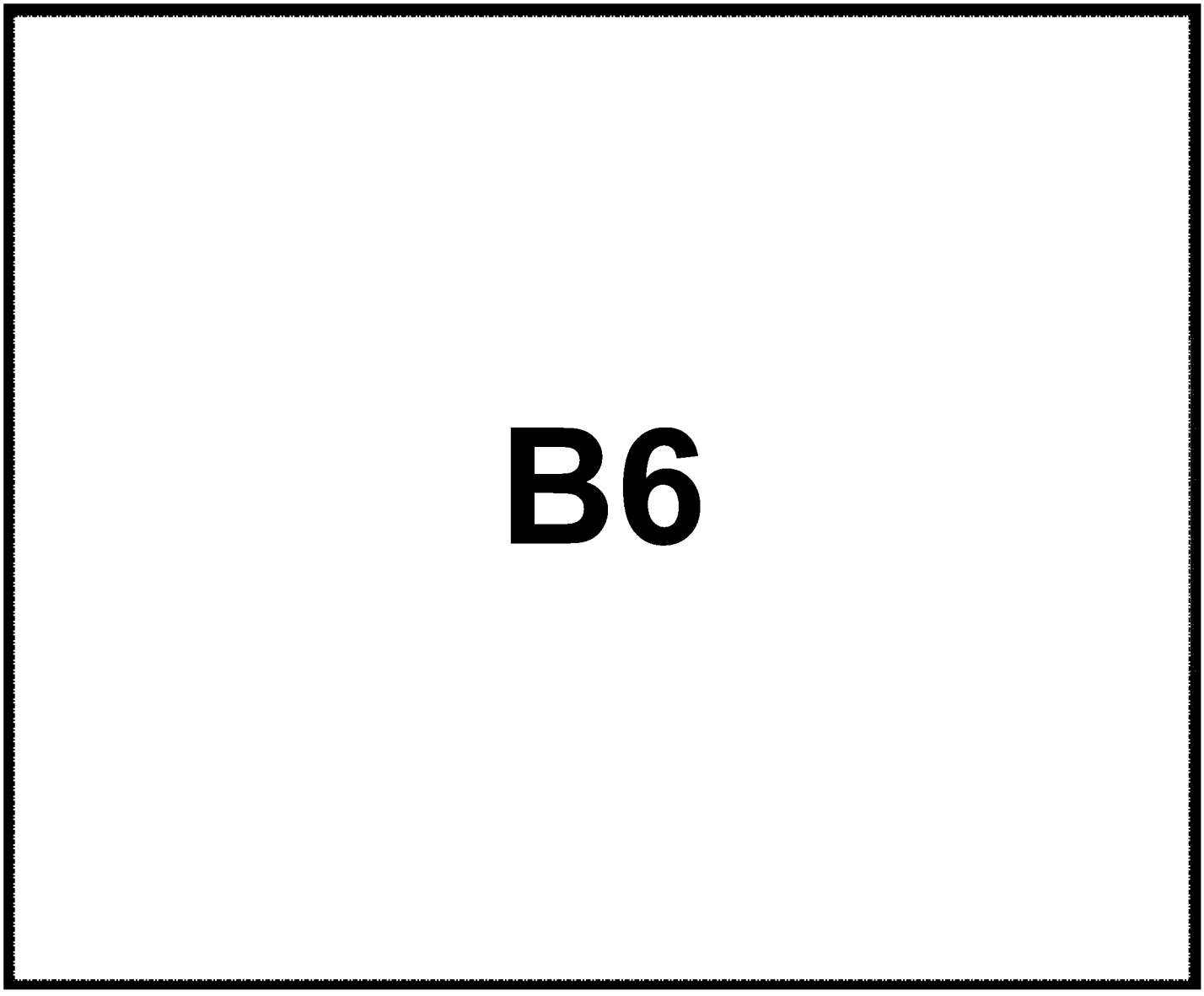
FDA-CVM-FOIA-2019-1704-010855



FDA-CVM-FOIA-2019-1704-010856

B6

FDA-CVM-FOIA-2019-1704-010857



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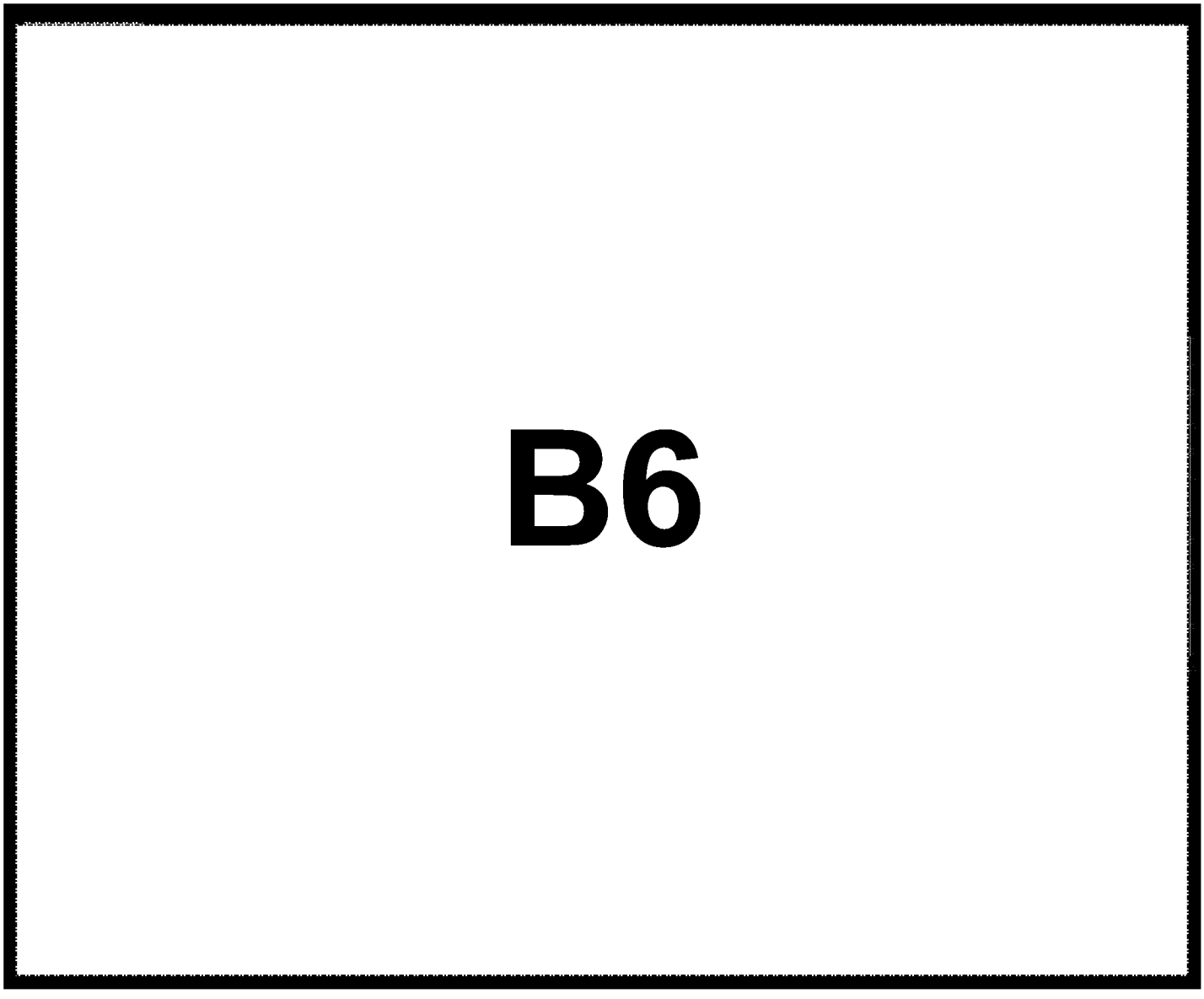

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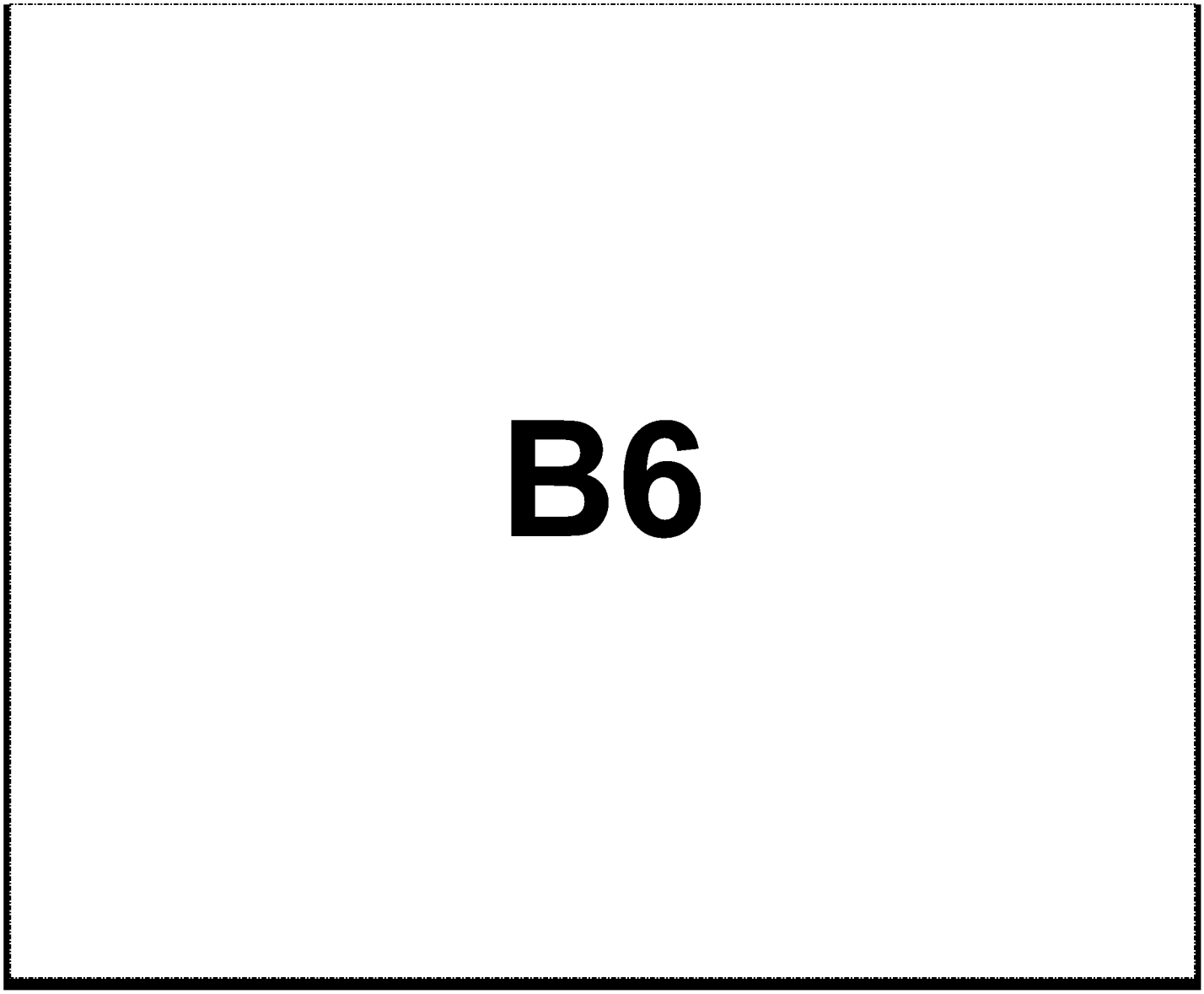

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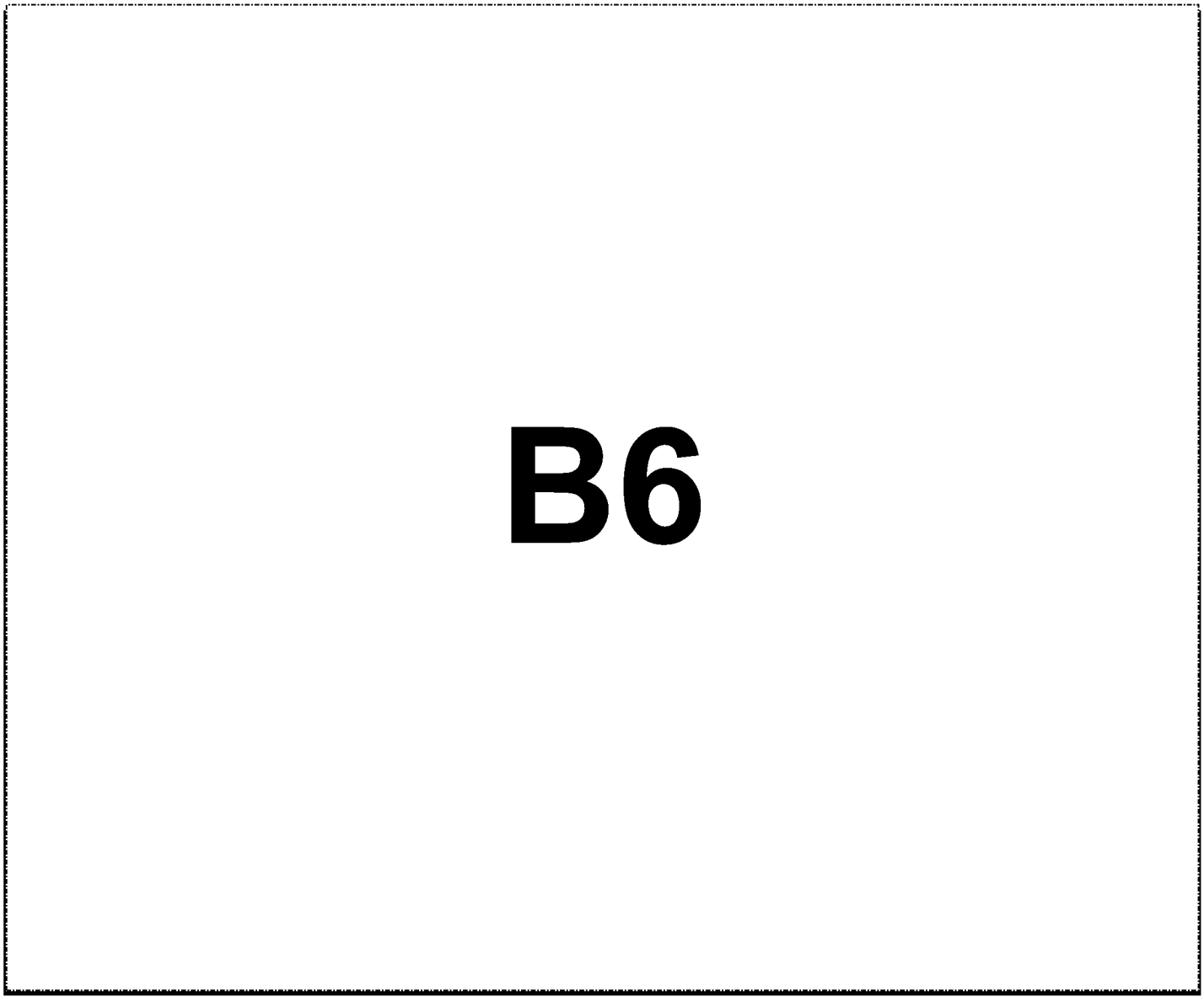

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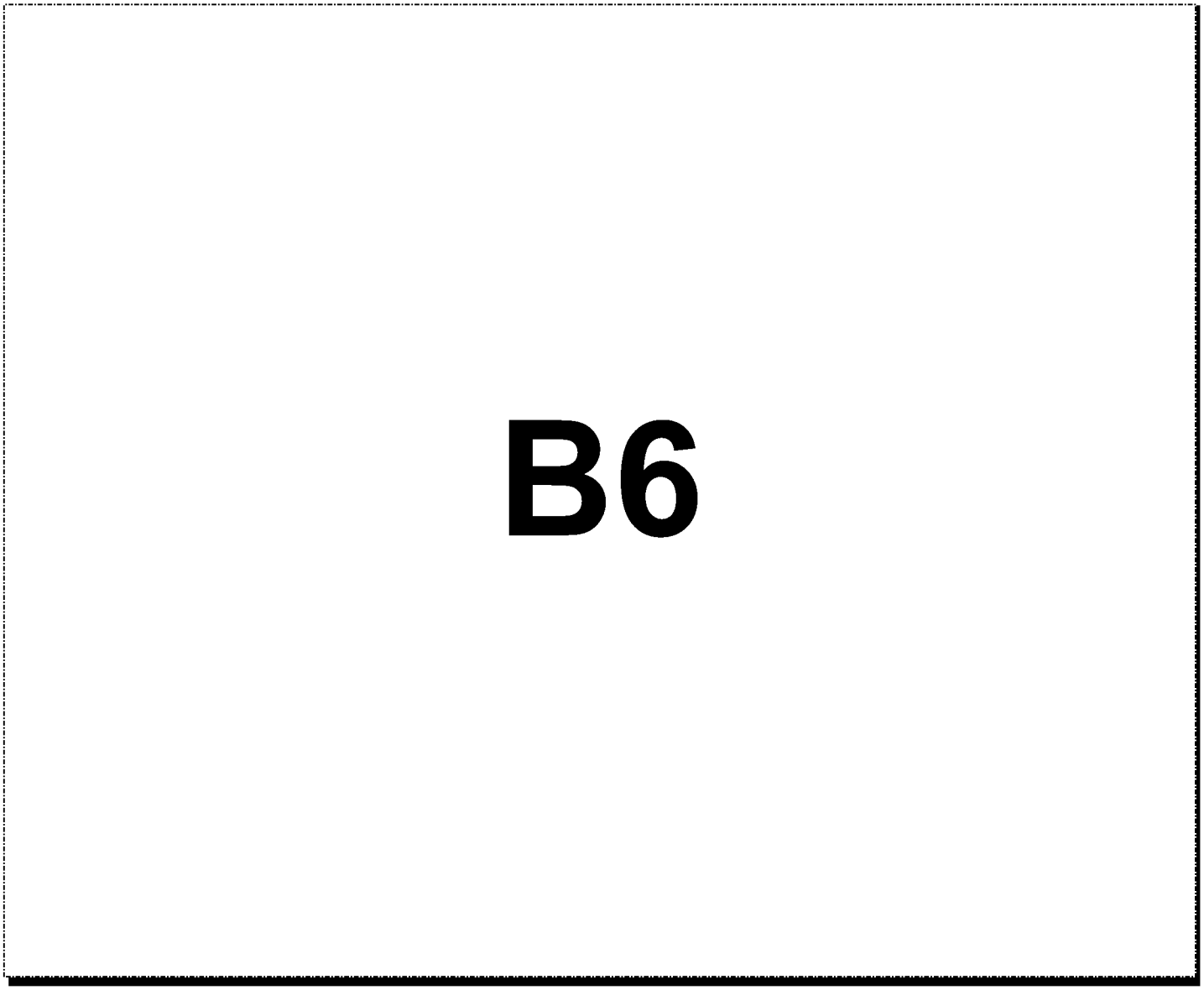
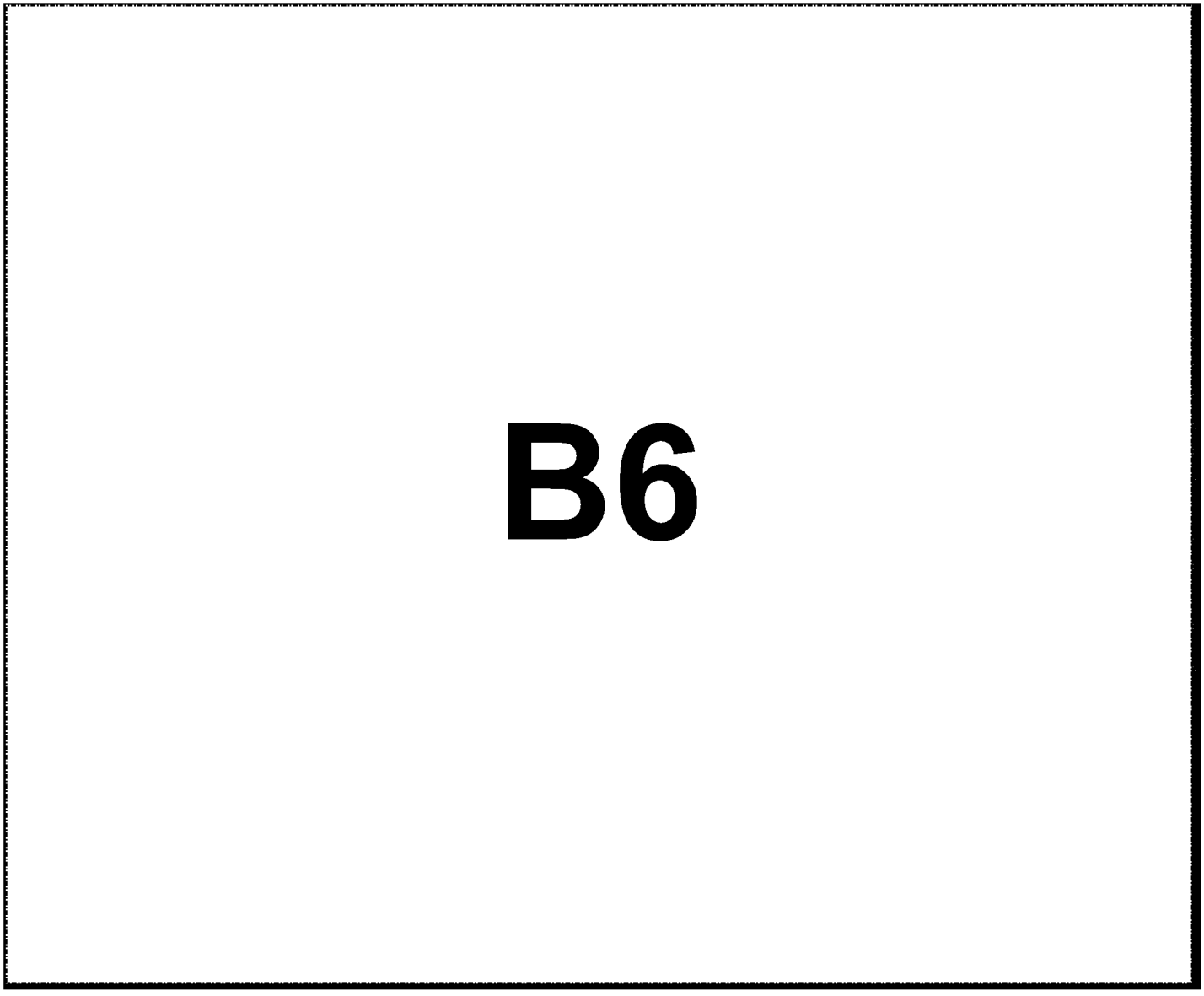
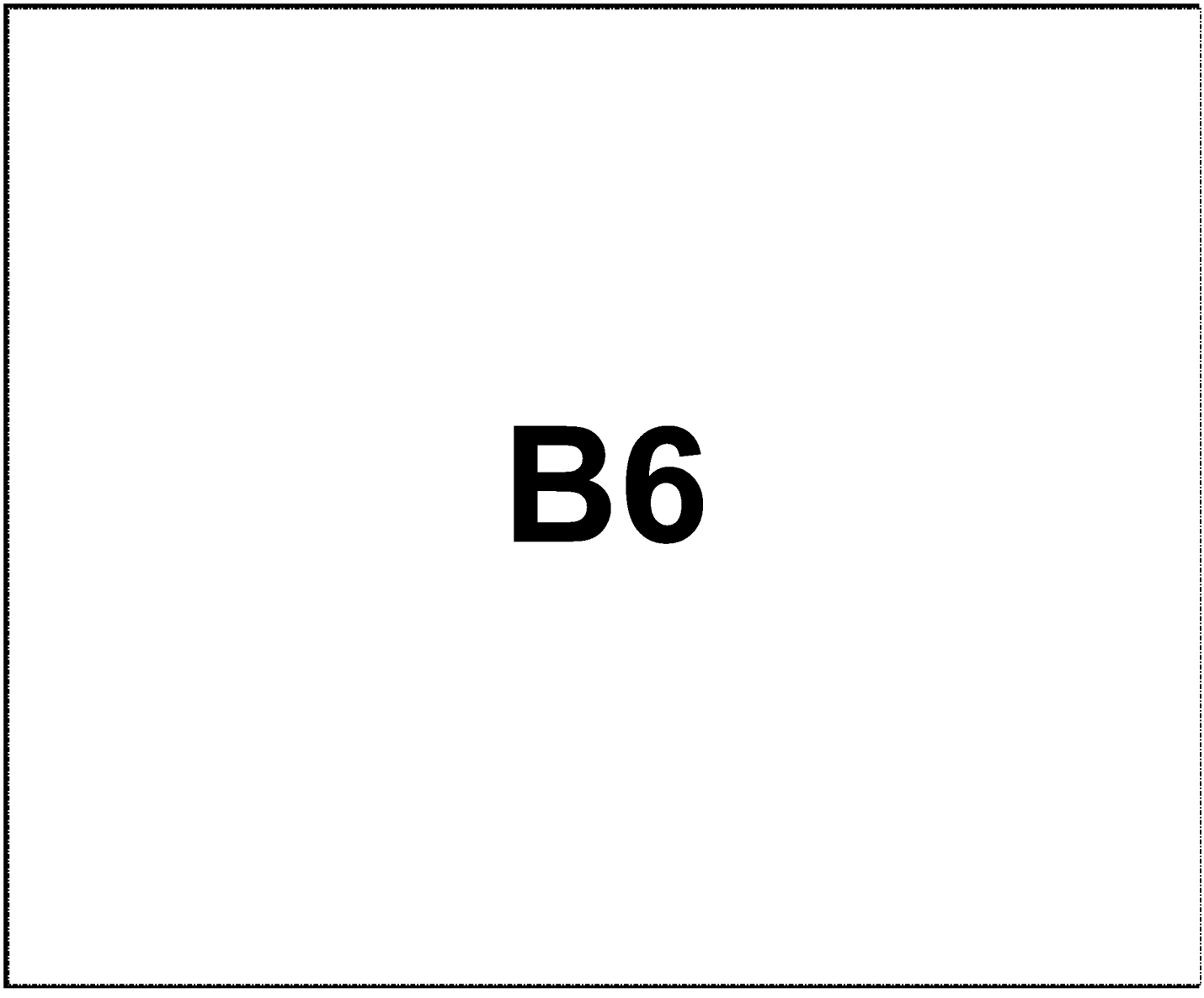


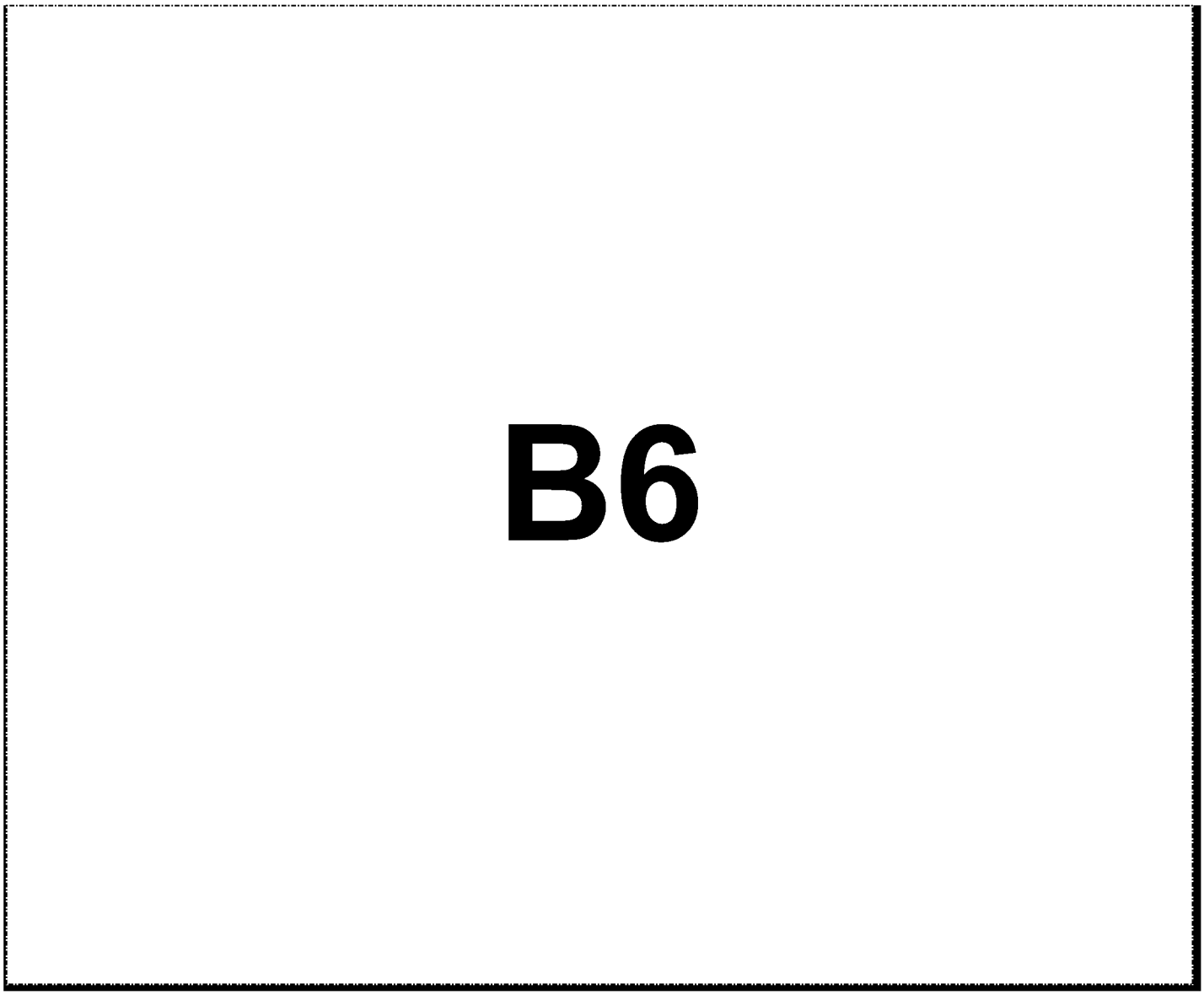
FDA-CVM-FOIA-2019-1704-010862



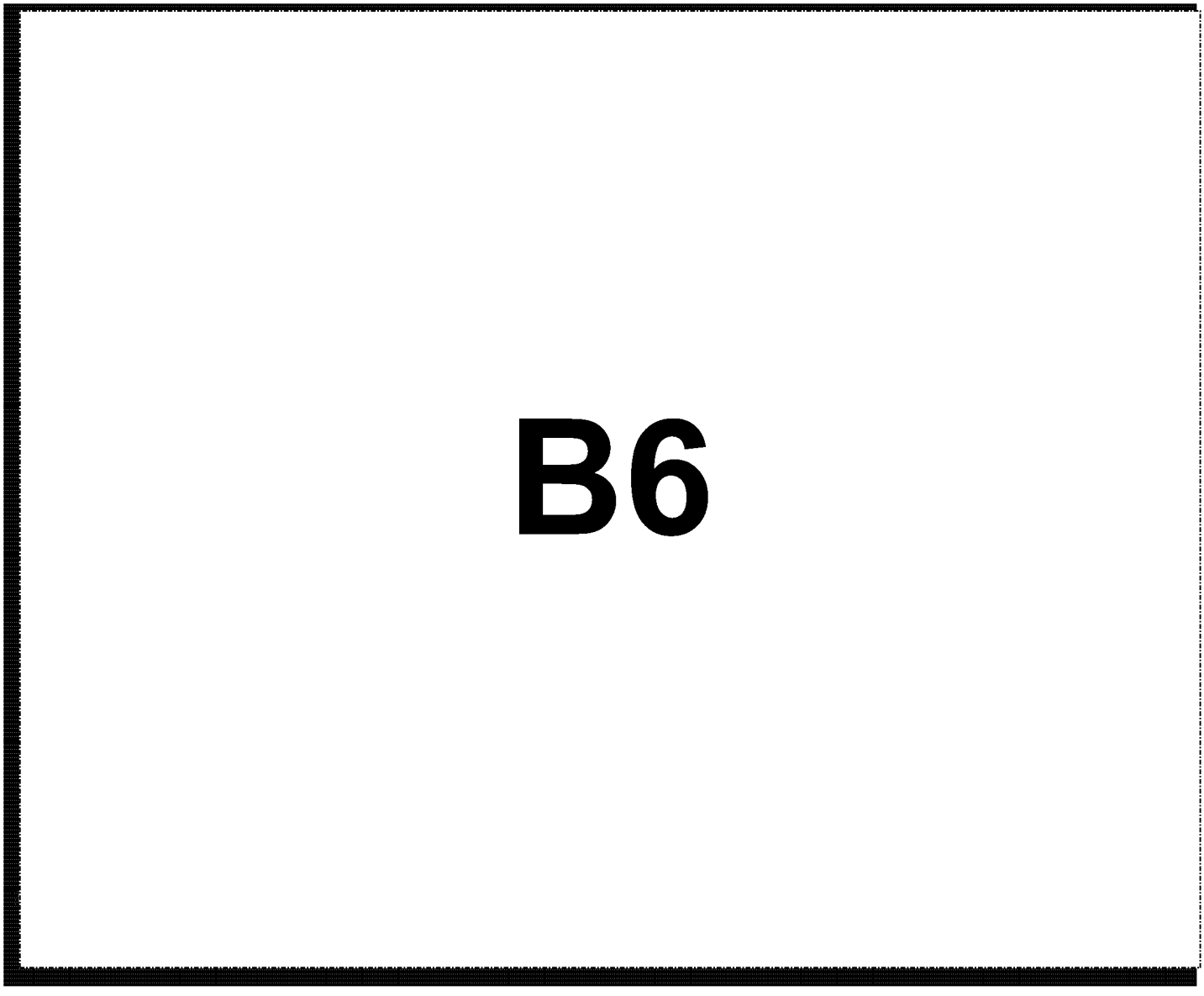
FDA-CVM-FOIA-2019-1704-010863



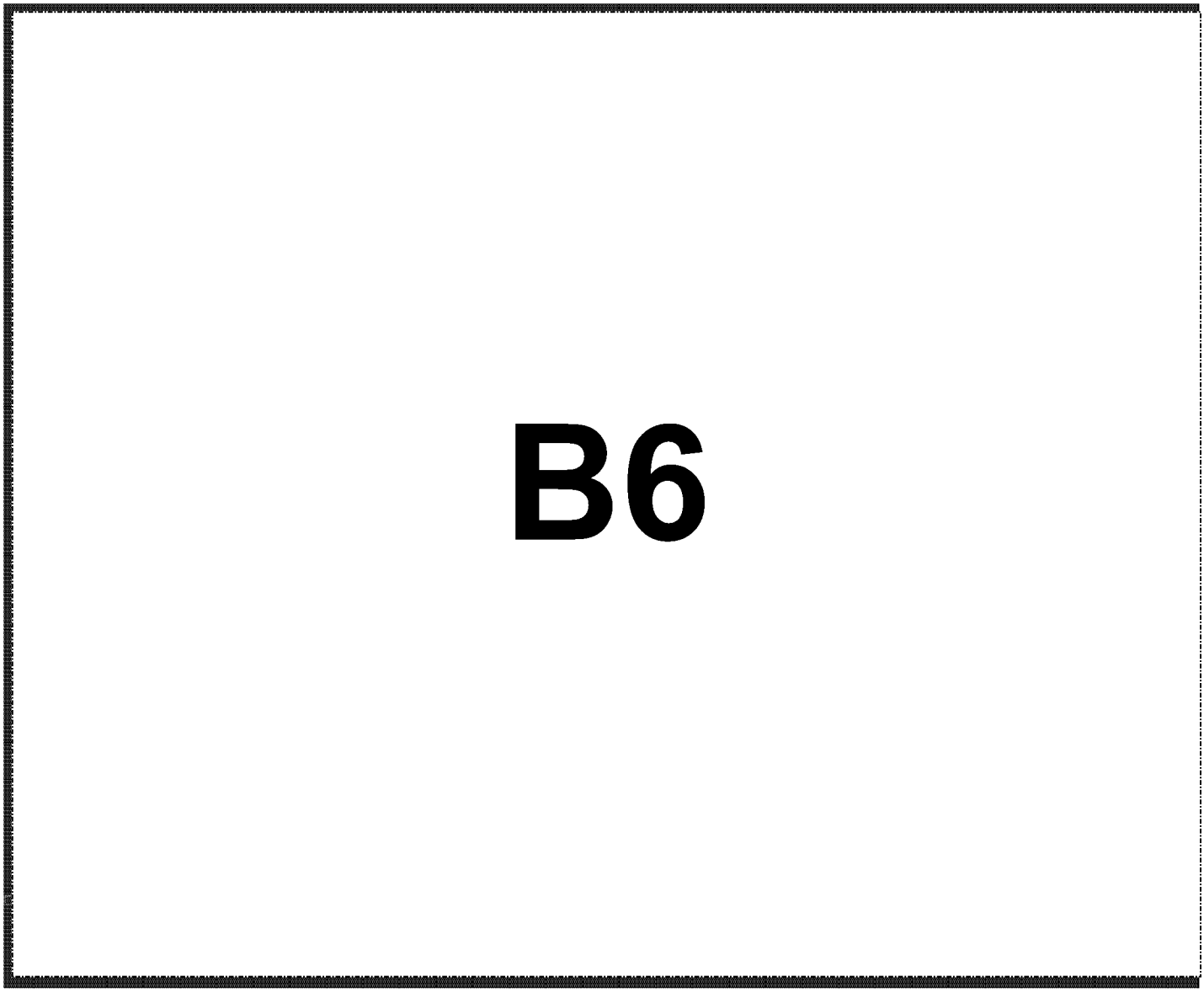
FDA-CVM-FOIA-2019-1704-010864



FDA-CVM-FOIA-2019-1704-010865



FDA-CVM-FOIA-2019-1704-010866



FDA-CVM-FOIA-2019-1704-010867

B6

FDA-CVM-FOIA-2019-1704-010868

B6

FDA-CVM-FOIA-2019-1704-010869

Client:
Patient: B6

Patient History

B6	10:58 AM	Appointment
	05:09 PM	Vitals
	05:09 PM	Vitals
	05:09 PM	Vitals
	05:18 PM	Purchase

B6

FDA-CVM-FOIA-2019-1704-010870

From: PFR Event <pfreventcreation@fda.hhs.gov>

To: Cleary, Michael *; HQ Pet Food Report Notification; B6

Sent: 10/8/2018 7:12:54 PM

Subject: Taste of the Wild Pacific Stream (dry): Lisa Freeman - EON-367849

Attachments: 2055795-report.pdf; 2055795-attachments.zip

A PFR Report has been received and PFR Event [EON-367849] has been created in the EON System.

A "PDF" report by name "2055795-report.pdf" is attached to this email notification for your reference. Please note that all documents received in the report are compressed into a zip file by name "2055795-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-367849
ICSR #: 2055795
EON Title: PFR Event created for Taste of the Wild Pacific Stream (dry); 2055795

AE Date	02/02/2018	**Number Fed/Exposed**	2
Best By Date		**Number Reacted**	1
Animal Species	Dog	**Outcome to Date**	Stable
Breed	Doberman Pinscher		
Age	B6 Years		
District Involved	PFR-New England DO		

Product information
Individual Case Safety Report Number: 2055795
Product Group: Pet Food
Product Name: Taste of the Wild Pacific Stream (dry)
Description: DCM and CHF diagnosed 2/2/18. Owner did not change diet after diagnosis. Just rechecked echo and no improvement. Taurine levels pending and will echo other dog in household on same diet to screen.
Submission Type: Initial
Report Type: Adverse Event (a symptom, reaction or disease associated with the product)
Outcome of reaction/event at the time of last observation: Stable
Number of Animals Treated With Product: 2

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Taste of the Wild Pacific Stream (dry)		

Sender information
Lisa Freeman
200 Westboro Rd
North Grafton, MA 01536
USA

Owner information
B6
USA

To view this PFR Event, please click the link below:
https://eon.fda.gov/eon//browse/EON-367849

To view the PFR Event Report, please click the link below:
https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jspa?decorator=none&e=0&issueType=12&issueId=384771

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Report Details - EON-367849

ICSR:	2055795	
Type Of Submission:	Initial	
Report Version:	FPSR.FDA.PETF.V.V1	
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)	
Reporting Type:	Voluntary	
Report Submission Date:	2018-10-08 15:05:04 EDT	
Reported Problem:	**Problem Description:**	DCM and CHF diagnosed 2/2/18. Owner did not change diet after diagnosis. Just rechecked echo and no improvement. Taurine levels pending and will echo other dog in household on same diet to screen.
	Date Problem Started:	02/02/2018
	Concurrent Medical Problem:	Yes
	Pre Existing Conditions:	B6
	Outcome to Date:	Stable
Product Information:	**Product Name:**	Taste of the Wild Pacific Stream (dry)
	Product Type:	Pet Food
	Lot Number:	
	Package Type:	BAG
	Product Use Information:	
	Manufacturer /Distributor Information:	
	Purchase Location Information:	
Animal Information:	**Name:**	B6
	Type Of Species:	Dog
	Type Of Breed:	Doberman Pinscher
	Gender:	Female
	Reproductive Status:	Neutered
	Weight:	26.8 Kilogram
	Age:	B6 Years
	Assessment of Prior Health:	Excellent
	Number of Animals Given the Product:	2
	Number of Animals Reacted:	1
	Owner Information:	**Owner Information provided:** Yes
		Contact: **Name:** B6
		Phone:
		Email:
		Address: B6 United States
	Healthcare Professional Information:	**Practice Name:** Tufts Cummings School of Veterinary Medicine
		Contact: **Name:** Lisa Freeman
		Phone: (508) 887-4523

FDA-CVM-FOIA-2019-1704-010874

		Email:	lisa.freeman@tufts.edu
		Address:	200 Westboro Rd North Grafton Massachusetts 01536 United States

Sender Information:	**Name:**	Lisa Freeman	
	Address:	200 Westboro Rd North Grafton Massachusetts 01536 United States	
	Contact:	**Phone:**	5088874523
		Email:	lisa.freeman@tufts.edu
	Permission To Contact Sender:	Yes	
	Preferred Method Of Contact:	Email	

Additional Documents:		
	Attachment:	B6 compiled records smaller.pdf
	Description:	B6 compiled records
	Type:	Medical Records

FDA-CVM-FOIA-2019-1704-010875

From:	Rotstein, David </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0A3B17EBFCF14A6CB8E94F322906BADD-DROTSTEI>
To:	Carey, Lauren; Ceric, Olgica; Glover, Mark; Jones, Jennifer L; Nemser, Sarah; Palmer, Lee Anne; Peloquin, Sarah; Queen, Jackie L; Rotstein, David
Sent:	10/26/2018 12:30:01 PM
Subject:	DCM cases 10/26/2018 0827
Attachments:	Blue Wilderness: B6 - EON-369415; Nov 2015-Nov 2017: Nature's Variety Instinct Limited Ingredient Lamb-Nov 2017- Aug 2018: Blue Buffalo Basics Grain Free-Aug 2018-Oct 2018: American Journey Lamb and Sweet Potato: B6 - EON-369375; taste of the wild grain free pacific stream-taste of the wild prey trout limited ingredients B6 - EON-369346; Taste of the Wild High Prairie: Lisa Freeman - EON-369325; WELLNESS CORE GRAIN FREE: B6 - EON-369373

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
CVM OSC/DC/CERT
7519 Standish Place
240-506-6763 (BB)

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From: PFR Event <pfreventcreation@fda.hhs.gov>

To: Cleary, Michael *; HQ Pet Food Report Notification; B6

Sent: 10/25/2018 11:52:42 AM

Subject: Taste of the Wild High Prairie: Lisa Freeman - EON-369325

Attachments: 2057945-report.pdf; 2057945-attachments.zip

A PFR Report has been received and PFR Event [EON-369325] has been created in the EON System.

A "PDF" report by name "2057945-report.pdf" is attached to this email notification for your reference. Please note that all documents received in the report are compressed into a zip file by name "2057945-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-369325
ICSR #: 2057945
EON Title: PFR Event created for Taste of the Wild High Prairie; 2057945

AE Date	02/20/2018	**Number Fed/Exposed**	1
Best By Date		**Number Reacted**	1
Animal Species	Dog	**Outcome to Date**	Died Naturally
Breed	Great Dane		
Age	9 Years		
District Involved	PFR-New England DO		

Product information
Individual Case Safety Report Number: 2057945
Product Group: Pet Food
Product Name: Taste of the Wild High Prairie
Description: DCM, CHF, atrial fibrillation WB taurine = B6 Dog's diet previously submitted to FDA Note: this may be a duplicate submission
Submission Type: Initial
Report Type: Adverse Event (a symptom, reaction or disease associated with the product)
Outcome of reaction/event at the time of last observation: Died Naturally
Number of Animals Treated With Product: 1

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Taste of the Wild High Prairie		

Sender information

Lisa Freeman
200 Westboro Rd
North Grafton, MA 01536
USA

Owner information

B6 USA

To view this PFR Event, please click the link below:
https://eon.fda.gov/eon//browse/EON-369325

To view the PFR Event Report, please click the link below:
https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jspa?decorator=none&e=0&issueType=12&issueId=386247

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Report Details - EON-369325

ICSR:	2057945	
Type Of Submission:	Initial	
Report Version:	FPSR.FDA.PETF.V.V1	
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)	
Reporting Type:	Voluntary	
Report Submission Date:	2018-10-25 07:45:50 EDT	
Reported Problem:	**Problem Description:**	DCM, CHF, atrial fibrillation WB taurine = B6 Dog's diet previously submitted to FDA Note: this may be a duplicate submission
	Date Problem Started:	02/20/2018
	Concurrent Medical Problem:	No
	Outcome to Date:	Died Naturally
	Date of Death:	B6
Product Information:	**Product Name:**	Taste of the Wild High Prairie
	Product Type:	Pet Food
	Lot Number:	
	Package Type:	BAG
	Product Use Information:	
	Manufacturer /Distributor Information:	
	Purchase Location Information:	
Animal Information:	**Name:**	B6
	Type Of Species:	Dog
	Type Of Breed:	Great Dane
	Gender:	Male
	Reproductive Status:	Intact
	Weight:	74 Kilogram
	Age:	9 Years
	Assessment of Prior Health:	Excellent
	Number of Animals Given the Product:	1
	Number of Animals Reacted:	1
	Owner Information:	**Owner Information provided:** Yes
		Contact: **Name:** B6 **Phone:** **Email:**
		Address: B6 United States
	Healthcare Professional Information:	**Practice Name:** Tufts Cummings School of Veterinary Medicine
		Contact: **Name:** Lisa Freeman **Phone:** (508) 887-4523 **Email:** lisa.freeman@tufts.edu

FDA-CVM-FOIA-2019-1704-010879

		Address:	200 Westboro Rd North Grafton Massachusetts 01536 United States
Sender Information:	**Name:**	Lisa Freeman	
	Address:	200 Westboro Rd North Grafton Massachusetts 01536 United States	
	Contact:	**Phone:**	5088874523
		Email:	lisa.freeman@tufts.edu
	Permission To Contact Sender:	Yes	
	Preferred Method Of Contact:	Email	
Additional Documents:			
	Attachment:	**B6** compiled records.pdf	
	Description:	Records	
	Type:	Medical Records	

From: Nemser, Sarah </O=FDA/OU=FIRST ADMINISTRATIVE GROUP/CN=RECIPIENTS /CN=SARAH.YACHETTI>
To: Rotstein, David; Carey, Lauren; CVM Vet-LRN-OR; Palmer, Lee Anne; Queen, Jackie L
Sent: 5/18/2015 6:53:37 PM
Subject: RE: EON-208329 - FW: Grandma Lucy's Artisan Chicken Grain Free/Freeze Dried Dog Food: B6

I can follow up on this case. It looks like testing was already completed at B6 lab for this case (endocrine).

B6 lab is currently working on another case to test for VIT D.
If there is enough product we could send some to B6 and some to B6 ?

S

Sarah Nemser M.S.

tel: 240-402-0892
sarah.nemser@fda.hhs.gov

From: Rotstein, David
Sent: Monday, May 18, 2015 2:41 PM
To: Nemser, Sarah; Carey, Lauren; CVM Vet-LRN-OR; Palmer, Lee Anne; Queen, Jackie L
Subject: RE: EON-208329 - FW: Grandma Lucy's Artisan Chicken Grain Free/Freeze Dried Dog Food: B6
B6

The complaint states that they possess open product and is stored in the original packaging.

Testing- Vitamin D2, Vitamin D3

Will Vet-LIRN be able to follow up?

Thanks,
dave

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
CVM OSC/DC/ICERT
7519 Standish Place, RM 120
240-402-5613 (Office and Fax) (NEW NUMBER)
240-506-6763 (BB)
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From: Nemser, Sarah
Sent: Monday, May 18, 2015 2:39 PM
To: Carey, Lauren; Rotstein, David; CVM Vet-LRN-OR; Palmer, Lee Anne; Queen, Jackie L
Subject: RE: EON-208329 - FW: Grandma Lucy's Artisan Chicken Grain Free/Freeze Dried Dog Food: B6
B6

What testing is recommended for this complaint?
Do we know if the owner still has the food.

Lauren B5

Thanks,
Sarah

Sarah Nemser M.S.

tel: 240-402-0892
sarah.nemser@fda.hhs.gov

From: Carey, Lauren
Sent: Thursday, May 14, 2015 2:40 PM
To: Rotstein, David; CVM Vet-LRN-OR; Palmer, Lee Anne; Queen, Jackie L
Subject: RE: EON-208329 - FW: Grandma Lucy's Artisan Chicken Grain Free/Freeze Dried Dog Food: B6
B6

Only one other report for Grandma Lucy's (Artisan chicken flavor) EON-167610 – No Adverse Event – reporter concerned that Phosphorus max (0.44%) was below AAFCO min, Ca/P ratio 2.27:1.4 per reporter

---

From: Rotstein, David
Sent: Thursday, May 14, 2015 2:25 PM
To: Carey, Lauren; CVM Vet-LRN-OR; Palmer, Lee Anne; Queen, Jackie L
Subject: RE: EON-208329 - FW: Grandma Lucy's Artisan Chicken Grain Free/Freeze Dried Dog Food: B6
B6

Would be interested in confirming other food exposures.

Here is the ingredient list:
USDA Chicken, Potatoes, Flax, Carrots, Celery, Apples, Blueberries, Cranberries, Garlic, Vitamin A, **Vitamin D3**, Vitamin E, Niacin, Iron, Calcium, Phosphorus, Zinc, Riboflavin, Thiamin, Potassium, Manganese, Chloride, Copper, Magnesium, Pyridoxine, Cyanocobalamin.

Do we have any other Grandma Lucy's?

B4

dave

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
CVM OSC/DC/ICERT
7519 Standish Place, RM 120
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From: Carey, Lauren
Sent: Thursday, May 14, 2015 2:15 PM
To: CVM Vet-LRN-OR; Palmer, Lee Anne; Queen, Jackie L; Rotstein, David
Subject: FYI: EON-208329 - FW: Grandma Lucy's Artisan Chicken Grain Free/Freeze Dried Dog Food: B6
B6

Elevated Calcium/Phosphorus with serum elevations of Vitamin D in a 4yo WHWT.
This is a raw diet I believe ("freeze dried")

From: PFR Event [mailto:pfreventcreation@fda.hhs.gov]
Sent: Thursday, May 14, 2015 2:00 PM
To: B6 HQ Pet Food Report Notification; B6 ; B6
Subject: Grandma Lucy's Artisan Chicken Grain Free/Freeze Dried Dog Food: B6

A PFR Report has been received and PFR Event [EON-208329] has been created in the EON System

A "PDF" report by name "1039540-report.pdf" is attached to this email notification for your reference. Please note that all documents received in the report are compressed into a zip file by name "1039540-attachments.zip" and is attached to this email notification.

Below is the summary of the report

EON Key: EON-208329
EON Title: PFR Event created for Grandma Lucy's Artisan Chicken Grain Free/Freeze Dried Dog Food; 1039540

To view this PFR Event, please click the link below:
https://eon.fda.gov/eon//browse/EON-208329

To view the PFR Event Report, please click the link below:
https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jspa?decorator=none&e=0&issueType=12&issueId=221181

Product information
Individual Case Safety Report Number: 1039540
Product Group: Pet Food
Product Name: Grandma Lucy's Artisan Chicken Grain Free/Freeze Dried Dog Food
Description: Has been eating Grandma Lucy's Artisan Chicken food for about 8 months. Presented B6 for intermittent gastrointestinal signs and lethargy. Overall health was good with unremarkable physical exam. Bloodwork showed increased serum calcium and phosphorus levels. Tested negative for Addison's disease, ultrasound showed renal mineralization, negative testing for malignancy (PTHrP) and hyperparathyroidism. Serum Vitamin D levels were elevated, consistent with ingestion of excessive dietary Vitamin D. No history of exposure to cholecalciferol rodenticides, Vitamin D supplements, or Vitamin D-containing ointments.
Submission Type: Initial
Report Type: Both
Outcome of reaction/event at the time of last observation: Stable
Number of Animals Treated With Product: 1
Number of Animals Reacted With Product: 1

Sender information

B6
USA

Owner information

B6

B6 USA

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