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:** 6/10/2019 4:39:12 PM

Subject: couple more related DCM- PFRs-FW: Zignature trout & salmon dry: Lisa Freeman -

EON-390034 + Pure VitaVenison and Red Lentisl

Attachments: 2067994-report.pdf; PureVita Venison & Red Lentils Grain-Free Dry Dog Food B6

EON-386301; Pure Vita Venison & Red Lentils Grain-Free Dry Dog Food: B6

EON-390031; Zignature trout & salmon dry: Lisa Freeman - EON-370715; 2067994-

attachments.zip

David Rotstein, DVM, MPVM, Dipl. ACVP CVM Vet-LIRN Liaison CVM OSC/DC/CERT 7519 Standish Place

**B6** 





This e-mail message is intended for the exclusive use of the recipient(s) named above. It may contain information that is protected, privileged, or confidential, and it should not be disseminated, distributed, or copied to persons not authorized to receive such information. If you are not the intended recipient, any dissemination, distribution, or copying is strictly prohibited. If you think you received this e-mail message in error, please e-mail the sender immediately at <a href="mailto:david.rotstein@fda.hhs.gov">david.rotstein@fda.hhs.gov</a>.

From: Related PFR Event cpfrsignificantactivitycreation@fda.hhs.gov>

Sent: Monday, June 10, 2019 11:13 AM

**To:** Rotstein, David <David.Rotstein@fda.hhs.gov>; Cleary, Michael \* <Michael.Cleary@fda.hhs.gov>; HQ Pet

Food Report Notification <HQPetFoodReportNotification@fda.hhs.gov>; B6

Subject: Zignature trout & salmon dry: Lisa Freeman - EON-390034

A PFR Report has been received and Related PFR Event [EON-390034] has been created in the EON System.

A "PDF" report by name "2067994-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 "2067994-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

**EON Key:** EON-390034

ICSR #: 2067994

EON Title: Related PFR Event created for Zignature trout & salmon dry; 2067994

AE Date	11/07/2018	Number Fed/Exposed	3
Best By Date		Number Reacted	2

Animal Species	Dog	Outcome to Date	Better/Improved/Recovering
Breed	Retriever - Labrador		
Age	3 Years		
District Involved	PFR-New England DO		

## **Product information**

Individual Case Safety Report Number: 2067994

Product Group: Pet Food

**Product Name:** Zignature trout & salmon dry

**Description:** Older housemate diagnosed with DCM and CHF. Screening **B6** because he has been eating the same diet. Does not have clearcut DCM on echo but has reduced cardiac contractility. Taurine pending and

owner has changed diet and started taurine supplementation

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: 3 Number of Animals Reacted With Product: 2

Product Name	Lot Number or ID	Best By Date
Zignature trout & salmon dry		

This report is linked to:

Initial EON Event Key: EON-370715

Initial ICSR: 2058683



To view this Related PFR Event, please click the link below: <a href="https://eon.fda.gov/eon//browse/EON-390034">https://eon.fda.gov/eon//browse/EON-390034</a>

To view the Related PFR Event Report, please click the link below: <a href="https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jspa?decorator=none&e=0&issueType=10100&issueId=407306&parentIssueTypeId=12">https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jspa?decorator=none&e=0&issueType=10100&issueId=407306&parentIssueTypeId=12</a>

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## Cummings Veterinary Medical Center

**B6** 

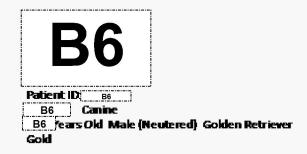
## Discharge Instructions

Dadwige nad ded da	
<b>B6</b>	Patient III; B6
<b>B6</b>	
Admit Date: 1/24/2019 10:26:41 AM Discharge Date: 1/24/2019 Diagnoses: Decreased contractile function and mildly enlarged heart (stable).	
Clinical Findings: Thank you for bringing B6 in today for his recheck echocardiogram. You report the although he sometimes has a dry cough after eating. On physical exam there were neart, and he had nice strong pulses.	_
Today on echocardiogram (ultrasound of the heart). B6 heart looks similar to he reduced contractile function and his heart is mildly enlarged which is abnormal for a enough that B6 requires any additional medications, however, we recommend a supplement and we will continue to monitor his heart dosely in the future.	dog of his age. This is not yet severe
Monitoring at Home:  B6 is very stable today and is not close to heart failure. However, please monitor collapse, a reduction in appetite, cough, or distension of the belly. If you notice any a for a recheck exam.	
If you ever have any concerns, please call or have B6 evaluated by a veterinarian a day.	. Our emergency dinic is open 24 hours

Diet Suggestions:	
Please continue feeding B6 the Purina Pro Plan diet.	
Exercise Recommendations B6 may continue his normal activity and ex	ercise regime
Recommended Medications:	
1. Taurine Supplement - Give 1000mg by mouth every 12 hours.	
(brands we recommend include TwinLab, Swanson, NOW and GNC brands)	
Taurine is an amino acid that is shown to be necessary for appropriate heart I has lead to reduction in heart enlargement and an increase in heart health in	
Recheck Visits: We would like to see B6 back for a recheck echocardiogra	rm in 6 months.
Thank you for entrusting us with B6 care- he is such a good boy!. Please	contact our Cardiology liaison at
B6 <b>for scheduling and non-e</b>	mergent questions or concerns.
Please visit our HeartSmart website for more information http://vet.tufts.edu/heartsmart/	
Prescription Refill Discloimer:	
For the safety and well-being of our patients, your pet must have had an examina year in order to obtain prescription medications.	ation by one of our veterinarians within the past
Ordering Food:	
Please check with your primary veterinarian to purchase the recommended diet(s)	
please call 7-10 days in advance (508-887-4629) to ensure the food is in stock. A	Itematively, veterinary diets can be ordered from
online retailers with a prescription/veterinory approval.	
Clinical Trials:	
Clinical trials are studies in which our veterinary doctors work with you and your p	
promising new test or treatment. Please see our website: vet.tufts.edu/cvmc/dinic	ol-studies
B6 Di	scharge Instructions

## Cummings Veterinary Medical Center

Cardiology Liaison: 508-887-4696



## **Cardiology Appointment Report**

**B6** 

<u>Presenting Complaint:</u> DCM Study, last echocardiogram performed 11/2018 revealing decreased <u>contractile function - r/o DCM vs. diet induce cardiomyopathy. Did not require medical intervention at that time, but initiated Taurine supplementation and diet change.</u>

Concurrent Diseases: Apparently healthy pet

<u>General Medical History</u>: Owner states <u>B6</u> coughs once in a while. When inquiring for more detail-owner said she notices it once a day after he eats a lot. Describes it as a dry cough. He vomited a week ago-unsure of consistency.

Diet and Supplements: Eats purina proplan sport, taurine supplement

## Cardiovascular History:

Prior CHF diagnosis? No
Prior heart murmur? No
Prior ATE? No
Prior arrhythmia? No
Monitoring respiratory rate and effort at home? No
Cough? Yes
Shortness of breath or difficulty breathing? No
Syncope or collapse? No

Current Medications Pertinent to CV System:			
B	6		
Medication: Formulation/Tab Size: Administration Frequency: Need refills?			
Medication: Formulation/Tab Size: Administration Frequency: Need refills?			
Cardiac Physical Examination:			
	36		
Muscle condition:  Normal  Mild muscle loss	■ Moderate cachesia ■ Marked cachesia		
Cardiovascular Physical Exam:			
Murmur Grade:  None  I/vi  II/vi  III/vi	IV/VI   V/VI   VI/VI		
Murmur location/description:			
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 Pulsedelicits Pulsus paradoxus Other:		
Arrhythmia:  None Sinus arrhythmia	■ Bradycardia ■ Tachycardia		

Premature beats	
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:  Differential Diagnoses:	
Diagnostic plan:  ☐ Echocardiogram ☐ Chemistry profile ☐ ECG ☐ Renal profile ☐ Blood pressure	☐ Dialysis profile ☐ Thoracic radiographs ☐ NT-proBNP ☐ Troponin I ☐ Other tests:
Echocardiogram Findings:	
	<b>B6</b>

<u>Assessment and recommendations</u>: Stable systolic dysfunction with similar LV function compared to previous exam. Recommend continue Taurine supplementation and current diet. Echocardiogram should be repeated in 3 months or sooner in case patient develops clinical signs consistent with worsening of the disease.

## Final Diagnosis:

- Decreased contractile function - r/o DCM vs. diet induce cardiomyopathy.

## Heart Failure Classification Score:

ISACHC Classification:	
🔲 la	🔲 Illa
<b>☑</b> lb	IIIb
■ II	
ACVIM Classification:	
■ A	<b>□ c</b>
<b>□</b> B1	■ D
₩ B2	

M-Mode	[	1
IVSd		cm
LVIDd		cm
LVPWd		cm
IVSs		om
LVIDs		om
LVPWs		om
EDV(Teich)		ml
ESV(Teich)		ml
EF(Teich)		%
%FS		%
SV(Teich)		ml
Max IA	DC	cm cm
Time	<b>B6</b>	ms
HR		BPM
CO(Teich)		l∕min
CI(Teich)		l/minm
Ao Diam		cm
LA Diam		cm
LA/Ao		
IVSd		cm
LVIDd		cm
EDV(Teich)		ml
LVIDs		cm
%FS		%
TAPSE		cm

**EPSS** an **M-Mode Normalized IVSdN**  $\{0.290 - 0.520\}$ ! LVIDdN (1.350 - 1.730)! LVPWdN  $\{0.330 - 0.530\}$ **IVSsN**  $\{0.430 - 0.710\}$ ! **LVIDsN**  $\{0.790 - 1.140\}$ ! LVPWsN  $\{0.530 - 0.780\}$ <u>2D</u> SA LA am Ao Diam cm. SA LA / Ao Diam **IVSd** cm. LVIDd am LVPWd  $\mathbf{cm}$ EDV(Teich) ml **IVSs** am **LVIDs** cm. **B6 LVPWs**  $\mathbf{cm}$ ESV(Teich) ml EF(Teich) % %FS % SV(Teich) ml Doppler 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

## Cummings Veterinary Medical Center

**B6** 

## Discharge Instructions

В6		Ī		<b>B6</b>	
Species: Carr Gold Male (!) Birthdate	ine Veutered) Golden B6	Retriever		DU	
		B	3		
	5/1/2019 12:00:5 ate: 5/1/2019	3 PM			
Diagnoses: I	Decreased contra	dile function an	nd mildly enlarged heart.		
not had any	<b>r bringing</b> B6				is doing well at home and has while listening to his heart,
decreased co additional m	intractile function	and is mildly e time, however,	nlarged which is abnorma we recommend continui	l for a dog of his age [	previously. His heart is has 86 ) does not require any upplement and we will
	y stable today and eduction in appeti				for any signs of weakness or lities, we would like to see him
if you ever h a day.	aveany concerns,	please call or h	evaluated by	a veterinarian. Our em	ergency dinic is open 24 hours
Diet Sugges	tions:				

Please continue feeding B6 the Purina Pro Plan diet.
Exercise Recommendations: 86 may continue his normal activity and exercise regime
Recommended Medications:
<b>B6</b>
Recheck Visits: We would like to see B6 back for a recheck echocardiogram in 2-3 months. B6 will call you to schedule this appointment.
Thank you for entrusting us with 86 care-he is such a sweet boy! 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 Refil Dischoiner:
For the safety and well-being of our patients, your pet must have had an examination by one of our veterinarians within the pa- 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/dinical-studies
Case B6 Owner B6 Discharge Instructions

## Cummings Veterinary Medical Center

Cardiology Liaison: 508-887-4696

**B6** 

B6 canne ears Old Male (Neutered) Golden Retriever

## **Cardiology Appointment Report**

Date: 5/1/2019

**B6** 

Presenting Complaint: recheck - DCM study; doing well at home, active, no coughing

## Concurrent Diseases:

none

## General Medical History:

Last echo performed 1/19/19 - decreased contractile function, no intervention needed at this time. Suspect diet-associated DCM

## Diet and Supplements:

Taurine 1000mg BID

## Cardiovascular History:

Prior CHF diagnosis? n

Prior heart murmur? n

Prior ATE? n

Prior arrhythmia? n

Monitoring respiratory rate and effort at home? n

Cough? very rarely -o cannot remember the last time he coughed

Shortness of breath or difficulty breathing? n

Syncope or collapse? n

Sudden onset lameness? n

## Exercise intolerance? n

## **Current Medications Pertinent to CV System:**

None

Cardiac Physical Examination:	
	36
Muscle condition:  Normal  Mild muscle loss	☐ Moderate cachexia ☐ Marked cachexia
Cardiovascular Physical Exam:  Murmur Grade:  None  I/VI  II/VI  III/VI	□ rv/vi □ v/vi □ vi/vi
Murmur location/description:  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	<ul><li>■ Bounding</li><li>■ Pulse deficits</li><li>■ Pulsus paradoxus</li><li>■ Other:</li></ul>
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
Abdominal exam:  Normal  Hepatomegaly	☐ Mild ascites ☐ Marked ascites

Abdominal distension	
Problems:	
DCM with mildly decreased contractile function	n
•	
Differential Diagnoses:	
Diet-associated DCM vs primary DCM	
Diagnostic plan:	
Echocardiogram	☐ Dialysis profile
Chemistry profile	Thoracic radiographs
ECG	MT-proBNP
Renal profile Blood pressure	Trapanin   Other tests:
iii bidd pesue	
Echocardiogram Findings:	
Assessment and recommendations:	<b>B6</b>
Findings consistent with stable mild LV dilation compared to previous exam. Recommend cont	and systolic dysfunction with similar LV function inue Taurine supplementation and current diet.  In sor sooner in case patient develops clinical signs
Final Diagnosis: - Decreased contractile function - r/o mild DCM	l vs. diet induced cardiomyopathy.
Heart Failure Classification Score:	
ISACHC Classification:	□
III la III lb	□ IIIa □ IIIb
<u>∞</u> 10	= IIID
<b>—</b> "	
ACVIM Classification:	
■A	<b>□ c</b>

M-Mode **IVSd FAID9** LVPWd IVS<sub>5</sub> **LVIDs LVPWs** EDV(Teich) ESV(Teich) EF(Teich) %FS SV(Teich) Max LA Ao Diam LA Diam LA/Ao **TAPSE EPSS** 

M-Mode Normalized

IVSdN LVIDdN LVPWdN IVSsN LVIDsN LVPWsN

<u>2D</u> SA IA Ao Diam SA IA / Ao Diam

IVSd LVIDd LVPWd EDV(Teich) IVSs

IVSs LVIDs LVPWs ESV(Teich) EF(Teich) %FS SV(Teich)

LV Major

LV Minor

**B6** 

cm cm cm cm cm cm ml ml % % ml cm cm cm cm cm

> (0.290 - 0.520) (1.350 - 1.730) ! (0.330 - 0.530) (0.430 - 0.710) (0.790 - 1.140) ! (0.530 - 0.780)

cm cm cm cm cm cm cm cm cm cm

cm

Sphericity Index LVLd A4C LVEDV MOD A4C LVESV MOD A4C LVEF MOD A4C SV MOD A4C

Doppler
MR Vmax
MR maxPG
MV E Vel
MV DecT
MV Dec Slope
MV A Vel
MV E/A Ratio

E'
E/E'
A'
S'
IVRT
AV Vmax
AV maxPG
PV Vmax
PV maxPG

TR maxPG

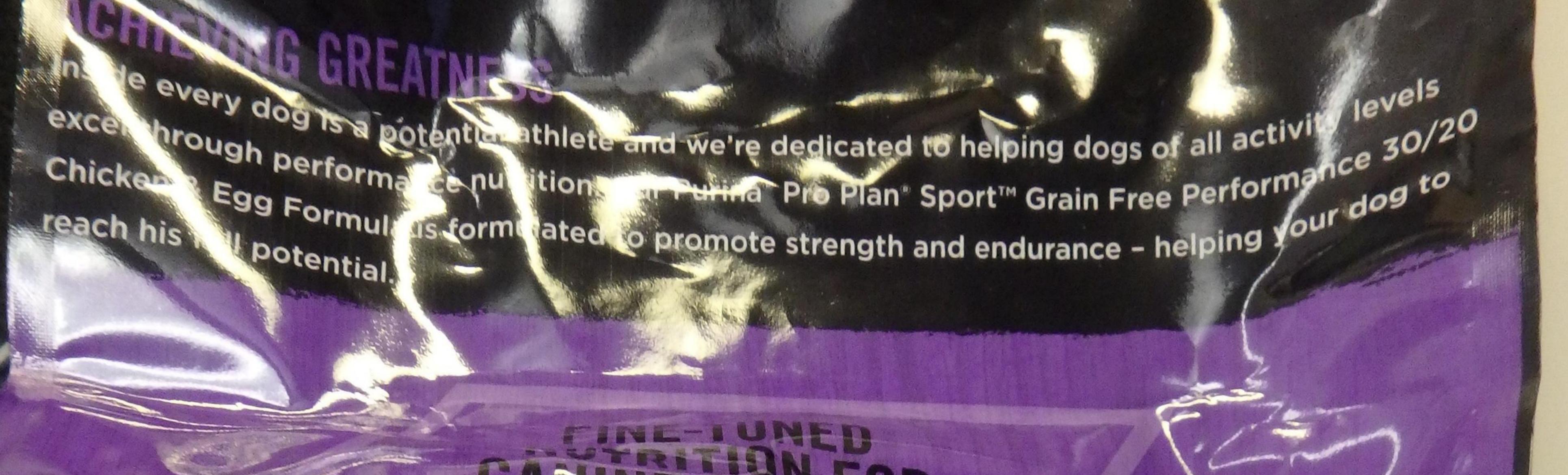
**B6** 

cm ml cm ml % ml

m/s mmHg m/s ms m/s m/s

m/s

m/s m/s ms m/s mmHg m/s mmHg m/s



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juscles including the crucial time/ following exercises

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Artificial Colors, Flavors
Or Preservatives

Poultry By-Product Meal

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& EGG

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- EPA, an omega-3 fatty acid, and glucosamine help support joint health and mobility
- Antioxidant-rich nutrition nourishes the immune system and helps defend against free radicals
- Contains no artificial colors, flavors or preservatives and no poultry by-product meal



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why lace of you're not satisfied, simply let us know date box and the information in the "BEST IF USED BY"

on recoint weight circle. Send within 60 days of

lecept on receipt along with your original purchase You with the price circled, a brief explanation of why you with the price circled, a brief explanation of and severe dissatisfied with the product, and your name and street address (P.O. Box not accepted) to:

STORE IN A COOL, DRY PLACE.





FDA-CVM-FOIA-2019-1704-005448



**B6** 

PET OWNER B6

Canine SPECIES:

BREED: Labrador Retriever

Female GENDER: AGE: 6 Years PATIENT ID: B6 **B6** 

ACCOUNT #: ATTENDING VET: В6 LAB ID: ORDER ID:

**B6** 

COLLECTION DATE: 2/26/18 DATE OF RECEIPT: 2/27/18 DATE OF RESULT: 3/9/18

**IDEXX Services** 

**B6** 

**IDEXX SDMA** 

Feb '18

Creatinine

Jan '18 Feb '18 BUN

Jan '18 Feb '18

Chemistry 🚁



RESULT

**B6** 

2/27/18 (Order Received) 3/9/18 9:58 AM (Last Updated)

0 - 14 µg/dL

0.5 - 1.5 mg/dL

9 - 31 mg/dL

2.5 - 6.1 mg/dL

8.4 - 11.8 mg/dL

142 - 152 mmol/L

4.0 - 5.4 mmol/L

108 - 119 mmol/L

13 - 27 mmol/L

2.7 - 3.9 g/dL

0.7 - 1.5

1/23/18

**IDEXX SDMA** 

Creatinine BUN

BUN:Creatinine

Ratio

Phosphorus

Calcium

Sodium

Potassium Na:K Ratio

Chloride

TCO2

(Bicarbonate) Anion Gap

Total Protein

Albumin Globulin

Alb:Glob Ratio

REFERENCE VALUE

28 - 37

11 - 26 mmol/L

5.5 - 7.5 g/dL

2.4 - 4.0 g/dL

**B6** 

Generated by VetConnect® PLUS March 12, 2018 07:41 AM

Page 1 of 2

## Chemistry (continued)

Cholesterol

TEST

Hemolysis Index

Lipemia Index

RESULT

**B6** 

REFERENCE VALUE

131 - 345 mg/dL

- Index of N, 1+, 2+ exhibits no significant effect on chemistry values.
- Index of N, 1+, 2+ exhibits no significant effect on chemistry values.

## Therapeutics/Toxicology



2/27/18 (Order Received) 3/9/18 9:58 AM (Last Updated)

Serum Iron

Ferritin

TIBC

RESULT

REFERENCE VALUE

73 - 245 ug/dL

89 - 489 ng/mL

270 - 530 ug/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.

 $<sup>{\</sup>bf a}$  Referral test performed at Kansas State University.

			e	
			220	

**B6** 

## Clinic:

NORTH CAROLINA ST UNIV- CLIN PATH LAB

**ROOM C269** 

1060 WILLIAM MOORE DR RALEIGH, NC 27607

Accession Number:

**B6** 

Reference Number:

**B6** 

Case Coordinator: LAB, COMP. HEMATOLOGY

Received: 02/27/2018 Finalized: 02/27/2018

Species: DOG

Sex: FEMALE Animal ID: B6

Specimen: SERUM

Sampled: 02/09/2018

## **FINAL REPORT**

This report supercedes all previous reports for this case

## Clinical Pathology

## **PROFILE, IRON & TIBC**

Animal Id:

B6 j

Sample Date:

Feb 9, 2018

Specimen Desc:

SERUM

B6

B6 H ug/dL

73 - 245

02/27/2018 05:14 PM

**TIBC Comment** 

UNABLE TO CALCULATE TIBC. UIBC IS BELOW THE ANALYZER TECHNICAL LIMIT.

Gross appearance of

NORMAL

serum:

Chemistry assays

reported by:

**B6** 

MT, CLIN PATH LAB

Accession Number: Status: Finalized

**B6** 

Tuesday, 27 Feb 2018 5:14 PM

Page 1 of 2

Report Details -	B6					
ICSR:	2023228					
Type Of Submission:	Initial					
Report Version:	FPSR.FDA.PETF.V.V1					
Type Of Report:	Adverse Event (a symptom,	roaction or disease	associated with the product)			
Reporting Type:	Voluntary	reaction of disease a	associated with the product)			
	:) ;;					
Report Submission Date:						
Reported Problem:	Problem Description:	She would like to be unsuccessfully with a vomiting prior to predict the continued CHF treat and aquaphoresis with the carnitine analysis cause for DCM and review of the myoca myofiber vacuoles rethe dog had not received by the continued CHF treat and aquaphoresis with the carnitine analysis cause for DCM and review of the myoca myofiber vacuoles rethe dog had not received by the considering from with time his housempresented with seven patient. Both dogs had nutritional aminounrelated lineages (a different ages but sin the considering common continued to the continued to th	inifer Jones was consulted prior to submission of this report. involved in the case review 3 week history of cough treated doxycycline and prednisone. 3 day history of inappetence and sentation to B6 emergency service for dyspnea. It is server pulmonary edema and echocardiogram showed inappetence and severe pulmonary edema and echocardiogram showed inappetence and severe pulmonary edema and echocardiogram showed inappetency support and many properties to wear off the ventilator were unsuccessful as performed. He continued to decline despite aggressive thanized. Infectious disease testing was negative and taurine is showed adequate levels. Necropsy initially did not reveal a supported alveolar injury (possibly ventilator related). A rerelated histopathology by one of our pathologist showed eminiscent of the changes seen in doxorubicin toxicity. Since sived doxorubicit B6  B6 had been fed Caifornia kangaroo with lentils and venison with lentils along with We have samples of these foods from 6/17 but not the hen he was presented 2/17. These samples were provided at atel. B6 unrelated, older miniature schnauzer) also re DCM and CHF. I will enter this dog as a separate affected ad extensive infectious disease testing which was negative actioned at the same breed, they were from different lines), milar time of presentation B6 had clinical signs at the time ut didn't present with CHF for several months), we are nenvironmental factors which could precipitate DCM, mination or toxin exposure.			
	Date Problem Started:	B6				
	Concurrent Medical Problem:	No				
	Outcome to Date:	Died Euthanized				
	Date of Death	B6				
Product Information:	Product Name:	Venison & Green Le	-California Natural Adult Limited Ingredient Grain Free ntils and Kangaroo & Red Lentils Recipe			
	Product Type:	Pet Food				
	Lot Number:					
		not available				
	Package Type:	<u> </u>				
		ze: 26 Pound				
	Purchase Date:	1 1				
	Possess Unopened Product:	ct.				
	Possess Opened Product:	ct:				
		ons: In a cabinet, in the original bag				
	Product Use Information:	Becompliant the state of the st				
		Time Interval between Product	2 Years			

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			Other Phone: B6	
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Sender Information:	Name:	Darcy Adin		
		1060 William Moore Dr Raleigh New York 27607 United States		
	Contact:	Other Phone:	9195136694 6145829798 dbadin@ncsu.edu	
	Permission To Contact Sender:	1		
	Preferred Method Of Contact:	Email		
	Reported to Other Parties:	Manufacturer		
Additional Documents:				

From: Rotstein, David </O=FDA/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DAVID.ROTSTEIN>

To: Reimschuessel, Renate; Queen, Jackie L; Palmer, Lee Anne; Jones, Jennifer

L; Ceric, Olgica; Carey, Lauren

**Sent:** 7/11/2017 9:45:50 PM

**Subject:** Fwd: Alternated feedings between:-California Natural Adult Limited Ingredient

Grain Free Venison & Green Lentils Recipe Dog Food and Kangaroo and

Lentils: Darcy Adin - EON-323519

Attachments: 2023230-report.pdf

David Rotstein, DVM, MPVM, Dipl.ACVP CVM Vet-LIRN Liaison CVM OSC/DC/CERT 7519 Standish Place B6 (BB)

This e-mail message is intended for the exclusive use of the recipient(s) named above. It may contain information that is protected, privileged, or confidential, and it should not be disseminated, distributed, or copied to persons not authorized to receive such information. If you are not the intended recipient, any dissemination, distribution, or copying is strictly prohibited. If you think you received this e-mail message in error, please e-mail the sender immediately at david.rotstein@fda.hhs.gov.

From: PFR Event cpfreventcreation@fda.hhs.gov>

Date: July 11, 2017 at 5:36:16 PM EDT

**To:** HQ Pet Food Report Notification <HQPetFoodReportNotification@fda.hhs.gov>,

B6 Cleary, Michael \*

<Michael.Cleary@fda.hhs.gov>

Subject: Alternated feedings between:-California Natural Adult Limited Ingredient Grain Free Venison

& Green Lentils Recipe Dog Food and Kangaroo and Lentils: Darcy Adin - EON-323519

A PFR Report has been received and PFR Event [EON-323519] has been created in the EON System.

A "PDF" report by name "2023230-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report:

**EON Key:** EON-323519

ICSR #: 2023230

EON Title: PFR Event created for Alternated feedings between: California Natural Adult Limited Ingredient

Grain Free Venison & Green Lentils Recipe Dog Food and Kangaroo and Lentils; 2023230

AE Date	06/22/2017	Number Fed/Exposed	2
Best By Date		Number Reacted	2
Animal Species	Dog	Outcome to Date	Stable
Breed	Schnauzer - Miniature		
Age	7 Years		
District Involved	PFR-New York DO		

## **Product information**

**Individual Case Safety Report Number: 2023230** 

**Product Group:** Pet Food

**Product Name:** Alternated feedings between: California Natural Adult Limited Ingredient Grain Free Venison &

Green Lentils Recipe Dog Food and Kangaroo and Lentils

Description: Please note: Dr. Jennifer Jones was consulted prior to submission of this report. She would like to be involved in the case review B6 housemate B6 (separate report submitted) was diagnosed with DCM and CHF 2/17 and was euthanized after aggressive treatment of CHF. At that time B6 had 2 syncopal events closely related to each other. His appetite for dog food declined but he would eat it if tempted with treats mixed in. He was presented 6/22/17 for more syncopal events and was similarly diagnosed with severe DCM and CHF. He was able to be successfully treated however and is clinically doing well on CHF medications as of 7/10/17. A re-review of the myocardial histopathology for B6 housemate B6 was requested at this time because of the unusual diagnosis of DCM in a small breed dog living in the same house as another dog similarly diagnosed a few months ago. This re-review by one of our pathologists showed myofiber vacuoles reminiscent of the changes seen in doxorubicin toxicity. Since the dog had not received B6

(unrelated, younger miniature schnauzer), **B6** had been fed Caifornia 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 2/17. These samples were provided at the time **B6** also presented with severe DCM and CHF. Lik **B6** 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, we are considering common environmental factors which could precipitate DCM, including food contamination or toxin exposure. We have plasma, serum, urine and myocardial tissue samples (latter only for **B6** stored at -80 Celsius in addition to food and treat samples.

**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: 2

Product Name	Lot Number or ID	Best By Date
Alternated feedings between: California Natural Adult Limited Ingredient Grain Free Venison & Green Lentils Recipe Dog Food and Kangaroo and Lentils		

## **Sender information**

Darcy Adin 1060 William Moore Dr Raleigh, NY 27607 USA

## **Owner information**



To view this PFR Event, please click the link below: https://eon.fda.gov/eon//browse/EON-323519

To view the PFR Event Report, please click the link below:

 $\underline{https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jspa?decorator=none\&e=0\&issueType=12\&issueId=338851$ 

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Fax: Admin

Fax: Referral

## **NC State University**

## Veterinary Hospital 1052 William Moore Drive Raleigh, NC 27607

**Discharge Comments** 

Small Animal (919) 513-6500 Large Animal (919) 513-6630

Client **Patient** Attending DVM Case # 212267 **B6** Student SCHNAUZER Discharging DVM 4 MC 8.2 kg Referring DVM BLACK CANINE Admission Date/Time Discharge Date/Time Discharge Status: Case Summary Diagnosis: 1) Biventricular congestive heart failure (left significantly worse than right) 2) Cardiomyopathy (suspect secondary) vs. myocarditis vs. tachycardia-induced cardiomyopathy vs. other B6 is a 2 and ½ year old male castrated Miniature Schnauzer who presented the NCSU ER on labored breathing and was subsequently transferred to NCSU Cardiology. B6 initially developed a cough three weeks ago; B6 B6 describes the cough as a wheezing-type cough that occurred more frequently at night. When B6 showed no signs of improvement. B6 presented to his primary veterinarian on Thursday (1/26). Kennel cough was suspected as the underlying cause

B6 On Monday B6 B6 became uninterested in his food and began vomiting. The following day B6 continued vomiting and developed labored breathing and subsequently re-presented to the rDVM for evaluation. Bloodwork and thoracic radiographs were performed. Bloodwork was reportedly unremarkable at this time and there While in-hospital, **B6** regurgitated. On Wednesday improvement in respiratory effort but he still was not eating; syringe fed **B6** but as she attempted he The day of presentation developed marked labored breathing following this and was presented to an emergency hospital. Thoracic radiographs were performed (uploaded in eFilm) and revealed cardiomegaly; a diffuse, severe mixed interstitial to alveolar pattern that is most severe caudodorsally; hepatomegaly; and decreased abdominal serosal contrast B6 was referred to NCSU for further care and ventilation if indicated. lives with one other dog (not a relative) who is healthy and is currently up to date on his vaccinations. B6 is not current on any flea/tick prevention but receives heartworm prevention. B6 is fed California Natural dog Physical Exam Findings (on presentation):

nt Date: 07/11/17	Page 2
ш раце. U//T1/T/	Page 2
	36
Brief Daily Summary:  B6 presented late in the evening on B6 to the Eleptocontractility of the ventricles in addition to reviewing the r	ER and after a TFAST was performed showing severe cardiomegaly with rDVM radiographs, B6 and B6 were given. An

Print Date: 07/11/17 Page 3

echocardiogram was then performed (performed sternally cage-side given patient status) and a diagnosis of severe cardiomyopathy (primary vs. secondary DCM vs. myocarditis, vs. pacing-induced cardiomyopathy vs. other) and he was quickly given another dose of B6

B6 After the second B6	was given he was immediate	ely placed on a	B6	and B6 a	ıt
	D	C			
	В	O			
B6 Immediately after	B6	·	(approximate	ly 1:30AM) which showed	а
marked improvement in terms of	ined on	B6	B6		
B6 Immediately after marked improvement in terms of significantly improved. He was mainta B6 He handled improved from presentation. His	this quite well and while Be	as the B6	B6	he clinically was marked	dly
	В	n			
	В	n			
Lama carry for the land of your nationt	Doth D6		v wondorful to	work with If you have an	
I am sorry for the loss of your patient. questions at all, please do not hesitate	to call us at <b>B6</b>	_i were apsoluter	y wondendi to	work with. If you have ar	ıy
B6	<u> </u>				

Print Date: 07/11/17 Page 1

## NC State University

Veterinary Hospital 1052 William Moore Drive Raleigh, NC 27607

**Discharge Comments** 

Small Animal (919) 513-6500 Large Animal (919) 513-6630

B6

Case # 216605
Schnauzer
MC
GRAY&WHITE
CANINE

Attending DVM
Student
Discharging DVM
Referring DVM
Referring DVM
Referring DVM

Admission Date/Time:JUN 22, 2017 10:46 AM

Discharge Date/Time: JUN 22, 2017 06:25 PM

Discharge Status: UNDETERMI

ΝED

CASE SUMMARY:

HISTORY:

Fax: Admin

Fax: Referral

**B6** 

PHYSICAL EXAM FINDINGS:

**B6** 

DIAGNOSTIC TESTS:

**B6** 

Pending Lab Results:

**B6** 



ASSESSMENT:

**B6** 

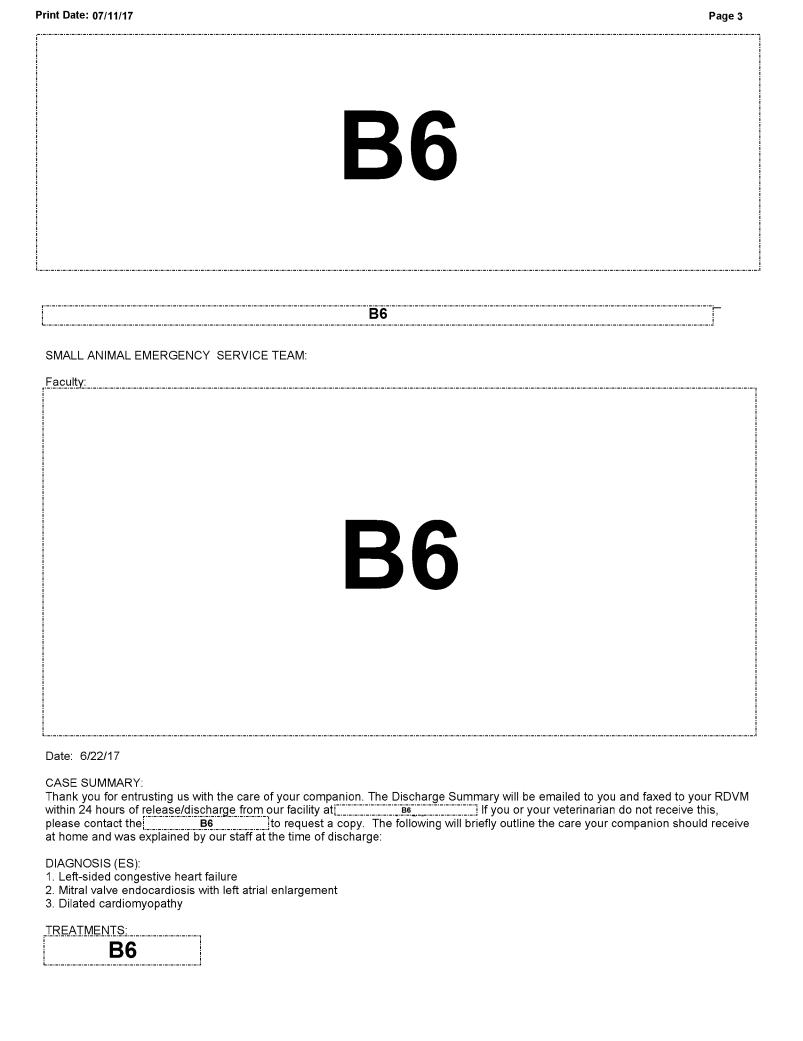
**B6** Unfortunately, B6 echocardiogram revealed evidence of mild mitral valve endocardiosis (i.e. chronic mitral valve disease) and suspected dilated cardiomyopathy. Mitral valve endocardiosis is a chronic, progressive condition in which the valve leaflets become progressively thickened and no longer close appropriately allowing mitral regurgitation. Over time, the left atrium will enlarge and this can lead to congestive heart failure. Typically, in patients with mitral valve disease, the systolic heart function/contractility is maintained until late stages of the disease. Unfortunately, B6; systolic function was significantly decreased, and he showed abnormal dilation of his left atrium and ventricle. These findings were most consistent with a condition called dilated cardiomyopathy (DCM). DCM is a disease of unknown etiology affecting the muscle of the heart and is most commonly seen in large breed dogs (such as Dobermans, Great Danes, and Labrador Retrievers), but there is a small case report of this disease occurring in Standard Schnauzers. Although the exact mechanism of DCM is currently unknown, dietary taurine/carnitine deficiencies, genetics, infectious diseases, and toxins have all been linked to DCM. In order to assess for some of these possible causes, we have submitted testing for multiple nutritional deficiencies and infectious diseases. The NCSU Cardiology Service will call you as these tests become available. DCM leads to poor contractility and low cardiac output, and we suspect that <u>B6</u> episodes of collapse are most likely due to his low cardiac output during exertion. DCM can also lead to fibrosis <u>and remodeling</u> of the myocardium, which can lead to secondary <u>arrhyth</u>mias. Fortunately, we saw no evidence of arrhythmias on B6 ECG today. We performed chest radiographs to evaluate B6 heart and lungs, and B6 had evidence of left-sided congestive heart failure on his radiographs and impending right-sided congestive heart failure on his echocardiogram today. We are starting him on three medications to treat his heart disease and congestive heart failure today, and we may consider adding additional medications and supplements in the future.

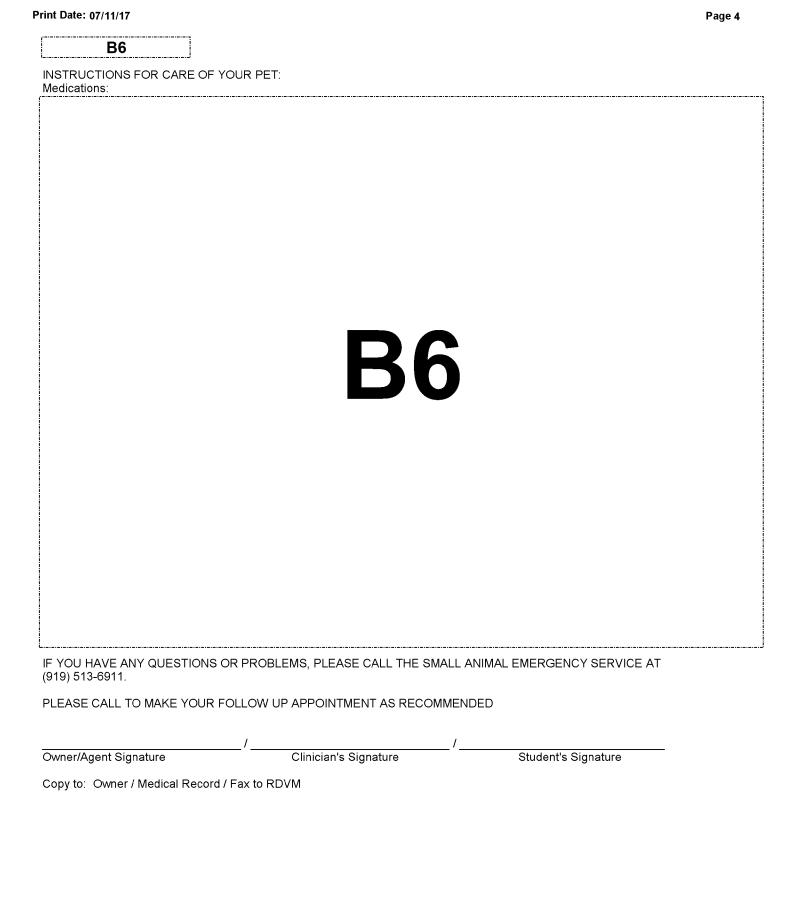
В6

INSTRUCTIONS FOR CARE OF YOUR PET:

Medications:

**B6** 





Print Date: 07/11/17 Page 1

## **NC State University**

## Veterinary Hospital 1052 William Moore Drive Raleigh, NC 27607

**Discharge Comments** 

Small Animal (919) 513-6500 Large Animal (919) 513-6630

Client **Patient** Attending DVM **B6** Case # 216605 B6 Student **SCHNAUZER** Discharging DVM MC  $9.9 \, \text{kg}$ Referring DVM **GRAY&WHITE** CANINE

Admission Date/Time: JUL 10, 2017 10:59 AM Discharge Date/Time: JUL 10, 2017 03:16 PM Discharge Status: CASE SUMMARY **DIAGNOSIS:** Dilated Cardiomyopathy (DCM) Mitral valve endocardiosis and regurgitation HISTORY: B6 a 7 year old neutered male miniature Schnauzer, was presented to the NCSU cardiology service for re-evaluation of dilated cardiomyopathy. At his prior visit, B6 presented to our Small Animal Emergency on 6/22/17 for episodes of collapse. B6 had his first two collapse episodes in mid February, he was described to fall over for ~6 seconds with no loss of consciousness, and he immediately returned to normal after. He later has several more collapsing episodes in June 2017, which prompted his presentation to NCSU SAES. Collapse episodes were preceded by excitement or exertion. He was discharged 6/22/17 with house mate, B6; unfortunately passed away from DCM and CHF in February 2017. Infectious disease testing and amino acid testing did not identify a cause for the DCM. Histopathology was relatively unremarkable, however, findings could have been consistent with a toxic insult. reports **B6** is doing much better. He has not had any more collapsing episodes, excepting one moment where he stumbled but did not fall when excited 7/4/17. He is tolerating the medications and eating well. No coughing, sneezing, vomiting or diarrhea. His RR has been very normal since starting medications. His diet has been changed to Science Diet adult small breed from California Naturals. The tests results from B6 6/22 visit were normal, including vector borne testing (IFA, PCR) and taurine and carnitine analysis. A full amino acid profile did not reveal significant abnormaliites, however, consultation with UCD is pending for a full interpretation. PHYSICAL EXAM FINDINGS RESULTS OF DIAGNOSTIC TESTS: BLOOD PRESSURE- 110 mmHg systolic CHEST RADIOGRAPHS- Moderate left sided cardiomegally with no signs of congestive heart failure. Moderate hepamegaly. RENAL PANEL: **B6** 

## ASSESSMENT:

Fax: Admin

Fax: Referral

B6 was presented today for a recheck of his recently diagnosed dilated cardiomyopathy (DCM). DCM is a disease of unknown cause affecting the muscle of the heart and is most commonly seen in large breed dogs (such as Dobermans, Great Danes, and Labrador Retrievers). Although the exact mechanism of DCM is currently unknown, dietary taurine/carnitine deficiencies, genetics and toxins have all been linked to DCM. Infectious and nutritional causes of DCM have been ruled out to the best of our ability to test for B6: The overall effect of DCM is a decrease in the contractility (pumping ability) of the heart. Because the heart is unable to pump

Print Date: 07/11/17 Page 2

with enough vigor to move blood adequately forward into circulation, a volume overload occurs and the heart dilates to accommodate it. As a result, the chambers of the heart become very large, and the walls of the heart become very thin. Ultimately, the heart is unable to accommodate and dilate further; the result is back-up of blood from the heart and into the lungs, known as congestive heart failure. It is important to know that this disease is progressive, and ultimately those patients affected with it will experience congestive heart failure. Given the unusual timing of B6 and B6 both developing dilated cardiomyopathy within the same time frame, their different ages, unrelatedness, same environment and lack of an identifiable cause, we are continuing to hunt for an environmental explanation for B6 DCM. We will keep you up to date as we pursue toxin testing in the food and treats you have brought us. However, negative toxin testing may not completely rule out a toxin since we do not have samples representative of the onset of cardiac signs in both dogs. We have changed B6 food to address this possibility. We are glad to see that Be is doing well clinically. His chest xrays showed resolution of congestive heart failure and his renal panel was normal indicating that he is tolerating the medications well. We would like to add B6 to his regime because his B6 while normal, is at the low end of the range, and because this may have some long term benefit through B6 We have also listed doses for supplements, that while unproven in their benefit, are not harmful and may help his myocardial function. Taurine and carnitine supplementation are unlikely to be helpful since his plasma and whole blood concentrations are normal. MEDICATIONS: Plesae continue the following medications: Please start the following medication: Please avoid strenuous exercise or situations which place undue stress on your pet. In general, pets with congestive heart failure will self-regulate their exercise. Please monitor for any change in exercise capability. Please continue to monitor B6 respiratory rate and call if this increases. Please also call if he begins coughing or collapse episodes recur. A diet that is moderately restricted in salt is ideal for cardiac patients, as excessive salt load can cause fluid accumulation. A commercial "Senior" diet is formulated with an appropriate amount of salt for your pet. Please also avoid salty treats, such as hot dogs or jerky treats. **NEXT APPOINTMENT:** B6 should have a recheck appointment with NCSU Cardiology in 3-4 months to evaluate chest X-rays, blood pressure, kidney vāiūds, echocardiogram, and troponin. If he begins to show signs of heart failure prior to your next recheck, please call NCSU Cardiology so that we can recheck your pet sooner. CLINICIANS: B6

CLINICAL TECHNICIANS:  B6
RESEARCH TECHNICIAN: B6
CLIENT SERVICES: B6
In order to help expedite medication refills, please visit us online at www.ncstatevets.org and select Pet Owners, Pharmacy Refills.
NOTE: If your pet is in need of emergency aid and you are not able to get to the NC State Veterinary Hospital quickly, please seek care at the nearest veterinary emergency facility. Take these discharge instructions and current medications with you so that the treating veterinarian will know as much as possible regarding your pet's medical condition.

Print Date: 07/11/17

Owner -

Referring Veterinarians - please visit us online at www.ncstatevets.org/veterinarians and fill out our RDVM Feedback Survey!

Student - B6

Clinician - Darcy Adin, DVM

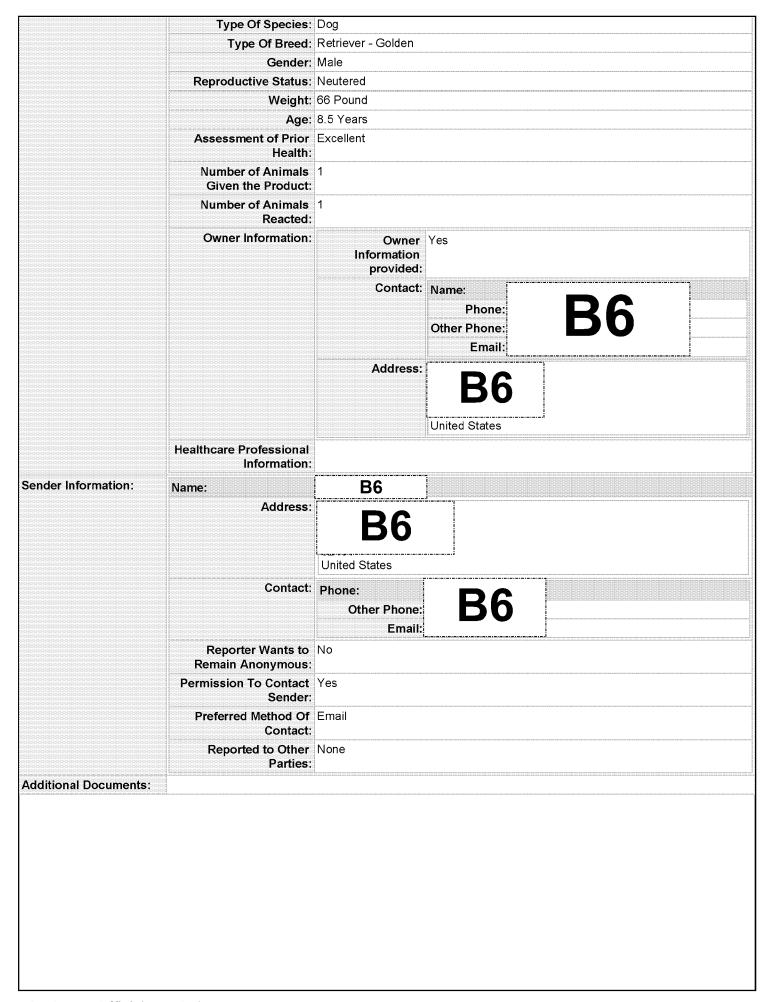
Page 3

From:	Freeman, Lisa <lisa.freemar< th=""><th>n@tufts.edu&gt;</th><th></th><th></th></lisa.freemar<>	n@tufts.edu>		
To:	Jones, Jennifer L			
Sent:	8/24/2018 10:17:06 PM	ļ <del></del>		
Subject:	FW: 800.267-FDA Case Inves	stigation fo	B6	(EON-308715)
		L		<u></u> l
Hi Jen,	,	<b>1</b>		
<b>B6</b> will <u>se</u>	nd records on <b>B6</b>	since I wasn't in	volve in that case b	ut since she and I have
worked together on	<b>B6</b> she asked me to			
records. I indicated in	the report that I had more red			
everything I have.	<b>B6</b> would be very ha	appy to provide m	ore info. She found	d a small amount of the
original diet which she	sent to me and I am includir	ng that in the food	l box that I'm submit	tting to you on Monday.
Thanks for all your wo	rk on this!			
Lisa				
	L [mailto:Jennifer.Jones@fd	la.hhs.gov]		
Sent: Thursday, Augus	st 23, 2018 11:51 AM			
To:	B6			
<b>Subject</b> : 800.267-FDA	Case Investigation for	B6 and	<b>B6</b> (EON-3	308715)
Cood marning				
Good morning B6		to FDA L'es some	, to boor obout	<b>B6</b> illness.
	ng your consumer complaint	ito FDA. I III Son	/ to near about	<b>B6</b> illness.
	ation, we'd like to request:			
• Full Medical Re		10 469E) a conv	é na lautius ma	alical biotomy (pot ivet
	nail (preferred) or fax (301-21		B6 entire	edical history (not just
	), including any ref <u>erral diagr</u> nitted a report for B6		varded the medical r	records and told from Dr
				records and told from Dr.
	nat you may have submitted a ur Vet-LIRN network procedu			
	o with our case investigations	•	ires describe now vi	et-Likin operates and
•	is email so that we can init		vation	
Thank you kindly,	is eman so that we can imi	iate our investig	<u>jation.</u>	
Dr. Jones				
D1. 001100				
Jennifer L. A. Jones, D	VM			
Veterinary Medical Officer				
U.S. Food & Drug Administration				
Center for Veterinary Medicine Office of Research				
	ation 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				
Web: http://www.fda.gov/Anima	aIVeterinary/ScienceResearch/ucm2473	334.htm		
U.S. FOOD & DRUG				
The state of the s	V C			

From: To:	B6 Jones, Jennifer L				
Sent:	8/25/2018 1:12:49 PM RE: 800.267-FDA Case Investiga	4:	<b>D</b>	J	(EON-308715)
Hi Dr. Jones, Dr. Freeman has take send you B6 any additional question Best,	n care of submitting an official re full records. Please let me l	port for		and I have	asked my secretary to
	36				
Sent: Thursday, Augu To: Subject: 800.267-FD/	r L [mailto:Jennifer.Jones@fda.h ist 23, 2018 11:51 AM B6 A Case Investigation for B6 ing your consumer complaint to	and	<b>B6</b> rry to hear a	(EON-30	08715) <b>B6</b> illness.
<ul> <li>Full Medical Research</li> <li>Please er this event</li> <li>Have you submare</li> <li>Lisa Freeman the lattached a copy of ohow veterinarians help Please respond to the Thank you kindly,</li> </ul>	ation, we'd like to request:  ccords  mail (preferred) or fax (301-210-4 c), including any referral diagnost  nitted a report for B6  nat you may have submitted a cour Vet-LIRN network procedures o with our case investigations.  nis email so that we can initiate	ics. I was fo implaint. I ca . The proced	rwarded the annot seem dures descr	e medical re to locate it	ecords and told from Dr. within our system.
8401 Muirkirk Road, G704 Laurel, Maryland 20708 new tel: 240-402-5421 fax: 301-210-4685 e-mail: jennifer.jones@fda.hhs	ion e ation and Response Network (Vet-LIRN)	<u>ıtm</u>			



Report Details - EON-	308715					
ICSR:	1064844					
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:	2017-03-30 15:52:14 EDT					
Reported Problem:	Problem Description:	Presented to local veterinarian for gagging cough. Regular veterinarian concerned about new heart murmur and large heart on ultrasound and referred to Emergency and Cardiology services at B6 Cardiac workup showed degenerative valvular disease, but also very depressed cardiac contractility and early congestive heart failure. Taurine level (plasma) was checked to rule out taurine deficiency as cause of depressed cardiac contractility and level was extremely low - 5.3 nmol/mL (normal is 60-120 nmol/mL; critical is < 40 nmol/mL). Concerned that diet may not have sufficient precursors to taurine.				
	Date Problem Started:	03/09/2017				
	Concurrent Medical Problem:					
	Outcome to Date:	Stable				
Product Information:	Product Name:	Nature's Variety Inst	inct Limited Ingredient diet Lamb Meal & Peas Formula			
	Product Type:	Pet Food				
	Lot Number:					
		769949653905				
	Package Type:					
	Package Size:	100				
	Possess Unopened Product:	1				
	Possess Opened Product:					
		: Stored in original bag				
	Product Use Information:	Description:	Fed 1 and 1/4 cup twice daily for several years according to pet owner			
		Last Exposure Date:				
		Product Use Stopped After the Onset of the Adverse Event:				
		Adverse Event Abate After Product Stop:				
		Product Use Started Again:				
		Perceived Relatedness to Adverse Event:	Possibly related			
		Other Foods or Products Given to the Animal During This Time Period:				
	Manufacturer /Distributor Information:					
	Purchase Location Information:					
Animal Information:	Name:	В6				



Report Details - EON-	360238					
ICSR:	2052688					
Type Of Submission:	Initial					
Report Version:	FPSR.FDA.PETF.V.V1					
Type Of Report:	Both					
Reporting Type:	Voluntary					
	2018-07-24 19:15:00 EDT					
Reporter is the Animal Owner:	Yes					
Reported Problem:	Problem Description:	a dry cough in the m taurine because she ml by the plasma tes Dr. Joshua Stern at the Mitral Valve Dys His report reads: "M dysfunction - ddx: ta significantly increase previous July 2016). supplements and re	second birthday, her energy level dropped and she developed nornings. On the advice of a friend, I had her blood tested for was on a grain-free food high in legumes. The result was B6 st (normal level is 60-120 ml). I then took her to cardiologist UCD VMTH. Dr. Stern did an echocardiogram and also found plasia, but did not see SAS. He found Mild to Moderate DCM. oderately dilated left ventricular chamber and LV systolic rurine responsive DCM vs idiopathic DCM. Lv chamber has ed in the recheck interim (LVIDD 5.13cm today, 4.14cm "He prescribed increasing the taurine and I-carnitine turn for repeat echo in 3-4 months.			
	Date Problem Started:	05/08/2017				
	Concurrent Medical Problem:	2				
	Pre Existing Conditions:	ons: She had inherited Mitral Valve Displasia that was diagnosed by a board certical cardiologist when she was one year of age. I was told that it was mild and should live a normal life. He also diagnosed SAS, which was later listed as equivocal.				
	Outcome to Date:	Better/Improved/Red	covering			
Product Information:	Product Name:	Taste of the Wild Pine Forrest, Venison and Legumes				
	Product Type:	<u> </u>	<i>α</i>			
	Lot Number:					
	Package Type:					
	Package Size:					
	Purchase Date:					
	Possess Unopened Product:	No				
	Possess Opened Product:	No				
	Storage Conditions:	In the bag it came in	ı until it was gone.			
	Product Use Information:	Description:	Kibble was fed in a stainless steel bowl with water and supplements twice a day			
		First Exposure Date:				
		Last Exposure Date:				
		Time Interval between Product Use and Adverse Event:				
		Product Use Stopped After the Onset of the Adverse Event:				
		Adverse Event Abate After Product Stop:				
		Product Use	No			

		Started Again:				
		[	Definitely related			
		Relatedness to Adverse Event:	Bollinially related			
		Other Foods or Products Given to the Animal During This Time Period:	No			
	Manufacturer /Distributor Information:					
	Purchase Location	Name:				
	Information:		Chewy.com 1855 Griffin Road	TROUGH TO THE TROUGH THE TROUGH TO THE TROUGH TO THE TROUGH TO THE TROUGH TO THE TROUG		
			Dania Beach Florida 33004 United States			
Animal Information:	Name:	B6				
	Type Of Species:	Dog				
		Retriever - Golden				
	Gender:	}				
	Reproductive Status:	Intact				
	Pregnancy Status:					
	Lactation Status:					
	Weight:	68.5 Pound				
	Age:	3 Years				
	Assessment of Prior Health:					
	Number of Animals Reacted:					
	Owner Information:	77				
	Healthcare Professional Information:	Practice Name: Contact:	UCD VMTH Cardiolog  Name: Joshua			
			Phone: 1-530-			
			Other Phone: 925989			
		Addross		337.33		
		Addless.	1 Garrod Drive Davis California 95616 United States			
		Type of Veterinarian:	Referred veterinarian			
		Date First Seen:	07/06/2016			
		Permission to Release Records to FDA:	Yes			
Sender Information:	Name: Address	<b>B6</b>				
	L.	United States				
	Contact:	Phone: Other Phone: Email:	B6			

	Permission To Contact Sender:	Yes
	Preferred Method Of Contact:	Email
	Reported to Other Parties:	Other
Additional Documents:		
	Attachment:	B6 ucd 7.6.17.pdf
	Description:	B6 Echocardiogram
	Туре:	
	Attachment:	7.7.2016 B6 results B6 pdf
	Description:	7.7.2016 B6 results B6 pdf  B6 echo at 1 y/o by Dr. B6 on 7/7 /2016
	Туре:	Echocardiogram
	Attachment:	3.29.18 Dr. Stern Rept.pdf
	Description:	B6 third and most recent Echo at UCD 3/29/18
	Туре:	Echocardiogram
	Attachment:	11.17.17 B6 Dr. Stern UCD echo.pdf
		B6second echo at UCD VMTH 11/17/17
		Echocardiogram



One Shields Avenue Davis, CA 95616-8747

Phone: 530.752.1393 Fax: 530.754.7297

Patient Name:  Medical Rec #:  DOB:  Age: 2 years  Sex: Fi  Sonographer:  B6  DVM, Cardiology  Resident  Cardiology Resident:  B6  DVM, Cardiology		Golden Retriever 66 lb 0.98 m <sup>2</sup> Not taken 103
Diagnosis: Dilated Cardiomyopathy (suspect to	aurine responsive	2)
B(	6	
2D UCD LA sax UCD LA lax LA d Ao s LA/Ao  UCD LA sax UCD LA lax cm cm cm (<1.5) B6 cm (<2.5)		
LA 2d/LV mmode B6		
M-mode RV IVS LVPW LA  Diastole cm %FS cm MRSIm median MRSI cm EDVI cm ESVI	B6 ml/m² ml/m²	LV EF LV SV LV SI LV CO LV CO LV CI EPSS    %   %
Normal Canine M-mode values (in cm) for 35 kg dogs.           LVIDd         LVPWd         IVSd         LA           B6         B6         B6         B6           Aortic Valve:         AoV           VMax         B6         m/s	AO	%FS
Mitral Valve:         E Vmax           Mn Grad         E Vmax           P1/2T         msec         A Vmax           MV Area         E/A           MV DT         nsec         MV VTI	m/s m/s	
Tricuspid valve:  TV E Max  TV Mn Grad  TV VTI  TR Vmax  TR Pk Grad  RVSP  TR Pk Grad  mmHg  mmHg  mmHg		

Page 1 of 3

Pulmonic valve:

Vmax PV AT

PV ET PV AT/ET **B6** 

**CLINICIAN INTERPRETATION:** 

Mitral Valve:

В6

**Pulmonary Artery:** 

B6

**B6** 

**ECHO SUMMARY:** 

- 1. Moderately dilated left ventricular chamber and LV systolic dysfunction ddx: taurine responsive DCM vs idiopathic DCM.
  - LV chamber size has significantly increased in the recheck interim (LVIDD **B6** m today, **B6** m previous July 2016).
- 2. Mild left atrial enlargement (LA/Ao = **B6**
- 3. Mild mitral regurgitation is static in the recheck interim. This likely represents mild mitral valve dysplasia as previously noted, but may be secondary to annular deformation from chamber dilation (cannot determine accurately until reevaluation)
- 4. Max Aortic / LVOT velocity is **B6** s. This has improved in the recheck interim (previously **B6** m/s), however it is likely due to decrease systolic function.
- 5. Trivial tricuspid regurgitation can be seen in normal dogs.
- 6. No other congenital heart diseases.

Recommendations:

**B6** 

**B6** 

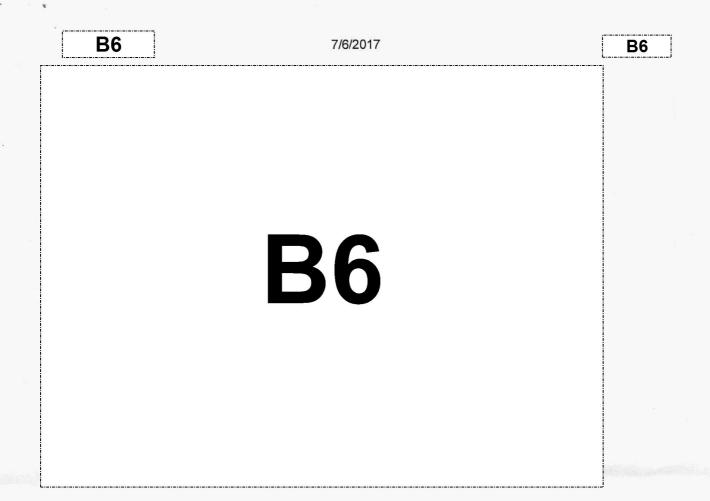
DVM, Cardiology Resident

Joshua A Stern DVM, PhD, Diplomate ACVIM (Cardiology)

Electronically signed on 7/6/2017 on 12:24:16 PM

**B6** 

Page 2 of 3



Veterinary Medical Teaching Hospital
One Shields Ave., Davis, CA 95616-5270
http://www.vetmed.ucdavis.edu (530) 752-1393

# Discharge Instructions - Record Copy

Admission: Discharge:	·	Small Animal Outpatien	<u>t</u>	/isit#: <u>80</u> Status:
Client #:	B6	Patio Pat Spo	Becies: K9 Breed: GOLDEN RETRIEVER	Sex: <u>F</u>
Dischar	ge Instructions	ging Re to the MC Davis	Cardiology service for eva	aluation
1)	of her heart.	ging Be to the of bavis		
2)	CLINICAL EXAMINAT	ON		
3)	On physical exam, audible on physical	B6 was bright and alert l exam and she has a Grade	. Her heart sounds were eas II/VI heart murmur. Her pu hysical exam was unremarkal	ulses
4)	DIAGNOSTIC TESTS:	ļ <u>-</u>		
	has moderately ded dilated cardiomyon mitral valve, which Her aortic velocit pumping function of	reased pumping function. To tathy (DCM). She continues th may be mitral valve dysp ty was normal today, but the	eart are dilated. Her heart his is due to a condition of to have mild leak through l lasia, but can be due to he is may also be due to decre	called her er DCM.
•	ASSESSMENT	to a laborate and popular	ne levels, we suspect that	her DCM
7)	is caused by tauring tauring, we are	ne deficiency. If her DCM hopeful that we can rever	is caused by a previous de se her heart disease by	ficiency
8)	B6 echo show is low immediate	ed that her left atrium is risk to develop congestive	ave already started to do. mildly enlarged, which mea heart failure (CHF) / flui	ns there
9)	report. This mean	have mild mitral valve re that some blood from her men her heart pumps. This a	egurgitation in her previou left ventricle flows backw amount of mild mitral valve c last echo. Her mitral val	ards into
	regurgitation may	be representative of mitra	al valve dysplasia, but it	may also
10)	B6 aortic ve the flow through subaortic stenosi blood flow throug stenosis, so we we hack to a normal	locity was normal today. We the aortic valve B6 was s, though today we didn't an her aortic valve. B6 buld like to assess her aortice.	e measure aortic velocity to previously noted to have appreciate any abnormalitie DCM may be masking her surtic velocity flow when her	equivocales of the abaortic heart is
11)	see now. Until we	see if the taurine suppleme get <b>B6</b> more stable, we elective procedures.	entation can reverse the DC would not advise anesthesi	M that we a for her
12) 13)	MONITORING Please monitor progressing. This weakness, lethar	at home for any evidence includes exercise intoleray, inappetence, abdominal of	ce that her heart disease i ance, increased coughing, c distension, or trouble/diff iately if any of these sign	collapse, Siculty

			В6	Dames 2			
Discharge	Instructions - Record Copy Visit#: 80420	CV Patient:	В	Page: 2			
	observed.						
	MEDICATIONS						
15)	1. Taurine: Supplement B6 diet with 1500mg taurine twice a day. THIS IS A DOSE CHANGE						
16)	from the amount of taurine B6 was pro	rine twice a eviously gett	ting.	A DOSE CHARGE			
171	2. L-carnitine:	2010001, 900.					
18)	Supplement B6 diet with 2000 mg L-carnitine three times a day.						
101	DECUECY						
20)	Please schedule an appointment in 3-4 mg	onths to reas	ssess Bb	heart. We will			
	likely repeat an echocardiogram at this	time to see	how her hear	chambers look			
	after supplementing with taurine and ca	rnitine. ho UC Davis (	Cardiology se	rvice She is			
21)	Thank you again for bringing B6 to to SUCH a beautiful and well-behaved girl!	ne uc Davis v	cardiology se.	LVICC. BIIC ID			
221	If you have any questions or concerns p	lease do not	hesitate to	contact us at			
22)	(530) 752-1393.						
23)	Senior Student: B6						
	Resident Clinician: Dr. B6						
25)	Faculty Veterinarian: Dr. Joshua Stern						
		•					
T have t	read and understand the discharge instruc	tions					
	knowledge receipt of the above animal.	<u> </u>					
	_	Clie	ent Signature	Date			
Meds	in Pharmacy Meds in Ward			T.A			
	page: Clinician; or						
Please ]	bage: Clinician, of						
Prepare	l by: ???	Prepared f	for: <u>???</u>	<del></del>			
- <u>-</u>				,			
	/	<u></u>	0:	/			
Dischar	ged by Date & Time	Clinician	Signature	Date			

From: Rotstein, David </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0A3B17EBFCF14A6CB8E94F322906BADD-

DROTSTEI>

To: Jones, Jennifer L; Peloquin, Sarah; Nemser, Sarah; Carey, Lauren; Ceric, Olgica; Glover, Mark;

Palmer, Lee Anne

**Sent:** 8/13/2018 4:52:20 PM

Subject:follow-up tau EON-360238-FW: Taste of the Wild Pine Forrest:B6- EON-362010Attachments:2053631-report.pdf; Taste of the Wild Pine Forrest:B6- EON-360238; 2053631-

attachments.zip

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





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From: Related PFR Event [mailto:pfrsignificantactivitycreation@fda.hhs.gov]

**Sent:** Monday, August 13, 2018 12:48 PM

**To:** Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Cleary, Michael \* <Michael.Cleary@fda.hhs.gov>; HQ Pet Food Report Notification <HQPetFoodReportNotification@fda.hhs.gov>; B6

Subject: Taste of the Wild Pine Forrest: B6 - EON-362010

A PFR Report has been received and Related PFR Event [EON-362010] has been created in the EON System.

A "PDF" report by name "2053631-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 "2053631-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

**EON Key:** EON-362010

ICSR #: 2053631

**EON Title:** Related PFR Event created for Taste of the Wild Pine Forrest Venison and Legumes; 2053631

AE Date	05/08/2017	Number Fed/Exposed	
Best By Date		Number Reacted	1

Animal Species	Dog	Outcome to Date	Better/Improved/Recovering
Breed	Retriever - Golden		
Age	3 Years		
District Involved	PFR- B6 DO		

**Individual Case Safety Report Number: 2053631** 

Product Group: Pet Food

Product Name: Taste of the Wild Pine Forrest, Venison and Legumes

Description: Just before B6 second birthday, her energy level dropped and she developed a dry cough in the mornings. On the advice of a friend, I had her blood tested for taurine at the B6 at UCDavis because she was on a grain-free food high in legumes. The result was B6 ml by the plasma test (normal level is 60-120 ml). I then took her to board certified cardiologist Dr. Joshua Stern at UCD VMTH. Dr. Stern did an echocardiogram and also found the Mitral Valve Dysplasia, but did not see SAS. He found Mild to Moderate DCM. His report reads: "Moderately dilated left ventricular chamber and LV systolic dysfunction - ddx: taurine responsive DCM vs idiopathic DCM. Lv chamber has significantly increased in the recheck interim (LVIDD B6 m today, B6 previous July 2016)." He prescribed increasing the taurine and l-carnitine supplements and return for repeat echo in 3-4 months. She returned for additional echos in November 2017 and March 2018. Copies of all three visit reports and echos are attached. I'm going to try to attach a copy of her blood report of before and after

Submission Type: Followup

Report Type: Both

supplementation.

Outcome of reaction/event at the time of last observation: Better/Improved/Recovering

**Number of Animals Reacted With Product: 1** 

Product Name	Lot Number or ID	Best By Date
Taste of the Wild Pine Forrest, Venison and Legumes		

This report is linked to:

**Initial EON Event Key: EON-360238** 

Initial ICSR: 2052688

Sender information

**B6** 

USA

To view this Related PFR Event, please click the link below: https://eon.fda.gov/eon//browse/EON-362010

To view the Related PFR Event Report, please click the link below: <a href="https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jspa?decorator=none&e=0&issueType=10100&issueId=378744&parentIssueTypeId=12">https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jspa?decorator=none&e=0&issueType=10100&issueId=378744&parentIssueTypeId=12</a>

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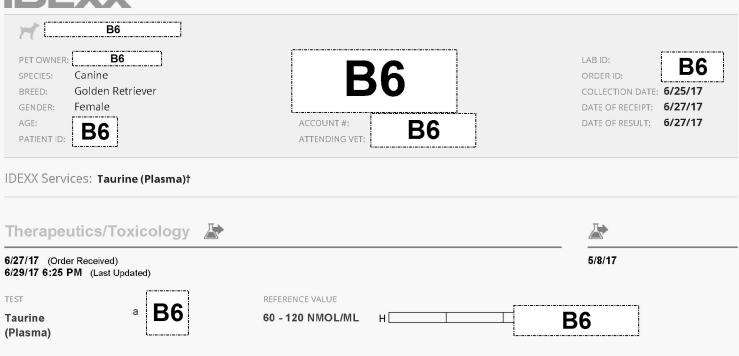
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ICED.	2052624				
ICSR: Type Of Submission:	2053631 Followup				
Report Version:	FPSR.FDA.PETF.V.V1	an ntaa neketan ntaa niontaa norta la ntaa nortakia nortaa neekia			
Type Of Report:	Both				
Reporting Type:	Voluntary				
Report Submission Date:					
Initial Report Date:	07/24/2018				
Reporter is the Animal Owner:	Yes				
Parent ICSR:	2052688				
Follow-up Report to FDA Request:	Yes				
Reported Problem:	Problem Description:	a dry cough in the mornings. On the advice of a friend, I had her bloo taurine at the B6 at UCDavis because she was on a grain-free in legumes. The result was B6 ml by the plasma test (normal level is 6 then took her to board certified cardiologist Dr. Joshua Stern at UCD Stern did an echocardiogram and also found the Mitral Valve Dysplasmot see SAS. He found Mild to Moderate DCM. His report reads: "Modilated left ventricular chamber and LV systolic dysfunction - ddx: tau responsive DCM vs idiopathic DCM. Ly chamber has significantly increcheck interim (LVIDI: B6 m today: B6 m previous July 2016)." I prescribed increasing the taurine and I-carnitine supplements and ret repeat echo in 3-4 months. She returned for additional echos in Nove and March 2018. Copies of all three visit reports and echos are attact going to try to attach a copy of her blood report of before and after supplementation.			
	Date Problem Started:	3			
	Concurrent Medical Problem:				
	Pre Existing Conditions:	She had inherited Mitral Valve Displasia that was diagnosed by a board certified cardiologist when she was one year of age. I was told that it was mild and she should live a normal life. He also diagnosed SAS, which was later listed as equivocal. Her initial Echo was done by Dr. B6 board certified Cardiologist, B6 Report from visit attached.			
	Outcome to Date:	Better/Improved/Red			
Product Information:	Product Name:	Taste of the Wild Pir	ne Forrest, Venison and Legumes		
	Product Type: Lot Number:	Pet Food			
	Package Type:				
	Package Size:	11			
	Purchase Date:	Ţ			
	Possess Unopened Product:				
	Possess Opened Product:				
	Storage Conditions:	In the bag it came in	until it was gone.		
	Product Use Information:	Description:	Kibble was fed in a stainless steel bowl with water and supplements twice a day		
		First Exposure Date:			
		Last Exposure Date:			
		Time Interval between Product	1 Years		

		Use and Adverse	7	
		Event:		
		Product Use Stopped After the Onset of the Adverse Event:	Yes	
		Adverse Event Abate After Product Stop:	Yes	
		Product Use Started Again:	No	
		Perceived Relatedness to Adverse Event:	Definitely relate	ed
		Other Foods or Products Given to the Animal During This Time Period:	No	
	Manufacturer /Distributor Information:			
	Purchase Location	Name:	Chewy.com	
	Information:	Address:	1855 Griffin Ro Dania Beach Florida 33004 United States	pad
Animal Information:	Name:	B6		
	Type Of Species:	? ?		
	2 \$	Retriever - Golden		
	Gender:	<del>-</del>		
	Reproductive Status:	Intact		
	Pregnancy Status:	1		
	Lactation Status:	<u> </u>		
		68.5 Pound		
		3 Years		
	Assessment of Prior Health:	ł		
	Number of Animals Reacted:	1		
	Owner Information:	7		
	Healthcare Professional	Practice Name:	UCD VMTH Ca	ırdiology
	Information:	Contact:	<del>?</del>	Joshua Stern
			1	1-530-752-2475
			Other Phone:	{
		Address:	1 Garrod Drive	
			Davis California 95616 United States	
		Veterinarian:	Referred veteri	narian
		Date First Seen:	07/06/2016	
		Permission to Release Records to FDA:	Yes	

Sender Information:	Name:	
	Address:	DC
	, (44, 666)	<b>B6</b>
		United States
	044	
	Contact:	Phone:
		Other Phone: <b>B6</b>
		Email:
	Permission To Contact Sender:	
	Preferred Method Of Contact:	
	Reported to Other Parties:	
Additional Documents:		
	Attachment:	<b>B6</b> 2017-06-27-0207.pdf
	Description:	This is a copy of two blood runs for B6 The first led to her visit to Dr. Stern at UCD. The second was after supplmentation with taurine and L-carnitine had started and just before our first appoint at UCD. I have no other documentation.
		: Laboratory Report
	. , ре.	7





 ${f a}$  Testing performed at University of California, Davis

From: PFR Event PFR Event

A PFR Report has been received and PFR Event [EON-362973] has been created in the EON System.

A "PDF" report by name "2054024-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 "2054024-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

**EON Key:** EON-362973

ICSR #: 2054024

EON Title: PFR Event created for Zignature Kangaroo Grain Free Formula, Earthborne Naturals Lamb Grain

Free; 2054024

AE Date	<b>B</b> 6	Number Fed/Exposed	
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Better/Improved/Recovering
Breed	Mastiff		
Age	6 Years		
District Involved	PFR-Atlanta DO		

#### Product information

**Individual Case Safety Report Number: 2054024** 

Product Group: Pet Food

Product Name: Zignature Kangaroo Grain Free Formula, Earthborne Naturals Lamb Grain Free

**Description:** Presented to NCSU ER **B6** for lethargy, coughing and a terminal wretch for 4 days. He was diagnosed and treated for atrial fibrillation, DCM and congestive heart failure. Taurine **B6** nmol/ml. Slowly transitioned from grain free to regular diet. Returned for recheck on 17 Aug 2018 and has shown significant improvement. Still not sure at this point if the DCM is breed or diet related, or both. Owner has another Mastiff which also was on Zignature Kangaroo Grain Free.

**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 Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Earthborne Naturals Lamb Grain Free		
Zignature Kangaroo Grain Free Formula		

Sender information			
	<b>B6</b>		
USA			

Owner information				
<b>B6</b>	USA			

To view this PFR Event, please click the link below: https://eon.fda.gov/eon//browse/EON-362973

To view the PFR Event Report, please click the link below: <a href="https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jspa?decorator=none&e=0&issueType=12&issueId=379707">https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jspa?decorator=none&e=0&issueType=12&issueId=379707</a>

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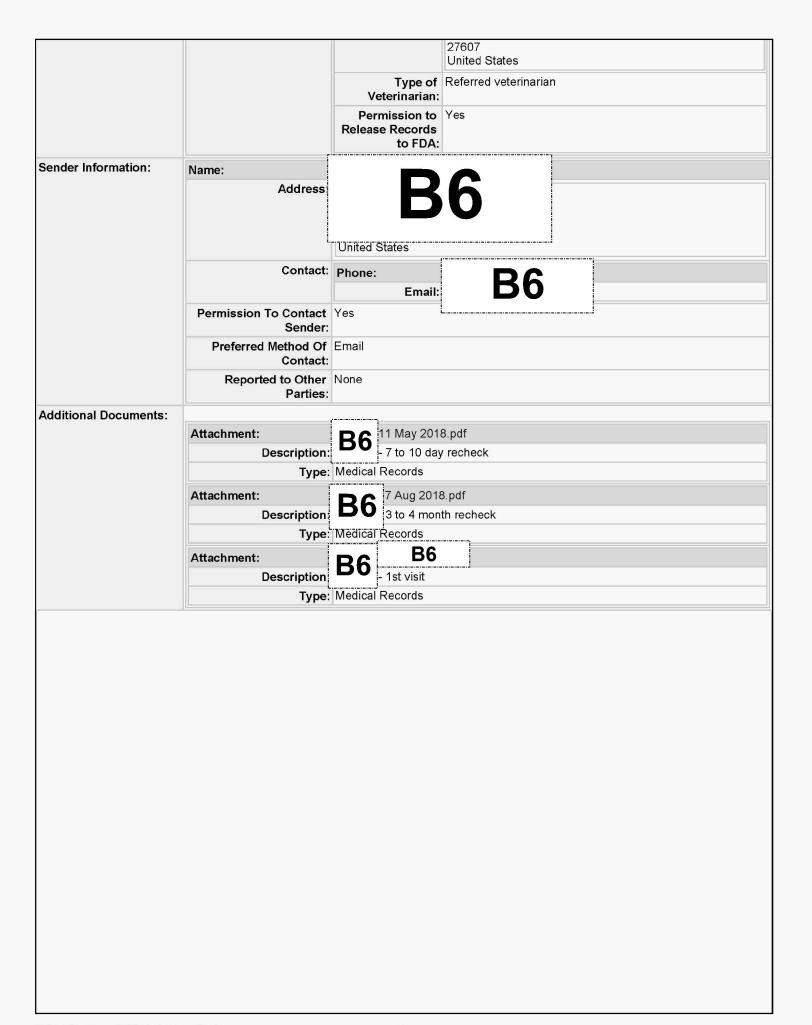
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Report Details - EON-	362973					
ICSR:	2054024					
Type Of Submission:	Initial					
Report Version:	FPSR.FDA.PETF.V.V1					
Type Of Report:	Adverse Event (a symptom,	reaction or disease	associated with the product)			
Reporting Type:	Voluntary					
Report Submission Date:	.) 					
Reported Problem:	Problem Description:	Presented to NCSU ER B6 for lethargy, coughing and a terminal wretch for 4 days. He was diagnosed and treated for atrial fibrillation, DCM and congestive heart failure. Taurine B6 mol/ml. Slowly transitioned from grain free to regular diet. Returned for recheck on 17 Aug 2018 and has shown significant improvement. Still not sure at this point if the DCM is breed or diet				
		related, or both. Owner has another Mastiff which also was on Zignature Kangaroo Grain Free.				
	Date Problem Started	В6				
	Concurrent Medical Problem:	No				
	Outcome to Date:	Better/Improved/Red	covering			
Product Information:	Product Name:	Earthborne Naturals				
	Product Type:  Lot Number:		Estino Cidili i 100			
	Package Type:	BAG				
	Storage Conditions:	<u> </u>	or .			
	Product Use	7				
	Information:	Description: First Exposure Date:	Used as a primary source of food 2013-2015 01/01/2013			
		Last Exposure Date:	01/01/2015			
		Time Interval between Product Use and Adverse Event:	5 Years			
		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:	Zianatura Vassess	Grain Free Formula			
	Product Name:	Zignature Kangaroo	Grain Hee Fullifula			
	Product Type:	rei roou				
	Lot Number:					
	Package Type: Possess Unopened Product:	No				
	Possess Opened Product:	Unknown				
	Storage Conditions:	Please contact owne	Pr			
	Product Use Information:	Description: First Exposure	Used as a primary source for food 2015 -May 2018			

	18	Date:		
		Last Exposure Date:	05/10/2018	
		Time Interval between Product Use and Adverse Event:	3 Years	
		Product Use Stopped After the Onset of the Adverse Event:		
		Adverse Event Abate After Product Stop:		
		Product Use Started Again:		
		Perceived Relatedness to Adverse Event:		
		}}	Yes	
	Manufacturer /Distributor Information:		75	
	Purchase Location Information:			
Animal Information:	Name:	В6		
	Type Of Species:	in in the second		,
	Type Of Breed:			Page and the second
	Gender:	<u> </u>		**************************************
	Reproductive Status:			
		96.4 Kilogram		and control
		6 Years		25 - 25 - 25 - 25 - 25 - 25 - 25 - 25 -
	Assessment of Prior	Excellent		
	Health: Number of Animals	1		article particle part
	Reacted: Owner Information:	7		The state of the s
	Owner information.	Owner Information provided:		***************************************
		Contact:	Name: Phone Email	
		Address:		
		i i	L United States	0 C C C C C C C C C C C C C C C C C C C
	He althous Drofospional		74	
	Healthcare Professional Information:		NC State College of Veterinary Medicin	e 
		Contact:	Name: Phone Emai	
		Address:	1060 William Moore Dr Raleigh North Carolina	



3. ECG: Atrial fibrillation with a rate of

Fax: Admin Fax: Referral

# NC State University Veterinary Hospital 052 William Moore Drive Raleigh, NC 27607

Small Animal (919) 513-6500 Large Animal (919) 513-6630

		Discharge Comments		1000
B6	Patient B6 MASTIFF MC FAWN CANINE	Case # <b>B6</b> 95.3 kg	Attending DVM Student Discharging DVM Referring DVM	B6 <b>B6</b>
Admission Date/Time:MAY ( CASE SUMMARY  DIAGNOSIS 1. Dilated cardiomyopathy - 2. Atrial fibrillation 3. Congestive heart failure -	r/o primary vs diet induced	charge Date/Time: MAY 04, and a second control of the control of t		harge Status:
with a terminal retch for four	r days. He was hospitalized	who was presented to the NC and transferred to the NCSU ouple of weeks. Approximate three days ago where blood B6	Cardiology Service for ful	
B6 is otherwise eating, and famotidine by his primal foreign body, and naproxen  Zignature kangaroo diet (gra	drinking, urinating, and defe ry veterinarian at his visit a toxicity. B6 has been s B6	B6  Try coughing 5-6 times per he decline, he was presented to ecating normally. He has a his couple of days ago. He also been by the NCSU!  Both events resolved will lergic skin disease). To support current medications, apart from	o NCSU for further evaluate story of allergies, and was has a history of frequent e  B6 thout hospitalization or intellement	tion. started on benedryl ar infections, light bulb
PHYSICAL EXAM FINDING		<b>B6</b>		
CV/RESP: rapid irregularly ir Gl/GU: no nain on abdomina	regular tachyarrhythmia, va	riable and weak femoral puls	es, increased lung sounds	s bilaterally
DIAGNOSTICS  1. Big 4. B6  2. Doppler blood pressure or	n admission <b>B6</b> nmHg			

pm and infrequent left sided VPC's

**B6** 

4. AFAST/TFAST - mild peritoneal effusion, no pleural or pericardial effusion Echocardiogram a. Dilated cardiomyopathy - r/o primary vs diet induced b. Severely increased LV size **B6** c. Decreased ventricular wall thickness CANINE d. Moderately enlarged right ventricle **B6**  Moderately reduced RV systolic function f. Severely dilated left atrium g. Moderate mitral valve regurgitation Mild to moderate tricuspid regurgitation 6. Thoracic radiographs \* final report pending \* a. Generalized cardiomegaly b. Mild pulmonary edema **B6** 

Whole blood taurine: pending

#### ASSESSMENT:

Thank you for bringing B6 in to see us today. He is a sweet boy and was a pleasure to work with.

As you know, B6 has been diagnosed with a heart condition known as dilated cardiomyopathy (DCM). DCM is a disease of unknown cause affecting the muscle of the heart and is most commonly seen in large breed dogs (such as Dobermans, Great Danes, and Labrador Retrievers). Although the exact mechanism of DCM is currently unknown, dietary taurine/carnitine deficiencies, genetics and toxins have all been linked to DCM. The overall effect of DCM is a decrease in the contractility (pumping ability) of the heart. Because the heart is unable to pump with enough vigor to move blood adequately forward into circulation, a volume overload occurs and the heart dilates to accommodate it. As a result, the chambers of the heart become very large, and the walls of the heart become very thin. Ultimately, the heart is unable to accommodate and dilate further; the result is back-up of blood from the heart and into the lungs, known as congestive heart failure ("fluid on the lungs").

It is important to know that this disease is progressive, and ultimately those patients affected with it will experience congestive heart failure. Based on the results of B6 diagnostics, it appears that he has experienced an episode of congestive heart failure secondary to DCM. This explains the clinical signs you observed at home - lethargy, panting, coughing B6 has responded well to heart failure medications in the hospital, and he is breathing comfortably. We will be sending him home on medications to help prevent further fluid accumulation, and improve the function of his heart. We will also recommend starting him on a supplement called taurine - that has been shown to improve heart function in DCM cases caused by nutritional deficiencies.

B6 has also been diagnosed with an arrhythmia call atrial fibrillation (AF). Cardiac enlargement in dilated cardiomyopathy can result in this rhythm. AF arises due to an abnormality in the electrical system of the heart. In AF, the pacemaker cells' normal electrical impulses are overwhelmed by disorganized electrical impulses that originate in other areas of the atria. The result is an erratic, usually rapid, heart rhythm. Although in and of itself not life-threatening, AF may lead to the development of decreased exercise tolerance, fainting, lethargy and decreased appetite. If sustained for prolonged periods of time at very rapid rates, AF can also lead to the development of congestive heart failure, which was likely a contributing factor in B6 episode of heart failure.

Changes in the muscle of the heart in dogs with DCM can lead to fibrosis and remodeling of the myocardium (heart muscle). This can lead to the development of ventricular arrhythmias. Intermittent ventricular arrhythmias are not dangerous, but if they occur in sequence and rapidly, they can result in sudden death. In the future we would like to place a holter monitor (24 hour ECG) to evaluate B6 average heart rate at home, but also to evaluate for underlying ventricular arrhythmias. This can be performed at his next recreek appointment.

Although we cannot cure DCM, we hope to manage B6 clinical signs with medical therapy as outlined below. The average survival for DCM patients after an episode of heart failure is 6-12 months. However, as we discussed, if B6 DCM is secondary to a nutritional deficiency - his heart structure and function may show improvement with taurine supplementation and diet change. Please see below for diet recommendations.

Please monitor him for signs of worsening of heart failure such as increased exercise intolerance, labored breathing, increased coughing or fainting. Call NCSU Cardiology or your referring veterinarian if any of these signs occur. Also, please learn to take a respiratory (breathing) rate when your pet is resting. This can be done by counting the number of breaths your pet takes in 15 seconds and multiplying by 4 (to get the total breaths per minute). This number should remain less than 36-40 at rest.

INSTRUCTIONS FOR CARE

F	Print Date: 05/04/18 Page 3
í	MEDICATIONS:
	Turki Turki
	<b>B6</b>
į	MONITORING:  1. Please continue to monitor B6 for signs of recurrent congestive heart failure. These would include exercise intolerance, increased respiratory rate, difficulty breathing, episodes of fainting/collapse, or decreased appetite. If you notice any of these signs, please contact us and have B6 evaluated by a veterinarian.
	2. Please also begin to monitor B6 respiratory rate at home when you observe him sleeping. You can do this by counting the number of breaths he takes in 15 seconds, then multiplying this number by 4 to obtain the number of breaths per minute. A normal respiratory rate should be less than 36 breaths per minute. If you feel that B6 respiratory rate is increasing - or if he is having more effort while breathing, please contact us.
	ACTIVITY:  Please avoid strenuous exercise or situations which place undue stress on your B6 In general, pets with congestive heart failure will self-regulate their exercise. Please monitor for any change in exercise capability.
	DIET: As we discussed, we would like to change B6 diet due to a concern for dietary induced DCM. We have seen an association between grain free diets and poor cardiac function recently. Although there is currently no scientific evidence, we have seen an increasing number of dogs with this problem. We would recommend transitioning him to a diet that contains grains. Some brands to consider include the major commercial brands (Purina, Hills, Royal Canin, Iams). There is a Royal Canin select protein adult KO diet that contains kangaroo as the protein source.
	RECOMMENDATIONS FOR FLIRTHER EVALUATION:
	R6

If you have any concerns with how your pet is doing, or to schedule an appointment, please contact the NC State Veterinary Hospital at 919-513-6694. There is a veterinarian on call 24 hours a day.

NOTE: If your pet is in need of emergency aid and you are not able to get to the NC State Veterinary Hospital quickly, please seek care at the nearest veterinary emergency facility. Take these discharge instructions and current medications with you so that the treating veterinarian will know as much as possible regarding your pet's medical condition.

Clinician -Student - c/o 2018 Print Date: 05/04/18
Clinicians:

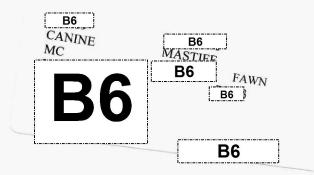
Dr. Darcy Adin

Residents:

Research Technician B6

Client Services: B6

In order to help expedite medication refills, please visit us online at www.ncstatevets.org and select Pet Owners, Pharmacy Refills.



VACCINATION STATUS: YES NO DATE Rabies Distemper or FVRCP Lepto or FeLV Tetanus EEE / WEE / VEE West Nile Virus Influenza Rhinopneumonitis Other:  B6  B6  General Appearance Integumentary Ophthalmic Otic Musculoskeletal Cardiovascular Respiratory Lactating?Yee	
CHIEF COMPLAINT:	
	6
I. Present History II. Past History III. Environm	nent Student Signature
A. Onset / Duration B. Progression C. Prior Treatment A. Medical Illness B. Surgical C. Reproductive D. Adverse Drug Reaction E. Trauma	

1018-6103

### NCSU, COLLEGE OF VETERINARY MEDICANE NCSU DIAGNOSTIC LABORATORIES

Client Patient Med Rec Case **B6 B6** MASTIFF FAWN MC 209.475 lbs CANINE **B6** TERRY CENTER TC-ICU ICU-XL Completed 17 of 17 Results Request Item Priority Status Dates H-773345 RENAL ROUTINE COMPLETE Requested: 05/04/18 08:55 AM Collection: 05/04/18 08:55 AM Requesting DVM: Received: 05/04/1809:05 AM **B6** Student: Needed: 05/04/18 08:55 AM Comments: Status: 05/04/18 09:52 AM CHEMISTRY - RENAL PANEL TEST RESULT UNITS **REF RANGE** RESULT DATETIME **UREA NITROGEN** MG/DL 6 - 26 05/04/2018 09:52 AM **CREATININE** MG/DL .7 - 1.5 05/04/2018 09:52 AM **PHOSPHORUS** MG/DL 2.5 - 5.6 05/04/2018 09:52 AM CALCIUM MG/DL 9.4 - 11.4 05/04/2018 09:52 AM PROTEIN- TOTAL G/DL 5.2 - 7.3 05/04/2018 09:52 AM ALBUMIN G/DL 3 - 3.905/04/2018 09:52 AM **GLOBULIN** G/DL 1.7 - 3.805/04/2018 09:52 AM ALB/GLOB RATIO .9 - 1.8 05/04/2018 09:52 AM SODIUM **B6** MMOL/L 140 - 156 05/04/2018 09:52 AM POTASSIUM MMOL/L 4 - 5.3 05/04/2018 09:52 AM CHLORIDE MMOL/L 108 - 122 05/04/2018 09:52 AM **BICARBONATE** MMOL/L 18 - 26 05/04/2018 09:52 AM ANION GAP 11.2 - 19.9 05/04/2018 09:52 AM NA / K RATIO 27.7 - 35.9 05/04/2018 09:52 AM ICTERIC INDEX 05/04/2018 09:52 AM HEMOLYSIS INDEX 05/04/2018 09:52 AM LIPEMIA INDEX 05/04/2018 09:52 AM Comments: CHLORIDE Containers

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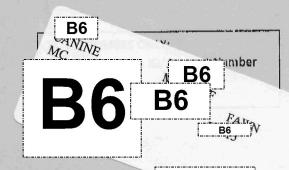
**B6** 

18742

# Sample Submission Form

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



**B6** 

http://www.vetmed.ucdavis.edu/vmb/aal/aal.html

Vet/Tech Contact	B6	
Company Name: No	orth Carolina State Univer	rsity College of Veterinary Medicine
Address Clinical Pa	thology Lab, Room C-269	
1052 William Moore		
A LOUIS A LOUI		
Tel B6		Fax: 919 513-6556
Billing Contact:		TAX ID:
Email:		Tel:
Patient Name:_	B6	
Species: Can	B6	
Owner's Name:	B6	
Sample Type:	Plasma Whole Blo	od Urine Food Other:
Test Items:	Taurine Complete	Amino Acid Other:
Taurine Results (nr	mol/ml)	
	14.0	<b>B6</b>
Plasma:	Whole Blood:	BO Urine: Food:

### Reference Ranges (nmol/ml)

	F	lasma	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			

Containers 1018-6087

#### NCSO, COLLEGE OF VETERINARY MEDIC... E NCSU DIAGNOSTIC LABORATORIES

Client Patient Med Rec Case **B6 B6** MASTIFE FAWN MC 209.475 lbs CANIN **B6** TERRY CENTER TC-ER ER-01 Completed 29 of 29 Results Request Item Priority Status Dates H-773260 SAF ROUTINE COMPLETE Requested: 05/03/18 04:40 PM Collection: 05/03/18 04:39 PM Requesting DVM: **B6** Received: 05/03/1804:46 PM Student: Needed: 05/03/18 04:39 PM Comments: Status: 05/03/18 05:18 PM CHEMISTRY - SMALL ANIMAL CHEMISTRY PANEL TEST RESULT UNITS REF RANGE RESULT DATETIME GLUCOSE MG/DL 70 - 131 05/03/2018 05:18 PM UREA NITROGEN MG/DL 6 - 26 05/03/2018 05:18 PM **CREATININE** 05/03/2018 05:18 PM MG/DL .7 - 1.5**PHOSPHORUS** MG/DL 2.5 - 5.6 05/03/2018 05:18 PM CALCIUM MG/DL 9.4 - 11.4 05/03/2018 05:18 PM **MAGNESIUM** 1.8 - 2.5MG/DL 05/03/2018 05:18 PM PROTEIN- TOTAL 5.2 - 7.3G/DL 05/03/2018 05:18 PM **ALBUMIN** G/DL 3 - 3.9 05/03/2018 05:18 PM **GLOBULIN** G/DL 1.7 - 3.805/03/2018 05:18 PM ALB/GLOB RATIO .9 - 1.805/03/2018 05:18 PM CHOLESTEROL MG/DL 05/03/2018 05:18 PM 124 - 344 **BILIRUBIN-TOTAL** 05/03/2018 05:18 PM ALKALINE PHOSPHATASE IU/L 16 - 140 05/03/2018 05:18 PM ALT IU/L 12 - 54 05/03/2018 05:18 PM **B6** AST IU/L 16 - 140 05/03/2018 05:18 PM GGT 05/03/2018 05:18 PM CK IU/L 43 - 234 05/03/2018 05:18 PM SODIUM MMOL/L 140 - 156 05/03/2018 05:18 PM POTASSIUM MMOL/L 4 - 5.3 05/03/2018 05:18 PM CHLORIDE MMOL/L 108 - 122 05/03/2018 05:18 PM **BICARBONATE** MMOL/L 05/03/2018 05:18 PM 18 - 26 ANION GAP 11.2 - 19.9 05/03/2018 05:18 PM NA / K RATIO 27.7 - 35.9 05/03/2018 05:18 PM OSMOLALITY- CALC. MOSM/KG 278.7 - 311.6 05/03/2018 05:18 PM **AMYLASE** IU/L 236 - 1337 05/03/2018 05:18 PM LIPASE IU/L 12 - 147 05/03/2018 05:18 PM ICTERIC INDEX 05/03/2018 05:18 PM HEMOLYSIS INDEX 05/03/2018 05:18 PM LIPEMIA INDEX 05/03/2018 05:18 PM Comments: CHLORIDE



1052 William Moore Drive Raleigh, NC 27607

Phone: 919.513.6694 Fax: 919.513.6712

# Canine Echocardiography Report

Patient Name: Medical Rec #: DOB: Age: Sex: Sonographer:	B6 B6 Mc		Date of Exa Breed: Weight: BSA: HR: BP-sys:	m: <b>B6</b> Mastiff  95 kg  2.10 m²	
Report Status: Ref. Clinician: Diagnosis: Study Details:	B6 Dilated Cardiomyopath	ny w/ heart failure r Doppler. The images	were of ade	quate diagnostic qι	ality. The
<b>2D</b> IVS LV LVPW					
<b>2D</b> LA Long Axis LA d Ao s LA/Ao		B	6		
M-mode RV IVS LV LVPW LV normalized LA			•		



## **CLINICIAN INTERPRETATION:**

Left Ventricle: The left ventricular cavity size is severely increased. Ventricular wall thickness is decreased. LV basel fractional shortening is account to the contraction of the con

decreased. LV basal fractional shortening is severely decreased. **Left Atrium:** The left atrium is severely dilated.

Right Atrium: The right atrium is moderately dilated.

Right Ventricle: The right ventricular size is moderately enlarged. Global RV systolic function is

moderately reduced.

Mitral Valve: The E-point septal separation is increased. Moderate mitral valve regurgitation. The MR jet is centrally-directed.

#### ECHO SUMMARY:

- The left ventricular cavity size is severely increased.
- 2. Ventricular wall thickness is decreased.
- 3. Moderately enlarged right ventricle.
- Moderately reduced RV systolic function.
- 5. Severely dilated left atrium.
- 6. Moderately dilated right atrium.
- 7. Moderate mitral valve regurgitation.
- 8. Mild to moderate tricuspid regurgitation.

#### CV Exam:

Body condition was overweight. The animal was panting. The mucous membranes appeared pink, with a normal capillary refill time. Femoral pulse quality was difficult to assess.

#### ECG:

The heart rate measured at 220 beats/minute. The ECG rhythm is atrial fibrillation.

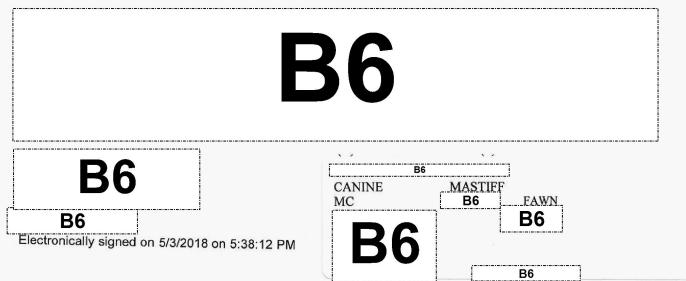
Recommendations: The echocardiogram was limited due to patient size and stability.

This study shows evidence of dilated cardiomyopathy and atrial fibrillation. The LV is severely dilated with thin walls. The systolic function is severely reduced - with the septum moving more adequately than the LV free wall. The mitral regurgitation was difficult to quantify - but appears to be at least moderate. The left atrium is severely dilated.

The ECG shows evidence of atrial fibrillation with a ventricular response rate of **B6** pm.

The patient eats a grain free diet (Zignature Kangaroo). Given the recent association with grain free diets and dilated cardiomyopathy - diet induced DCM is possible. However, given the breed and age idiopathic DCM is also considered.

There is a small volume of free fluid within the abdomen - consistent with R-CHF. Thoracic radiographs show mild pulmomary edema.



Page 2 of 2

Some tests require shared indicate any synthesis indicate any synthesis in activity.  Change in activity.  Change in water.  Change in urinat.  Change in appeti.  Coughing.  Difficulty breath.  Sneezing.	quilize your pet today if  I IVWW WEIVE  ving to obtain the best re  nptoms your pet has exp  y level	esults – may we shave your last	CARDIOLOGY PA  Contact numbe (Please try to be	e available between am for questions or ssary? YES NO the space provided:
Weakness / faint	:WCY			
☐ Diarrhea				
Current diet: Frm Have you seen your fa		Ald wixld & Kon	Has your pet been fed to If yes, what time	
Drug Name	How often given?	Was medication given today?	What time?	REFILL NEEDED TODAY?
	BID	UU.	7:15	YES NO
	310			YES NO
	BID	- due		YES NO
<b>B6</b>	1 210	745		YES NO
	I BIR	1	+ +	YES NO
	WWHA	NO		YES NO
	avarterly	1 NA		YES NO
Owner Signature:	Use back of sheet for any of		Date: 5/1	

## **NC State University**

**Veterinary Hospital** 1052 William Moore Drive



**Small Animal** Large Animal (919) 513-6630

(919) 513-6500

Raleigh, NC 27607 **Discharge Comments** 

Fax: Admin Fax: Referral

Client **Patient** Attending DVM **B6 B6 B6** Student **MASTIFF** Discharging DVM MC 93.5 kg Referring DVM **FAWN** CANINE

Admission Date/Time:MAY 11, 2018 08:53 AM

Discharge Date/Time: MAY 11, 2018 03:00 PM

**Discharge Status:** 

CASE SUMMARY

#### DIAGNOSIS:

1. Dilated cardiomyopathy - r/o primary vs. diet induced

2. Atrial fibrillation
3. Congestive heart failure - pulmonary edema, pleural effusion, abdominal effusion - resolved
HISTORY
B6 is a 5 year old male castrated Mastiff who was presented to the NCSU Cardiology Service on 5/11/18 for a recheck of dilated cardiomyopathy, atrial fibrillation, and congestive heart failure.
B6 was first presented to the NCSU B6 or lethargy and coughing with a terminal retch for four days. Bloodwork performed at his regular veterinarian on 5/2/18 showed hypoalbuminemia (2.6), with normal kidney values (BUN 86 Creat B6 A
CBC and T4 were within normal limits. The urinalysis revealed proteinuria, and pyuria, and the collection method was not reported.
The coughing progressed until his presentation at the ER, where he was coughing 5-6 times per hour. He also refused to eat the
morning of presentation, which was abnormal. While at NCSU an echocardiogram showed evidence of dilated cardiomyopathy, small
volume pleural effusion, and moderate volume abdominal effusion. Thoracic radiographs showed mild pulmonary edema. An ECG showed atrial fibrillation with a ventricular response rate of B6 ppm
treatment. He was discharged of B6
B6
Since discharge, B6 has been doing well at home. He has increased energy and activity levels. Sleeping respiratory rate has been around B6 bpm and owner does not feel as though he has an increased respiratory effort. B6 had one brief episode of coughing this morning and one episode of vomiting a few days ago after being fed a cold food item which is known to cause stomach upset. His owner reports that he has reduced frequency of defecation (1-2x/day as opposed to previous 3-4x/day) and increased water consumption and urination, but is no longer dribbling urine in the house or when lying down.
B6 has a history of allergies, and was started on B6 by his primary veterinarian at his visit on 5/2/18. He also has a history of frequent ear infections, light bulb toreign body, and naproxen toxicity. B6 was previously seen by the NCSU B6 Both events resolved
without hospitalization or intervention. Prior to his diagnosis of cardiac disease, he was eating Zignature kangaroo diet (grain-free; for another dog's allergic skin disease) with raw liver added to supply additional taurine. Since his discharge from the cardiology service on 5/4/18 he has been transitioned to 75% Fromm Salmon a la Veg dry dog food and 25% Zignature with the plan to transition
completely to Fromm in the next few days. He also receives monthly preventatives (Sentinel and Bravecto).
completely to Fromm in the next few days. He also receives monthly preventatives (Sentinel and Bravecto).

CVR: Grade III/VI left apical systolic murmur, irregularly irregular arrhythmia appreciated; eupneic, lung fields clear with normal bronchovesicular sounds noted on bilateral auscultation

please contact us.

ACTIVITY: Please avoid strenuous exercise or situations which place undue stress on your B6 In general, pets with congestive heart failure will self-regulate their exercise. Please monitor for any change in exercise capability.

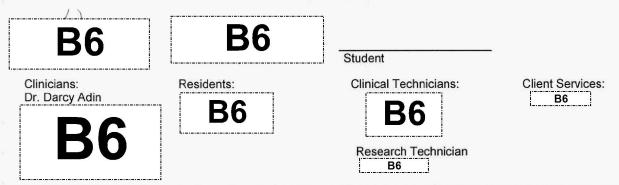
DIET: As we discussed, B6 should be on a diet that contains grains due to a concern for dietary induced DCM. We have seen an association between grain free diets and poor cardiac function recently. Although there is currently no scientific evidence, we have seen an increasing number of dogs with this problem. The Fromm Salmon a la Veg that you are transitioning him to is an acceptable diet and contains several different grains. Please keep him on this diet and continue taurine supplementation as well.

#### NEXT VISIT:

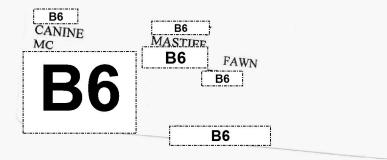
- 1. We would like B6 to come back to NCSU in 7-10 days for a QUICK TEST appointment. At this visit we will perform a kidney panel after beginning therapy with B6 We will also place a holter monitor.
- 2. We would otherwise like to se **B6** back for a recheck exam, blood pressure, renal panel, and echocardiogram in 3 months.

If you have any concerns with how your pet is doing, or to schedule an appointment, please contact the NC State Veterinary Hospital at 919-513-6694. There is a veterinarian on call 24 hours a day.

NOTE: If your pet is in need of emergency aid and you are not able to get to the NC State Veterinary Hospital quickly, please seek care at the nearest veterinary emergency facility. Take these discharge instructions and current medications with you so that the treating veterinarian will know as much as possible regarding your pets' medical condition.



In order to help expedite medication refills, please visit us online at www.ncstatevets.org and select Pet Owners, Pharmacy Refills.



B6 CANINE MASTIF MC  B6	F FAWN B6	NC S TE VETERINARY HOSPITAL HISTORY & PHYSICAL  Admission / Exam Date: 5 / 1/ / 8  Weight: 18
VACCINATION STATUS: YES NO Rabies	DATE  General Appearance Integumentary Ophthalmic Otic Musculoskeletal Cardiovascular Respiratory  Lactating? \( \triangle \tr	ABN No Exam
	В	36

## **NC State Veterinary Hospital**

## **Cardiology Pet Diet History**

	CANINE MASTIFF
51.	CANINE MASTIFF MC B6 FAWN
Date: 5/11/18	B6
	<b>B6</b>
	B6
Current diet:	
Brand + VOM M	+ Fignature
Brund _ 1 1 Or ( 1 ) 1	, gyract SV
1/ 1/ 20 1/2	
Variety Salmon Ala Ve	g / Kangarbo
2.1	
Is this diet Grain-free?	765
How long has your pet eaten this fo	2 1 1 1 1 1 1
How long has your pet eaten this fo	bod? 1 00 CM / 2 9 P/ND
Are there other pets in your house e	eating this food? \\\
	· ·
Other diets eaten in the last 3 years and d	lates:
Earlyborn Nutural	0
Fignature Kango	0CV () ()
v	
Other food (treats, rawhides, table food):	
Various	
No van hider	
Supplements (e.g. fish oil, CoQ10, vitamin	s etc)
	riple Strength, Tourine
	10004(11)

Fax: Admin

Fax: Referral

## **NC State University**

Veterinary Hospital 1052 William Moore Drive Raleigh, NC 27607

**Discharge Comments** 

Small Animal (919) 513-6500 Large Animal (919) 513-6630

B6	Patient B6 MASTIFF MC	Case # <b>B6</b> 96.2197kg	Attending DVM Student Discharging DV	`
	FAWN	90.2197 kg	Referring DVM	
	CANINE			

Admission Date/Time:AUG 17, 2018 08:54 AM

Discharge Date/Time: AUG 17, 2018 11:42 AM

Discharge Status:

CASE SUMMARY

#### DIAGNOSIS:

- 1. Dilated cardiomyopathy suspect at least partially diet induced
- 2. Atrial fibrillation
- 3. Congestive heart failure pulmonary edema, pleural effusion, abdominal effusion well controlled

HISTORY

B6 s a 6 year old male castrated Mastiff who was presented to the NCSU Cardiology Service on 8/17/18 for a recheck of dilated cardiomyopathy, atrial fibrillation, and congestive heart failure.

was first presented to the NCSU ER & B6 or lethargy and coughing with a terminal retch for four days. Bloodwork performed at his regular veterinarian on B6 showed hypoalbuminemia B6, with normal kidney values (BUN B6 Creat B6). A CBC and T4 were within normal limits. The urinalysis revealed proteinuria, and pyuria, and the collection method was not reported. The coughing progressed until his presentation at the ER, where he was coughing 5-6 times per hour. He also refused to eat the morning of presentation, which was abnormal. While at NCSU an echocardiogram showed evidence of dilated cardiomyopathy, small volume pleural effusion, and moderate volume abdominal effusion. Thoracic radiographs showed mild pulmonary edema. An ECG showed atrial fibrillation with a ventricular response rate of ~250bpm. A whole blood taurine returned within normal limits B6 more limits. B6 was hospitalized overnight and responded well to treatment. He was discharged on B6

B6 cardiomegaly, mildly improved pulmonary venous distention, and similar to mildly improved unstructured interstitial pattern. His renal panel showed no significant findings and his digoxin level was B6 ng/nL. His fluid check showed no evidence of abdominal or pericardial effusion, with possible scant pleural effusion. His heart rate was between bbm during his exam, therefore his dose was increased to 360mg BID. In addition, therapy with B6 ng SID). A holter monitor performed 1

B6 dose was increased to 360mg BID. In addition, therapy with B6 hg SID). A holter monitor performed 1 week later showed adequate atrial fibrillation rate control (average heart rate 950pm), with a low number of ventricular arrhythmias.

B6 owner began supplementation with fish oil, and no other changes were made.

Since his last visit, B6 has been doing well at home. He has increased energy and activity levels and has been initiating play with his housemate. He has been able to play for up to an hour, limiting his own activity well and still only panting after playing. They have not noticed any periods of increased respiratory effort and have heard only a rare cough. At rest, they have found his respiratory rate to consistently be below 40 brpm consistently and his heart rate to be between B6 bmp.

B6 has a history of allergies, and was started on benedryl and famotidine by his primary veterinarian at his visit or B6 He arso reas a history of frequent ear infections, light bulb foreign body, and naproxen toxicity.

From 2013-2015, and then Zignature Kangaroo Grain-free (for another dog's allergic skin disease) with raw liver added to supply additional taurine. Since May, he has been transitioned to Fromm Salmon a la Veg dry dog food (not a grain free diet) and it has gone smoothly. He also receives monthly preventatives (Sentinel and Bravecto).

**B6** 

**B6** 

**B6** 

ASSESSMENT:

Thank you for entrusting us with B6 care, he was a very sweet boy!

Today we performed a recheck echocardiogram to evaluate B6 cardiac structure and function. We are happy to report that his echo shows significant improvement. His heart remains moderately to severely enlarged, and continues to show evidence of reduced function - but overall has shown significant improvement in the past 3 months. This is great news, and indicates at least some portion of his cardiac changes are responding to a diet change. As we discussed, it is still very possible B6 has underlying diated cardiomyopathy secondary to his genetics, but we are very pleased to see this improvement with a diet change B6 kidney panel showed normal values - indicating he is tolerating his medications well. In addition B6 heart rate was slow and well controlled during his exam. His heart rate became elevated when stressed, but this is not unexpected. Given these findings, we would like B6 to continue receiving his medications at their current dosages.

We would like to see **B6** pack in 3-4 months for another recheck echocardiogram. If his heart continues to show improvement, we may be able to discontinue some of his cardiac medications. At this visit, we can also perform a recheck holter monitor, to monitor for any worsening arrhythmias. Please continue to monitor him for any signs of worsening cardiac disease - such as lethargy, increased respiratory rate/effort, coughing, weakness, or collapse. If you are concerned about how he is doing, please contact us and have him evaluated by a veterinarian.

INSTRUCTIONS FOR CARE

**B6** 

**B6** 

MONITORING:

- 1. Please continue to monitor B6 for signs of recurrent congestive heart failure. These would include exercise intolerance, increased respiratory rate, difficulty breathing, episodes of fainting/collapse, or decreased appetite. If you notice any of these signs, please contact us and have B6 evaluated by a veterinarian.
- 2. Please continue monitoring **B6** respiratory rate at home when you observe him sleeping. If you feel that **B6** respiratory rate is increasing, or if he is having more effort while breathing, please contact us.

ACTIVITY: Please avoid strenuous exercise or situations which place undue stress on you B6 In general, pets with congestive heart failure will self-regulate their exercise. Please monitor for any change in exercise capability.

DIE **B6** can continue on his Fromm Salmon a la Veg diet.

PLAN FOR RE-EVALIBRIAN.

1. We would like to se B6 back for a recheck exam, blood pressure, renal panel, echocardiogram, and holter monitor in 3-4 months. Please let us know if you feel he needs to be seen sooner.

If you have any concerns with how your pet is doing, or to schedule an appointment, please contact the NC State Veterinary Hospital at 919-513-6694. There is a veterinarian on call 24 hours a day.

NOTE: If your pet is in need of emergency aid and you are not able to get to the NC State Veterinary Hospital quickly, please seek care at the nearest veterinary emergency facility. Take these discharge instructions and current medications with you so that the treating veterinarian will know as much as possible regarding your pets' medical condition.

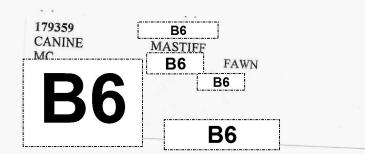
**B6** 

Senior Student:

**B6** 

**B6** 

In order to help expedite medication refills, please visit us online at www.ncstatevets.org and select Pet Owners, Pharmacy Refills.



B6	FAWN B6			inary Teaching Hospital TIENT QUESTIONNAIRE
36				† B6
)U	B6		Contact numb	pe available between
ould like to pick up m		today if possible	Q-30 and 10:30	am for questions or
tween 1pm and 4pm	1)		updates)	
	uilize your pet today if n ving to obtain the best re	esults – may we shave you	ur pet's fur today if nec visit – please describe i	essary? YES NO n the space provided:
Change in activity				
Change in water				
Change in urinat				
Change in appeti	ite			
Coughing  Difficulty breath	• -			
Difficulty breath	ing			
Sneezing				
Sneezing Weakness / fain Vomiting				
Sneezing  Weakness / fain  Vomiting  Diarrhea	ting	almon ala Va	. Has your pet been fe	d today? (YES) NO
Sneezing  Weakness / fain  Vomiting  Diarrhea  Current diet: FOD  Have you seen your fa	nn 4 S4ar So amily vet since your last		How much?	rup>
Sneezing  Weakness / fain  Vomiting  Diarrhea  Current diet: FOOD Have you seen your fa	nm 4 S4ar So amily vet since your last	Almon ala Veg visit? <u>No</u> Was medication given today?	ir yes, what time/	REFILL NEEDED TODAY?
Sneezing  Weakness / fain  Vomiting  Diarrhea  Current diet: FOD  Have you seen your fa	nn 4 S4ar So amily vet since your last	Was medication given today?	How much?	REFILL NEEDED TODAY? YES NO
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Sneezing  Weakness / fain  Vomiting  Diarrhea  Current diet: FOO  Have you seen your factoring  CURRENT MEDICATION  Drug Name	nn 4 S4ar So amily vet since your last	Was medication given today?	How much?	REFILL NEEDED TODAY? YES NO YES NO (ES) NO
Sneezing  Weakness / fain  Vomiting  Diarrhea  Current diet: FOD  Have you seen your fa	nn 4 S4ar So amily vet since your last	Was medication given today?	How much?	REFILL NEEDED TODAY? YES NO YES NO YES NO YES NO YES NO YES NO
Sneezing  Weakness / fain  Vomiting  Diarrhea  Current diet: FOO  Have you seen your factoring  CURRENT MEDICATION  Drug Name	nn 4 S4ar So amily vet since your last	Was medication given today?	What time?	REFILL NEEDED TODAY? YES NO
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Sneezing  Weakness / fain  Vomiting  Diarrhea  Current diet: From Have you seen your factoring Name	nn 4 S4ar So amily vet since your last	Was medication given today?	What time?	REFILL NEEDED TODAY? YES NO

## **NC State Veterinary Hospital**

## **Cardiology Pet Diet History**

Date: 8/17/18  B6 CANINE MASTIFF MC B6 FAWN B6 B6
Current diet: B6
Brand Fromm 4 Star
Variety Salmon ala Veg
Is this diet Grain-free?
How long has your pet eaten this food? 3 months
Are there other pets in your house eating this food? 1 other pet
Other diets eaten in the last 3 years and dates:
Zignature Kangaroo Grain-Gree 2015 - May 2018 Earthborne Naturals Lamb Grain-Gree 2013-2013
Other food (treats, rawhides, table food):  Treats & table foods
Supplements (e.g. fish oil, CoQ10, vitamins etc)  Join + Max Triple Strength, Fish oil, Taurine

<b>B6</b>	General Appearance Integumentary Ophthalmic Otic Musculoskeletal Cardiovascular Respiratory	N ABN No Exam  Reproduction Mammary  Urinary  Nervous  Alimenta  Lymphat	Respiration: Pant Capillary Refill: Pain Score: N ABN No Exametive Ty
Other:	Lactating? _Yes  Lactating? _Yes		
	В	6	
FAMERONI BU - 8			
SER THE CAN'S ASSESSED			!
I. Present History  A. Onset / Duration B. Progression C. Prior Treatment  II. Past Histor A. Medica B. Surgica C. Reprod	ory III. Environmer al Illness IV. Preventativ III. V. Systems Red ductive se Drug Reaction	e Student Signatur	B6

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CANINE	MASTIFF B6 FAWN
MC	B6 FAWN
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NC STATE VETERINARY HOSPITAL DAILY TREATMENT RECORD

IV CATHETER SITE(S):				PLACED:_	81	17/18	)	IN	ITIAL	<b>B6</b>	_
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OLINIOAL GOMMATTI										ar	V.C.
DATE:	CAGE: B-3	5_	DIET:			VATER:			VEIGHT:	90	ry
TREATMENT PLAN (RECORD OBSERVATIONS ON BACK)	TIME (	D	(2)	3)	MONITO	RING					
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STUDEN	IT.	<b>36</b>				LINICIAI		B	3		

DAILY TREATMENT Record 8/5/2011



## 1052 William Moore Drive Raleigh, NC 27607

Phone: 919.513.6694 Fax: 919.513.6712

## Canine Echocardiography Report

Patient Name: Medical Rec #: DOB: Age: Sex: Sonographer: Report Status: Ref. Clinician: Diagnosis: Study Details:	B6 Dilated cardiomyopathy - s	Date of Exam Breed: Weight: BSA: HR: BP-sys: suspect diet induced, atrial fibrillati ppler. The images were of adequ	Mastiff 96 kg 2.12 m <sup>2</sup>
<b>2D</b> IVS LV LVPW			
LV Area LV Vol Vol Index Maj Axis <b>2D</b> LA Long Axis LA d Ao s LA/Ao		<b>B6</b>	
M-mode RV IVS LV LVPW LV normalized LA			
Normal Canine N LVIDd	M-mode values (in cm) for 50 LVPWd IVSd	LA AO	%FS
<b>Aortic Valve:</b> VMax Pk Grad	<b>B6</b>	36	
<b>Tricuspid valve</b> P 1/2 T	B6		

Page 1 of 2

#### CLINICIAN INTERPRETATION:

**Left Ventricle:** The left ventricular cavity size is moderate to severely increased. Ventricular wall thickness is normal. LV basal fractional shortening is mild to moderately decreased.

Left Atrium: The left atrium is moderately dilated.

Right Atrium: The right atrium is mildly dilated.

Right Ventricle: The right ventricular size is mildly enlarged. RV wall thickness is normal. Global RV

systolic function is mildly reduced.

Aortic Valve: No degree of aortic stenosis is present. No evidence of aortic valve regurgitation.

Mitral Valve: The E-point septal separation is increased. Mild to moderate mitral valve regurgitation. The

MR jet is centrally-directed.

Pulmonic Valve: The pulmonic valve is normal.

Pericardium/Effusions: No pericardial effusion is seen.

Aorta: The aortic sinuses, arch, ascending and descending aorta appear all normal.

Pulmonary Artery: The pulmonary artery is of normal size and origin.

#### ECHO SUMMARY:

1. Dilated cardiomypathy - suspect diet induced

- The left ventricular cavity size is moderate to severely increased.
- 3. Moderately dilated left atrium.
- 4. Mildly dilated right atrium.
- 5. Mild to moderate mitral valve regurgitation.
- 6. Mild tricuspid regurgitation.

#### CV Exam:

Body condition was normal. The animal was panting. The mucous membranes appeared pink, with a normal capillary refill time. Femoral pulse quality was normal. Cardiac auscultation revealed a systolic murmur of grade I-II/VI intensity loudest at the left apex. Pulmonary auscultation revealed normal lung sounds.

#### ECG:

The heart rate measured at B6 eats/minute. The ECG rhythm is atrial fibrillation. The heart rate in the exam room was B6 m

**Recommendations:** This is a recheck echocardiogram and is compared to the prior study. **B6** was eating a grain free diet at the time of the prior study - and was transitioned to a non-grain free diet approximately 3 months ago.

This study shows improvement in the cardiac size and function. The LV remains moderately to severely dilated - but has shown a significant decrease in size over the past 3 months. The LV wall thickness has increased as well. The systolic funciton has shown improvement - but remains mildly to moderately reduced. The mitral regurgitation has decreased in severity, and the left atrium has decreased in size (but remains moderately enlarged).

A diagnostic ECG was not performed. The ECG during the echocardiogram showed atrial fibrillation with a ventricular response rate of B6 pm. The heart rate in the exam room was B6 pm, and the owners count a resting heart rate of B6 pm at home.

Overall these findings show a significant improvement after the patient was transitioned off a grain free diet. Recommend continuing the cardiac medications at the current dosages. Recommend beginning taurine and fish oil supplementation. Recommend a recheck echocardiogram and holter monitor in 3-4 months.

**B6** 

Electronically signed on 8/17/2018 on 5:08:14 PM

Rotstein, David </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP From:

(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

9/10/2018 7:44:25 PM Sent:

FW: Earthborn Naturals Lamb Grain Free for 1 year-Zignature Kangaroo Grain Free for 2 years: Subject:

- EON-364808 plus first dog's PFR EON-362973

Attachments: 2054800-report.pdf; Zignature Kangaroo Grain Free Formula

EON-362973; **B6** 

2054800-attachments.zip

David Rotstein, DVM, MPVM, Dipl. ACVP CVM Vet-LIRN Liaison CVM OSC/DC/CERT 7519 Standish Place (BB) **B6** 





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From: PFR Event cpfreventcreation@fda.hhs.gov>

Sent: Monday, September 10, 2018 3:36 PM

To: Cleary, Michael \* < Michael. Cleary@fda.hhs.gov>; HQ Pet Food Report Notification

<HQPetFoodReportNotification@fda.hhs.gov>; usha.gulati@doveltech.com

<u>Subject</u>: Earthborn Naturals Lamb Grain Free for 1 year-Zignature Kangaroo Grain Free for 2 years

**B6** EON-364808

A PFR Report has been received and PFR Event [EON-364808] has been created in the EON System.

A "PDF" report by name "2054800-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 "2054800-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

**EON Key: EON-364808** 

ICSR #: 2054800

EON Title: PFR Event created for Earthborn Naturals Lamb Grain Free for 1 year Zignature Kangaroo Grain

Free for 2 years; 2054800

AE Date	05/23/2018	Number Fed/Exposed	2
Best By Date		Number Reacted	2

Animal Species	Dog	Outcome to Date	Better/Improved/Recovering
Breed	Mastiff		
Age	6 Years		
District Involved	PFR-Atlanta DO		

#### **Product information**

**Individual Case Safety Report Number: 2054800** 

Product Group: Pet Food

Product Name: Earthborn Naturals Lamb Grain Free for 1 year Zignature Kangaroo Grain Free for 2 years Description: Other mastiff in the house B6 was presented in congestive heart failure, possibly due to a grain free diet B6 was presented on 5/23/18 for occult DCM screening B6 has been doing well at home and not showing any signs of heart disease. He had been eating the same grain free diet as B6 and was transitioned to a diet containing grains 3 weeks prior to this visit. Whole blood taurine basically normal. Echo revealed moderate to severe left ventricular enlargement, mild MR, mildly decreased LV ejection fraction. No arrhythmias detected B6 was placed on taurine supplementation B6 returned for a 3 month recheck 8/31/18. His echo showed considerable improvement in size, although still enlarged.

Submission Type: Initial Report Type: Both

Outcome of reaction/event at the time of last observation: Better/Improved/Recovering

Number of Animals Treated With Product: 2 Number of Animals Reacted With Product: 2

Product Name	Lot Number or ID	Best By Date
Earthborn Naturals Lamb Grain Free for 1 year Zignature Kangaroo Grain Free for 2 years		

#### Sender information

**B6** 

Owner information

USA

B6 JUSA

To view this PFR Event, please click the link below: <a href="https://eon.fda.gov/eon//browse/EON-364808">https://eon.fda.gov/eon//browse/EON-364808</a>

To view the PFR Event Report, please click the link below: <a href="https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jspa?decorator=none&e=0&issueType=12&issueId=381567">https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jspa?decorator=none&e=0&issueType=12&issueId=381567</a>

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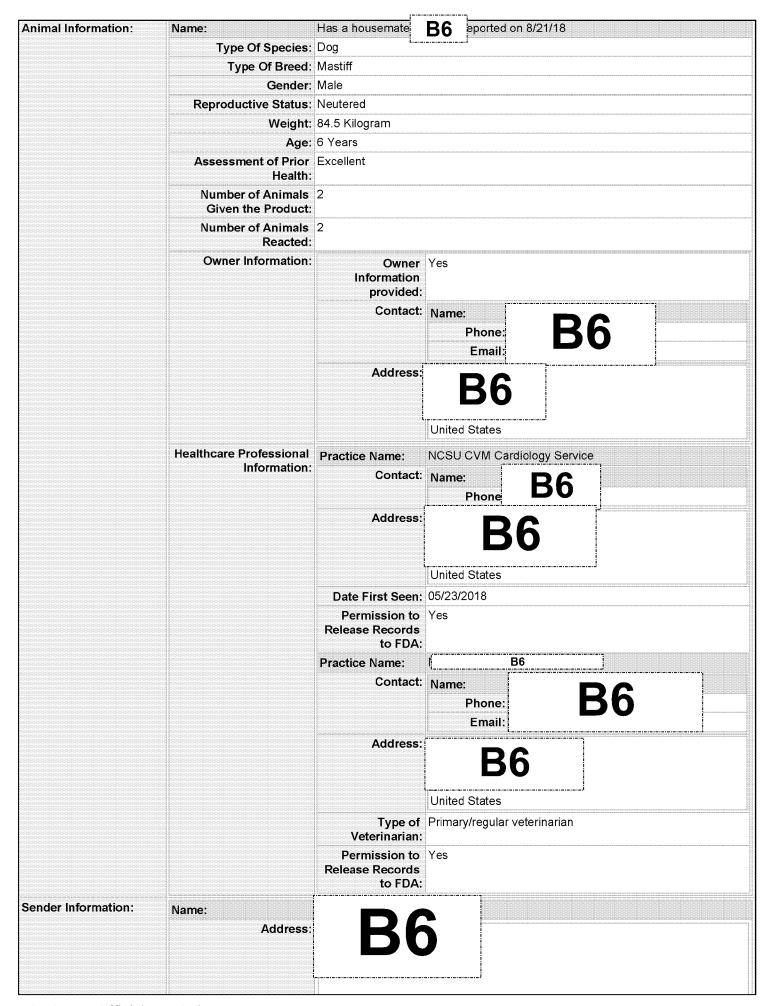
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Report Details - EON-	364808								
ICSR:	2054800								
Type Of Submission:	Initial								
Report Version:	FPSR.FDA.PETF.V.V1								
Type Of Report:	Both								
Reporting Type:	Voluntary								
Report Submission Date:	2018-09-10 15:30:53 EDT								
Reported Problem:	Problem Description:	Other mastiff in the house B6 was presented in congestive heart failure, possibly due to a grain free diet. B6 was presented on 5/23/18 for occult DCM screening B6 has been doing well at home and not showing any signs of heart disease. He had been eating the same grain free diet as B6 and was transitioned to a diet containing grains 3 weeks prior to this visit. Whole blood taurine basically normal Echo revealed moderate to severe left ventricular enlargement, mild MR, mildly decreased LV ejection fraction. No arrhythmias detected B6 was placed on taurine supplementation B6 returned for a 3 month recheck 8/31/18. His echo showed considerable improvement in size, although still enlarged.							
	Date Problem Started:	5							
	Concurrent Medical Problem:								
	Outcome to Date:	: Better/Improved/Recovering							
Product Information:	Product Name:	Earthborn Naturals I for 2 years	Lamb Grain Free for 1 year Zignature Kangaroo Grain Free						
	Product Type:								
	Lot Number:								
	Package Type:	BAG							
	Possess Unopened Product:								
	Possess Opened Product:								
	Storage Conditions:	s: Unknown							
	Product Use	Description:	Orally administered						
	Information:	Time Interval between Product Use and Adverse Event:							
		Product Use Stopped After the Onset of the Adverse Event:							
		Adverse Event Abate After Product Stop:							
		Product Use Started Again:	MA Print						
		Perceived Relatedness to Adverse Event:	Possibly related						
		Other Foods or Products Given to the Animal During This Time Period:							
	Manufacturer /Distributor Information:								
	Purchase Location Information:								



		B6 United States
	0	'
	Contact:	
	Demoissies T. O	
	Permission To Contact Sender:	
	Preferred Method Of Contact:	Email
	Reported to Other Parties:	None
Additional Documents:		
	Attachment:	<b>B6</b> 225633.pdf
	Description:	NC State medical records (we do not have the rDVM medical records).
	Туре:	Medical Records

From:	PFR Event <pfreventcreation@fda.hhs.gov></pfreventcreation@fda.hhs.gov>						
То:	Cleary, Michael *; HQ Pet Food Report Notification <b>B6</b>						
Sent:	8/21/2018 7:48:36 PM						
Subject:	Zignature Kangaroo Grain Free Formula <b>B6</b>	EON-362973					
Attachments:	2054024-report.pdf; 2054024-attachments.zip						

A PFR Report has been received and PFR Event [EON-362973] has been created in the EON System.

A "PDF" report by name "2054024-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 "2054024-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

**EON Key:** EON-362973

ICSR #: 2054024

EON Title: PFR Event created for Zignature Kangaroo Grain Free Formula, Earthborne Naturals Lamb Grain

Free; 2054024

AE Date	B6	Number Fed/Exposed	
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Better/Improved/Recovering
Breed	Mastiff		
Age	6 Years		
District Involved	PFR-Atlanta DO		

roduct information
ndividual Case Safety Report Number: 2054024
Product Group: Pet Food
<b>Product Name:</b> Zignature Kangaroo Grain Free Formula, Earthborne Naturals Lamb Grain Free
<b>Description:</b> Presented to NCSU ER <b>B6</b> for lethargy, coughing and a terminal wretch for 4 days.He
was diagnosed and treated for atrial fibrillation, DCM and congestive heart failure. Taurine = <b>B6</b> nmol/ml.
lowly transitioned from grain free to regular diet. Returned for recheck on 17 Aug 2018 and has shown
ignificant improvement. Still not sure at this point if the DCM is breed or diet related, or both. Owner has
nother Mastiff which also was on Zignature Kangaroo Grain Free.

**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 Reacted With Product: 1** 

Product Name	Lot Number or ID	Best By Date
Earthborne Naturals Lamb Grain Free		
Zignature Kangaroo Grain Free Formula		

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=									-	-			=-		-	-	-	-	-	•

**B6** 

**USA** 

#### Owner information

**B6** Js.

To view this PFR Event, please click the link below: https://eon.fda.gov/eon//browse/EON-362973

To view the PFR Event Report, please click the link below:

 $\underline{https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jspa?decorator=none\&e=0\&issueType=12\&issueId=379707$ 

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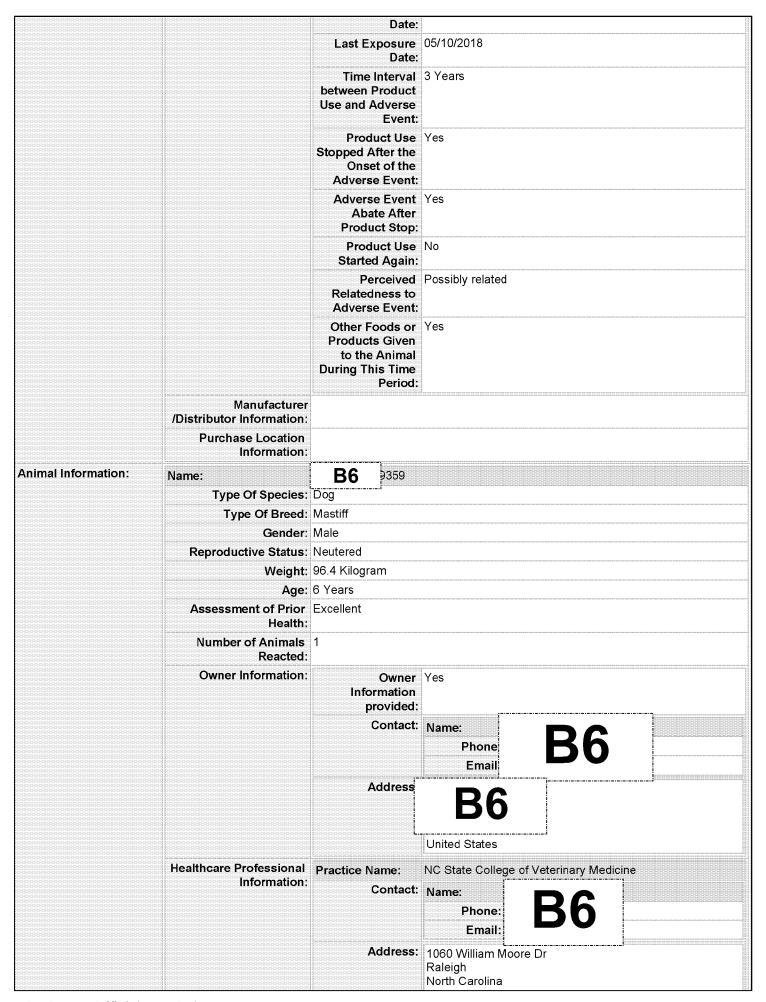
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Report Details - EON-	362973								
ICSR:	2054024								
Type Of Submission:	Initial								
Report Version:	FPSR.FDA.PETF.V.V1								
Type Of Report:	Adverse Event (a symptom,	reaction or disease	associated with the product)						
Reporting Type:	Voluntary								
Report Submission Date:									
Reported Problem:		Drocontod to NICCL	ER B6 for lethargy, coughing and a terminal wretch						
reported Freshelm.	Problem Description:  Date Problem Started	for 4 days. He was diagnosed and treated for atrial fibrillation, DCM and congestive heart failure. Taurine - Be   nmol/ml. Slowly transitioned from grain free to regular diet. Returned for recheck on 17 Aug 2018 and has shown significant improvement. Still not sure at this point if the DCM is breed or diet related, or both. Owner has another Mastiff which also was on Zignature Kangaroo Grain Free.							
	Concurrent Medical Problem:								
		e: Better/Improved/Recovering							
Decduat Information	4	2							
Product Information:	Product Name:	Earthborne Naturals	Lamb Grain Free						
	Product Type:	Pet Food							
	Lot Number:	DAO							
	Package Type:	<u> </u>							
	; [	s: Please contact owner							
	Product Use Information:	Description: First Exposure	Used as a primary source of food 2013-2015 01/01/2013						
		Date: Last Exposure Date:	01/01/2015						
		Time Interval between Product Use and Adverse Event:	5 Years						
		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:	2							
	Product Name:	Zignature Kangaroo	Grain Free Formula						
		<u> </u>	Grain (1661 Official)						
	Product Type: Lot Number:	I GU OUU							
	Package Type:								
	Possess Unopened Product:	No							
	Possess Opened Product:	Unknown							
	Storage Conditions:	Please contact owne	Pr						
	Product Use Information:	Description: First Exposure	Used as a primary source for food 2015 -May 2018						



			27607 United States
		Type of	Referred veterinarian
		Veterinarian:	(100,100 100,1100,1100,1100,1100,1100,11
		Permission to Release Records to FDA:	
Sender Information:	Name:		
	Address:	B(	<b>5</b>
	Contact:	Phone: Email:	B6
	Permission To Contact Sender:	Yes	<u> </u>
	Preferred Method Of Contact:	Email	
	Reported to Other Parties:	None	
Additional Documents:			
	Attachment:	<b>B6</b> 11 May 201 7 to 10 day	8.pdf
			y recheck
		Medical Records	
		<b>B6</b> 17 Aug 201	8.pdf th recheck
		Medical Records	
	Attachment:	DG B6	df
	Description:	B6 B6	
	Type:	Medical Records	

Fax: Admin Fax: Referral

# NC State University Veterinary Hospital 052 William Moore Drive Raleigh, NC 27607

Small Animal (919) 513-6500 Large Animal (919) 513-6630

		Discharge Comments		
B6	Patient B6 MASTIFF MC FAWN CANINE	Case <b># B6</b> 95.3 kg	Attending DVM Student Discharging DVM Referring DVM	B6 B6
Atrial fibrillation	7 03, 2018 03:42 PM Disc - r/o primary vs diet induced - pulmonary edema, abdomi	charge Date/Time: MAY 04, i	2018 03:30 PM <b>Disc</b>	harge Status:
B6 has been more let terminal retch. He was tak  B6 B6 B6 B6 B6 B7	le castrated English Mastiff, vur days. He was hospitalized hargic at home for the past or en to his primary veterinarian progressed, and he is currer formal. Due to his progressive any veterinarian at his visit a contoxicity. Murphy has been selected arrivers for another dog's all dditional taurine. He is on no	and transferred to the NCSU ouple of weeks. Approximate three days ago where blood B6 B6 ntly coughing 5-6 times per h e decline, he was presented to ecating normally. He has a hi couple of days ago. He also been by the NCSU Both events resolved wi lergic skin disease). To supp	Cardiology Service for fully 1 week ago he also begwork and a urinalysis were our. He also refused a ear o NCSU for further evaluates a history of frequent and the service of thout hospitalization or interpret in the service of the	Over the past the morning of tion.
CV/RESP: rapid irregularly	irregular tachyarrhythmia, va	B6	es. increased lung sownd	s. bilaterally
DIAGNOSTICS  1. Big 4: PCV B6 T5 B6 B0  2. Doppler blood pressure	B6 Azo B6	<b>B6</b>	and the same of th	

Page 2 4. AFAST/TFAST - mild peritoneal effusion, no pleural or pericardial effusion Echocardiogram a. Dilated cardiomyopathy - r/o primary vs diet induced b. Severely increased LV size c. Decreased ventricular wall thickness CANINEd. Moderately enlarged right ventricle **B6**  Moderately reduced RV systolic function WASTIEF f. Severely dilated left atrium g. Moderate mitral valve regurgitation **B6**  Mild to moderate tricuspid regurgitation **B6** 6. Thoracic radiographs \* final report pending \* a. Generalized cardiomegaly b. Mild pulmonary edema **B6** 9. Whole blood taurine: pending

ASSESSMENT:
Thank you for bringing B6 in to see us today. He is a sweet boy and was a pleasure to work with.

As you know, B6 has been diagnosed with a heart condition known as dilated cardiomyopathy (DCM). DCM is a disease of unknown cause affecting the muscle of the heart and is most commonly seen in large breed dogs (such as Dobermans, Great Danes, and Labrador Retrievers). Although the exact mechanism of DCM is currently unknown, dietary taurine/carnitine deficiencies, genetics and toxins have all been linked to DCM. The overall effect of DCM is a decrease in the contractility (pumping ability) of the heart. Because the heart is unable to pump with enough vigor to move blood adequately forward into circulation, a volume overload occurs and the heart dilates to accommodate it. As a result, the chambers of the heart become very large, and the walls of the heart become very thin. Ultimately, the heart is unable to accommodate and dilate further; the result is back-up of blood from the heart and into the lungs, known as congestive heart failure ("fluid on the lungs").

It is important to know that this disease is progressive, and ultimately those patients affected with it will experience congestive heart failure. Based on the results of Ba diagnostics, it appears that he has experienced an episode of congestive heart failure secondary to DCM. This explains the clinical signs you observed at home - lethargy, panting, coughing. Ba has responded well to heart failure medications in the hospital, and he is breathing comfortably. We will be sending him home on medications to help prevent further fluid accumulation, and improve the function of his heart. We will also recommend starting him on a supplement called taurine - that has been shown to improve heart function in DCM cases caused by nutritional deficiencies.

B6 has also been diagnosed with an arrhythmia call atrial fibrillation (AF). Cardiac enlargement in dilated cardiomyopathy can result in this rhythm. AF arises due to an abnormality in the electrical system of the heart. In AF, the pacemaker cells' normal electrical impulses are overwhelmed by disorganized electrical impulses that originate in other areas of the atria. The result is an erratic, usually rapid, heart rhythm. Although in and of itself not life-threatening, AF may lead to the development of decreased exercise tolerance, fainting, lethargy and decreased appetite. If sustained for prolonged periods of time at very rapid rates, AF can also lead to the development of congestive heart failure, which was likely a contributing factor in B6 episode of heart failure.

Changes in the muscle of the heart in dogs with DCM can lead to fibrosis and remodeling of the myocardium (heart muscle). This can lead to the development of ventricular arrhythmias. Intermittent ventricular arrhythmias are not dangerous, but if they occur in sequence and rapidly, they can result in sudden death. In the future we would like to place a holter monitor (24 hour ECG) to evaluate B6 average heart rate at home, but also to evaluate for underlying ventricular arrhythmias. This can be performed at his next recreek appointment.

Although we cannot cure DCM, we hope to manage B6 clinical signs with medical therapy as outlined below. The average survival for DCM patients after an episode of heart failure is 6-12 months. However, as we discussed, if B6 DCM is secondary to a nutritional deficiency - his heart structure and function may show improvement with taurine supplementation and diet change. Please see below for diet recommendations.

Please monitor him for signs of worsening of heart failure such as increased exercise intolerance, labored breathing, increased coughing or fainting. Call NCSU Cardiology or your referring veterinarian if any of these signs occur. Also, please learn to take a respiratory (breathing) rate when your pet is resting. This can be done by counting the number of breaths your pet takes in 15 seconds and multiplying by 4 (to get the total breaths per minute). This number should remain less than 36-40 at rest.

INSTRUCTIONS FOR CARE

Clinicians:
Dr. Darcy Adin

B6

Residents:

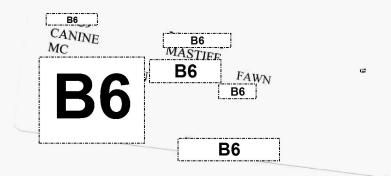
B6

Research Technician

**B6** 

Client Services: B6

In order to help expedite medication refills, please visit us online at www.ncstatevets.org and select Pet Owners, Pharmacy Refills.



B6  VACCINATION STATUS: YES	B6 ASTIFF B6 FAWN B6 B6 B6 General Appe	Admission / E Weight: Temp: Membrane Co Body Conditi  N ABN No Exam arance					
Distemper or FVRCP	Integumentar Ophthalmic Otic Musculoskele Cardiovascul Respiratory Lactating?	etal	Reproductive				
I. Present History II. A. Onset / Duration B. Progression C. Prior Treatment	A. Medical Illness IV. P	nvironment reventative Student S ystems Review Clinician S					

#### NCSU, COLLEGE OF VETERINARY MEDICANE NCSU DIAGNOSTIC LABORATORIES

Client Patient Med Rec Case **B6** B6 MC 209,475 lbs MASTIFF FAWN CANINE TERRY CENTER TC-ICU ICU-XL Completed 17 of 17 Results Request Item Priority Status Dates В6 RENAL ROUTINE COMPLETE Requested: 05/04/18 08:55 AM Collection: 05/04/18 08:55 AM Requesting DVM: Received: 05/04/1809:05 AM **B6** Student: Needed: 05/04/18 08:55 AM Comments: Status: 05/04/18 09:52 AM CHEMISTRY - RENAL PANEL TEST RESULT UNITS **REF RANGE** RESULT DATETIME **UREA NITROGEN** MG/DL 6 - 26 05/04/2018 09:52 AM **CREATININE** MG/DL .7 - 1.5 05/04/2018 09:52 AM **PHOSPHORUS** MG/DL 2.5 - 5.6 05/04/2018 09:52 AM CALCIUM MG/DL 9.4 - 11.4 05/04/2018 09:52 AM PROTEIN- TOTAL G/DL 5.2 - 7.3 05/04/2018 09:52 AM ALBUMIN G/DL 3 - 3.9 05/04/2018 09:52 AM **GLOBULIN** G/DL 1.7 - 3.805/04/2018 09:52 AM ALB/GLOB RATIO .9 - 1.8 05/04/2018 09:52 AM SODIUM B6 MMOL/L 140 - 156 05/04/2018 09:52 AM POTASSIUM MMOL/L 4 - 5.3 05/04/2018 09:52 AM CHLORIDE MMOL/L 108 - 122 05/04/2018 09:52 AM **BICARBONATE** MMOL/L 18 - 26 05/04/2018 09:52 AM ANION GAP 11.2 - 19.9 05/04/2018 09:52 AM NA / K RATIO 27.7 - 35.9 05/04/2018 09:52 AM ICTERIC INDEX 05/04/2018 09:52 AM HEMOLYSIS INDEX 05/04/2018 09:52 AM LIPEMIA INDEX 05/04/2018 09:52 AM Comments: CHLORIDE Containers 1018-6103

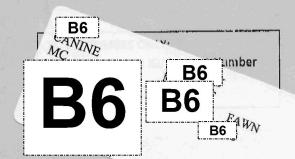
PAGE.

18742

### Sample Submission Form

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



**B6** 

http://www.vetmed.ucdavis.edu/vmb/aal/aal.html

Carried and American				
Vet/Tech Contact	B6			
Company Name: North C	arolina State Universi	ty College of Veter	inary Medicine	
Address: Clinical Patholog	y Lab, Room C-269		-	
1052 William Moore Drive		1770年1450		
Raleigh, NC 27607				
Email:				
Tel B6 Fax: 919 513-6556				
Billing Contact:			AX ID:	
Billing Contact: TAX ID: Email: Tel:				
Patient Name:	B6			
Species: Choine				
Species: Canine Owner's Name:	B6			
Sample Type: Plass	ma Nothole Bloom	Urine	Food Othe	er:
Test Items: Tauri	50 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 -			
restriems: Stauri	III Complete Vi	milo Acid Lo	LITET S	
Taxalan Danislas (www.sl./u	-1)			
Taurine Results (nmol/r	(10)	3.0		
Plasma:	Whole Blood:	Urine:_	<u> </u>	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	

#### NCSU, COLLEGE OF VETERINARY MEDIC... (E NCSU DIAGNOSTIC LABORATORIES

Client Patient Med Rec Case **B6** В6 MASTIFF FAWN CANINE B6 MC 209.475 lbs TERRY CENTER TC-ER ER-01 Completed 29 of 29 Results Request Item **Priority** Status Dates B6 Requested: 05/03/18 04:40 PM Collection: 05/03/18 04:39 PM Received: 05/03/1804:46 PM Needed: 05/03/18 04:39 PM SAF ROUTINE COMPLETE Requesting DVM: Student: Comments: **B6** Status: 05/03/18 05:18 PM CHEMISTRY - SMALL ANIMAL CHEMISTRY PANEL

TEST	RESULT	UNITS	REF RANGE	RESULT DATETIME
GLUCOSE		MG/DL	70 - 131	05/03/2018 05:18 PM
UREA NITROGEN		MG/DL	6 - 26	05/03/2018 05:18 PM
CREATININE		MG/DL	.7 - 1.5	05/03/2018 05:18 PM
PHOSPHORUS		MG/DL	2.5 - 5.6	05/03/2018 05:18 PM
CALCIUM		MG/DL	9.4 - 11.4	05/03/2018 05:13 PM
MAGNESIUM		MG/DL	1.8 - 2.5	05/03/2018 05:18 PM
PROTEIN- TOTAL		G/DL	5.2 - 7.3	05/03/2018 05:18 PM
ALBUMIN		G/DL	3 - 3.9	05/03/2018 05:18 PM
GLOBULIN		G/DL	1.7 - 3.8	05/03/2018 05:18 PM
ALB/GLOB RATIO			.9 - 1.8	05/03/2018 05:18 PM
CHOLESTEROL		MG/DL	124 - 344	05/03/2018 05:18 PM
BILIRUBIN- TOTAL				05/03/2018 05:18 PM
ALKALINE PHOSPHATASE		IU/L	16 - 140	05/03/2018 05:18 PM
ALT		IU/L	12 - 54	05/03/2018 05:18 PM
AST	<b>B6</b>	IU/L	16 - 140	05/03/2018 05:18 PM
GGT				05/03/2018 05:18 PM
CK		IU/L	43 - 234	05/03/2018 05:18 PM
SODIUM		MMOL/L	140 - 156	05/03/2018 05:18 PM
POTASSIUM		MMOL/L	4 - 5.3	05/03/2018 05:18 PM
CHLORIDE		MMOL/L	108 - 122	05/03/2018 05:18 PM
BICARBONATE		MMOL/L	18 - 26	05/03/2018 05:18 PM
ANION GAP			11.2 - 19.9	05/03/2018 05:18 PM
NA / K RATIO			27.7 - 35.9	05/03/2618 05:18 PM
OSMOLALITY- CALC.		MOSM/KG	278.7 - 311.6	05/03/2018 05:18 PM
AMYLASE		IU/L	236 - 1337	05/03/2018 05:18 PM
LIPASE		IU/L	12 - 147	05/03/2018 05:18 PM
ICTERIC INDEX				05/03/2018 05:18 PM
HEMOLYSIS INDEX				05/03/2018 05:18 PM
LIPEMIA INDEX				05/02/2019 05:10 DX
Comments: CHLORIDE			<b>B6</b>	
Containers				7
1018-6087				



1052 William Moore Drive Raleigh, NC 27607

Phone: 919.513.6694 Fax: 919.513.6712

**B6** 

Mastiff

95 kg

2.10 m<sup>2</sup>

## Canine Echocardiography Report

Patient Name: Date of Exam: Medical Rec #: Breed: DOB: Weight: Age: BSA: Sex: Mc HR: Sonographer: **B6** BP-sys:

Report Status: READ

Ref. Clinician: **B6** 

Diagnosis: Dilated Cardiomyopathy w/ heart failure

2D Echo/Doppler/Color Doppler. The images were of adequate diagnostic quality. The Study Details:

patient was awake.

2D **IVS** LV LVPW 2D LA Long Axis LA d Ao s LA/Ao M-mode RV **IVS** LV LVPW LV normalized LA

Mitral Regurgitation: В6 **B6** MR Vmax CANINE MASTIFF MR Peak Gradient **B6** Est SBP by MR FAWN **B6** Tricuspid valve: P 1/2 T **B6** 

## CLINICIAN INTERPRETATION:

Left Ventricle: The left ventricular cavity size is severely increased. Ventricular wall thickness is

decreased. LV basal fractional shortening is severely decreased.

Left Atrium: The left atrium is severely dilated. Right Atrium: The right atrium is moderately dilated.

Right Ventricle: The right ventricular size is moderately enlarged. Global RV systolic function is

moderately reduced.

Mitral Valve: The E-point septal separation is increased. Moderate mitral valve regurgitation. The MR jet is centrally-directed.

#### ECHO SUMMARY:

- The left ventricular cavity size is severely increased.
- 2. Ventricular wall thickness is decreased.
- 3. Moderately enlarged right ventricle.
- Moderately reduced RV systolic function.
- 5. Severely dilated left atrium.
- 6. Moderately dilated right atrium.
- 7. Moderate mitral valve regurgitation.
- 8. Mild to moderate tricuspid regurgitation.

#### CV Exam:

Body condition was overweight. The animal was panting. The mucous membranes appeared pink, with a normal capillary refill time. Femoral pulse quality was difficult to assess.

## ECG:

The heart rate measured at B6 beats/minute. The ECG rhythm is atrial fibrillation.

Recommendations: The echocardiogram was limited due to patient size and stability.

This study shows evidence of dilated cardiomyopathy and atrial fibrillation. The LV is severely dilated with thin walls. The systolic function is severely reduced - with the septum moving more adequately than the LV free wall. The mitral regurgitation was difficult to quantify - but appears to be at least moderate. The left atrium is severely dilated.

The ECG shows evidence of atrial fibrillation with a ventricular response rate of bpm.

The patient eats a grain free diet (Zignature Kangaroo). Given the recent association with grain free diets and dilated cardiomyopathy - diet induced DCM is possible. However, given the breed and age idiopathic DCM is also considered.

There is a small volume of free fluid within the abdomen - consistent with R-CHF. Thoracic radiographs show mild pulmomary edema.

B6

B6

CANINE MC B6

Electronically signed on 5/3/2018 on 5:38:12 PM

B6

Electronically signed on 5/3/2018 on 5:38:12 PM

Page 2 of 2

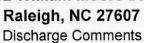
Patient Name:	В6			Carolina State University rinary Teaching Hospital
Clien CANINE	MASTIFF FAWN		CARDIOLOGY PA	ATIENT QUESTIONNAIRE
MC	B6		Contact numb	er
l would (betwee	B6	today il possib	9:30 and 10:30 updates)	be available between ) am for questions or
Some tests require share		esults – may we shave y	our pet's fur today if nec	_
Please indicate any syn	nptoms your pet has exp	. since your last	VIOLE PICAGO ACCESSION	
Change in activity	level Im	W/69		
Change in water		neromed		
<b>V</b> Change in urinati	on frequency TM	Lasix max	ed him void	in himself
Change in appeti	te			
Coughing				
Difficulty breathi	ng			
Sneezing	Allegila			
Weakness / faint				
	MIX		and the second s	
Diarrhea	Jiik			
		Vlg mixed E Kom visit? NO	Has your pet been fed If yes, what time 1: How much? 3 tu	
Drug Name	How often given?	Was medication given today?	What time?	REFILL NEEDED TODAY?
	810	given today:	7:15	YES NO
	310			YES NO
	BID			YES NO
<b>B6</b>	1917)	1745		YES NO
	A) N	1	+ +	YES NO
	MMHAL	NO		YES NO
	a carterly	l'ind		YES NO
Owner Signature:	B6 Use back of sheet for any of	additional information.	Date: 5	10/18

Fax: Admin

Fax: Referral

## **NC State University**

## **Veterinary Hospital** 1052 William Moore Drive





(919) 513-6500 **Small Animal** (919) 513-6630 Large Animal

**Patient** Client Attending DVM **B6** Case # B6 В6 Student **MASTIFF** Discharging DVM MC 93.5 kg Referring DVM **FAWN** CANINE

Admission Date/Time:MAY 11, 2018 08:53 AM

Discharge Date/Time: MAY 11, 2018 03:00 PM

Discharge Status:

CASE SUMMARY

DIAGNOSIS: 1. Dilated cardiomyopathy - r/o primary vs. diet induced
2. Atrial fibrillation
3. Congestive heart failure - pulmonary edema, pleural effusion, abdominal effusion - resolved
HISTORY  B6 is a 5 year old male castrated Mastiff who was presented to the NCSU Cardiology Service on 5/11/18 for a recheck of dilated
cardiomyopathy, atrial fibrillation, and congestive heart failure.
B6 was first presented to the NCSU ER ( B6 for lethargy and coughing with a terminal retch for four days. B6
B6
B6 He also refused to eat the
B6 While at NCSU an echocardiogram showed evidence of dilated cardiomyopathy, small volume pleural effusion, and moderate volume abdominal effusion. Thoracic radiographs showed mild pulmonary edema. An ECG
showed atrial fibrillation with a ventricular response rate of B6 pm B6 was hospitalized overnight and responded well to treatment. He was discharged ort
B6
Since discharge, B6 has been doing well at home. He has increased energy and activity levels. Sleeping respiratory rate has been around 20 bpm and owner does not feel as though he has an increased respiratory effort. B6 had one brief episode of coughing this morning and one episode of vomiting a few days ago after being fed a cold food item which is known to cause stomach upset. His owner reports that he has reduced frequency of defecation (1-2x/day as opposed to previous 3-4x/day) and increased water consumption and urination, but is no longer dribbling urine in the house or when lying down.
B6 has a history of allergies, and was started or B6 his primary veterinarian at his visit or B6 He also has a B6 was previously seen by the NCSU B6 Both events resolved
without hospitalization or intervention. Prior to his diagnosis of cardiac disease, he was eating Zignature kangaroo diet (grain-free; for another dog's allergic skin disease) with raw liver added to supply additional taurine. Since his discharge from the cardiology service on 5/4/18 he has been transitioned to 75% Fromm Salmon a la Veg dry dog food and 25% Zignature with the plan to transition completely to Fromm in the next few days. He also receives monthly preventative B6
<b>B6</b>

CVR: Grade III/VI left apical systolic murmur, irregularly irregular arrhythmia appreciated; eupneic, lung fields clear with normal bronchovesicular sounds noted on bilateral auscultation

please contact us.

ACTIVITY: Please avoid strenuous exercise or situations which place undue stress on your. B6 In general, pets with congestive heart failure will self-regulate their exercise. Please monitor for any change in exercise capability.

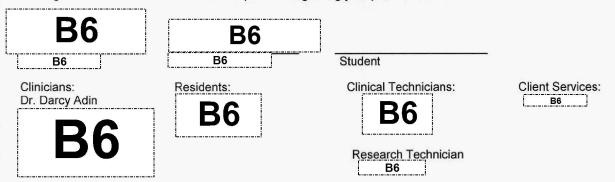
DIET: As we discussed, B6 should be on a diet that contains grains due to a concern for dietary induced DCM. We have seen an association between grain free diets and poor cardiac function recently. Although there is currently no scientific evidence, we have seen an increasing number of dogs with this problem. The Fromm Salmon a la Veg that you are transitioning him to is an acceptable diet and contains several different grains. Please keep him on this diet and continue taurine supplementation as well.

#### NEXT VISIT:

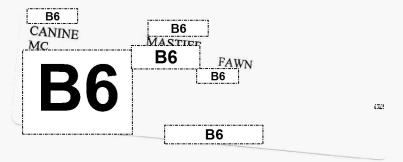
- 1. We would like B6 to come back to NCSU in 7-10 days for a QUICK TEST appointment. At this visit we will perform a kidney panel after beginning therapy with B6 We will also place a holter monitor.
- 2. We would otherwise like to see B6 back for a recheck exam, blood pressure, renal panel, and echocardiogram in 3 months.

If you have any concerns with how your pet is doing, or to schedule an appointment, please contact the NC State Veterinary Hospital at 919-513-6694. There is a veterinarian on call 24 hours a day.

NOTE: If your pet is in need of emergency aid and you are not able to get to the NC State Veterinary Hospital quickly, please seek care at the nearest veterinary emergency facility. Take these discharge instructions and current medications with you so that the treating veterinarian will know as much as possible regarding your pets' medical condition.



In order to help expedite medication refills, please visit us online at www.ncstatevets.org and select Pet Owners, Pharmacy Refills.



		$\overline{}$	NC SFE	VETERINARY HO	OSPITAL
CANINE MC	B6  MASTIFF  B6 FAWN  B6		Admission / Exam Weight: □ Temp: Pu	Date: 5/11/18 Date: 93.5  Ibs (A)kgs 93.5  Ise: Respirate Capillary Pain Sco	ion: Pawt, Refill: 475(C
CACCINATION STATUS: Rabies Distemper or FVRCP Lepto or FeLV Tetanus LEE / WEE / VEE West Nile Virus Influenza Rhinopneumonitis Other:		General Appearance Integumentary Ophthalmic Otic Musculoskeletal Cardiovascular Respiratory Lactating?	N ABN No Exam	Reproductive	N ABN No Exam
		В	O		
Present History     A. Onset / Duration     B. Progression     C. Prior Treatment	II. Past History  A. Medical Illness  B. Surgical  C. Reproductive	III. Environme IV. Preventati V. Systems R	ve Student Signa		26
or resource	D. Adverse Drug R E. Trauma	eaction	Cimician signa	ture.	36

## **NC State Veterinary Hospital**

## **Cardiology Pet Diet History**

B6
Date: 5/11/8  CANINE MASTIFF MC B6 FAWN  B6 B6
B6 B6
Current diet:
Brand From & Fignature
variety Salmon Ala Veg / Kangarbo
Is this diet Grain-free?
How long has your pet eaten this food? \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \
Are there other pets in your house eating this food? \\
Other diets eaten in the last 3 years and dates:
Earthborn Nuturals Meadow Blend
Fignature Kangaroo
Other food (treats, rawhides, table food):
Various
No van hide
Supplements (e.g. fish oil, CoQ10, vitamins etc)
Joint Max triple Strength, Tourine
·

Fax: Admin

Fax: Referral

## **NC State University**

## **Veterinary Hospital** 1052 William Moore Drive Raleigh, NC 27607

**Discharge Comments** 

**Small Animal** (919) 513-6500 Large Animal (919) 513-6630

Client **Patient** Attending DVM **B6** Case # B6 Student MASTIFF Discharging DVI MC 96.2197 kg Referring DVM **FAWN** CANINE

Admission Date/Time: AUG 17, 2018 08:54 AM

Discharge Date/Time: AUG 17, 2018 11:42 AM

Discharge Status:

CASE SUMMARY

## DIAGNOSIS:

- 1. Dilated cardiomyopathy suspect at least partially diet induced

Atrial fibrillation     Congestive heart failure - pulmonary edema, pleural effusions	on, abdominal e	ffusion - well controlled
HISTORY  B6 is a 6 year old male castrated Mastiff who was presercardiomyopathy, atrial fibrillation, and congestive heart failure	nted to the NCSI	U Cardiology Service on 8/17/18 for a recheck of dilated
B6 was first presented to the NCSUER a B6 or letter performed at his regular veterinarian d		B6
The coughing progressed until his presentation at the ER, wh morning of presentation, which was abnormal. While at NCSI volume pleural effusion, and moderate volume abdominal effusioned atrial fibrillation with a ventricular response rate of Enmol/mL). B6 was hospitalized overnight and responded	nere he was couç U an echocardio usion. Thoracic r 36 ppm. A whole	gram showed evidence of dilated cardiomyopathy, small radiographs showed mild pulmonary edema. An ECG blood taurine returned within normal limits Rs 1
	<b>B6</b>	
panel showed no significant findings and his digoxin level was pericardial effusion, with possible scant pleural effusion. His had dose was increased to 360mg BID. In addition, tweek later showed adequate atrial fibrillation rate control (ave B6 where began supplementation with fish oil, and no control his last visit B6 has been doing well at home. He leads to significant findings and his digoxin level was pericardial effusion. His had been doing well at home. He leads to significant findings and his digoxin level was pericardial effusion. His had been doing well at home.	and similar to miss. B6 ing/nL. His neart rate was be therapy with erage heart rate; other changes we has increased er	s fluid check showed no evidence of abdominal or etweer B6 ppm during his exam, therefore his B6 (200mg SID). A holter monitor performed 1 B6 pm; with a low number of ventricular arrhythmias.
his housemate. He has been able to play for up to an hour, lir not noticed any periods of increased respiratory effort and have to consistently be below. Be arm consistently and his heart ra	niting his own ac	care cough. At rest, they have found his respiratory rate
B6 as a history of allergies, and was started on	В6	by his primary veterinarian at his visit or B6 8. He
	B6	
from 2013-2015, and then Zignature Kangaroo Grain-free (for	r carulac uisease another doc's a	e, rie was eating Earthborne Naturals Lamb Grain-free
additional taurine. Since May, he has been transitioned to Fro	mm Salmon a la	Veg dry dog food (not a grain free diet) and it has gone

smoothly. He also receives monthly preventatives (Sentinel and Bravecto).

CURRENT MEDICATIONS:

**B6** 

CVR: Grade II/VI left apical systolic murmur, irregular rhythm appreciated; eupneic, lung fields clear with normal bronchovesicular sounds noted on bilateral auscultation

**B6** 

RESULTS OF DIAGNOSTIC TESTS:

- 1. Blood Pressure
- **B6**
- 2. Renal Panel
- **B6**
- 3. Echocardiogram
- a. Moderate to severe LV dilation significantly improved compared to prior
- b. Moderately reduced LV systolic function static
- c. Moderate left atrial enlargement significantly improved compared to prior
- d. Mild to moderate mitral regurgitation significantly improved compared to prior
- e. No free fluid noted

ASSESSMENT:

Thank you for entrusting us with **B6** care, he was a very sweet boy!

Today we performed a recheck echocardiogram to evaluate echo shows significant improvement. His heart remains moderately to severely enlarged, and continues to show evidence of reduced function - but overall has shown significant improvement in the past 3 months. This is great news, and indicates at least some portion of his cardiac changes are responding to a diet change. As we discussed, it is still very possible B6 has underlying dilated cardiomyopathy secondary to his genetics, but we are very pleased to see this improvement with a diet change. B6 kidney panel showed normal values - indicating he is tolerating his medications well. In addition B6 heart rate was slow and well controlled during his exam. His heart rate became elevated when stressed, but this is not unexpected. Given these findings, we would like B6 to continue receiving his medications at their current dosages.

We would like to see **B6** pack in 3-4 months for another recheck echocardiogram. If his heart continues to show improvement, we may be able to discontinue some of his cardiac medications. At this visit, we can also perform a recheck holter monitor, to monitor for any worsening arrhythmias. Please continue to monitor him for any signs of worsening cardiac disease - such as lethargy, increased respiratory rate/effort, coughing, weakness, or collapse. If you are concerned about how he is doing, please contact us and have him evaluated by a veterinarian.

INSTRUCTIONS FOR CARE

MEDICATIONS:

**B6** 

**B6** 

MONI	TOR	ING:

- 1. Please continue to monitor **B6** or signs of recurrent congestive heart failure. These would include exercise intolerance, increased respiratory rate, difficulty breathing, episodes of fainting/collapse, or decreased appetite. If you notice any of these signs, please contact us and have **B6** evaluated by a veterinarian.
- 2. Please continue monitoring B6 respiratory rate at home when you observe him sleeping. If you feel that rate is increasing, or if he is having more effort while breathing, please contact us.

ACTIVITY: Please avoid strenuous exercise or situations which place undue stress on your B6 In general, pets with congestive heart failure will self-regulate their exercise. Please monitor for any change in exercise capating.

DIET: **B6** can continue on his Fromm Salmon a la Veg diet.

PLAN FOR RE-EVALUATION:

B6

months. Please let us know if you feel he needs to be seen sooner.

If you have any concerns with how your pet is doing, or to schedule an appointment, please contact the NC State Veterinary Hospital at 919-513-6694. There is a veterinarian on call 24 hours a day.

NOTE: If your pet is in need of emergency aid and you are not able to get to the NC State Veterinary Hospital quickly, please seek care at the nearest veterinary emergency facility. Take these discharge instructions and current medications with you so that the treating veterinarian will know as much as possible regarding your pets' medical condition.

**B6** 

Senior Studen B6

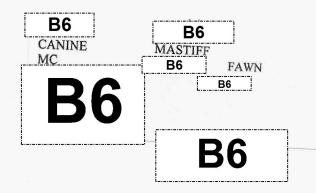
Clinical Technicians:

Clinicians:

Residents:

R6

In order to help expedite medication refills, please visit us online at www.ncstatevets.org and select Pet Owners, Pharmacy Refills.



. Do	FAWN B6		Veter	rolina State University inary Teaching Hospital
	<u> </u>		CARDIOLOGY PA	TIENT QUESTIONNAIRE
Sh Rubin			Contact number	B6
	B6	today if possible	(Please try to b	e available between
ould like to pick up my pet	at:	_ today ii possible	9:30 and 10:30	am for questions or
tween 1pm and 4pm)			updates)	
y we sedate or tranquilize	your pet today if necessa	14.	NO L	(F)
y we sedate of tranquise	obtain the best results -	may we shave you	ur pet's fur today if nec	essary? YES NO
me tests require shaving to	Obtain the best results		nloase describe il عامة	the space provided:
ease indicate any symptom	s your pet has experience	ed since your last \	<u> NSIT</u> – piease deserise ii	
,				
Change in activity level		J		
Change in water consu				
Change in urination fre	equency		N. 15 7	
Change in appetite				
Coughing		384 2 2 200		
Difficulty breathing				
Sneezing				
Sneezing Weakness / fainting				
Weakness / fainting				
Weakness / fainting Vomiting Diarrhea	U.O.A Calca	an ala Vas	Has your not been fee	H today? VES NO
Weakness / fainting Vomiting Diarrhea	4 Star Salm	on ala Veg	if yes, what time/_	any/pin
Weakness / fainting Vomiting Diarrhea	4 S4ar Salm vet since your last visit?	on ala Veg	Has your pet been fer If yes, what time 1	an/pin
Weakness / fainting Vomiting Diarrhea  urrent diet: Fomm	4 SAar Salm vet since your last visit?	on ala Veg	if yes, what time/_	an/pin
Weakness / fainting Vomiting Diarrhea  urrent diet: From Maye you seen your family we consider the constant of	vet since your last visit?	ns medication	if yes, what time/_	REFILL NEEDED
Weakness / fainting Vomiting Diarrhea  From Marches   From Marches    Jave you seen your family we would be compared to the co	vet since your last visit?	<u>00</u>	How much?	REFILL NEEDED TODAY?
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Weakness / fainting Vomiting Diarrhea  urrent diet: From Maye you seen your family we go with the company of th	vet since your last visit?	ns medication	How much?	REFILL NEEDED TODAY? YES NO YES NO
Weakness / fainting Vomiting Diarrhea  urrent diet: From Maye you seen your family we go with the company of th	vet since your last visit?	ns medication	How much?	REFILL NEEDED TODAY? YES NO YES NO YES NO
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Weakness / fainting Vomiting Diarrhea  urrent diet: From Maye you seen your family we go with the company of th	vet since your last visit?	ns medication	How much?	REFILL NEEDED TODAY? YES NO YES NO YES NO YES NO
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Weakness / fainting Vomiting Diarrhea  urrent diet: Form lave you seen your family volume  URRENT MEDICATIONS: Drug Name Ho	ow often given?  Wagiv	ns medication	What time?	REFILL NEEDED TODAY? YES NO
Weakness / fainting Vomiting Diarrhea  urrent diet: Form lave you seen your family volume  URRENT MEDICATIONS: Drug Name Ho	ow often given?  Wagiv	ns medication	What time?	REFILL NEEDED TODAY? YES NO
Weakness / fainting Vomiting Diarrhea Current diet: From Make you seen your family we consider the constant of	ow often given?  Wagiv	ns medication	What time?	REFILL NEEDED TODAY? YES NO

## **NC State Veterinary Hospital**

## **Cardiology Pet Diet History**

CANIN	,	
Date: 8/17/18	B6 FAWN B6	
	<b>36</b> B6	
Current diet:		
Brand Fromm 4 Star		
variety Salmon ala Ve	g	
Is this diet Grain-free?		
How long has your pet eaten this food?	3 months	
Are there other pets in your house eating the	nis food? 1 other pet	
Other diets eaten in the last 3 years and dates:		
Zignature Kangaroo	Grain-Free 2015 - May 20	18
Zignature Kangaroo ( Earthborne Naturals L	amb Grain-free 2013-20	115
Other food (treats, rawhides, table food):		
Treats of table foods		
Supplements (e.g. fish oil, CoQ10, vitamins etc)		
Join + Max Triple Streng	th, Fish oi), Taurine	

B6 B6 MASTIFF B6 B6 B6 B6	NC STATE VETERINARY HOSPITAL HISTORY & PHYSICAL  Admission / Exam Date: 9 17 18  Weight: 212 Hibs kgs 96 4 49  Temp: Pulse: 40 Respiration: pand Membrane Color: pind Capillary Refill: 42  Body Condition: 99 17 18  N ABN No Exam
Rabies Distemper or FVRCP Lepto or FeLV Tetanus  Rabies Integui Ophtha Otic Muscu	Alimentary
Other:	m (diet induced?) + CHF
	<b>B6</b>
Education and the - Inches	d was 12 was the 810
I. Present History  A. Onset / Duration B. Progression C. Prior Treatment  II. Past History  A. Medical Illness B. Surgical C. Reproductive D. Adverse Drug Reaction E. Trauma	III. Environment IV. Preventative V. Systems Review  Clinician Signatur



B6 CANINE MC	B6 MASTIFF	FAWN
	<b>B6</b>	B6

DAILY TREATMENT Record 8/5/2011

NC STATE VETERINARY HOSPITAL DAILY TREATMENT RECORD

IV CATHETER SITE(S):	Via territoria		DATE I	PLACED:	8/1	1/18	INI	TIALS $B6$	<b>5</b>
CLINICAL SUMMARY:	recrue	V +				1		<u> </u>	i 
CLINICAL SUIVIVIANT.			171 00-	1 (60		**		0.4	110
DATE:	CAGE: B-	3	DIET:		WAT		W	EIGHT: 95	ry
TREATMENT PLAN				M	ONITORIN	G			T
(RECORD OBSERVATIONS ON BACK)	TIME	1	(2)	(3)					
i) walk a, 6	8:00 AM								-
0	9:00 AM			12/30					
a) water a u	10:00 AM	0	DLC						
	11:00 AM				, "				
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	6:00 AM				ee value a				
ï	.7:00AM								
STUDE	F	36			CLIN	ıc	B6	;	



1052 William Moore Drive Raleigh, NC 27607

Phone: 919.513.6694 Fax: 919.513.6712

## Canine Echocardiography Report

Patient Name: Date of Exam: 8/17/2018 Medical Rec#: Breed: Mastiff DOB: Weight: 96 kg Age: 6 years BSA: 2.12 m<sup>2</sup> Sex: Mc HR: Sonographer: BP-sys: **B6** Report Status: **READ** Ref. Clinician: **B6** Diagnosis: Dilated cardiomyopathy - suspect diet induced, atrial fibrillation Study Details: 2D Echo/Doppler/Color Doppler. The images were of adequate diagnostic quality. The patient was awake. 2D **IVS** LV **LVPW** LV Area LV Vol Vol Index Maj Axis **B6** 2D LA Long Axis LA d Ao s LA/Ao M-mode RV **IVS** LV **LVPW** LV normalized LA Normal Canine M-mode values (in cm) for 50 kg dogs. LVIDd LVPWd IVSd **B6** Aortic Valve: VMax Pk Grad

Tricuspid valve: P 1/2 T

**B6** 

Page 1 of 2

## CLINICIAN INTERPRETATION:

**Left Ventricle:** The left ventricular cavity size is moderate to severely increased. Ventricular wall thickness is normal. LV basal fractional shortening is mild to moderately decreased.

**Left Atrium:** The left atrium is moderately dilated. **Right Atrium:** The right atrium is mildly dilated.

**Right Ventricle:** The right ventricular size is mildly enlarged. RV wall thickness is normal. Global RV systolic function is mildly reduced.

Aortic Valve: No degree of aortic stenosis is present. No evidence of aortic valve regurgitation.

Mitral Valve: The E-point septal separation is increased. Mild to moderate mitral valve regurgitation. The

MR jet is centrally-directed.

Pulmonic Valve: The pulmonic valve is normal.

Pericardium/Effusions: No pericardial effusion is seen.

Aorta: The aortic sinuses, arch, ascending and descending aorta appear all normal.

Pulmonary Artery: The pulmonary artery is of normal size and origin.

### ECHO SUMMARY:

1. Dilated cardiomypathy - suspect diet induced

- 2. The left ventricular cavity size is moderate to severely increased.
- 3. Moderately dilated left atrium.
- 4. Mildly dilated right atrium.
- 5. Mild to moderate mitral valve regurgitation.
- 6. Mild tricuspid regurgitation.

#### CV Exam:

Body condition was normal. The animal was panting. The mucous membranes appeared pink, with a normal capillary refill time. Femoral pulse quality was normal. Cardiac auscultation revealed a systolic murmur of grade I-II/VI intensity loudest at the left apex. Pulmonary auscultation revealed normal lung sounds.

### ECG:

The heart rate measured at B6 eats/minute. The ECG rhythm is atrial fibrillation. The heart rate in the exam room was B6 pm

Recommendations: This is a recheck echocardiogram and is compared to the prior study B6 was eating a grain free diet at the time of the prior study - and was transitioned to a non-grain free diet approximately 3 months ago.

This study shows improvement in the cardiac size and function. The LV remains moderately to severely dilated - but has shown a significant decrease in size over the past 3 months. The LV wall thickness has increased as well. The systolic funciton has shown improvement - but remains mildly to moderately reduced. The mitral regurgitation has decreased in severity, and the left atrium has decreased in size (but remains moderately enlarged).

A diagnostic ECG was not performed. The ECG during the echocardiogram showed atrial fibrillation with a ventricular response rate of **B6** pm. The heart rate in the exam room was **B6** pm, and the owners count a resting heart rate of **B6** m at home.

Overall these findings show a significant improvement after the patient was transitioned off a grain free diet. Recommend continuing the cardiac medications at the current dosages. Recommend beginning taurine and fish oil supplementation. Recommend a recheck echocardiogram and holter monitor in 3-4 months.

**B6** 

Electronically signed on 8/17/2018 on 5:08:14 PM

## NC STATE VETERINARY HOSPITAL

## MASTER PROBLEM LIST

B6 CANINE MC	B6 FAWN
<b>B</b> 6	B6 B6

NO.	PROBLEM	DATE IDENTIFIED	DATE RESOLVED
	i) occult Dem	5/23/18	
ASTER PROBLEM LIST 12/15/20			

## NC State University - Veterinary Hospital

Date of Admission: 08/31/2018

Owner: DA	Client :	⊭ В6					
DU	Home Phon Work Phon Cell Phon	e:					
Patient: B6	Patient #{	B6					
Species: CANINE Breed: MASTIFF	Sex: M Color: F						
Referring Vet: <b>B6</b>	RDVM # Work Phone Cell Phone FAX	<b>B6</b>					
Referring Clinic: <b>B6</b>	AL Clinic # Phone FAX	B6					
Insurance: None	ID <b>В6</b>						
Is there another veterinarian involved in your pet's ca	are other than the veterina	rian listed above?	(circle one)				
Yes	No						
(Name of Veterinarian and Clinic)							
*******************	**********	*******	*******				
FINANCIAL AGREEMENT: I assume full financial responsibility for all charges in services. I agree to make a payment prior to service hospitalization of the low end of my estimate range, where charges will be compared to my pet's medical I also understand that if there are any additional charbusiness days from the date on which my net is disc.	es received to be used tow I understand that my bill v record to determine accu	rards my pet's care will go through a ver racy for services re	during ification process indered at this visit.				
Owner's Signature <b>B6</b>	(SEAL)	Date:	11/18				
Owner's EMAIL <b>B6</b>							
***************************************	*************	*******	******				
PERMISSION TO USE IMAGES/AUDIO RECORDII NC State may take and use photographs, video or of examination and treatment at the Veterinary Hospita educational and advanced learning purposes.	ther images or recordings	(including audio) re dings may be used	elated to my animal's for nonprofit				
Check only if: ( ) I do not agree to photo/media use by NC State. F	Please inform your cliniciar	n if you do not agree	e to this.				
***************	************	**********	*******				
PERMISSION TO USE SAMPLES THAT REMAIN A Unused blood and urine are usually discarded after 7 these samples have research or teaching value. Clie through this paragraph and initial and date the strike	7 days. Excess tissue is frents who prefer that pet's	equently available. samples not be use	d may strike				

Print Date: 08/31/18

Fax: Admin

Fax: Referral

## NC State University Veterinary Hospital

1052 William Moore Drive Raleigh, NC 27607

Discharge Comments



Page 1

D.

Small Animal (919) 513-6500 Large Animal (919) 513-6630

B6

Patient
B6
MASTIFF
MC
FAWN
CANINE

Case # **B6** 

84.5 kg

Attending DVM Student Discharging DVM Referring DVM

B6

Admission Date/Time: AUG 31, 2018 09:52 AM

Discharge Date/Time: AUG 31, 2018 11:27 AM

**Discharge Status:** 

CASE SUMMARY

#### **DIAGNOSIS:**

- 1. Occult dilated cardiomyopathy suspect diet induced
- 2. Historic otitis externa and atopic dermatitis

HISTORY:

B6 is a 6 year old male castrated Mastiff that was presented to NCSU Cardiology Service on 8/31/18 for a recheck evaluation of occult dilated cardiomyopathy.

was initially evaluated by the NCSU Cardiology Service on 5/23/18. He was proactively screened after his littermate was diagnosed with DCM, atrial fibrillation, and congestive heart failure earlier in May. An echocardiogram revealed evidence of dilated cardiomyopathy, with moderate to severe LV enlargement and reduced systolic function. A whole blood taurine level returned within normal limits. No cardiac medications were prescribed, but taurine supplementation (3000mg BID) was recommended. Both Were eating the same grain free diet for years prior to diagnosis. Both dogs were transitioned to FROMM Salmon Al La Veg (contains whole grains) after B6 Hiagnosis in May 2018.

Since his last visit <u>B6</u> has been doing well at home, and remains asymptomatic. He has shown no episodes of collapse, weakness, trouble breathing, or coughing. He is eating and drinking well with no vomiting or diarrhea. He was initially eating Earthbound Naturals Lamb Grain Free, and was transitioned to Zignature Kangaroo Grain Free in 2016. He is now eating 6 cups daily of Fromm Salmon A La Veg (contains whole grains). <u>B6</u> has a history of otitis externa and atopic dermatitis.

**B6** 

CV/RESP: Soft grade II/VI left basilar systolic murmur. No arrhythmia auscultated. Femoral pulses strong and synchronous. Clear bronchovesicular sounds bilaterally.

В6

## **RESULTS OF DIAGNOSTIC TESTS:**

- 1. ECHOCARDIOGRAM
- a. Moderate LV dilation improved from prior study
- b. Mild left atrial enlargement improved from prior study

- c. Mild mitral regurgitation static
- d. Mildly reduced LV systolic function static

#### ASSESSMENT:

Thank you for entrusting us with **B6** care, he was a very good boy.

Today we performed a recheck echocardiogram to evaluate <u>56</u> cardiac structure and function. We are happy to report that his echo shows considerable improvement in his heart size. His heart remains enlarged, and continues to show evidence of reduced function - but overall has shown improvement in the past 3 months. This is great news, and indicates at least some portion of his cardiac changes are responding to a diet change. As we discussed, it is still possible <u>86</u> has underlying dilated cardiomyopathy secondary to his genetics, but we are very pleased to see this improvement with a diet change. We would like him to continue receiving taurine supplementation.

We would like to see **B6** back in 4-6 months for another recheck echocardiogram to evaluate for further improvement. As we discussed, **B6** heart may return to normal over time, or he may have mild cardiac changes throughout his life. Please continue to monitor him for any signs of worsening cardiac disease - such as lethargy, increased respiratory rate/effort, coughing, weakness, or collapse. If you are concerned about how he is doing, please contact us and have him evaluated by a veterinarian.

#### INSTRUCTIONS FOR CARE

MEDICATIONS: No cardiac medications are currently indicated. Please continue to supplement taurine (3000mg twice daily).

#### ACTIVITY:

Please avoid strenuous exercise or situations which place undue stress on B6 In general, pets with heart disease will self-regulate their exercise. Please monitor for any change in exercise capability.

DIET: **B6** can continue to enjoy his current diet.

#### MONITORING:

Please continue to monitor **B6** for any signs of worsening cardiac disease - such as lethargy, increased respiratory rate/effort, coughing, weakness, or collapse. If you are concerned about how he is doing, please contact us and have him evaluated by a veterinarian.

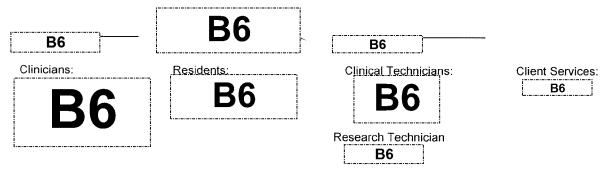
#### PLAN FOR NEXT EVALUATION:

1. We would like to see B6 back in 4-6 months for a recheck exam, blood pressure, and echocardiogram. Please let us know if you feel he needs to be seen sooner.

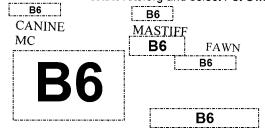
#### COMMENTS:

If you have any concerns with how your pet is doing, or to schedule an appointment, please contact the NC State Veterinary Hospital at 919-513-6694. There is a veterinarian on call 24 hours a day.

NOTE: If your pet is in need of emergency aid and you are not able to get to the NC State Veterinary Hospital quickly, please seek care at the nearest veterinary emergency facility. Take these discharge instructions and current medications with you so that the treating veterinarian will know as much as possible regarding your pets' medical condition.



In order to help expedite medication refills, please visit us online at www.ncstatevets.org and select Pet Owners, Pharmacy Refills.



(between 1pm and a May we sedate or tr	B6 B6 B6 B6 B7 B7 B7 B8	today if poss f necessary? <b>(ES</b> )	CARDIOLOGY P  Contact number (Please try to 9:30 and 10:3 updates)  NO  your pet's fur today if necessity in the contact number (Please try to 9:30 and 10:3 updates)	•
Please indicate any s	symptoms your pet has ex	perienced <u>since your la</u>	<mark>st visit</mark> – please describe ir	n the space provided:
Change in activ	vity level			
Change in water	er consumption			
Change in urin	ation frequency			
Change in appo	etite			
Coughing				
☐ Difficulty breat	thing			
Sneezing	allegy Sl	M47 17		
Weakness / fai	inting			
☐ Vomiting				
Diarrhea				
Current diet: Have you seen your  CURRENT MEDICATI	family vet since your last v	 visit?	Has your pet been fed to the lif yes, what timeHow much?	•
Drug Name	How often given?	Was medication given today?	What time?	REFILL NEEDED
	(1)	A SU	800	TODAY? YES NO
	BID	yes	San	YES NO
<b>B6</b>	quartery-	'NO		YES NO
DU	BID '	+ yw	Sam	YES NO
	way	TO NO.		YES NO
ļ	•			YES NO
				YES NO
Owner Signature:	B6 Use back of sheet for any a		Date: \( \frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\fin}}}}}}{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac}}}}}}}{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\fin}}}}}}}}}{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\fir}}}}}}}{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\fir}}}}}}}{\frac{\frac{\frac{\frac{\frac{\frac{\frac}}}}}{\frac{\firac{\frac{\frac{\frac{\frac{\frac{\f{\frac{\frac{\frac{\fi	31(18

	STIFF B6 FAWN B6		NC STATE VETERINARY HOSPITAL HISTORY & PHYSICAL  Admission / Exam Date: 8/3/1/8  Weight:   Ibs   Dikgs   S45  Temp:   Pulse:   Q4   Respiration:   Q45    Membrane Color:   Q16   Pain Score:   Q14    Body Condition:   Q16   Pain Score:   Q14
VACCINATION STATUS: YES Rabies Distemper or FVRCP Lepto or FeLV Tetanus EEE / WEE / VEE West Nile Virus Influenza Rhinopneumonitis Other: CHIEF COMPLAINT:	G   Ir   O   O   O   O   O   O   O   O   O	General Appearance integumentary Ophthalmic Otic Musculoskeletal Cardiovascular Respiratory Pes	N ABN No Exam   Reproductive
		В	6
I. Present History A. Onset / Duration B. Progression C. Prior Treatment	II. Past History A. Medical Illness B. Surgical C. Reproductive D. Adverse Drug Reaction E. Trauma	III. Environment IV. Preventative V. Systems Revie	Student Signature  Clinician Signature:

## **NC State Veterinary Hospital**

**Cardiology Pet Diet History** 

Date:	CANINE MC	B6 AASTIFE FAWN B6 B6
Current diet:  Brand TV DM 4 - 5	itar	
Variety Salmum	ala VI	<del>J</del>
Is this diet Grain-free?		***************************************
How long has your pet eaten this food?	3 mont	ho
Are there other pets in your house eating	this food? \\	
Other diets eaten in the last 3 years and dates:  Tignatul Kongaro  Earth born Watur		dow flost
Other food (treats, rawhides, table food):	e Z vain	hide
Supplements (e.g. fish oil, CoQ10, vitamins etc)		Ciple Strength



1052 William Moore Drive Raleigh, NC 27607

Phone: 919.513.6694 Fax: 919.513.6712

# 8/31/18 JB

## Canine Echocardiography Report

В6 Patient Name: Date of Exam: 8/31/2018 Medical Rec #: Breed: Mastiff **B6** DOB: Weight: 83 kg Age: 6 years BSA: 1.92 m<sup>2</sup> Sex: Мс HR: Sonographer: В6 BP-sys: Report Status: Ref. Clinician: **B6** Diagnosis: Dilated cardiomyopathy - suspect diet induced Study Details: 2D Echo/Doppler/Color Doppler. The images were of adequate diagnostic quality. The patient was awake. 2D IVS LV **LVPW** 2D LA Long Axis LA d Ao s LA/Ao M-mode RV**IVS** LV **LVPW** LV normalized Normal Canine M-mode values (in cm) for 50 kg dogs. LVIDd LVPWd **B6 B6** Aortic Valve: VMax **CANINE** MASTIFF MC.... Pk Grad **B6 FAWN** B6 Tricuspid valve: P 1/2 T **B6** Pulmonic valve: Vmax Pk Grad

Final

Page 1 of 2

## **CLINICIAN INTERPRETATION:**

Left Ventricle: The left ventricular cavity size is moderately increased. Ventricular wall thickness is

normal. LV basal fractional shortening is mildly decreased.

**Left Atrium:** The left atrium is mildly dilated. **Right Atrium:** The right atrium is normal in size.

Right Ventricle: The right ventricular size is normal. RV wall thickness is normal.

Aortic Valve: No degree of aortic stenosis is present. No evidence of aortic valve regurgitation.

Mitral Valve: The E-point septal separation is increased. Mild mitral valve regurgitation. The MR jet is

centrally-directed.

Pulmonic Valve: The pulmonic valve is normal.

Pericardium/Effusions: No pericardial effusion is seen.

Aorta: The aortic sinuses, arch, ascending and descending aorta appear all normal.

Pulmonary Artery: The pulmonary artery is of normal size and origin.

#### **ECHO SUMMARY:**

1. The left ventricular cavity size is moderately increased.

- 2. Mildly dilated left atrium.
- 3. Mild mitral valve regurgitation.
- 4. No tricuspid regurgitation.

## CV Exam:

Body condition was normal. Normal respirations. The mucous membranes appeared pink, with a normal capillary refill time. Femoral pulse quality was normal. No pulse deficits were noted. Cardiac auscultation revealed a systolic murmur of grade I-II/VI intensity loudest at the left base. Pulmonary auscultation revealed normal lung sounds.

#### ECG:

The heart rate measured at B6 beats/minute. The ECG rhythm is regular sinus rhythm.

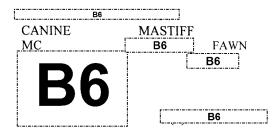
**Recommendations:** A standing echocardiogram was performed and was limited by panting. This is a recheck echocardiogram and is compared to the prior study dated 5/23/18. **B6** has been supplemented with taurine (3000mg BID) since that time, and he has continued to eat a diet containing grains.

The LV has shown a reduction in size and is now moderately enlarged. The systolic function remains mildly reduced and is unchanged compared to prior. There is evidence of persistent mild mitral regurgitation. The left atrium has shown a reduction in size as well, and is now equivocally enlarged.

Overall these changes support a diagnosis of diet induced DCM - with improving cardiac structure and function. No cardiac medications are indicated. Recommend continuing taurine supplementation (3000mg BID). Recommend a recheck echocardiogram in 3-6 months to evaluate for further improvement.

B6

Electronically signed on 8/31/2018 on 4:42:59 PM



Page 2 of 2

## NC state University - Veterinary Lospital

Date of Admission: 05/23/2018

Owner: D.C	Client #:	В6	
ВО	Home Phone:	B6	]
	Work Phone:		.!
<u> </u>	Cell Phone:		
Patient: B6	Patient # B(	3	
Species: CANINE Breed: MASTIFF	Sex: MC Color: FAW	'N	
Referring Vet:	RDVM #:	B6	
RA	Work Phone:		7
	Cell Phone:	B6	
	FAX:		j
Referring Clinic:	Clinic #: 39	94	
<b>B6</b>	Phone:		
<b>D</b> 0	FAX:	<b>B6</b>	
Insurance: None	ID: B6	!	
(Name of Veterinarian and Clinic)  ***********************************	ces received to be used toward e. I understand that my bill will cal record to determine accurac narges or credits found during t	ds my pet's care go through a ve by for services re his process (wh nal invoices refle	during rification process endered at this visit. ich can take up to 10
Owner's EMAIL:			
PERMISSION TO USE IMAGES/AUDIO RECORT NC State may take and use photographs, video or examination and treatment at the Veterinary Hospi educational and advanced learning purposes.	other images or recordings (in		
Check only if: ( ) I do not agree to photo/media use by NC State	. Please inform your clinician if	you do not agre	e to this.
******************	**********	*******	******
PERMISSION TO USE SAMPLES THAT REMAIN Unused blood and urine are usually discarded afte these samples have research or teaching value. Of through this paragraph and initial and date the stril	r 7 days. Excess tissue is freq Clients who prefer that pet's sar	uently available nples not be us	ed may strike

# NC State University

Fax: Admin Fax: Referral 1052 William Moore Drive Raleigh, NC 27607

**Discharge Comments** 

Small Animal (919) 513-6500

Large Animal (919) 513-6630

		9		
Client	Patient B6	Case # <b>B6</b>	Attending DVM Student	В6
Bo	MASTIFF MC	92.2ka	Discharging DVM	
	FAWN	82.3 kg	Referring DVM	<b>B6</b>
	CANINE			
Admission Date/Time:MA	Y 23, 2018 08:54 AM Di	ischarge Date/Time: MAY 23,	2018 10:00 AM	ischarge Status:
CLINICIAN B6				
Date: 5/22/18				
within 24 hours of release	e/discharge from our facility quest a copy. The following	panion. The Discharge Summ via email. If you or your veterir will briefly outline the care you	narian do not receive th	nis, please contact the B6
DIAGNOSIS (ES): 1. Suspected DCM				
INSTRUCTIONS FOR CA				
Activity / Cautions: Please monitor <b>B6</b> for least reconstruction of the second	lethargy, weakness, increase	ed respiratory rate and effort a	nd coughing. If this ha	ppens please contact a
PLAN FOR RE-EVALUA echocardiogram. Please	TION OF YOUR PET: We we schedule this appointment a	ould like to see <b>B6</b> at the N0 at your earliest convenience.	CSU Cardiology service	e after 3 months for an
IF YOU HAVE ANY QUE (919) 513-6911.	STIONS OR PROBLEMS, P	LEASE CALL THE SMALL AN	IIMAL EMERGENCY S	ERVICE AT
PLEASE CALL TO MAKE	E YOUR FOLLOW UP APPO	DINTMENT AS RECOMMEND	ED	
F	 B6			
		j		
Copy to: Owner / Medica	al Record / Fax to RDVM			
CASE SUMMARY				
DIAGNOSIS				
Occult Dilated Cardion     Otitis Externa     Suspected Atopic Deri		taurine deficiency vs idiopathi	c)	
HISTORY				
dilated cardiomyopathy (l been doing well at home has a normal appetite. He	DCM) after his littermate was . He has had no visible chan e was transitioned off of a gr	presented to the NCSU Cardio s diagnosed with the same ear ges to respiratory rate or effor ain free diet (Earthborn Natura non A La Veg which is a grain	flier this month. The ow t, no coughing, letharg als Lamb Grain Free ar	ner reports that B6 has y, vomiting or diarrhea and add Zignature Kangaroo

**B6** 



#### **DIAGNOSTICS**

- 1) Echocardiogram: Moderate to severe left ventricular enlargement, mild mitral valve regurgitation, mildly decreased left ventricular ejection fraction
- 2) ECG: NSR (Normal Sinus Rhythm), no arrhythmias detected
- 3) Taurine Levels (whole blood): pending

## **ASSESSMENT**

Thank you for bringing B6 into the Cardiology Service, he is a very sweet dog and a wonderful patient! Today we performed an echocardiogram which revealed moderate dilation of the left ventricle and decreased systolic function (ability of the heart to pump blood effectively). Based on these findings, we suspect occult (early, asymptomatic) dilated cardiomyopathy (DCM). Although the exact mechanism of DCM is currently unknown, dietary taurine/carnitine deficiencies, genetics and toxins have been linked to DCM. Recent clinical cases of DCM in atypical breeds have also resulted in an association being elicited between some grain free diets and DCM.

We discussed that the underlying cause of <u>B6</u> DCM could be dietary or related to taurine deficiency based on his history but that he is also the correct breed and age to develop primary DCM. Based on the current stage of his heart disease, we are recommending continuing his new grain containing diet and subsequent monitoring with echocardiogram. We also submitted his blood sample to estimate taurine levels during this visit. We will contact you with the results are available and discuss supplementation at that time if he is deficient. Furthermore, we also did an ECG in order to detect the presence of any abnormal heart rhythms (arrhythmias) and are happy to report that his heart rhythm is normal at this time.

It is impossible to predict how B6 DCM will progress. We have seen several cases in which transition off of the grain free diet has resulted in significant improvement of the structural changes and cardiac function. Taurine responsive DCM also carries also carries a good prognosis. If his DCM is not diet or taurine responsive, then it is more difficult to predict the timeframe of his disease and we will continue to monitor his structural changes and cardiac function and may prescribe medication B6 in order to optimize his cardiac health. Please monitor B6 at home for any increased respiratory rate or effort, exercise intolerance, coughing, syncope (collapse), lethargy and decreased appetite. If you notice any of these signs, please contact the Cardiology Service, the Small Animal Emergency Service or your primary care veterinarian.

#### INSTRUCTIONS FOR CARE

## **MEDICATIONS**

No medications are being prescribed at this time

#### **ACTIVITY**

Please allow B6 to set his own activity level. Please try and avoid any extremely stressful or strenuous activity

DIET

Please continue to feed the Fromm 4 Star A La Veg dry food. If you choose to transition to another diet, please select a senior diet containing grain.

#### MONITORING

Please monitor <u>B6</u> for coughing, syncopal (collapse) episodes or increased respiratory rate or effort. Please count his respiratory rate when he is at rest and not panting. We would like his respiratory rate to stay under 40 breaths per minute (no more than 10 breaths in 15 seconds). Other signs of difficulty breathing include abdominal effort, extended head and neck and cyanotic (blue tinged) or pale gums. Please also watch him for lethargy, exercise intolerance, decreased appetite, vomiting, diarrhea or changes in urination or drinking. If you notice any of these signs, please contact the NCSU CVM Cardiology Service, your primary care veterinarian or an emergency clinic immediately.

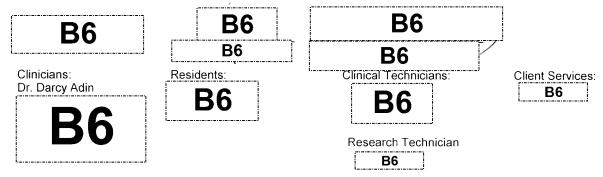
## PLAN FOR FURTHER EVALUATION

Please plan to recheck with the Cardiology Service in 3 months for an echocardiogram to monitor the progression of his heart disease.

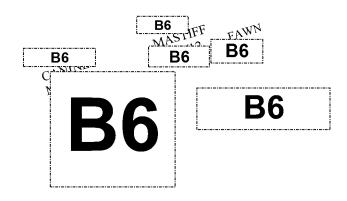
#### COMMENTS:

If you have any concerns with how your pet is doing, or to schedule an appointment, please contact the NC State Veterinary Hospital at 919-513-6694. There is a veterinarian on call 24 hours a day.

NOTE: If your pet is in need of emergency aid and you are not able to get to the NC State Veterinary Hospital quickly, please seek care at the nearest veterinary emergency facility. Take these discharge instructions and current medications with you so that the treating veterinarian will know as much as possible regarding your pets' medical condition.



In order to help expedite medication refills, please visit us online at www.ncstatevets.org and select Pet Owners, Pharmacy Refills.



Fax: Admin

Fax: Referral

## **NC State University**

## **Veterinary Hospital** 1052 William Moore Drive

Raleigh, NC 27607 **Discharge Comments**  Small Animal (919) 513-6500

Large Animal (919) 513-6630

D C	Patient B6	Case <b>B6</b>	Attending DVM Student	B6	
DO	MASTIFF MC FAWN CANINE	82.3 kg	Discharging DVM Referring DVM	<b>B6</b>	
Admission Date/Time:MA	AY 23, 2018 08:54 AM Disc	harge Date/Time: MAY 23,	2018 10:00 AM Disc	harge Status:	
CLINICIAN: B6					
Date: 5/22/18					
within 24 hours of releas	us with the care of your compa se/discharge from our facility via equest a copy. The following wil the time of discharge:	email. If you or your veterir	narian do not receive this,	please contact the	В
DIAGNOSIS (ES): 1. Suspected DCM					
INSTRUCTIONS FOR C Medications: None at thi					
Activity / Cautions: Please monite <b>B6</b> for veterinarian.	lethargy, weakness, increased	respiratory rate and effort a	and coughing. If this happe	ens please contact a	ì
	ATION OF YOUR PET: We woul e schedule this appointment at y		CSU Cardiology service af	ter 3 months for an	
IF YOU HAVE ANY QUE (919) 513-6911.	ESTIONS OR PROBLEMS, PLE	ASE CALL THE SMALL AN	NIMAL EMERGENCY SER	RVICE AT	
PLEASE CALL TO MAK	E YOUR FOLLOW UP APPOIN	ITMENT AS RECOMMEND	ED		
	<b>B6</b>				
B6 (owner)	B6	(clinician)			
Copy to: Owner / Medic	cal Record / Fax to RDVM				

B6 CANINE MC  B6 MASTIFF B6 FAWN B6 B6 B6 B6	NC STATE VETERINARY MOSPITAL HISTORY & PHYSICAL  Admission / Exam Date: 5 23 / 1 8  Weight: 3   Ibs   kgs     Respiration: pan +   Membrane Color: pt   Capillary Refill: 42  Body Condition: 6 9   Pain Score: 0 9
Distemper or FVRCP         Integular	N ABN No Exam  ral Appearance
	<b>B6</b>
I. Present History  A. Onset / Duration  B. Progression  C. Prior Treatment  II. Past History  A. Medical Illness  B. Surgical  C. Reproductive  D. Adverse Drug Reaction  E. Trauma	III. Environment IV. Preventative Student Signature V. Systems Review  Clinician Signature

## **NC State Veterinary Hospital**

**Cardiology Pet Diet History** MASTIFF MC **B6 FAWN B6 B6 Current diet:** Star Salmon ala Is this diet Grain-free? How long has your pet eaten this food? Are there other pets in your house eating this food? Other diets eaten in the last 3 years and dates: Naturals Lamb grain-free + Kangardo grain-free - 2 yr until Juks -av Moorn Naturals Other food (treats, rawhides, table food): gang's wheat-fill or grain-tiel treats, Supplements (e.g. fish oil, CoQ10, vitamins etc) 1011 h max triple Strength

# NCS, COLLEGE OF VETERINARY MEDIANE NCSU DIAGNOSTIC LABORATORIES

Client		Patient		Med Rec Case	В6	
<b>B6</b>		B6 MC 181.4715 lbs		MASTIFF FAWN CANINE B6		
		Completed 2 of 2 Resu	lts			
Request	Item	Priority	Status	Date	es filosopo Ten Medicality (1983)	
H-776718	TA	ROUTINE	COMPLETE	Requested: 05/2 Collection: 05/2		
Requesting DVM: Student:	B6			Received: 05/2 Needed: 05/2	3/1810:20 AM 3/18 10:15 AM	
Comments:		SENDOUT L	AB - TESTING	Status: 05/2	9/18 09:47 AM	
TEST		RESULI	UNITS	REF RANGE RES	ULT DATETIM	E
TAURINE- WHOLI	E BLOOD	SEE SCANNED DOCU	JMÉNT	en e		www.woodlineenston.com
Questions and Ans						
TAURINE- WHOI TAURINE- WHOI		HISTORY? TEXT-PO NEW SAMPLE OR ON		BMITTED TO CLINPATE	I NEW	
Containers 9018-759						

18932

# Sample Submission Form

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

ē	Contraction of the Contract of	
-	UC CUSTOMERS ONLY	<b></b>
	Non-federal funds ID/Account Number	
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	The same of the sa	

http://www.vetmed.ucdavis.edu/vmb/a	al/asi h+mi
Vet/Tech Contact: D6	
Company Name: Norm Carolina State Univ Address: Clinical Pathology Lab. Room C-26 1052 William Moore Drive	rersity College of Veterinary Medicine
Raleigh, NC 27607	
Email: Tei <b>B6</b>	
	Fax: 919 513-6556
Billing Contact:	TAX ID:
	Tel:
Patient Name: B6 Species: (C9) Owner's Name: B6	
Sample Type: Plasma Whole Bloo Test Items: Taurine Complete A	odUrine FoodOther:
Taurine Results (nmol/ml)	

## Reference Ranges (nmol/ml)

Plasma	
Normal Range No Known Did Whole Blood	
Tauring Deficiency Normal Range No Known Bick	for
Dos Jaurine Deficie	3CV
300-600 300-600 >200 >200 >200 >200 >200 >200 >200 >	
>150	The state of the s

**B6** 

Whole Blood:



# 1052 William Moore Drive Raleigh, NC 27607

Phone: 919.513.6694 Fax: 919.513.6712

## Canine Echocardiography Report

Patient Name: Medical Rec #:	B6			Date of Exam: Breed:	5/23/2018 Mastiff	
DOB:	B6			Weight:	82 kg	
Age:	5 years			BSA:	1.91 m²	
Sex:	Mc			HR:		
Sonographer:		В6		BP-sys:		
Report Status:	READ					
Ref. Clinician:	В6					
Diagnosis:	Dilated cardio	myopathy				
Study Details:	2D Echo/Dopp patient was av	oler/Color Doppler. vake.	The images	were of adequa	ite diagnostic	quality. The

#### **Additional Comments:**

DCM screening. Littermate diagnosed with DCM recently- both were eating a grain-free diet until 3 weeks ago. Now eating Fromm's adult diet.

<b>2D</b> LA d Ao s LA/Ao	
M-mode RV IVS LV LVPW LV normalized LA	<b>B6</b>

## **CLINICIAN INTERPRETATION:**

Left Ventricle: The left ventricular cavity size is moderate to severely increased. LV ejection fraction is

mildly decreased. LV basal fractional shortening is mild to moderately decreased.

**Left Atrium:** The left atrium is normal in size. **Right Atrium:** The right atrium is normal in size.

Right Ventricle: The right ventricular size is normal. RV wall thickness is normal.

Aortic Valve: No evidence of aortic valve regurgitation.

Mitral Valve: The E-point septal separation is increased. Mild mitral valve regurgitation.

Pulmonic Valve: The pulmonic valve is normal.

Pericardium/Effusions: No pericardial effusion is seen.

Aorta: The aortic sinuses, arch, ascending and descending aorta appear all normal.

**Pulmonary Artery:** The pulmonary artery is of normal size and origin.

## ECHO SUMMARY:

- 1. The left ventricular cavity size is moderate to severely increased.
- 2. Mild mitral valve regurgitation.
- 3. No tricuspid regurgitation.

Page 1 of 2

4. Mildly decreased LV ejection fraction.

#### ECG:

The heart rate measured at **B6** beats/minute. The ECG rhythm is regular sinus rhythm. Was/were noted. Complexes suggest no ventricular enlargement. The frontal axis has a normal orientation. ECG complex measurements are normal.

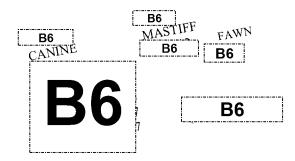
Recommendations: A standing echo was performed. Image quality affected by panting.

The LV is moderately to severely dilated with increased LV end-diastolic and end-systolic dimensions. Systolic function is mildly to moderately reduced. There is mild MR. No ectopy was noted during the diagnostic or echo ECG.

Findings are consistent with occult DCM. Based on the dog's signalment and history (full sibling with DCM and AF), idiopathic DCM and/or diet-associated DCM (recent grain-free diet) are possible. Recommend recheck echo in 3 months (due to recent diet change). Taurine level pending. No cardiac meds are recommended at this time pending the recheck echo in 3 months. If changes are persistent/progressive at the recheck echo, initiation of B6 and be considered.

**B6** 

Electronically signed on 5/23/2018 on 3:48:48 PM



Page 2 of 2

В6

5/23/2018

9:58:46 AM

В6

NCSU CARDIOLOGY

Page 1 of 2

**B6** 

B6 B6 B6 B6 B6

Fac: NCSU-CVM

**B6** 

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

**Sent:** 9/25/2018 5:16:12 PM

Subject: Fromms Four Star Grain Free Beef Frittata Veg Dry Dog Food: B6

EON-366756

Attachments: 2055325-report.pdf

A PFR Report has been received and PFR Event [EON-366756] has been created in the EON System.

A "PDF" report by name "2055325-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report:

**EON Key:** EON-366756

ICSR #: 2055325

**EON Title:** PFR Event created for Fromms Four Star Grain Free Beef Frittata Veg Dry Dog Food, The Farmer's

Dog Beef Recipe; 2055325

AE Date	09/24/2018	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Stable
Breed	Retriever - Golden		
Age	8.5 Years		
District Involved			

#### **Product information**

**Individual Case Safety Report Number: 2055325** 

**Product Group:** Pet Food

Product Name: Fromms Four Star Grain Free Beef Frittata Veg Dry Dog Food, The Farmer's Dog Beef Recipe Description B6 has been fed grain free dog food since 2013. I acquired B6 at 9 weeks of age from a reputable breeder. She was fed Purina ProPlan for Puppies from birth - early 2013. In early 2013 B6 was diagnosed with an impacted anal gland that ruptured and the vet recommended she be fed grain-free dog food. At that time, I began feeding Fromm's Beef Firtitta Grain Free. In late 2016 B6 pegan to experience steady diarrhea. After much vet intervention including a 2 night stay at vet hospital on IV, I changed B6 from Fromm's to a short transition time on ground beef w/rice and then to a fresh dog food, The Farmer's Dog Beef with Lentils.

Her diarrhea completed cleared and she remained on The Farmer's Dog Beef with Lentils until I begin reading about the issue with Low Taurine in Golden Retrievers. Based on UC Davis and Dr Stern studies, I obtained a blood sample for testing. UC Davis completed the test and her taurine level is low a **B6** while the level for a Golden Retriever is 250+. I had an echocardiogram done yesterday, Sept 24, 2018. The canine cardiologist evaluation is as follows: "Mild/early dilated cardiomyopathy-suspect taurine responsive. Trace mitral valve regurgitation. Normal left atrial dimensions. High normal left ventricular dimensions with moderately decreased heart muscle function. Normal right heart size. History of eating a grain-free diet. Low taurine." "No medications are indicated at this time. Begin Taurine 1000 mg twice daily. In two weeks, begin L-carnitine 1850 mg three times daily. In four weeks, begin fish oil supplements (omega-3 fatty acids) at approximately EPA 1500 mg and DHA 925 mg total per day. Change diet from grain free, legume foods. Cardiologist recommends follow up in 6 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
Fromms Four Star Grain Free Beef Frittata Veg Dry Dog Food		
The Farmer's Dog Beef Recipe		

Sender	inform	ation
E	36	

USA

To view this PFR Event, please click the link below: https://eon.fda.gov/eon//browse/EON-366756

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=383670

\_\_\_\_\_

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From: Freeman, Lisa <Lisa.Freeman@tufts.edu>

**To:** Jones, Jennifer L **Sent:** 8/27/2018 1:23:54 PM

Subject: FW: Taurine result for patients B6

**Attachments:** T\_20484.pdf; T\_20485.pdf

Taurine results on **B6**Lisa

Lisa M. Freeman, DVM, PhD, DACVN
Board Certified Veterinary Nutritionist<sup>TM</sup>
Professor
Cummings School of Veterinary Medicine
Friedman School of Nutrition Science and Policy
Tufts Clinical and Translational Science Institute
Tufts University
<a href="https://www.petfoodology.org">www.petfoodology.org</a>

#### **Sample Submission Form**

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

UC CUSTOMERS ONLY:	
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to bill:	

http://www.vetmed.ucdavis.edu/vmb/aal/aal.html

**B6** 

Vet/Tech Contact: B6	8/20/2018 1:58 PM TAURINE (WHOLE BLOOD)
Company Name: Tufts Cummings School of Vet Med - Clinical Pathology Labor	1 1 4 1 1 1 1
Address: 200 Westboro Road	
North Grafton, MA 01536	
Email: clinpath@tufts.edu; cardiovet@tufts.edu	
Tel: 508-887-4669 Fax: 508-839-7936	
Billing Contact: B6 TAX ID:	
Billing Contact:         B6         TAX ID:           Email:         B6         Tel:         B6	
Patient Name B6	
Species: canine	
Owner's Name B6	
Sample Type: Plasma Whole Blood Urine Food Oth	er.
Test Items: Varie Complete Amino Acid Other:	C1
rest items.	
Taurine Results (nmol/ml)	
P6	
Plasma: Whole Blood:_ Urine:	Food:

#### Reference Ranges (nmol/ml)

	Plasma		Who	ole Blood
	Normal Range	No Known Risk for	Normal Range	No Known Risk for
	reside.	Taurine Deficiency		Taurine Deficiency
Cat	80-120	>40	300-600	>200
Dog	60-120	>40	200-350	>150



**B6** 

n

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

UC CUSTOMERS ONLY:
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to bill:

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; cardiovet@tufts.edu
Tel: 508-887-4669 Fax: 508-839-7936
Billing Contact: B6 TAX ID:  Email: B6 Tel: B6
Patient Name: B6
Species: Canine
Species: Canine Owner's Name: B6
Sample Type:
Taurine Results (nmol/ml) B6
Plasma: Whole Blood Urine: Food:

#### Reference Ranges (nmol/ml)

		Plasma		ole Blood
	Normal Range	No Known Risk for	Normal Range	No Known Risk for
		Taurine Deficiency		Taurine Deficiency
Cat	80-120	>40	300-600	>200
Dog	60-120	>40	200-350	>150

Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group From: (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo> Rotstein, David; Queen, Jackie L; Palmer, Lee Anne; Carey, Lauren To: CC: Peloquin, Sarah; Ceric, Olgica 10/2/2018 6:36:27 PM Sent: RE: 800.267-EON-362878- B6 -Acana Free Run Poultry dry Subject: EON-362878-owner interview-10.2.2018.pdf Attachments: Jennifer Jones, DVM Veterinary Medical Officer Tel: 240-402-5421 PA U.S. FOOD & DRUG ADMINISTRATION From: Jones, Jennifer L Sent: Thursday, September 20, 2018 10:27 AM To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov> Cc: Peloquin, Sarah <Sarah.Peloquin@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; 'Reimschuessel, Renate (Renate.Reimschuessel@fda.hhs.gov)' <Renate.Reimschuessel@fda.hhs.gov> Subject: RE: 800.267-EON-362878 B6 Acana Free Run Poultry dry Interview pending, Cough since early 2017! Norm Tau; Housemate B6 lalso Tau norm, maybe got echo (checking) **B6** MC Doberman Pinscher report of nonproductive hacking cough recently-O thought after sniffing dust, eating Valor Freeze dried food; 3/10/2017-PD, morning cough-o thinks allergies, MAP crytalsàrecheck had none-rare; 7/26/2017-possible anxiety in dark, seasonal allergies (spring/summer) worse, occ little cough but normal for him, on Grandma Lucy raw and Earthborne; 2/14/2018-Grandma Lucy and Acana poultry **B6** 



**B6** Housemate

8/20/2018 WB Tau- **B6** 

Jennifer Jones, DVM Veterinary Medical Officer

Tel: 240-402-5421



From: PFR Event cpfreventcreation@fda.hhs.gov

Sent: Monday, August 20, 2018 4:44 PM

To: Cleary, Michael \* < Michael. Cleary@fda.hhs.gov>; HQ Pet Food Report Notification

<hr/>HQPetFoodReportNotification@fda.hhs.gov> B6

Subject: Acana Free Run Poultry dry: Lisa Freeman - EON-362878

A PFR Report has been received and PFR Event [EON-362878] has been created in the EON System.

A "PDF" report by name "2053969-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 "2053969-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

**EON Key:** EON-362878

ICSR #: 2053969

EON Title: PFR Event created for Acana Free Run Poultry dry; 2053969

AE Date	08/06/2018	Number Fed/Exposed	2
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Stable
Breed	Doberman Pinscher		
Age	<b>B6</b> Years		
District Involved	PFR-New England DO		

#### **Product information**

Individual Case Safety Report Number: 2053969

Product Group: Pet Food

Product Name: Acana Free Run Poultry dry

Description:	: Taken to RDVM fo	or lameness.	. Dilated c	ardiomyopathy	and CHF	diagnosed	8/6/18.	В6	
	В6	j	We saw a	at Tufts 8/16/18.	Clinically	/ improved	but still	has signifi	ican
DCM and	B6	We added		B6	fis	h oil, and ta	aurine. \	NB taurine	Э

pending. Another dog in household (also a Doberman) was eating the same food but was echoed today and has no signs of DCM.

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 Free Run Poultry dry		

#### Sender information

Lisa Freeman 200 Westboro Rd North Grafton, MA 01536 USA

#### Owner information

**B6** 

To view this PFR Event, please click the link below: https://eon.fda.gov/eon//browse/EON-362878

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

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### Follow-up Case Information Uniform Data Entry Form Vet-LIRN

Date (mm/dd/yy) Oct 2, 2018

EON/CC Number: 362,878

PATIENT INFORMATION	
(Marie Control of Cont	
Pet Name B6	
● Dog Cat	This form serves as a Uniform Data Entry Form to capture additional case
Breed Doberman Pinscher	specific information not clear from the Consumer Complaint or Medical Records in a standardized manner. Because each follow-up interview
Age in years (if < 6 months, put 0.5) 7  Gender:	made with owners features questions tailored specifically to the case, each box of information contained in this Uniform Data Entry Form may not be completed.
○M	
HSTORY-Additional Comments from Owner	
What Happened: wellness visit, saw growth on bor	/playing, limping on one foot (not uncommon if hard play), taken in for ne, taken him to oncologist and stumbled upon his heart condition; taken fluid in chest cavity and abdomen: in July owner noticed he was a little
Prior to the Event  (e.g. allergies surgeries)  healthier and all natural B6	owner had B6 first, then came to owners B6 very overweight, him for 5 years), periodically coughs; owner fed grain free b/c read it was always fed it), B6 been on grain free; B6 has always been a good pre sensitive stomach B6 had a history of struvite crystalluria; when
Sensitive GI tract (e.g. stomach	Changes to the pet's diet prior to illness Yes
upset when switching foods, Xes eats a lot of grass)	Data Diet Change
	Date Diet Change:
CLINICAL INFORMATIONAdditional Comments from Owner of	on What Happened
Appetite 🔲 Increased 🔲 Decreased	Water Consumption 🔲 Increased 🔲 Decreased
Vomiting Yes	Urination 🔲 Increased 🔲 Decreased
Diarrhea  Yes	Lethargy   Yes
Duration of Diarrhea (days)	Other: limping, quiet, less playful, rounder belly
Blood in Feces Fresh, Red	
Coffee Ground	
Black,Tarry	
AFDICATIONS To be a Direct of the Country of the Co	
MEDICATIONS-Taken Prior to the Event and Mentioned by Ow	vner
List medications mentioned by owner (e.g. NSAIDs, steroids,	
heartworm/flea prevention,	B6
antibiotics, etc.)	
List probiotics, vitamins, or supplements mentioned by owner:	

1 of 3 Continued other side

#### Follow-up Case Information Uniform Data Entry Form EON/CC Number: | 362,878 **Vet-LIRN** Owner: Pet's Name: **B6 B6** DIET-Any other foods the owner mentions were given to the animal during this period. (check all that apply) Commercial Dry Product Use as Part of Diet: ☐ Primary ☐ Secondary Occasional fed Taste of the Wild until 1.5 to 2 yr ago, then switched to Acana Free Run Poultry-only variety, fed b/ List Product Label Name c mineral levels, first fed 1.5 to 2 year ago, 2 cups BID for each dog, measuring cup, last fed this food Commercial Wet-Canned Product Use as Part of Diet: Primary ☐ Secondary ☐ Occasional List Product Label Name Commercial Wet-Pouch Product Use as Part of Diet: ☐ Primary ☐ Secondary Occasional List Product Label Name: Product Use as Part of Diet: ☐ Primary ☐ Secondary ☐ Occasional Grandma Lucy's Freeze Dried Raw (more of this than kibble)-Grain Free, 1 scoop for each dog BID, List Product Label Name: anywhere from 1/4 to 1/2 cup mixed with water, BID for each dog; Chicken flavor fed most often but ☐ Homemade-Raw Product Use as Part of Diet: ☐ Primary ☐ Secondary ☐ Occasional Describe Product Type: Product Use as Part of Diet: ☐ Primary ☐ Secondary ☐ Occasional Describe Product Type: chicken breast, green beans, carrots, long grain brown rice-sometimes in lieu of raw Table Scraps/Human Food (as an Describe Product Type(s): frozen blueberries, organic pumpkin puree, peanut butter, apples, occasional contribution to diet) Pet Treat Products Product Use as Part of Diet: Primary ☐ Secondary ☐ Occasional Commercial Product Label Name/Lot: Mother Hubbard tiny cookies Date first fed How Product Administered: gotten occasionally, not handfuls daily Date last fed Rawhides or Product Label Name/Lot: Bully sticks for **B6** as a puppy but not recently Date first fed Pig Ears How Product Administered: Date last fed Marrow Product Label Name/Lot: occ got knuckle bone but was 3 years ago Date first fed Bones How Product Administered: Date last fed Chicken Product Label Name/Lot: Date first fed Jerky How Product Administered: Date last fed ☐ Duck Jerky Product Label Name/Lot: Date first fed How Product Administered: Date last fed Product Label Name/Lot: Date first fed Sweet Potato Jerky or Treats How Product Administered: Date last fed

Vet-LIRN	ase intorma	tion Unito	rm Data Entry I	-orm	EON/CC	Number: 362,	878	
Owner: B6	]			Pet's Name:	В6			
DIET-continued-An	y other foods t	the owner m	entions were given	to the animal du	ring this pe	riod. (check all	that apply)	
_		duct Label Na	nme/Lot:				Date <u>first</u> fed	
☐ Oth	er Treats How	/ Product Ad	ministered:				Date last fed	
ENVIRONMENTAL Health Prior to the			Exposures Mentioi /)	ned by the Owne	r Potentiall <u>y</u>	y Affecting the	Animal's Overa	l State of
	☐ Out	tdoor	☐ Indoor & Outdoor	☐ Carrion	☐ Roden	its 🔲 Gr	apes or Raisins	Nuts
Plants	☐ Tra	sh	☐ Hunt	Pet Shows	Sporti Events		t Recreation Fa	cilities
Livestoc	k 🗌 Pou	ultry	Reptiles	Pet Birds	☐ Small Mamn	nals 🔲 Ur	ntreated Surfac	e Water
☐ Anti-free	eze 🗵 Mu	shrooms	Heavy Metals	▼ Ticks	Urban	☐ Su	burban	Rural
Comments:	owner goes to with the owner grape vines widown;	b barn often- er; ere growing 36 will	exposure to whatevelong fence and be nibble grass. B6 g events or dog soci year both dogs were to the second soci of the second second soci of the second se	ver dog/cat/horse came curious of t will constantly	touched the them recentry to eat m	tly, trying to ge nushrooms or a they got B6 v	gs don't go to tl t them-owner c corns	ne barn cut them
HOUSEHOLD-Sign	alment of Addi	itional Anima	als Given the Produc	ct mentioned by	the owner.			
Animal 1			Echocardiogram, ha ing cough: she will		or	☐ Reacted		
Animal 2						☐ Reacted		
Animal 3						Reacted		
Comments								

3 of 3

Submit

From:	PFR Event <pfreventcreation@fda.hhs.gov></pfreventcreation@fda.hhs.gov>	
То:	Cleary, Michael *; HQ Pet Food Report Notification; B6	
Sent:	12/27/2018 3:16:35 PM	
Subject:	Acana Free Run Poultry dry: Lisa Freeman - EON-374786	
Attachments:	2060599-report.pdf; 2060599-attachments.zip	

A PFR Report has been received and PFR Event [EON-374786] has been created in the EON System.

A "PDF" report by name "2060599-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 "2060599-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

**EON Key:** EON-374786

ICSR #: 2060599

**EON Title:** PFR Event created for Acana Free Run Poultry dry; 2060599

AE Date	08/20/2018	Number Fed/Exposed	2
Best By Date		Number Reacted	2
Animal Species	Dog	Outcome to Date	Stable
Breed	Doberman Pinscher		
Age	10 Years		
District Involved	PFR B6 DO		

#### **Product information**

**Individual Case Safety Report Number: 2060599** 

**Product Group:** Pet Food

**Product Name:** Acana Free Run Poultry dry

**Description:** Housemate was diagnosed with DCM (<u>B6</u> previously reported). <u>B6</u> was asymptomatic but eating same diet (Acana) so was screened 8/20/18 - reduced contractile function. Owner changed diet to Pro Plan Weight Management dry. No improvement on 12/12/18 echo. Will recheck in 3 months

WB taurine **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: Stable

Number of Animals Treated With Product: 2 Number of Animals Reacted With Product: 2

Product Name	Lot Number or ID	Best By Date
Acana Free Run Poultry dry		

#### **Sender information**

Lisa Freeman 200 Westboro Rd North Grafton, MA 01536 USA



To view this PFR Event, please click the link below: https://eon.fda.gov/eon//browse/EON-374786

To view the PFR Event Report, please click the link below:

 $\underline{https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jspa?decorator=none\&e=0\&issueType=12\&issueId=391795$ 

\_\_\_\_\_

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Report Details - EON-	374786		
ICSR:	2060599		
Type Of Submission:	Initial		
Report Version:	FPSR.FDA.PETF.V.V1		
Type Of Report:	Adverse Event (a symptom,	reaction or disease a	associated with the product)
Reporting Type:	Voluntary		
Report Submission Date:	2018-12-27 10:09:22 EST		
Reported Problem:	Problem Description:	B6 was asympto - reduced contractile	gnosed with DCM (B6 - previously reported). Imatic but eating same diet (Acana) so was screened 8/20/18 If function. Owner changed diet to Pro Plan Weight Improvement on 12/12/18 echo. Will recheck in 3 months
	Date Problem Started:	08/20/2018	
	Concurrent Medical Problem:	6	
	Pre Existing Conditions:	Hypothyroidism, inco	ontinence, history of UTIs/crystalluria
	Outcome to Date:	Stable	
Product Information:	Product Name:	Acana Free Run Pou	ultry dry
	Product Type:		
	Lot Number:	<u> </u>	
	Package Type:	BAG	
	Product Use Information:	Description:	Fed since approximately 9/2016 (see diet history form) Changed to Pro Plan Weight Management Aug 2018
	Manufacturer /Distributor Information:		
	Purchase Location Information:		
Animal Information:	Name:	В6	
	Type Of Species:		
	Type Of Breed:	Doberman Pinscher	
	Gender:	Female	
	Reproductive Status:	Neutered	
	Weight:	38.1 Kilogram	
	Age:	10 Years	
	Assessment of Prior Health:		
	Number of Animals Given the Product:		
	Number of Animals Reacted:	2	
	Owner Information:	Owner Information provided:	Yes
		Contact:	Phone: B6
		Address:	Email:
			<b>B</b> 6
	Healthcare Professional Information:	Practice Name: Contact:	Tufts Cummings School of Veterinary Medicine  Name: Lisa Freeman

			Phone	(508) 887-4523
				lisa.freeman@tufts.edu
		Addroso:	200 Westboro	
		Address.	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@t	ufts.edu
	Permission To Contact Sender:	Yes		
	Preferred Method Of Contact:	Email		
Additional Documents:	-			
	Attachment:		al records.pdf	
		Medical records		
	Type:	Medical Records		

From:	Related PFR Event <pre>pfrsignificantactivitycreation@fda.hhs.gov&gt;</pre>
То:	Carey, Lauren; Cleary, Michael *; HQ Pet Food Report Notification;  B6
Sent:	3/21/2019 9:41:00 PM
Subject:	Acana Free Run Poultry dry: Lisa Freeman - EON-383005
Attachments:	2064397-report.pdf; 2064397-attachments.zip
A PFR Report has been rece	eived and Related PFR Event [EON-383005] has been created in the EON System.
	064397-report.pdf" is attached to this email notification for your reference. Please eived in the report are compressed into a zip file by name "2064397-attachments.zip' notification.
Below is the summary of th	e report:

**EON Key:** EON-383005

**Submission Type:** Followup

ICSR #: 2064397

EON Title: Related PFR Event created for Acana Free Run Poultry dry; 2064397

AE Date	08/20/2018	Number Fed/Exposed	2
Best By Date		Number Reacted	2
Animal Species	Dog	Outcome to Date	Better/Improved/Recovering
Breed	Doberman Pinscher		
Age	В6		
District Involved	PFR- B6 DO		

Product information
Individual Case Safety Report Number: 2064397
Product Group: Pet Food
Product Name: Acana Free Run Poultry dry
<b>Description:</b> Housemate was diagnosed with DCM ( B6 - previously reported). B6 was
asymptomatic but eating same diet (Acana) so was screened B6 - reduced contractile function. Owner
changed diet to Pro Plan Weight Management dry. No improvement on <b>B6</b> echo. Will recheck in 3 months
WB taurine B6

**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: 2 Number of Animals Reacted With Product: 2

Product Name	Lot Number or ID	Best By Date
Acana Free Run Poultry dry		

This report is linked to:

**Initial EON Event Key: EON-374786** 

**Initial ICSR: 2060599** 

#### **Sender information**

Lisa Freeman 200 Westboro Rd North Grafton, MA 01536 USA

#### **Owner information**

**B6** 

To view this Related PFR Event, please click the link below: https://eon.fda.gov/eon//browse/EON-383005

To view the Related PFR Event Report, please click the link below:

https://eon.fda.gov/eon//EventCustomDetailsAction|viewReport.ispa?decorator=none&e=

 $\underline{https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jspa?decorator=none\&e=0\&issueType=10100\&issueId=400103\&parentIssueTypeId=12$ 

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# Cummings Veterinary Medical Center

#### **Foster Hospital for Small Animals**

55 Willard Street North Grafton, MA 01536 (508) 839-5395

		-	-
A 11	Medical	ROCOR	nle
$\Delta$	viculca	IXCCUL	u.

Client:	DA
Address:	<b>B6</b>

Patient: B6
Breed: Doberman
DOB: B6

Species: Canine Sex: Female (Spayed)

Home Phone: B6
Work Phone: Cell Phone: B6

Referring	Information

**B6** 

Client: Patient: **B6** 

#### **Initial Complaint:**

Cardiology Study Appointment

SOAP Text Aug 20 2018 1:58PM - B6

#### **Initial Complaint:**

Recheck - B6 - DCM study

SOAP Text Dec 12 2018 12:23PM - B6

#### **Initial Complaint:**

Recheck - B6 - DCM study

#### **Initial Complaint:**

PAGE ANTOON - HOLTER REMOVAL

Client:	
Patient:	

**B6** 

Disposition/Recommendations

## Cummings Veterinary Medical Center

AT	TU	FTS	UNI	VE	RS	ITY

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

### Lab Results Report

stringsoft

#### **Foster Hospital for Small Animals**

55 Willard Street North Grafton, MA 01536 (508) 839-5395

Patient:	B6
Species:	Canine
Breed:	Doberman
Sex:	Female (Spayed)
Age:	<b>B6</b> Years Old

		Accession ID:
Test	Results	Reference Range Units
•	4/49	B6

Printed Thursday, March 21, 2019

#### **UCDavis Taurine Level**

**B6** 

LIC CLISTOMERS ONLY.			
UC CUSTOMERS ONLY: Non-federal funds ID/Account Number			
<b>D</b> 0			
B6			
B6 Canine			
TAURINE (WHOLE BLOOD)			
Clinical Pathology Labor			
,			
508-839-7936			
TAX ID:			
Tel: B6			
ing Food Other			
ine Food Other:			
ine Food Other:			

#### 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	

#### Lab Results IDEXX CARDIOPET proBNP 12/12/18

**B6** IDEXX Reference Laboratories IDEXX VetConnect 1-888-433-9987 Date: 12/12/2018 Client: TUFTS UNIVERSITY **B6** 200 WES TBORO RD NORTH GRAFTON, Massachusetts 01536-1828 Patient: Requisition #: 455387 Species: CANINE Accession#i B6
Ordered by B6 Breed: DOBERMAN\_PINSCH 508-839-5395 Gender: FEMALE 5 PAYED Age: 10Y Account#80735 CARDIOPET proBNP - CANINE CARDIOPET proBNP **B6** 0 - 900 pmol/L HIGH - CANINE Comments: 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.

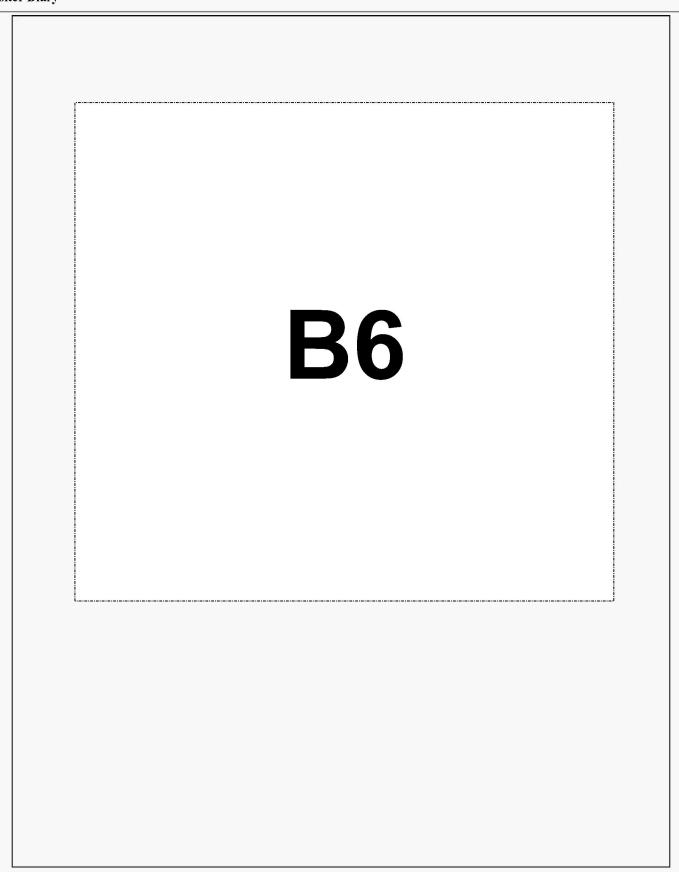
#### Diet history 12/12/18

	DC	s about your p		
t's name: B6 Owner's name:	В6		Today's date:	12/12/18
How would you assess your pet's appetite? On a scale of	f 1-10 with 1 bei	ing poor and 10 b	eing excellent:	10
Have you noticed a change in your pet's appetite over the	a last 1-2 wooks	2 (abook all that a	annha)	
Eats about the same amount as usual	ess than usual	Eats more th		
		igs. I'm scared of bloat. Her brothe		
			personal and an and an analysis	
Over the last few weeks, has your pet (check one)  Control Con	out the same we	eight ODon't l	now	
Please list below ALL pet foods, people food, treats, snac currently eats. Please include the brand, specific product.	ck, dental chews , and flavor so w	, rawhides, and a ve know exactly w	ny other food it hat you pet is e	em that your
Food (include specific product and flavor) For Examples are shown in the table – please provide enoug	m Am	ount How	often?	Fed since
Examples are shown in the table – please provide enoug	n detail that we	coula go ao the si	fore and buy the	exact same
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 2018 Jan 2015
Pupperoni original beef flavor	treat	1/2	1x/day	Aug 2015
Rawhide	treat	6 inch twist	1x/week	Dec 2015
Purina Pro Plan Healthy Weight Adult	dry	1.5 cups	2x/day	August 2018
Purina Pro Plan Healthy Weight Adult (1.5 cups 2x/day + 1 cup 1x/day)	dry	1 cup	1x/day	Oct. 2018
fills Science Diet Beef&Barley   Chicken&Barley   Chicken&Beef	wet	1/4 can	2x/day with 1.5dry	
Organic salt free, sugar free peanut butter	wet/frozen	1 teaspoon	1x/day or less	since little
Organic pumpkin puree	wet/frozen	1 to 2 teaspoons	1x/day or less	2015?
anana	mashed	1/2 banana or small	1x/day or less	since little
lue berries or watermelon	organic	a taste	seasonally	since little
Brand/C	oncenhalion		73111	ount per day
Taurine         OYes ONo	oncentration			
Taurine         OYes ONo           Carnitine         OYes ONo           Antioxidants         OYes ONo           Multivitamin         OYes ONo           Fish oil         OYes ONo           Coenzyme Q10         OYes ONo			2 per day but unsu	ire , have questions
Taurine         OYes ONo           Carnitine         OYes ONo           Antioxidants         OYes ONo           Multivitamin         OYes ONo           Fish oil         OYes ONo           CVS Natures Bounty 1200mg 350 on	nega 3		500 mg table	ets – 1 per da
Taurine	nega 3		201141 30 300	ets – 1 per da
Taurine OYes ONo Carnitine OYes ONo Carnitine OYes ONo Antioxidants OYes ONo Multivitamin OYes ONo Coenzyme Q10 OYes ONo Other (please list): Example: Vitamin C Thyrotab OXE  Nature's OXENDATE OF THE OYER ONO OXENDATE OF THE OYER OYER OYER OYER OYER OYER OYER OYE	nega 3 Bounty		500 mg table 1 tablet twice p	ets – 1 per da
Taurine OYes ONo Carnitine OYes ONo Carnitine OYes ONo Antioxidants OYes ONo Multivitamin OYes ONo Coenzyme Q10 OYes ONo Other (please list): Example: Vitamin C Thyrotab O.8mg  How do you administer pills to your pet? I do not give any medications I put them dire I put them in my pet's dog/cat food I put them in a	Bounty  ectly in my pet's a Pill Pocket or s	similar product	500 mg table 1 tablet twice p	ets – 1 per da er day
Taurine OYes ONo Carnitine OYes ONO Coenzyme Q10 OYes OYes OYes OYes OYes OYes OYes OYes	Bounty  ectly in my pet's a Pill Pocket or s	similar product	500 mg table 1 tablet twice p	ets – 1 per da er day
Taurine OYes ONo Carnitine OYes ONo Antioxidants OYes ONo Multivitamin OYes ONo Tish oil OYes ONo Coenzyme Q10 OYes ONo Other (please list): Example: Vitamin C Thyrotab O.8mg  How do you administer pills to your pet? I do not give any medications I put them dire	Bounty  ectly in my pet's a Pill Pocket or s	similar product	500 mg table 1 tablet twice p	ets – 1 per da er day
Taurine OYes ONo Carnitine OYes ONo Carnitine OYes ONo Antioxidants OYes ONo Multivitamin OYes ONo Coenzyme Q10 OYes ONo Other (please list): Example: Vitamin C Thyrotab O.8mg  How do you administer pills to your pet? I do not give any medications I put them dire I put them in my pet's dog/cat food I put them in a	Bounty  ectly in my pet's a Pill Pocket or sill of canned food an	similar product	500 mg table 1 tablet twice p	ets – 1 per da er day appily take as is

#### Diet history 8/20/18

t's name: _	B6 _	Owner's name :	B6		Today's date	8/2-
!	:	-			Today's date	-01 ccl
How would you a	issess your pet's	appetite? (mark the p	oint on the line b	elow that best rep	resents vour pe	it's annetite)
Example: ,	Poor			L Exc	ellent	uppoints;
	oor			1		
9	.001		restrated to the constitution of the constitut	Ехс	ellent	
Have you noticed	a change in yo	ur pet's appetite over tr	ie last 1.2 wook	c? /check all that	Lantiti e	
			than usual	DEats more tha	appiy)	
USeems to prefe	r different foods	than usual DOther_			::	
Over the last few	GRANE WELTER					
□Lost weight I	Weeks, nas you IGained weight	r pet (check one)				
		***				
Please list below	ALL pet foods, p	eople food, treats, sna	ck dental chaw	o manifestara and o	adversion of the second control of the secon	
currently eats. Ple	ase include the	brand, specific produc	i. and flavor so a	o, rawilloes, and a	iny other food its	∍m that your
				· · · · · · · · · · · · · · · · · · ·	naryou peris e	ating.
From the second	ecific product	and flavor) For	ті Ал	<u>iount</u> How	often?	Fed since
Examples are sno	wn in the table :	anu navor) - For - please provide enoug	th detail that we	could go do the s	ore and buy the	exact same
		duct and flavor)	Tr. Maries and Company of the Compan		A	
Nutro Grain Free	Chicken Lentil	& Sweet Potato Adult	Form	Amount	How often?	Fed since
85% lean hambur	ger	a arract r otter o moral	dry microwound	1 ½ cup	2x/day	Jan 2018
Pupperoni origina	beef flavor		microwaved treat	3 oz	1x/week	Jan 2015
Rawhide			treat	6 Inch twist	1x/day	Aug 2015
Yaca Fory F	200 Durton	C	I W Salt	15 6,005	1x/week	Dec 2015
Hurbenves,	Apriliz Jeron	alan			2x/094	9/14?
bolis, cre	Borcon	melsin		1717.1749-7-3.6	Daghud Szesonal	keely
Bangness		***		1/2 A40	- Homa / W	
CHANIS Or	anshute	<del>\ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ </del>		1 traspars		TT COL
Brille 153	5			CLART	other du	/
		managaria.		12 640		chery
	The second second second					
*Any additional die	t information ca	n be listed on the back	of this shoot			
Do you give any di	etary suppleme	nts to your pet (for example to the state of	nple: vitamins, o	lucosamine fatty	acide or any of	MAS.
supplements)?	□Yes ÆLNo	an and hindran itse wills	al Unies and dive	brands and amou	ints:	itei
Taurine	□Yes □No_	prang/C	oncentration			int per day
Carnitine	DYes DNo	02075		The second liver with the second liver		
untioxidants	□Yes □No					
Aultivitamin	□Yes □No			The state of the s		
ish oil	□Yes □No_				Marine Committee of the	
Coenzyme Q10	□Yes □No			-		
Other (please list) Example: Vitamin (					Printed in the second	
->onipie. Vitaliilli (	<i>2.</i>		re's Bounty		500 mg tablet	s – 1 per dau
	- constant	ninks				70.0
	March September					
A CONTRACTOR OF THE CONTRACTOR			7.444.000000000000000000000000000000000	The state of the s		
			The second secon		man, and a second	
					-	- West and a second second
ow do you admini I I do not give any	ster pills to your	pet?				
	medications					
I I nut them direct	of the more production	and the second of the second o				
I I put them directi I put them in my	y in my pet's mo	outh without food				

**Holter Diary** 



#### **Diet Hx 3/6/19**

		CARDIOLOGY Please answer the follo			our net	
Pet's name:	<b>B6</b>		В			date: 3/6/19
1. How would	you assess yo	our pet's appetite? (mark the po				
Example:	Poor			L LINE DE	Excellent	di pers'appelite)
	Poor	· · · · · · · · · · · · · · · · · · ·			_Excellent	
V. Ilana		ř á				
preats abou	it the same ar	ge in your pet's appetite over th nount as usual   □Eats less nt foods than usual  □Other	ne last 1-2 weel than usual	ks? (check all □Eats more	that apply) e than usual	_
Over the las	t few weeks, l nt □Gained	has your pet (check one) weightStayed about the	same weight	□Don't know		
Please list b currently eat	elow <u>ALL</u> pet ts and that you	foods, people food, treats, sna u have fed in the last 2 years.	ck, dental chev	ws, rawhides, a	and any other fo	ood item that your pe
		etail that we could go to the sto		exact same fo	od - examples	are shown in the tabl
Nutro Grain	Free Chicken	ific product and flavor) , Lentil, & Sweet Potato Adult	Form	Amount	How often?	Dates fed
85% lean ha	mburaer	, Lorini, di Gweet i otato Addit	dry microwaved	1 ½ cup 3 oz	2x/day	Jan 2016-present
	riginal beef fla	ivor	treat	1/2	1x/week 1x/day	June -Aug 2016
Rawhide			treat	6 inch twist	1x/week	Sept 2016-present
Purina P	no Olyna La	xisht management	KISDIY	1.5 Wps	3 x Iday	Dec 2018-present
H.115 8cm	ence dec	+ Darlay Cunned	In convo	V2 440		
Bananas	ETTE ISLE	T MILES CANCEL	fresh	73 /40	2 x /day	1
OFFGRUIT	Dana *1 -11	er (Salt & super from	frish	Ya banena	ten times o	week as treat
	Punath			traspean	1 x lawy	DC HSS in King
Dlur be wi			Organi lar	and tople	9200 IX 0	lay Kong
watermile				handel		14 as troat
TAN SEE FROM		*	firsh	hantel	1.5	
*Any addition	nal diet inform	ation can be listed on the back	of this sheet			
Do you give a supplements	)/ Lives	ipplements to your pet (for exal ☑No If yes, please list whic Brand/C ☑No	mple: vitamins, ch ones and give concentration	glucosamine, e brands and	fatty acids, or a amounts:	Amount per day
Carnitine Antioxidants	□Yes	□No □No				
Multivitamin		ØNo			- 1 1 1 <u>1</u>	
Fish oil	□Yes					
Coenzyme Q	10 □Yes	No				
Other (please	e list):	-			-	
Example: Vita	amin C	Natu	ıre's Bounty		500 mg	tablets – 1 per day
☐ I put them	re any medica directly in my in my pet's do in a Pill Pocke	ntions pet's mouth without food g/cat food et or similar product	v 8 8			a :
put them	in foods (list fo	oods): put them h	a little b	all of n	and bod	and She

Client: <b>B6</b> Patient:			
Vitals Results			
8/20/2018 1:25:17 PM	Weight (kg)	B6	

В6

8/20/2018 1:26:13 PM

Page 1 of 2



В6

8/20/2018 1:26:13 PM

Page 2 of 2



В6

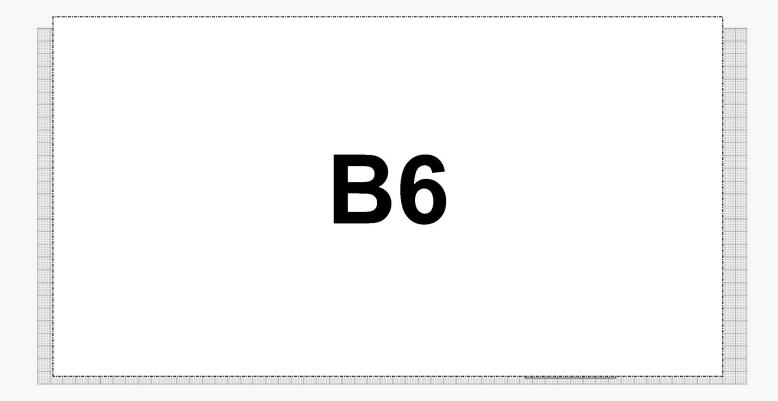
8/20/2018 1:25:05 PM



B6

3/6/2019 12:36:12 PM

Page 1 of 2

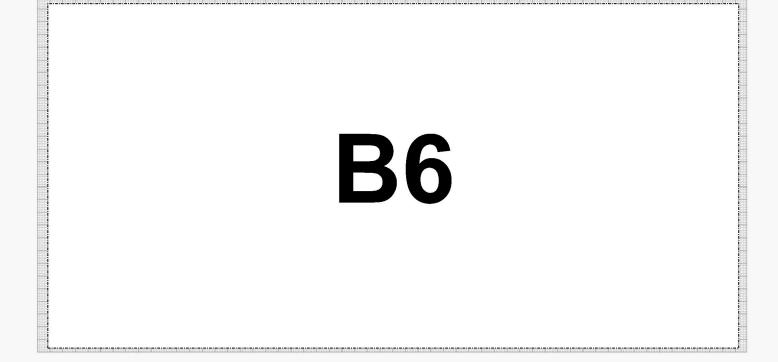


**ECG** from Cardio

**B6** 

3/6/2019 12:36:12 PM

Page 2 of 2



**ECG** from Cardio

В6

3/6/2019 12:36:17 PM

Page 1 of 2



В6

**ECG** from Cardio

3/6/2019 12:36:17 PM

Page 2 of 2



В6

3/6/2019 12:37:14 PM

Page 1 of 2

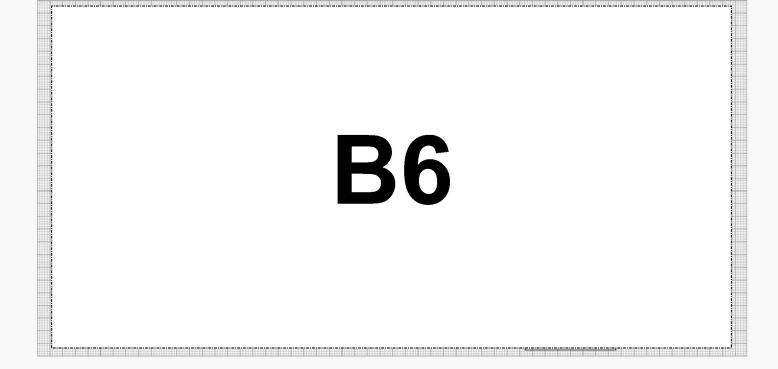


**ECG** from Cardio

B6

3/6/2019 12:37:14 PM

Page 2 of 2



### **Patient History**

Patient Account History	Description	Qty	price	Extended Disc	Pmt
03/07/2019 02:34 PM	Purchase	<u></u>			
03/07/2019 09:24 AM	Appointment				
03/06/2019 01:10 PM	Appointment				
03/06/2019 12:31 PM	Purchase				
03/06/2019 12:04 PM	Treatment				
03/06/2019 11:58 AM	Purchase				
03/06/2019 11:58 AM	Purchase				
03/06/2019 11:58 AM	Purchase				
00/06/0010 11 50 135	D 1				
03/06/2019 11:30 AM	UserForm				
03/06/2019 11:05 AM	UserForm				
12/12/2018 12:47 PM	Appointment				
12/12/2018 12:24 PM	Purchase				
12, 12, 2010 12,00 1141	OSSII OIII			<b>36</b>	
12/12/2018 11:99 PM	UserForm				
12/12/2018 11:59 AM	Purchase			JL	
12/12/2018 11:59 AM	Purchase		<u></u>		
12/12/2018 11:07 AM	Treatment				
12/12/2018 11:04 AM	UserForm				
12/11/2018 07:22 PM	Appointment				
10/17/2018 09:42 AM	Appointment				
08/20/2018 01:27 PM	Purchase				
08/20/2018 01:27 PM	Purchase				
08/20/2018 01:26 PM	Purchase				
08/20/2018 01:25 PM	Vitals				
08/20/2018 01:20 PM	UserForm				
08/20/2018 01:07 PM	Treatment				
08/20/2018 12:48 PM	UserForm	į.			

Patient Account Hist	ory Description	Qty	price	Extende	d Disc	Pmt
Monday, 20 August 2018 13:27	Appointment: Cardiology Study	1.000	0.000	0.0000	0.0000	0.0000

Patient Account Histo	ory Description	Qty	price	Extende	ed Disc	Pmt	
Wednesday, 12 December 2018 11:59	Appointment: Cardiology Study	1.000	0.000	0.0000	0.0000	0.0000	_

Client:	D6
Patient:	ВО

Patient Account History	Description	Qty	price	Extended	Disc	Pmt	
Wednesday, 12 NT P December 2018 12:24 FHS.	Pro BNP Canine (IDEXX 2665) A	-		<b>B6</b>			

Patient Account History	Description	Qty	price	Extende	d Disc	Pmt
Wednesday, 06 March Ag 2019 11:57	ppointment: Cardiology Study	1.000	0.000	0.0000	0.0000	0.0000

Patient Account History Description	Qty	price	Extended Disc	Pmt
Wednesday, 06 March Alba Holter Monitor 2019 12:31			B6	

Patient Account Hist	tory Description	Qty	price	Extende	ed Disc	Pmt	
Thursday, 07 March 2019 14:34	Appointment: Cardiology Holter Removal	1.000	0.000	0.0000	0.0000	0.0000	_

**Patient** 

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

### Discharge Instructions

Owner

Name: B6	Name:	B6		Patient ID: B6
Species: Canine	<b>Address</b> :	<b>B6</b>		
Black/Tan Female (Spayed) Doberman Birthdate: B6	i,		. <b></b> l	
B0				
Attending Cardiologist:				
John E. Rush DVM, MS, DACVIM (	Cardiology), [	ACVECC		
B6				
Cardiology Resident:				
	36			
	,,,			
Student: B6				
Cardiology Technician:	<u>-</u>			
B6				
Admit Date: 8/20/2018 12:44:33 PM				
Discharge Date: 8/20/2018				
Diagnoses: Apparently healthy animal!				
Clinical Findings: On physical exam, her h sinus arrhythmia, which happens when the dogs. On auscultation, there was no murn	e heart rate d	ecreases and incr	eases with res	piration. This is a normal finding in
Echocardiogram & ECG Findings: The echocardiogram today found no evide contractility of the heart, which is someth monitor in the future. The ECG showed a si	ing that does	not need to be tr	eated at this t	ime; however, it is something to
Monitoring at Home: 1. We would like you to monitor your dog' noticed any trends or abnormalities, please		ate and effort at h	ome, ideally d	luring sleep or at a time of rest. If yo
2. We also want you to watch for weaknes as these findings indicate that we should d			petite, worsen	ing cough, or distention of the belly
3. If you have any concerns, please call or hours/day.	have your do	g evaluated by a v	eterinarian. O	ur emergency dinic is open 24
Diet Suggestions: We would like to change B6 diet to a l	ow sodium d	iet. A few diet opt	ions would be	s

Purina Canin Boxer
Purina Pro Plan Adult Weight Management (this does not have low calories in spite of the name of the food)
Canned Food:
Hills Science diet adult beef and barley entree
Exercise Recommendations:
B6 does not need any exercise restriction at this time.
Recommended Medications:
B6 does not need any cardiac medications at this time. Depending on the results of her bloodwork, taurine
supplementation may need to be initiated. We will call you with the bloodwork results when they become available.
Recheck Visits: A recheck visit is scheduled for 4 months. At this visit we will want to check breathing effort and heart function and do a blood test. A recheck echocardiogram is recommended at this time as well to track any progression of structural or functional abnormalities.
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 Discloimer: For the safety and well-being of our patients, your get 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:

Dry Food:

Royal Canin Early Cardiac diet

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: set tuffs edutement/chical-studies.

promising new test or treatment.	Please see our website: <u>vet.tufts.edu/evn</u>	ne/elinieal-studies
Case: B6	Current B6	Discharge Instructions

Cardiology Liaison: 508-887-4696

Prior ATE? No.

Prior arrhythmia? No

Cough? Occasionally, random events

Monitoring respiratory rate and effort at home? Yes, occasionally

B	6	
Patient ID:	B6 Canine	
B6	Female (Spayed)	Doberman
Black/Tan		

### **Cardiology Appointment Report**

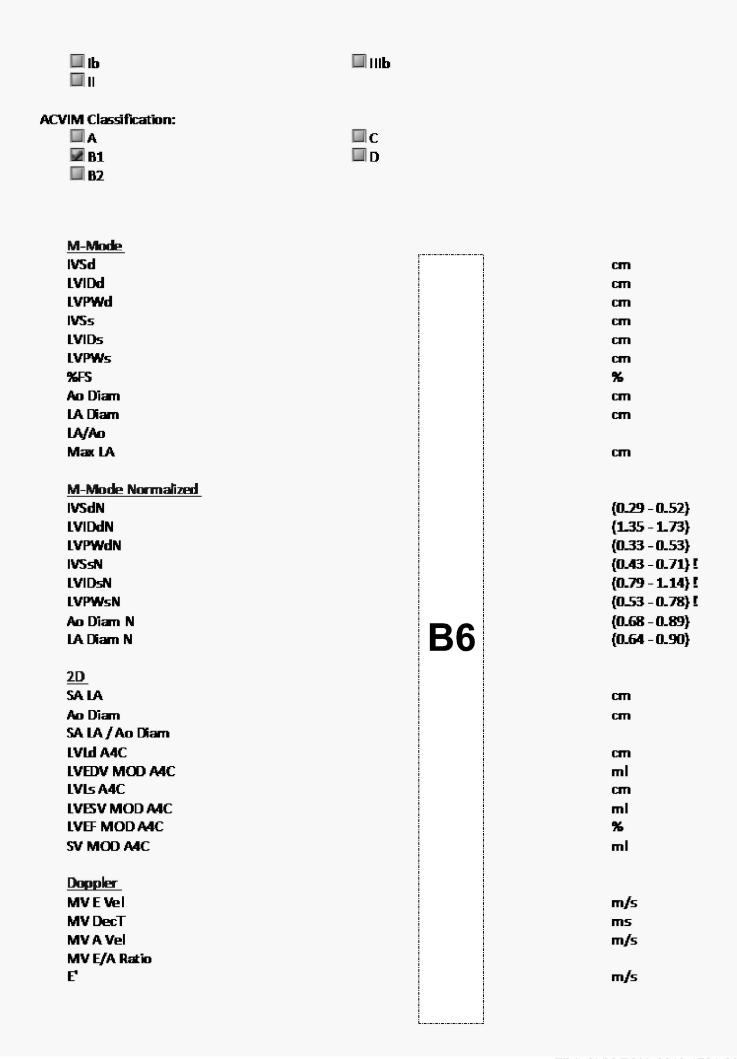
Date: 8/20/2018
Attending Cardiologist:
☐ John E. Rush DVM, MS, DACVIM (Cardiology), DACVECC
B6
Cardiology Resident:
B6
Cardiology Technician:
B6
Student: B6
Presenting Complaint: Brother from same litter was unexpectingly diagnosed with DCM with secondary CHF recently
Concurrent Diseases:
Hypothyroidism (for 3 yrs) - medically managed
Spay incontinence
History of UTIs/crystalluria - managed with diet
General Medical History: Acting normally, eating and drinking normally, no changes in bathroom habits, coughing occasionally (randomly), no vomiting, diarrhea, or sneezing noticed.
Diet and Supplements:
Akana Free-Reign Poultry Formulation 1.5-2 cups BID
Cardiovascular History:
Prior CHF diagnosis? No
Prior heart murmur? No

Shortness of breath or difficulty breathing? No Syncope or collapse? No Sudden onset lameness? No Exercise intolerance? No

### **Current Medications Pertinent to CV System:**

<b>B</b> 6	
Cardiac Physical Examination:	
	<b>B6</b>
Muscle condition:  Normal  Mild muscle loss	☐ Moderate cacheda ☐ Marked cacheda
Cardiovascular Physical Exam:  Murmur Grade:  None  I/VI  II/VI  III/VI	
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	<ul> <li>Bounding</li> <li>Pulse deficits</li> <li>Pulsus paradoxus</li> <li>Other:</li> </ul>
Arrhythmia:  None Sinus arrhythmia Premature beats	☐ Bradycardia ☐ Tachycardia
Gallop: Yes No Intermittent	Pronounced Other:
Pulmonary assessments:  Eupneic  Mild dyspnea  Marked dyspnea	☐ Pulmonary crackles ☐ Wheezes ☐ Upper ainway stridor

Mormal BV sounds	
Abdominal exam:  Normal Hepatomegaly Abdominal distension	☐ Mild ascites ☐ Marked ascites
<u>Problems</u> : Apparently healthy animal Genetic predisposition to DCM	
<u>Differential Diagnoses</u> : DCM	
Diagnostic plan:  Echocardiogram Chemistry profile ECG Renal profile Blood pressure	☐ Dialysis profile ☐ Thoracicradiographs ☑ NT-proBNP ☐ Troponin   ☐ Other tests:
	<b>B6</b>
early cardiomyopathy. Taurine levels were sub the grain-free diet. If contractile function is not	tile function is mildly decreased. This may be indicative of mitted for analysis, and the patient will be switched off of timproved at the 4 month rechecked despite change in the use diagnose if the changes is indicated of primary DCM
<u>Final Diagnosis</u> : Mild MMVD R/O diet-related vs. primary DCM related mild o	decrease in contractile function vs normal variation
Heart Failure Classification Score: ISACHC Classification:	■ Wa



A' E/E' PV Vmax PV maxPG AV Vmax AV maxPG

**B6** 

m/s

m/s mmHg m/s mmHg

noticed any trends or abnormalities, please contact us.

as these findings indicate that we should do a recheck examination.

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

### Discharge Instructions

<u>Patient</u>		Owner	
Name: B6		Name: 86	Patient ID: B6
Species: Canine		Address: B6	
Black/Tan Ferna	ale (Spayed) Doberman	<b>D0</b>	
Birthdate	B6	<del></del>	
Attending Card	dialogict-		
	Bush DVM. MS. DACVIM (	Cardiologyi, DACVECC	
	DC		
	Bo		
Cardiology Res			
_ L <u></u>		86	j
Cardiology Tec			
	B6		
L		<u></u>	
Student:	B6		
<u> </u>			
Admit Date: 8/	20/2018 12:44:33 PM		
Discharge Date	± 12/12/2018		
_			
Diagnoses:			
Mild decreased	l contractile function		
Clinical Finding	re-		
	=	her recheck echocardiogram (ultrasour	rd of the heart)
man journe	ware to the control of the control o	ic reales canonically an (an assu	
On physical exa	amination toda B6 v	ital parameters (heart rate, respiratory	rate, and temperature) were within
		ogram (ultrasound of the heart) in ord	
			ppeared stable. However, when we got
		of her heart measured slightly bigger th	an previously and her contractile function
measures slight	tly lower as well.		
B			DC III
	( <del></del>	anges are just a variation of normal for athy. In order to get more information	B6 . However, we cannot rule out that
		the results by tomorrow and will call y	
B6		archestra by which our are an are	our vide to usuas archestsup to
Monitoring at l	hame:		
		's breathing rate and effort at home, id	eally during sleep or at a time of rest. If you

2. We also want you to watch for weakness or collapse, a reduction in appetite, worsening cough, or distention of the belly

3. If you have any concerns, please call or have your dog evaluated by a veterinarian. Our emergency dinic is open 24 hours/day.
Diet Recommendations:  Please continue feeding B6 her Purina Pro Plan Weight Management dry food and Hill's Science Diet adult beef and barley entree. These foods are low in sodium and do not have low calories despite the name.
Exercise Recommendations:  B6 does not need any exercise restriction at this time.
Recommended Medications:  B6 does not need any cardiac medications at this time.
Recheck Visits:  A recheck appointment March 6th 11 am with B6 At this time we will recheck an echocardiogram.
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.
Sincerely,  B6  Please visit our HeartSmart website for more information
http://vet.tufts.edu/heartsmart/
Prescription Refil Discloimer: 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 veterinarion 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 Triuls: Clinical triuls 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: <a href="mailto:vet.tufts.edu/cvmc/dinical-studies">vet.tufts.edu/cvmc/dinical-studies</a>
Case: B6 Owner: B6 Discharge Instructions

Cardiology Liaison: 508-887-4696

Cardiovascular History:

		4		
	J			
	•		7	
			_	

Patient	ID: B6
B6	Canine
	Female (Spayed) Doberman
Black/T	an

### **Cardiology Appointment Report**

Date: 12/12/2018
Attending Cardiologist:    Indicated the property of the prope
Cardiology Resident:
B6
Cardiology Technician:
B6
Student: B6
Presenting Complaint:
Mild MMVD  Mild decreased contractile function R/O diet-related vs. primary DCM related mild decrease in contractile function vs normal variation  DCM Study
Mild decreased contractile function R/O diet-related vs. primary DCM related mild decrease in contractile function vs normal variation
Mild decreased contractile function R/O diet-related vs. primary DCM related mild decrease in contractile function vs normal variation DCM Study  B6  Diet and Supplements:
Mild decreased contractile function R/O diet-related vs. primary DCM related mild decrease in contractile function vs normal variation DCM Study  B6  Diet and Supplements:
Mild decreased contractile function R/O diet-related vs. primary DCM related mild decrease in contractile function vs normal variation DCM Study  B6  Diet and Supplements:

Prior CHF diagnosis? N Prior heart murmur? N Prior ATE? N Prior arrhythmia? Sinus arrhythmia Monitoring respiratory rate and effort at home Cough? Occasional, no change from prior Shortness of breath or difficulty breathing? N Syncope or collapse? N Sudden onset lameness? N Exercise intolerance? N - will occasionally whe	eze with cold
Current Medications Pertinent to CV System:  Medication B6	
Formulation/Tab Size: B6	
Administration Frequency: B6	
Need refills? No	
Cardiac Physical Examination:	
	36
Muscle condition:  Normal  Mild muscle loss	■ Moderate cachecia ■ Marked cachecia
Cardiovascular Physical Exam:  Murmur Grade:  None  I/VI  II/VI  III/VI	■ IV/VI ■ V/VI ■ VI/VI
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: None Sinus arrhythmia Premature beats	■ Bradycardia ■ Tachycardia
Gallop: Yes	Pronounced

☑ No ☑ Intermittent	Other:			
Pulmonary assessments:  Eupneic  Mild dyspnea  Marked dyspnea  Normal BV sounds	Pulmonary crackles Wheezes Upper ainway strider			
Abdominal exam:  Normal Hepatomegaly Abdominal distension	■ Mild ascites ■ Marked ascites			
Problems: Mild MMVD Mildly decreased contractile function r/o diet-recontractile function vs normal variation	elated vs. primary DCM related mild decrease in			
Diagnostic plan:  Echocardiogram Chemistry profile ECG Renal profile Blood pressure	Dialysis profile Thoracic radiographs NT-proBNP Troponin   Other tests:			
B6				

### Assessment and recommendations:

Subjectively today's echo appeared very similar than previously but when comparing the numbers it appears that the contractile function is slightly decreased. Depending on which measurement is assess, the LV cavity appears stable to slightly bigger. It is unclear if the changes visualized today are just a variant of normal for this patient versus true progression of a heart disease. The patient was switched

diet since the last appointment and Taurine level were also normal. Since the significance of today's findings is unclear, an NT-proBNP was submitted today. If the level is higher than normal for a Doberman (i.e. >550) then we would most likely recommend starting pimobendan BID. A recheck echocardiogram is recommended in 3 months or sooner if the patient develops clinical signs consistent with worsening heart disease such as increased RR/RE, cough, exercise intolerance, or syncope.

### **Final Diagnosis:**

- Very early DMVD
- Mild decreased contractile function r/o diet-related vs. primary DCM related mild decrease in contractile function vs normal variation

Heart Failure Classification Score:		
ISACHC Classification:		
🔲 la	🔲 Illa	
<b>☑</b> lb	□ IIIb	
ACVIM Classification:		
<b>□</b> A	<b>□ c</b>	
<u>■</u> B1	<b>□</b> D	
<b>☑</b> B2		
M-Mode		
IVSd		cm
LVIDd		cm
LVPWd		cm
I <b>V</b> Ss		cm
LVIDs		cm
LVPWs		cm
EDV(Teich)		ml
ESV(Teich)		ml
EF(Teich)		%
%FS		%
SV(Teich)		ml
Ao Diam		cm
LA Diam	<b>B6</b>	cm
LA/Ao	DU	
Max LA		cm
<u>2D</u>		
SA LA		cm
Ao Diam		cm
SA LA / Ao Diam		
IVSd		cm
LVIDd		cm
LVPWd		cm
EDV(Teich)		ml
I <b>V</b> Ss		cm
LVIDs		cm

LVPWs cm ESV(Teich) ml EF(Teich) % %FS % SV(Teich) ml LVId A4C cm LVEDV MOD A4C ml LVLs A4C cm **LVESV MOD A4C** ml LVEF MOD A4C % SV MOD A4C ml **B6** Doppler 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 **AV Vmax** m/s AV maxPG mmHg

PV Vmax

PV maxPG

m/s

mmHg

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

### Discharge Instructions

<u>Pabent</u>	Owner		
Name: B6	Name:	В6	Patient ID: B6
Species: Canine	Address:	B6	
Black/Tan Female (Spayed) Doberman		В	
Birthdate: B6			
Attending Cardiologist:			
<b>B6</b>			
Cardiology Resident:			
B6			
Cardiology Technician:	!		
<b>B6</b>			
Student: B6	. <u></u>		
Admit Date: 3/6/2019 10:59:12 AM			
Discharge Date: 3/6/2019			
Diagnoses: Mild decreased contractile function that is im	proved cor	mpared to previ	ously.
Case summary: Thank you for bringing B6 to Tufts cardio	logy servici	efor her rechect	t echocardiogram.
	tion appear	rs better than be	rt) which revealed that B6 heart is slightly efore although still not completelyet normal. This is condary to the recent addition of B6
rhythms of the heart), meaning that her hear diagnostics – such as a Holter monitor, which you elect to use the Holter monitor prior to s journal to record her activities. We will see	t occasiona records an starting any B6 Jagai	lly beats sooner ECG over 24 ho r treatment. We n tomorrow to r	cardiogram (ECG, which measures the electrical than it should. Today we discussed possible urs – and possible treatment options. At this time will send 86 home wearing the monitor and a remove the monitor. It will take 1-2 weeks to get the ide if we need to start new cardiac medications or

### Monitoring at home:

O 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 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 in normal dogs.

- O 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.
- O If you have any concerns, please call or have your dog evaluated by a veterinarian. Our emergency dinic is open 24 hours/day.

<b>B6</b>
Diet suggestions:
Please continue feeding B6 her Purina Pro Plan Weight Management dry food and Hill's Science Diet adult beef and barley entree. These foods are low in sodium but contain appropriate calories.
Exercise Recommendations:
B6 does not need any exercise restriction at this time.
Recheck Visits:
Please bring 86 in tomorrow to have her Holter monitor removed.
We would like B6 to have a recheck echocardiogram in 3 months as part of the DCM study, as long as she continues to do well at home. She has an appointment schedule with B6 June 11th at 11am.
Thank you for entrusting us with B6 are. Please contact our Cardiology liaison at (508)-887-4696 or email us at cardiovet@tufts.edu for scheduling and non-emergent questions or concerns.
Sincerely, B6
Please visit our HeartSmart website for more information
http://vet.tufts.edu/heartsmart/
Prescription Refill Discloiner:
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 Trink:
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: <a href="mailto:vet.tufts.edu/cvmc/clinical-studies">vet.tufts.edu/cvmc/clinical-studies</a>
Case B6 Owner: B6 Discharge Instructions

Cardiology Liaison: 508-887-4696

E	36
Patient B6	ID: B6 Canine
· · · · · · · · · · · · · · · · · · ·	6 Fernale (Spayed) Doberman an

### Cardiology Appointment Report ENROLLED IN DOM DIET STUDY

Date: 3/6/2019
Attending Cardiologist:
John E. Rush DVM. MS. DACVIM (Cardiology). DACVECC.
<b>B6</b>
Cardiology Resident:
B6
Cardiology Technician:
<b>B6</b>
Student: B6
Presenting Complaint:
<u>Presenting Complaint:</u> Mild MMVD Mild decreased contractile function R/O diet-related vs. primary DCM related mild decrease in contractile

### **B6**

### Diet and Supplements:

function vs normal variation

DCM Study

Purina Pro Plan (Weight Management) 1.5c AM w/ Hill's Sci Diet canned (1/4 can) AM and PM, 1 cup afternoon

### Cardiovascular History:

Prior CHF diagnosis? N

Prior heart murmur? N Prior ATE? N Prior arrhythmia? Sinus arrhythmia Monitoring respiratory rate and effort at home? Not as much, frequent panting Cough? Occasional, no change from prior Shortness of breath or difficulty breathing? N Syncope or collapse? N Sudden onset lameness? N Exercise intolerance? N **B6** Cardiac Physical Examination: Muscle condition: Moderate cacheda Mormal Mild muscle loss Marked cachesia Cardiovascular Physical Exam: Murmur Grade: Mone. Jugular vein: 1/2 way up the neck Bottom 1/3 of the neck Middle 1/3 of the neck Top 2/3 of the neck Arterial pulses: Weak Bounding Fair Pulse deficits Good 🗹 Pulsus paradoxus Other: Strong Arrhythmia: Bradycardia None Sinus arrhythmia Tachycardia Premature beats

Gallop: Yes No Intermittent	Pronounced Other:				
Pulmonary assessments:  Eupneic  Mild dyspnea  Marked dyspnea  Normal BV sounds	Pulmonary crackles Wheezes Upper airway strider				
Abdominal exam:  Normal Hepatomegaly Abdominal distension	Mild ascites Marked ascites				
Problems: Mild MMVD Mildly decreased contractile function r/o diet-recontractile function contractile function vs normal variation Elevated proBNP	elated vs. primary DCM related mild decrease in				
Diagnostic plan:  Echocardiogram Chemistry profile ECG Renal profile Blood pressure	☐ Dialysis profile ☐ Theracic radiographs ☐ NT-proBNP ☐ Troponin   ☐ Other tests:				
<b>B6</b>					



### Assessment and recommendations:

Echocardiogram reveals improvement of the cardiac dimensions and contractile function. All of the measurements obtained today were improved compared to the previous examination. It is unclear if the changes visualized are secondary to the start of pimobendan vs. being on a new diet for a longer period of time. B6 did had relatively frequent VPCs today which were all isolated. However, due to her breed and predisposition for arrhythmia, there is some concern that she has more malignant arrhythmia. A Holter was placed today in order to assess the amount and severity of arrhythmia and decide if we want to start a beta-blocker vs. sotalol vs. amiodarone. No blood was pulled today. A recheck echocardiogram and ECG are recommended in 3 months or sooner if the patient develops clinical signs consistent with worsening heart disease.

### **Final Diagnosis:**

- Very early DMVD
- Mild decreased contractile function that is improved compared to last examination.

Heart Failure Classification Score:			
ISACHC Classification:			
🔲 la	🔲 IIIa		
<b>☑</b> lb	IIIIb		
<b>□</b> II			
ACVIM Classification:			
■A	<b>□</b> c		
■ <b>B1</b>	■ D		
<b>☑</b> B2			
M-Mode	<del> </del>		
IVSd			ст
LVIDd			cm
LVPWd			cm
I <b>V</b> Ss			cm
LVIDs			cm
LVPWs			cm
EDV(Teich)		10	ml
ESV(Teich)		36	ml
EF(Teich)		-	%
%FS			%
SV(Teich)			ml
Ao Diam			cm
LA Diam			cm
LA/Ao			
TAPSE			cm

**EPSS** cm M-Mode Normalized **IVSdN** (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 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 **B6** 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 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 5 m/s **AV Vmax** m/s AV maxPG mmHg **PV Vmax** m/s

Carey, Lauren </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP
(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F0226BD682844FA2B71EA3750D4FCB82-

LAUREN.CARE>

To: Rotstein, David; Ceric, Olgica; Glover, Mark; Jones, Jennifer L; Nemser, Sarah; Palmer, Lee

Anne; Peloquin, Sarah; Queen, Jackie L

**Sent:** 2/25/2019 6:54:31 PM

Subject: RE: DCM - More from L Freeman 2/25/2019 0915

EON-380745 is part of that household as well. 3 with DCM so far.

From: Rotstein, David

Sent: Monday, February 25, 2019 9:19 AM

To: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Glover, Mark

<Mark.Glover@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Nemser, Sarah

<Sarah.Nemser@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Peloquin, Sarah

<Sarah.Peloquin@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>; Rotstein, David

<David.Rotstein@fda.hhs.gov>

Subject: DCM - More from L Freeman 2/25/2019 0915

Note: 380742 & 380743 are from the same household. Other dogs in household – 2 not tested yet & 1 normal

**BNP** 

From:

David Rotstein, DVM, MPVM, Dipl. ACVP CVM Vet-LIRN Liaison CVM OSC/DC/CERT 7519 Standish Place B6 (BB)





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From: Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group

Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>

To: 'Freeman, Lisa'

**Sent:** 3/4/2019 12:13:14 PM.

Subject: RE: taurine results for **B6** 

Thanks, Lisa!

Jennifer Jones, DVM Veterinary Medical Officer

Tel: 240-402-5421



From: Freeman, Lisa <Lisa.Freeman@tufts.edu>

Sent: Friday, March 01, 2019 4:51 PM

To: Jones, Jennifer L < Jennifer. Jones@fda.hhs.gov>

Subject: FW: taurine results for B6

FYI

	3 bulldogs from same household	and on san	ne diet
DG	- DCM and CHF had E – with ARVC and arrhythmias had	36	
DU	– with ARVC and arrhythmias had	B6	
<u> </u>	this most recent one (likely ARVC)	was	B6

Lisa

Lisa M. Freeman, DVM, PhD, DACVN
Board Certified Veterinary Nutritionist<sup>TM</sup>
Professor
Cummings School of Veterinary Medicine
Friedman School of Nutrition Science and Policy
Tufts Clinical and Translational Science Institute
Tufts University
<a href="https://www.petfoodology.org">www.petfoodology.org</a>

### Cummings Veterinary Medical Center

### Foster Hospital for Small Animals

55 Willard Street North Grafton, MA 01536 (508) 839-5395

A 11	Med	1	D	
AII	wieu	ıcaı	Rec	orus

Client: Address:	B6
	L

Home Phone:
Work Phone:
Cell Phone:

Patient: B6
Breed: English Bulldog
DOB: B6

Species: Canine
Sex: Female
(Spayed)

Referring 1	Information
-------------	-------------

	B6
Client: B6	

### **Initial Complaint:**

New	B6	DCM	study

SOAP Text Feb 20 2019 3:37PM - B6

### **Disposition/Recommendations**

Client: Patient:

Client:	B6
Patient:	DU

Cun	ımiı	ngs	
Veterir		-	Center

### AT TUFTS UNIVERSITY

Client:	B6
Veterinaria	n:
Patient ID:	В6
Visit ID:	

### **Lab Results Report**

### Foster Hospital for Small Animals

55 Willard Street North Grafton, MA 01536 (508) 839-5395

Patient:	B6
Species:	Canine
Breed:	English Bulldog
Sex:	Female (Spayed)
Age:	<b>B6</b> Years Old

	Accession ID:		
Test	Results	Reference Range Units	
	3/2	/21 <b>B6</b>	
stringsoft		D: . 114 1- E1 25 2010	

Printed Monday, February 25, 2019

### CBC/CHEM



### Tufts Cummings School Of Veterinary Medicine 200 Westboro Road North Grafton, MA 01536

### DUPLICATE

Name/DOB: B6	Sex: SF	Provider B6 Order Location: V320539: Investigation into
Phone number:	Age: 8	Sample ID: 1902200170
Collection Date: 2/20/2019 3:39 PM	Species: Canine	Conductor • Consecutive Conductor Co
Approval date: 2/20/2019 5:50 PM	Breed:	

02/20/19 5:50 PM	B6	
SMACHUNSKI WBC (ADVIA) RBC (Advia) Hemoglobin (ADVIA) Hematocrit (Advia) MCV (ADVIA) MCH (ADVIA)	36	Ref. Range/Female 4.40-15.10 K/ul 5.80-8.50 M/ul 13.3-20.5 g/dl 39-55 % 64.5-77.5 fl 21.3-25.9 pg
CHCM MCHC (ADVIA) RDW (ADVIA) Platelet Count (Advia) Mean Platelet Volume (Advia)		31.9-34.3 g/dl 11.9-15.: 173-486 K/ul 8.29-13.20 t
02/20/19 3:56 PM	B6	
Platelet Crit 02/20/19 3:56 PM	B6	0.129-0.403 %
PDW Reticulocyte Count (Advia) Absolute Reticulocyte Count (Advia) CHr MCVr	B6	0.20-1.60 % 14.7-113.7 K/ul
Microscopic Exam of B	ood Smear (Advia)	
SMACHUNSKI Seg Neuts (%) Lymphocytes (%) Monocytes (%) Eosinophils (%) Seg Neutrophils (Abs) Advia Lymphs (Abs) Advia Mono (Abs) Advia Eosinophils (Abs) Advia WBC Morphology RBC Morphology Poikilocytosis	<b>B6</b>	Ref. Range/Female 43-86 % 7-47 % 1-15 % 0-16 % 2.800-11.500 K/ul 1.00-4.80 K/ul 0.10-1.50 K/ul 0.00-1.40 K/ul

Sample ID: 1902200170/1 This report continues... (Final)

Reviewed by: \_\_\_

### CBC/CHEM



### Tufts Cummings School Of Veterinary Medicine

200 Westboro Road North Grafton, MA 01536

#### DUPLICATE

Name/DOB: Patient ID:	Sex: SF	Provider B6 Order Location: V320559: Investigation into
Phone number:	Age: 8	Sample ID: 1902200170
Collection Date: 2/20/2019 3:39 PM	Species: Canine	Contraction ■ accepts to Live — season to colored contraction to the color
Approval date: 2/20/2019 5:50 PM	Breed:	

#### Research Chemistry Profile - Small Animal (Cobas) (cont'd) DNOYES Ref. Range/Females Glucose 67-135 mg/dL Urea 8-30 mg/dL 0.6-2.0 mg/dL Creatinine Phosphorus 2.6-7.2 mg/dL 9.4-11.3 mg/dL 1.8-3.0 mEq/L Calcium 2 Magnesium 2+ 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 0.7-1.6 140-150~mEq/LSodium Chloride 106-116 mEq/L **B6** Potassium 3.7-5.4 mEq/L tCO2(Bicarb) 14-28 mEq/L AGAP 8.0-19.0 NA/K 29-40 0.10-0.30 mg/dL Total Bilirubin 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 409-1250 U/L Amylase Osmolality (calculated) 291-315 mmol/L

Sample ID: 1902200170/2

REPRINT: Orig. printing on 2/20/2019 (Final)

Reviewed by: \_\_\_\_\_ Page 2

### IDEXX BNP - 2/20/2019

IDEXX Reference Laboratories Client B6 IDEXX VetConnect 1-888-433-9967 Client: **B6** Date: 02/20/2019 TUFTS UNIVERSITY 200 WES TBORO RD NORTH GRAFTON, Massachusetts 01536 Patienti Requisition #: 1A Accession | B6 Ordered by | B0 Species: CANINE Breed: BULLDOG 508-839-5395 Gender: FEMALE 5 PAYED Age: 8Y Account #88933 CARDIOPET proBNP - CANINE CARDIOPET **B6 B6** 0 - 900 pmol/L - CANINE Comments: 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.

### Diet history 2/20/19

	CARDIO Please answer t		DIET HISTOR		ur net	
et	's name: B6 Owner's n					date: 2/20/19
	How would you assess your pet's appetite? (ma	ark the po	oint on the line	below that bes	st represents yo	the same of the sa
				+ -	Excellent	
	Poor			1	_Excellent	
	Have you noticed a change in your pet's appetit Eats about the same amount as usual Seems to prefer different foods than usual	Eats less	than usual	ks? (check all i □Eats more		_
	Over the last few weeks, has your pet (check or □Lost weight □Gained weight □Stayed a	ne) bout the	same weight	□Don't know		
	Please list below <u>ALL</u> pet foods, people food, tre currently eats and that you have fed in the last 2	eats, sna 2 years.	ck, dental chev	vs, rawhides, a	and any other fo	ood item that your per
	Please provide enough detail that we could go t		re and buy the	exact same fo	od - examples	are shown in the tabl
	Food (include specific product and flavor	or)	Form	Amount	How often?	Dates fed
L	Nutro Grain Free Chicken, Lentil, & Sweet Potat	to Adult	dry	1 1/2 cup	2x/day	Jan 2016-present
L	85% lean hamburger	2.3720	microwaved	3 oz	1x/week	June -Aug 2016
	Pupperoni original beef flavor		treat	1/2	1x/day	Sept 2016-present
	Rawhide B6	1	treat	6 inch twist	1x/week	Dec 2018-present
		·	1			
-						
	*Any additional diet information can be listed on	the back	of this sheet			
	Do you give any dietary supplements to your per supplements)?   Yes  No If yes, please	e list which	mple: vitamins, ch ones and giv concentration	glucosamine, ve brands and	fatty acids, or a	any other  Amount per day
	Taurine	30210101	e to see the second second			
	Carnitine					
	Antioxidants					
	Multivitamin					
	Fish oil					
	Coenzyme Q10					
	Other (please list): Example: Vitamin C					
	Example, vitamin C	Natu	ure's Bounty		500 mg	tablets – 1 per day
	Ho Rotic Materia	> Krun	nes bounty n∈€		_ 50	billion
					-	
1	How do you administer pills to your pet?		7	7 1		
1	I do not give any medications			CHANI	olve to	
1	□/I put them directly in my pet's mouth without fo I put them in my pet's dog/cat food I put them in a Pill Pocket or similar product	ood		RC	olve to	
1	□ I put them in foods (list foods):					

Client: <b>B6</b>			
Vitals Results			
2/20/2019 3:00:08 PM	Weight (kg)	B6	

12 Lead: Standard Placement

ECG from cardio

В6

2/20/2019 4:05:01 PM

Tufts University Tufts Cummings School of Vet Med Cardiology

ECG from cardio

**B6** 

2/20/2019 4:05:13 PM

Page 1 of 2

Tufts University Tufts Cummings School of Vet Med Cardiology

ECG from cardio

B6 2/20/2019 4:05:13 PM

Page 2 of 2

Tufts University Tufts Cummings School of Vet Med Cardiology

ECG from cardio

В6

2/20/2019 4:05:43 PM

Tufts University Tufts Cummings School of Vet Med Cardiology

12 Lead; Standard Placement

### **Patient History**

02/12/2019 10:57 AM Appointment  02/13/2019 09:14 AM Appointment  02/13/2019 10:56 AM Appointment  02/20/2019 02:30 PM UserForm 02/20/2019 02:56 PM Treatment 02/20/2019 02:57 PM Treatment 02/20/2019 03:00 PM Vitals 02/20/2019 03:00 PM Purchase 02/20/2019 03:19 PM Purchase 02/20/2019 03:19 PM Purchase 02/20/2019 03:47 PM UserForm  02/20/2019 03:47 PM UserForm  02/20/2019 10:42 PM UserForm  02/20/2019 05:15 PM Appointment	02/08/2019 09:18 AM	Appointment	
02/20/2019 10:56 AM Appointment  02/20/2019 02:30 PM UserForm 02/20/2019 02:56 PM Treatment 02/20/2019 02:57 PM Treatment 02/20/2019 03:00 PM Vitals 02/20/2019 03:00 PM Purchase 02/20/2019 03:19 PM Purchase 02/20/2019 03:19 PM Purchase 02/20/2019 03:47 PM UserForm  02/20/2019 10:42 PM Email	02/12/2019 10:57 AM	Appointment	
02/20/2019 02:30 PM	02/13/2019 09:14 AM	Appointment	
02/20/2019 02:56 PM       Treatment         02/20/2019 02:57 PM       Treatment         02/20/2019 03:00 PM       Vitals         02/20/2019 03:00 PM       Purchase         02/20/2019 03:19 PM       Purchase         02/20/2019 03:19 PM       Purchase         02/20/2019 03:47 PM       UserForm         02/20/2019 10:42 PM       Email	02/13/2019 10:56 AM	Appointment	
02/20/2019 03:00 PM       Purchase         02/20/2019 03:19 PM       Purchase         02/20/2019 03:19 PM       Purchase         02/20/2019 03:47 PM       UserForm         02/20/2019 10:42 PM       Email			
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02/20/2019 10:42 PM Email	02/20/2019 03:19 PM	Purchase	
i i	02/20/2019 03:47 PM	UserForm	
02/22/2019 05:15 PM Appointment		Email	
	02/22/2019 05:15 PM	Appointment	

# Cummings Veterinary Medical Center

**Patient** 

Monitoring at Home:

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

Owner

<b>Maine:</b> B6	)	N N	lane	B6	Pal	present in 186	
Species: Car			ddress	B6		i	!
_	te Fernale (Spa	ayed) English	<u></u>		<u>.</u> j		
Buildog	DC						
DE LI LLOYE:	B6						
Attending (		n.ms.dacvim/card	ioloevì. DAC	ÆOC			
Cardiology	Resident:						
		В	6				
Caronougy			·		j		
	B6	<b>)</b>					
Student:	В6						
Date: 2/20/2	2019						
		could be consistent v cardiomyopathy	vith early arr	hythmogenic right v	entricular cardiomy	ropathy (ARVC) c	<b>r</b> a
report that o	or bringing B other than an	6 to the Tufts cardio elevated BNP, there h home have appeared	nas been no i				
an electroca was mildly e No arrhythn do not clear	irdiogram (EK nlarged. Her i nias were det ly require me	her heart, we perform G). On each B6 had right heart, however, ected on the EKG took dication at this stage, rt are related to ARW	d mildly decr was more sig sy, but we ca but we will v	eased contractile fu gnificantly enlarged, nnot rule out intern vant to monitor for p	nction of the left ve which is something nittent arrhythmia. progression over tir	ntricle. Her left a we can see with Overall B6 d	strium h ARVC. hanges
A blood sam	plewas also o	collected for bloodwo	rk for the st	dy, and we will cont	act you as the result	samein.	
At this time	we will only t	rea B6 with the tar	rine sum le	nent. Wedo recom	mend periodic edv	recheds to mal	e gre

there have been no changes to her heart over time and for the DOM study that she has been enrolled in.

Please monito: B6 at home for any concerning cardiac signs such as increased breathing rate or effort, exercise intolerance, or collapsing episodes. If she collapses, evaluate her gums for any darker coloration. If this occurs, please have B6 seen by a veterinarian immediately.
Please obtain a Kardia/Aliveour ECG reading from B6 at home once every few weeks. You can email this result to cardiovet@tufts.edu.
Diet Suggestions:  We recommend feeding B6 a commercial dog food diet, as directed by Dr Freeman.
Berrise Recommendations:  B6 may continue her regular exercise regimen.
Recommended Medications:    B6
We may not need to continue this once we get B6 tourine results back.
Recheck Visits: Please call to schedule an appointment for about 3 months for a recheck echocardiogram as part of the DOM study.
Thank you for entrusting us with $B6$ care. She is such a sweet girl, and was an excellent patient to work with!
Please contact our Cardiology liaison at (508)-887-4696 or email us at cardioret@tults.edu for scheduling and non-emergent questions or concerns.
Please visit our HeartSmart website for more information http://wet.tufts.edu/heartsmart/
Prescription Refill Discloimer: 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/dinical-studies
Case B6 Owner: B6 Discharge Instructions

### **Cummings** Veterinary Medical Center

AT TUFTS UNIVERSITY

Cardiology Liaison: 508-887-4696

Patient ID: B6

B6 Canine
B6 ears Old Female (Spayed) English Buildog
Brown/White

### **Cardiology Appointment Report**

Attending Cardiologist:		
John E. Rush DVM, M	S, DACVIM (Cardiology)	), DACVECC
	B6	
Cardiology Resident:		
	B6	
Cardiology Technician:		
<b>B6</b>		
Student: B6		
Presenting Complaint:		
DCM Study		
C		
Concurrent Diseases: None		
none		
General Medical History:		
Elevated BNP B6		
Had surgery for	B6	finished pain meds about a w
ago.		
B6		
B6 <b>(O do c</b>	esn't remember) - sx cor	rrected as a puppy
В	6	
		·
Diet and Supplements:		
<del>-</del>	t (dry (fish) and wet (tu	rkey and chicken)} - 3 ounces of wet food BID,
cup dry BID		
Probiotic for B6		
Cardiovascular History:		
Prior CHF diagnosis? N		
THE COLUMN TO SERVICE STATE OF THE COLUMN TO SERVICE STATE STATE OF THE COLUMN TO SERVICE STATE		

Prior ATE? N				
Prior arrhythmia? N				
Monitoring respiratory rate and effort at home? Y, owner thinks no higher than 40 at rest, usually 20-30				
Cough? N				
Shortness of breath or difficulty breathing?	Not when at rest			
Syncope or collapse? N				
Sudden onset lameness? N				
Exercise intolerance? Yes, when taken for l	ong walks			
Current Medications Pertinent to CV Syste	en:			
None at this time				
Cardiac Physical Examination:				
	<b>B6</b>			
Muscle condition:				
Normal	Moderate cachecia			
Mild muscle loss: mild wasting over	Marked cacheda			
epaxials				
Cardiovascular Physical Exam:				
Murmur Grade:	El auto			
None	□ N/VI			
□ I/VI □ II/VI	□ v/vı □ vı/vı			
□ ii/vi	□ og of			
Jugular vein:				
Bottom 1/3 of the neck	1/2 way up the neck			
Middle 1/3 of the neck	Top 2/3 of the neck			
Arterial pulses:				
■ Weak	Bounding			
□ Fair □ Good	Pulse deficits The large representation of			
□ G000 □ Strong	<ul> <li>■ Pulsus paradoxus</li> <li>☑ Other: difficult to assess due to trembling</li> </ul>			
르 31대명	e one. Unital to asses use to remain			
Arrhythmia:				
None	□ Bradycardia			
<ul><li>Sirus arrhythmia</li><li>Premature beats</li></ul>	☐ Tachycardia			
Callana				
Gallop:	Pronounced			
□ τεs ☑ No	Other:			
Intermittent	= OIEI.			
Pulmonary assessments:				

<ul> <li>✓ Eupmeic</li> <li>✓ Mild dyspnea</li> <li>✓ Marked dyspnea</li> <li>✓ Normal BV sounds</li> </ul>	☐ Pulmonary crackles ☐ Wheezes ☐ Upper airway stridor				
Abdominal exam:  Normal Hepatomegaly Abdominal distension	Mild ascites Marked ascites				
<u>Problems</u> : No cardiac anomaliesto report					
Diagnostic plan:  Echocardiogram  Chemistry profile  ECG  Renal profile  Blood pressure	☐ Dialysis profile ☐ Thoracic radiographs ☐ NT-proBNP ☐ Troponin I ☐ Other tests:				
Echocardiogram Findings: General/2-D findings:	В6				
	<b>B6</b>				
Doppler findings:  B6					
Mitral inflow:  Summated  Normal  Delayed relaxation	Pseudonormal Restrictive				
ECG findings:					
Assessment and recommendations:  Echocardiogram reveals structural changes that could be consistent with ARVC, but no arrhythmia was documented today. 24 hour Holter monitor could be considered to rule out intermittent arrhythmia. Owner has a Kardia at home and will obtain monthly readings. No cardiac medications are clearly indicated based on today's exam, but recommend supplementing with taurine until blood levels return from the lab. Patient was enrolled in the DCM study. Recheck echo in 3 and 6 months for the study.					
<u>Final Diagnosis</u> : Possible early ARVC; r/o nutrition related cardiomyopathy or a combination					
Heart Failure Classification Score:  ISACHC Classification:  la  la	■ IIIa ■ IIIb				

■ B1 **₽** R2 M-Mode **IVSd** cm LVIDd cm LVPWd cm **IVSs** cm **LVIDs** cm **LVPWs** cm EDV(Teich) ml ESV(Teich) ml **B6** EF(Teich) % %FS % SV(Teich) ml Ao Diam cm LA Diam cm LA/Ao Max LA cm **TAPSE** cm **EPSS** cm M-Mode Normalized **IVSdN**  $\{0.290 - 0.520\}$ LVIDdN  $\{1.350 - 1.730\}$ LVPWdN  $\{0.330 - 0.530\}$ **IVS**sN **B6**  $\{0.430 - 0.710\}$ 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 **SALA** cm Ao Diam cm **B6** SALA / Ao Diam **IVSd** cm **LVIDd** cm

**ACVIM Classification:** 

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 **LVAJ LAX** cm **LVEDV A-L LAX** ml **LVEDV MOD LAX** ml LVLs IAX cm **LVAs LAX** cm **LVESV A-L LAX** ml **LVESV MOD LAX** ml HR **BPM EF A-L IAX** % **B6 LVEF MOD LAX** % SV A-L LAX ml SV MOD LAX ml CO A-L LAX l/min CO MOD LAX l/min <u>Doppler</u> 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 TR Vmax m/s TR maxPG mmHg

## Cummings Veterinary Medical Center



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

B6 Female (Spaye)	1
Canine English Bulldog	
Brown/White	
B6	

2/21/2019	2/21	/2019
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ear [ Thank you	B6 for referring	B6	with their pe	B6
if you hav	e any questi	ons, or concerns	, please contact u	rs at 508-887-4988
Thank you	ļ.			
B6	DVM (Can	liology)		

		Related PFR Event <pfrsignificantactivitycreation@fda.hhs.gov>  Carey, Lauren; Cleary, Michael *; HQ Pet Food Report Notification;  B6</pfrsignificantactivitycreation@fda.hhs.gov>				
То:	,					
Sent:	6/11/2019 7:00	:42 PM				
Subject:		Wellness CORE Grain-Free Ocean Whitefish dry-Wellness Core grain free turkey: Lisa Freeman - EON-390205				
Attachments:	2068096-report	t.pdf				
PFR Report has be	een received and Related P	FR Event [EON-390205]	nas been created in the	EON Syste		
"PDF" report by na	ame "2068096-report.pdf"	is attached to this email no	otification for vour refe	rence.		
1						
low is the summer	w of the report:					
ON Key: EON-390 SR #: 2068096 ON Title: Related I	)205 PFR Event created for Wel		•			
	0205 PFR Event created for Wel eken liver and turkey liver		•			
ON Key: EON-390 CSR #: 2068096 ON Title: Related I rain free turkey chic nicken and turkey re	PFR Event created for Welcken liver and turkey liver ecipe; 2068096	formula canned Wellness	Core Hearty Cuts grain			
ON Key: EON-390 CSR #: 2068096 ON Title: Related I rain free turkey chic nicken and turkey re AE Date Best By Date	PFR Event created for Welcken liver and turkey liver ecipe; 2068096	Number Fed/Exposed	Core Hearty Cuts grain			
ON Key: EON-390 CSR #: 2068096 ON Title: Related I ain free turkey chic cicken and turkey re AE Date  Best By Date  Animal Species	PFR Event created for Welcken liver and turkey liver ecipe; 2068096	Number Fed/Exposed Number Reacted	Core Hearty Cuts grain  6  4			
ON Key: EON-390 CSR #: 2068096 ON Title: Related I rain free turkey chic nicken and turkey re	Dog	Number Fed/Exposed Number Reacted	Core Hearty Cuts grain  6  4			

screened by RDVM for BNP which was elevated. Evaluated at Tufts 2/1/19. ARVC/diet-induced DCM with ventricular arrhythmia. Diet changed to Royal Canin Early Cardiac and will re-evaluate in 3 months I have diet

sample. 3 other dogs in household (1 had normal BNP, other 2 not yet evaluated) Patient DOA when owners
arrived home on ( B6 Suspected sudden death. Heart muscle samples were collected by rDVM and
submitted to FDA for further evaluation.
Submission Type: Followup
<b>Report Type:</b> Adverse Event (a symptom, reaction or disease associated with the product)

**Number of Animals Treated With Product:** 6 **Number of Animals Reacted With Product:** 4

Outcome of reaction/event at the time of last observation: Died Other

Product Name	Lot Number or ID	Best By Date
Wellness CORE Grain-Free Ocean Whitefish dry Wellness Core grain free turkey, chicken liver, and turkey liver formula canned Wellness Core Hearty Cuts grain-free in gravy chicken and turkey recipe		

This report is linked to:

**Initial EON Event Key: EON-380743** 

Initial ICSR: 2063134

### **Sender information**

Lisa Freeman 200 Westboro Rd North Grafton, MA 01536 USA

### Owner information

**B6** 

To view this Related PFR Event, please click the link below:

https://eon.fda.gov/eon//browse/EON-390205

To view the Related PFR Event Report, please click the link below:

 $\frac{https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jspa?decorator=none\&e=0\&issueType=10100\&issueId=407477\&parentIssueTypeId=12$ 

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Report Details - EON-	390205		
ICSR:	2068096		
Type Of Submission:	Followup		
Report Version:	FPSR.FDA.PETF.V.V1	а пота а пъта о пъта о пота о пота в о пъта о пъта о пъта о пъта о пъта о	
Type Of Report:	Adverse Event (a symptom,	reaction or disease a	ssociated with the product)
Reporting Type:	Voluntary		, , , , , , , , , , , , , , , , , , , ,
Report Submission Date:	)		
Initial Report Date:	02/25/2019		
Parent ICSR:	2063134		
Follow-up Report to FDA Request:	Yes		
Reported Problem:	Problem Description:	Housemate (half sist	er; B6 (ICSR) of 2063133) diagnosed with
	Problem Description.	DCM and CHF so so Tufts 2/1/19. ARVC/o to Royal Canin Early 3 other dogs in hous DOA when owners a	reened by RDVM for BNP which was elevated. Evaluated at diet-induced DCM with ventricular arrhythmia. Diet changed Cardiac and will re-evaluate in 3 months I have diet sample. ehold (1 had normal BNP, other 2 not yet evaluated) Patient
	Date Problem Started:	02/01/2019	
	Concurrent Medical Problem:	Yes	
	Pre Existing Conditions:	Spinal trauma as pu	рру
	Outcome to Date:	Died Other	
	Date of Death:	В6	
Product Information:	Product Name:	Wellness CORE Gra chicken liver, and tur free in gravy chicken	in-Free Ocean Whitefish dry Wellness Core grain free turkey, key liver formula canned Wellness Core Hearty Cuts grain- and turkey recipe
	Product Type:	Pet Food	
	Lot Number:		
	Product Use Information:	Description:	Please see diet history for more info (and refer to B6 diet history for more complete info - all dogs eat same diets)
	Manufacturer /Distributor Information:		
	Purchase Location Information:		
Animal Information:	Name:	В6	
	Type Of Species:	2	
	Type Of Breed:	1	
	Gender:	5	
	Reproductive Status:	Neutered	
	Weight:	22.1 Kilogram	
	Age:	8 Years	
	Assessment of Prior Health:	<del>1</del>	
	Number of Animals Given the Product:	6	
	Number of Animals Reacted:	4	
	Owner Information:	Owner Information provided:	Yes
		Contact:	Name: B6

Healthcare Professional Information:  Healthcare Professional Information:  Practice Name: Contact: Name: Lisa Freeman Phone: (508) 887-4523 Email: lisa.freeman@tufts.edu  Address: 200 Westboro Rd North Grafton Massachusetts 01536 United States  Parmission To Contact: Sender: Preferred Method Of Contact: Contact: Contac				Email:	<b>B6</b>	
Healthcare Professional Information:    Practice Name:   Tufts Cummings School of Veterinary Medicine			Address:		100000000000000000000000000000000000000	
Healthcare Professional Information:    Healthcare Professional Information:				<b>B6</b>		
Information: Contact: Name: Lisa Freeman Phone: (508) 887-4523 Email: lisa.freeman@tufts.edu  Address: Name: Lisa Freeman Name: Lisa Freeman Name: Lisa Freeman Nath Grafton Massachusetts 01536 United States  Contact: Phone: 5088874523 Email: lisa.freeman@tufts.edu  Permission To Contact Sender: Preferred Method Of Contact: Sender: Preferred Method Of Contact: Phone: 5088874523 Email: lisa.freeman Name: Lisa Freeman Name: Lisa Freeman North Grafton Massachusetts 01536 United States  Email: lisa.freeman@tufts edu  Permission To Contact Sender: Preferred Method Of Contact: Preferred Method Of						
Contact: Name: Lisa Freeman Phone: (508) 887-4523 Email: lisa.freeman@tufts.edu  Address: 200 Westboro Rd North Grafton Massachusetts 01536 United States  Contact: Phone: 5088874523 Email: lisa.freeman@tufts.edu  Permission To Contact: Sender: Preferred Method Of Contact: Sender:  Preferred Method Of Contact: Sender: Preferred Method Of Contact: Sender: Preferred Method Of Contact: Sender: Sende		Healthcare Professional	Practice Name:	Tufts Cummings So	chool of Veterinary	Medicine
Address: 200 Westboro Rd North Grafton Massachusetts 01536 United States  Inder 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: Preferred Method Of Contact:: Preferred Method Of Contact:: Preferred Method Of Contact:		Information:	Contact:	Name: Lisa	a Freeman	
Address: 200 Westboro Rd North Grafton Massachusetts 01536 United States  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: Preferred Method Of Contact: Email				[[	************************************	
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Massachusetts 01536 United States  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: Preferred Method Of Contact: Contact: Preferred Method Of Contact: Permission To Contact Sender: Preferred Method Of Contact: Permission To Contact Sender: Preferred Method Of Contact:			Address:	200 Westboro Rd		
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North Grafton Massachusetts 01536 United States  Contact: Phone: 5088874523 Email: lisa.freeman@tufts.edu  Permission To Contact Sender: Preferred Method Of Contact: Contact: Email						
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Preferred Method Of Contact:		Permission To Contact	Yes			
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From: Related PFR Event <pfrsignificantactivitycreation@fda.hhs.gov>

To: Carey, Lauren; Cleary, Michael \*; HQ Pet Food Report Notification;

B6

Sent: 6/11/2019 6:52:47 PM

Subject: Wellness CORE Grain-Free Ocean Whitefish dry-Wellness Core grain free turkey: Lisa Freeman - EON-390203

Attachments: 2068095-report.pdf; 2068095-attachments.zip

A PFR Report has been received and Related PFR Event [EON-390203] has been created in the EON System.

A "PDF" report by name "2068095-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 "2068095-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

**EON Key:** EON-390203

ICSR #: 2068095

**EON Title:** Related PFR Event created for Wellness CORE Grain-Free Ocean Whitefish dry Wellness Core grain free turkey chicken liver and turkey liver formula canned Wellness Core Hearty Cuts grain-free in gravy chicken and turkey recipe; 2068095

AE Date	02/20/2019	Number Fed/Exposed	6
Best By Date		Number Reacted	4
Animal Species	Dog	Outcome to Date	Stable
Breed	Bulldog		
Age	B6 Years		
District Involved	PFR-New England DO		

### **Product information**

**Individual Case Safety Report Number: 2068095** 

Product Group: Pet Food

**Product Name:** Wellness CORE Grain-Free Ocean Whitefish dry Wellness Core grain free turkey, chicken liver,

and turkey liver formula canned Wellness Core Hearty Cuts grain-free in gravy chicken and turkey recipe

Description: Eating BEG diet - 2 other dogs in household diagnosed with DCM B6

already reported) RDVM screened this dog with NT-proBNP which was elevated so we evaluated	at Tufts
2/20/19 Probable ARVC/diet-associated DCM but no arrhythmia detected (enlarged right ventricle	e, reduced
contractility) Changing diet to Royal Canin Early Cardiac and will re-evaluate in 3 months. Low p	olasma and
whole blood taurine levels - started taurine supplement 3/1/2019 Troponin - <b>B6</b>	

**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:** 6 **Number of Animals Reacted With Product:** 4

Product Name	Lot Number or ID	Best By Date
Wellness CORE Grain-Free Ocean Whitefish dry Wellness Core grain free turkey, chicken liver, and turkey liver formula canned Wellness Core Hearty Cuts grain-free in gravy chicken and turkey recipe		

This report is linked to:

**Initial EON Event Key:** EON-380745

Initial ICSR: 2063135

### **Sender information**

Lisa Freeman 200 Westboro Rd North Grafton, MA 01536 USA

### **Owner information**

**B6** 

To view this Related PFR Event, please click the link below:

https://eon.fda.gov/eon//browse/EON-390203

To view the Related PFR Event Report, please click the link below:

 $\underline{https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jspa?decorator=none\&e=0\&issueType=10100\&issueId=407475\&parentIssueTypeId=12$ 

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Report Details - EON-	390203				
ICSR:	2068095				
Type Of Submission:	Followup				
Report Version:	FPSR.FDA.PETF.V.V1				
Type Of Report:	Adverse Event (a symptom,	reaction or disease a	ssociated with the product)		
Reporting Type:	Voluntary		· · · · · · · · · · · · · · · · · · ·		
Report Submission Date:	2				
Initial Report Date:	02/25/2019				
Parent ICSR:	2063135				
Follow-up Report to FDA Request:	Yes				
Reported Problem:	Problem Description:	Fating BEG diet - 2 (	other dogs in household diagnosed with DCM B6 and		
•	riobem bescription.	B6 - a which was elevated associated DCM but contractility) Changir	ready reported) RDVM screened this dog with NT-proBNP so we evaluated at Tufts 2/20/19 Probable ARVC/diet-no arrhythmia detected (enlarged right ventricle, reduced ag diet to Royal Canin Early Cardiac and will re-evaluate in 3 and whole blood taurine levels - started taurine supplement 3		
	Date Problem Started:	02/20/2019			
	Concurrent Medical Problem:	Yes			
	Pre Existing Conditions:		B6		
	Outcome to Date:	Stable			
Product Information:	Product Name:	Wellness CORE Grain-Free Ocean Whitefish dry Wellness Core grain free turkey, chicken liver, and turkey liver formula canned Wellness Core Hearty Cuts grain-free in gravy chicken and turkey recipe			
	Product Type:	Pet Food			
	Lot Number:				
	Product Use Information:	Description:	Please see diet history for more info (and also see B6 B6 B6 diet history for exact diets)		
	Manufacturer /Distributor Information:				
	Purchase Location Information:				
Animal Information:		DC			
Ammai miormanon.	Name:	B6			
	Type Of Species:	ļ			
	Type Of Breed:				
	Gender:	<u> </u>			
	Reproductive Status:	7			
	5	24.2 Kilogram			
	2)	B6 Years			
	Assessment of Prior Health:				
	Number of Animals Given the Product:				
	Number of Animals Reacted:	4			
	Owner Information:	Owner Information provided:			
		Contact:	Name: B6		

			Email:	B6	
		Address:	<b>B6</b>		
	Healthcare Professional	Practice Name:	me: Tufts Cummings School of Veterinary Medicine		
	Information:	Contact:	Name:	Lisa Freeman	
				(508) 887-4523	
			Email: lisa.freeman@tufts.edu		
		Address:	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@t	ufts.edu	
	Permission To Contact Sender:	Yes			
	Preferred Method Of Contact:	Email			
Additional Documents:					
	Attachment:	Follow-up med recor	ds pt 2.pdf		
	Description:				
		Medical Records			
	Attachment:	Follow-up med recor	ds pt 1.pdf		
	Description:				
	Type:	Medical Records			

### Diet hx 5/8/2019

Please answer the following questions about your pet  Anow would you assess your pet's appetite? (mark the point on the line below that best represents your pet's appetite).  How would you assess your pet's appetite? (mark the point on the line below that best represents your pet's appetite).  Example:  Poor			CARDIOLOGY Please answer the follo			ur net	L
How would you essess your pet's appetite? (mark the point on the line below that best represents your pet's appetite?    Poor		D6	i	-	1		-11-
Excellent   Poor	t's nam	e:	Owner's name:	D0		Today's	date: <u>5/8/19</u>
Have you noticed a change in your pet's appetite over the last 1-2 weeks? (check all that apply)   Easts about the same amount as usual	How w	ould you assess you	r pet's appetite? (mark the po	oint on the line I	below that bes	it represents yo	ur pet's appetite)
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  Cher  Over the last few weeks, has your pet (check one)  Lost weight  Gained weight  Gained weight  Stayed about the same weight  Don't know  Please list below ALL pet foods, people food, treats, snack, dental chews, rawhides, and any other food item that your 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 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 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 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 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 last 5 years.  Please provide enough detail that we could go to the store and buy the exact same food - examples are shown in the last 5 years.  Please provide enough detail that we could go to the store and buy the exact same food - examples are shown in the last 5 years.  Please provide enough detail that we could go to the store and buy the exact same food - examples are shown in the last 5 years.  Please provide enough detail that we could go to the store and buy the exact same food - examples are shown in the last 5 years.  Please provide enough detail that we could go to the store and buy the exact same food - examples are shown in the last 5 years.  Please provide enough detail that we could go to the store and buy the exact same food - examples are shown in the last 5 years.  Please provide enough detail that we could go to the store and buy the exact same food - examples are shown in the last 5 years.  Please pr	Examp	ole: Poor			1	Excellent	
Have you noticed a change in your pet's appetite over the last 1-2 weeks? (check all that apply)  East about the same amount as usual		Door			'\		
Eats about the same amount as usual Seems to prefer different foods than usual Other.    Seems to prefer different foods than usual Other.		POOF				Excellent	
Eats about the same amount as usual Seems to prefer different foods than usual Other.    Seems to prefer different foods than usual Other.					,		
Please list below ALL pet foods, people food, treats, snack, dental chews, rawhides, and any other food item that your 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 source and buy the exact same food - examples are shown in the source and buy the exact same food - examples are shown in the source and buy the exact same food - examples are shown in the source and buy the exact same food - examples are shown in the source and buy the exact same food - examples are shown in the source and buy the exact same food - examples are shown in the source and buy the exact same food - examples are shown in the source and buy the exact same food - examples are shown in the source and buy the exact same food - examples are shown in the source and buy the exact same food - examples are shown in the shown in the same food - examples are shown in the shown in the same food - examples are shown in the shown in the same food - examples are shown in the shown in the same food - examples are shown in the shown in the same food - examples are shown i	■ Eats	about the same amo	ount as usual	e last 1-2 week than usual	ss? (check all t Eats more	that apply) than usual	
Please provide enough detail that we could go to the store and buy the exact same food - examples are shown in the last 2 years.    Food (Include specific product and flavor)   Form   Amount   How often?   Dates fed				same weight	☑Don't know		
Food (include specific product and flavor)  Nutro Grain Free Chicken, Lentil, & Sweet Potato Adult  Nutro Grain Free Chicken, Lentil, & Sweet Potato Adult  dry  1 ½ cup  2x/day  Jan 2016-press  microwaved  3 oz  1x/week  June-Aug 2019  Pupperorio original beef flavor  Rawhide  freat  6 inch twist  1x/week  Dec 2018-press  Poya  Any additional diet information can be listed on the back of this sheet  Do you give any dietary supplements to your pet (for example: vitamins, glucosamine, fatty acids, or any other supplements)?  Yes No  Anount per day  Taurine  Yes No  Antioxidants  Yes No  Multivitamin  Yes No  Other (please list):  Example: Vitamin C  Nature's Bounty  Nature's Bounty  How do you administer pills to your pet?  I do not give any medications	Please	e list below <u>ALL</u> pet for tly eats and that you	oods, people food, treats, sna have fed in the last 2 years.	ck, dental chev	vs, rawhides, a	and any other fo	ood item that your per
Nutro Grain Free Chicken, Lentil, & Sweet Potato Adult dry 1 ½ cup 2x/day Jan 2016-press 85% lean hamburger microwaved 3 oz 1x/week June-Aug 2016 Press Rawhide treat ½ 1x/day Sept 2016-press Rawhide treat 6 inch twist 1x/week Dec 2018-press Could (Arm)	Please	provide enough det	ail that we could go to the sto	re and buy the	exact same fo	od - examples	are shown in the tab
Nutro Grain Free Chicken, Lentil, & Sweet Potato Adult dry 1 ½ cup 2x/day Jan 2016-press 85% lean hamburger microwaved 3 oz 1x/week June-Aug 2016-press 1x/day Sept 2016-press 1x/day Sept 2016-press 1x/day Sept 2016-press 1x/week Dec 2018-press 1x/week	F	ood (include specif	ic product and flavor)	Form	Amount	How often?	Dates fed
### Any additional diet information can be listed on the back of this sheet  Do you give any dietary supplements to your pet (for example: vitamins, glucosamine, fatty acids, or any other supplements)?  Taurine  Tyes  No  Antioxidants  Tyes  No  Antioxidants  Tyes  No  Coenzyme Q10  Nature's Bounty  Mature's Bounty  How do you administer pills to your pet?  I to not give any medications	Nutro	Grain Free Chicken,	Lentil, & Sweet Potato Adult				Jan 2016-present
Pupperoni original beef flavor Rawhide treat 6 inch twist 1x/week Dec 2018-press Coya Cura Corollon Co							
*Any additional diet information can be listed on the back of this sheet  Do you give any dietary supplements to your pet (for example: vitamins, glucosamine, fatty acids, or any other supplements)?	Puppe	roni original beef flav	or	treat			
*Any additional diet information can be listed on the back of this sheet  Do you give any dietary supplements to your pet (for example: vitamins, glucosamine, fatty acids, or any other supplements)?   Byes No If yes, please list which ones and give brands and amounts:  Brand/Concentration  Amount per day  Carnitine Yes No  Antioxidants Yes No  Multivitamin Yes No  Coenzyme Q10 Yes No  Other (please list):  Example: Vitamin C  Nature's Bounty  How do you administer pills to your pet?  I I do not give any medications	Rawhie			treat	6 inch twist		Dec 2018-present
*Any additional diet information can be listed on the back of this sheet  Do you give any dietary supplements to your pet (for example: vitamins, glucosamine, fatty acids, or any other supplements)? Byes No If yes, please list which ones and give brands and amounts:  Brand/Concentration Amount per day  Amount per day	Pour	Cours Co	rdioc			Oxland	ECO OCC - DOC
Do you give any dietary supplements to your pet (for example: vitamins, glucosamine, fatty acids, or any other supplements)?	Loder	· Corpiers		- trid	1/200	Marg	LED SOM LAVE
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  Yes No No  Carnitine Yes No  Antioxidants 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  How do you administer pills to your pet?				-	,		
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  Yes No Antioxidants Pyes No Multivitamin Pyes No  Coenzyme Q10 Pyes No  Other (please list):  Example: Vitamin C Nature's Bounty 500 mg tablets – 1 per day  How do you administer pills to your pet?							
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  Yes No Antioxidants Pyes No Multivitamin Pyes No  Coenzyme Q10 Pyes No  Other (please list):  Example: Vitamin C Nature's Bounty 500 mg tablets – 1 per day  How do you administer pills to your pet?							
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  Yes No Antioxidants Pyes No Multivitamin Pyes No  Coenzyme Q10 Pyes No  Other (please list):  Example: Vitamin C Nature's Bounty 500 mg tablets – 1 per day  How do you administer pills to your pet?							
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  Yes No Antioxidants Yes No Multivitamin Yes No No Coenzyme Q10 Yes No Other (please list):  Example: Vitamin C Nature's Bounty 500 mg tablets – 1 per day  How do you administer pills to your pet?							
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  Yes No Antioxidants Yes No Multivitamin Yes No No Coenzyme Q10 Yes No Other (please list):  Example: Vitamin C Nature's Bounty 500 mg tablets – 1 per day  How do you administer pills to your pet?							
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  Yes No Antioxidants Yes No Multivitamin Yes No No Coenzyme Q10 Yes No Other (please list):  Example: Vitamin C Nature's Bounty 500 mg tablets – 1 per day  How do you administer pills to your pet?							
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  Yes No Antioxidants Pyes No Multivitamin Pyes No  Coenzyme Q10 Pyes No  Other (please list):  Example: Vitamin C Nature's Bounty 500 mg tablets – 1 per day  How do you administer pills to your pet?							
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  Yes No No  Carnitine Yes No  Antioxidants 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  How do you administer pills to your pet?	*Anv a	dditional diet informa	tion can be listed on the back	of this sheet			
Supplements)?  Simplements Signature	· u.y ·		and the motor of the pack	or tino aricot			
Supplements)?	Do you	give any dietary sur	plements to your pet (for exa	mole: vitamins	alucosamine	fatty acids or a	any other
Taurine	supple	ments)?	□No If ves, please list which	ch ones and div	e hrands and	amounte	any other
Taurine			Brand/C		re brands and	amounts.	Amount per day
Carnitine	Taurine	e <b>⊡</b> Yes	INO MOND 1500	)		,	
Antioxidants	Carnitir	ne □Yes	□No				
Multivitamin	Antioxi					-	
Fish oil							
Coenzyme Q10	Fish oil	□Yes	□No			-	
Other (please list):  Example: Vitamin C  Nature's Bounty  500 mg tablets – 1 per de  How do you administer pills to your pet?  I do not give any medications	Coenzy	me Q10 □Yes	□No				
Example: Vitamin C Nature's Bounty 500 mg tablets – 1 per de							
How do you administer pills to your pet? □ I do not give any medications			Nati	ure's Bounty		500 ma	tablets 1 perday
How do you administer pills to your pet? □ I do not give any medications			, ide	no o bounty		Joo nig	tablets – T per day
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□ I do not give any medications	-			1 1 1 1		30	
□ I do not give any medications		To the country of the same of					
	How do	you administer pills	to your pet?				
D I but them directly in my net's mouth without food							
par dieni directy ii iiiy pera iiioddi witiiodd iood	Dut put	them directly in my p	et's mouth without food				
1 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):	i put	them in a Pill Pocket	or similar product				

### Idexx NT-proBNP 5/8/2019

Client: B6 IDEXX Reference Laboratories IDEXX VetConnect 1-888-433-9967 Client: B6 Date: 05/08/2019 TUFTS UNIVERSITY 200 WESTBORO RD NORTH GRAFTON, Massachusetts 01536 Patienti. Requisition #: 1A Accession # B6 ; Ordered by B6 ; Species CANINE Breed: ENGLISH\_BULLDOG 508-839-5395 Gender: FEMALE 5 PAYED Age: 8Y Account B6 CARDIOPET proBNP - CANINE CARDIOPET proBNP B6 B6 0 - 900 pmol/L - CANINE 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.

**B6** 

### **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: В6 @tufts.edu GI Lab Assigned Clinic ID: 23523 B6 Phone: 508 887 4696 Tufts Cummings School of Vet Med - Cardiology/Nutrition Fax: 200 Westboro Road Animal Name: North Grafton, MA 01536 Owner Name: USA Species: Canine Date Received: May 30, 2019 GI Lab Accession: B6 Tufts Cummings School of Vet Med -Cardiology/Nutrition Tracking Number: 438993 Assay Date Test Result Reference Interval Ultra-Sensitive Troponin I Fasting В6 ≤0.06 05/31/19

GI Lab Contact Information

Phone: (979) 862-2861 Fax: (979) 862-2864

Comments:

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

# Cummings Veterinary Medical Center

Cardiology Liaison: 508-887-4696

**B6** 

Patient D: B6 B6 Canine B6 ears Old Female (Spayed) English Bulldog Brown/White

### **Cardiology Appointment Report**

Date: 5/8/2019
Attending Cardiologist:
☐ John E. Rush DVM, MS, DACVIM (Cardiology), DACVECC
B6 .
Cardiology Resident:
B6
Cardiology Technician:
DC
<b>B6</b>
Student: B6
Presenting Complaint: 3 month recheck DCM study
Hx BNP of B6 at rDVM. Possible ARVC but no hx of arrhythmia.
The bit of Do at Dotte. To Ender vite out the first of defly the first
Concurrent Diseases:
Chronic enteritis
General Medical History:
O reports doing well at home.
B6
Diet and Supplements:
RC Cardiac diet
Now Taurine 500 mg BID
Cardiovascular History:
Prior CHF diagnosis? N
Prior heart murmur? N
Prior ATE? N
Prior arrhythmia? N
Monitoring respiratory rate and effort at home? Y, 30-40 breaths/min when resting
Cough? N
Shortness of breath or difficulty breathing? N

Syncope or collapse? N Sudden onset lameness? N Exercise intolerance? N

<u>Current Med</u>	ications	<u>Pertinent</u>	<u>ть CV :</u>	System:

None

Cardiac Physical Examination:			
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		
Jugular vein:  Bottom 1/3 of the neck  Middle 1/3 of the neck	1/2 way up theneck Top 2/3 of theneck		
Arterial pulses:  Weak  Good Strong	Bounding Pulse deficits Pulsus paradoxus Other:		
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		
Abdominal exam:  Normal  Hepatomegaly	Mild ascites Marked ascites		

Abdominal distension	
<u>Problems</u> : History of possible early ARVC	
Diagnostic plan:  Echocardiogram  Chemistry profile  ECG  Renal profile  Blood pressure	☐ Dialysis profile ☐ Thoracic radiographs ☐ NT-proBNP ☐ Troponin I ☑ Other tests: bloodwork for DCM study
	<b>B6</b>
consistent with ARVC, but no arrhythmia was d	lly improved systolic function. There is still RH dilation locumented today. No cardiac medications are clearly end continuing to supplement with taurine. Recheck echo in
	ith early arrhythmogenic right ventricular cardiomegaly opathy - stable to slightly improved from appointment in
Heart Failure Classification Score:  ISACHC Classification:  la  ib  lb	□ IIIa □ IIIb
ACVIM Classification:  A B1 B2	□ c □ D

M-Mode		
IVSd		cm .
LVIDd		om
LVPWd	1	om
IVSs		om
LVIDs		om
LVPWs		om
EDV(Teich)	1	ml
ESV(Teich)	i i	ml
EF(Teich)	į i	%
%FS	!	%
SV(Teich)	† :	ml
Ao Diam		om
LA Diam		
LA/Ao		cm
Max LA		cm
TAPSE		om
EPSS		
Eraa		cm
M-Mode Normalized		
IVSdN		(0.290 - 0.520)
LVIDdN	· ·	(0.250 - 0.520) (1.350 - 1.730)
LVPWdN		(0.330 - 0.530) !
IVSsN	:	(0.430 - 0.710)
LVIDSN		(0.430 - 0.710) (0.790 - 1.140)
	- Kh	[U.73U - T.14U]
	LUU	n con n zoni i
LVPWsN Ap Diam N		(0.530 - 0.780) !
Ao Diam N		(0.680 - 0.890) !
Ao Diam N		(0.680 - 0.890) !
Ao Diam N LA Diam N		(0.680 - 0.890) !
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Ao Diam N LA Diam N  2D SA LA Ao Diam SA LA / Ao Diam IVSd LVIDd LVPWd EDV(Teich)		(0.680 - 0.890) ! (0.640 - 0.900) cm cm cm cm
Ao Diam N LA Diam N  2D SA LA Ao Diam SA LA / Ao Diam IVSd LVIDd LVPWd EDV(Teich) IVSs		(0.680 - 0.890) ! (0.640 - 0.900) cm cm cm cm cm
Ao Diam N LA Diam N  2D SA LA Ao Diam SA LA / Ao Diam IVSd LVIDd LVPWd EDV(Teich) IVSs LVIDs		(0.680 - 0.890) ! (0.640 - 0.900) cm cm cm cm
Ao Diam N LA Diam N  2D SA LA Ao Diam SA LA / Ao Diam IVSd LVIDd LVPWd EDV(Teich) IVSs LVIDs LVPWs		(0.680 - 0.890) ! (0.640 - 0.900) om om om om om om om
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Ao Diam N LA Diam N  2D SA LA Ao Diam SA LA / Ao Diam IVSd LVIDd LVPWd EDV(Teich) IVSs LVIDs LVPWs ESV(Teich) EF(Teich)		(0.680 - 0.890) ! (0.640 - 0.900) om om om om om om om om
Ao Diam N LA Diam N  2D SA LA Ao Diam SA LA / Ao Diam IVSd LVIDd LVPWd EDV(Teich) IVSs LVIDs LVPWs ESV(Teich) EF(Teich) EF(Teich)		(0.680 - 0.890) ! (0.640 - 0.900) om om om om om om om om
Ao Diam N LA Diam N  2D SA LA Ao Diam SA LA / Ao Diam IVSd LVIDd LVPWd EDV(Teich) IVSs LVIDs LVPWs ESV(Teich) EF(Teich) %FS SV(Teich)		(0.680 - 0.890) ! (0.640 - 0.900) cm cm cm cm cm cm cm cm
Ao Diam N LA Diam N  2D SA LA Ao Diam SA LA / Ao Diam IVSd LVIDd LVPWd EDV(Teich) IVSs LVIDs LVPWs ESV(Teich) EF(Teich) %FS SV(Teich) LVId A4C		(0.680 - 0.890) ! (0.640 - 0.900)  am
Ao Diam N LA Diam N  2D SA LA Ao Diam SA LA / Ao Diam IVSd LVIDd LVPWd EDV(Teich) IVSs LVIDs LVPWs ESV(Teich) EF(Teich) %FS SV(Teich) LVID AAC LVEDV MOD AAC		(0.680 - 0.890) ! (0.640 - 0.900)  cm
Ao Diam N LA Diam N  2D SA LA Ao Diam SA LA / Ao Diam IVSd LVIDd LVPWd EDV(Teich) IVSs LVIDs LVPWs ESV(Teich) EF(Teich) %FS SV(Teich) LVId A4C		(0.680 - 0.890) ! (0.640 - 0.900)  am

LVEF MOD A4C		%
SV MOD A4C		ml
<u>Doppler</u>		
MV E Vel		m/s
MV DecT		ms
MV Dec Slope		m/s
MV A Vel	DA	m/s
MV E/A Ratio	<b>B6</b>	
E		m/s
E/E'		
A'		m/s
2		m/s
AV Vmax		m/s
AV maxPG		mmHg
PV Vmax		m/s
PV maxPG		mmHg
	Li	

# 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

	Owner		
lame: B6	Name: (	B6	Patient II); B6
pedes: Canine	Address	В6	
rown/White Female(Spayed) English	<u></u>	DU	
uldog			
<b>irthdate:</b> B6			
ttending Cardiologist:			
John E. Rush DVM, MS, DACVIM (	(Cardiology), DAC	NEOC .	
B6			
<b>DO</b> .			
ardiology Resident:			
B6	j 		
ardiology Technician:	··-·		
DC			
ВО			
	<u></u> j		
itudent: B6			
Dalle: 5/8/2019			

#### **Clinical Findings:**

Thank you for bringing 56 in for her three month recheck as a part of the DOM study. You report that B6 has been doing well at home and that you have been giving her Taurine supplement twice a day. Her respiratory rate has been normal and she has had a good energy level at home.

During the appointment today, we performed a recheck echocardiogram (ultrasound of the heart). On the echocardiogram, the structural changes to: 86 heart that we had previously seen in February were still present, but are stable to slightly improved. We also used electrocardiogram (EKG) to assess \_\_\_86 \_\_heart rhythm and did not see any arrhythmias. Based on B6 achocardiogram and EKG today, we still do not think that B6 needs any medication at this point. Please continue to give her Taurine supplement twice daily.

We drew a blood sample from B6 for the DCM study and will contact you once we have the results back.

#### Monitoring at Home:

Please continue to watch: B6 at home for any signs such as increased respiratory rate or effort, exercise intolerance or episodes of collapse. If you see any of these signs, please contact a veterinarian.

#### Diet Suggestions:

Please continue to feed B6 the Royal Canin Cardiac diet.
Exercise Recommendations:  B6 may continue her normal exercise at home.
Recommended Medications: Please continue to give B6 her Taurine supplement (500 mg by mouth twice daily).
Recheck Visits: We would like to see B6 for a recheck appointment in 3 months. At this visit we will want to check breathing effort and heart function, do a blood test for the DOM study, and perform a recheck echocardiogram. B6 we contact you to schedule this appointment once the troponin results are back in a week or so.
Thank you for entrusting us with B6 care. She is a wonderful dog! Please contact our Cardiology laison at (508)-887-4696 or email us at cardiovet@tults.edu for scheduling and non-emergent questions or concerns.
Please visit our HeartSmart website for more information http://vet.tufts.edu/heartsmart/
Prescription Refil Discloimer: For the safety and well-being of our patients, your pet must have had an examination by one of our veterinarians within the payeer 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 Tripls:  Clinical Tripls:  Clinical tripls 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: <a href="https://www.clinical-studies">website: website: website</a>
Case B6 Owner B6 Discharge Instructions

From: Rotstein, David </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0A3B17EBFCF14A6CB8E94F322906BADD-

DROTSTEI>

To: Carey, Lauren; Palmer, Lee Anne; Jones, Jennifer L

Sent: 11/8/2018 12:07:21 PM

Subject: FW: Merrick LID Grain Free dry (salmon: Lisa Freeman - EON-369322

2057941-report.pdf; 2057941-attachments.zip Attachments:

David Rotstein, DVM, MPVM, Dipl. ACVP CVM Vet-LIRN Liaison CVM OSC/DC/CERT 7519 Standish Place

(BB) **B6** 





This e-mail message is intended for the exclusive use of the recipient(s) named above. It may contain information that is protected, privileged, or confidential, and it should not be disseminated, distributed, or copied to persons not authorized to receive such information. If you are not the intended recipient, any dissemination, distribution, or copying is strictly prohibited. If you think you received this e-mail message in error, please e-mail the sender immediately at david.rotstein@fda.hhs.gov.

From: PFR Event cpfreventcreation@fda.hhs.gov>

Sent: Thursday, October 25, 2018 7:29 AM

To: Cleary, Michael \* <Michael.Cleary@fda.hhs.gov>; HQ Pet Food Report Notification

<HQPetFoodReportNotification@fda.hhs.gov> Subject: Merrick LID Grain Free dry (salmon: Lisa Freeman - EON-369322

A PFR Report has been received and PFR Event [EON-369322] has been created in the EON System.

A "PDF" report by name "2057941-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 "2057941-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

**EON Key:** EON-369322

ICSR #: 2057941

EON Title: PFR Event created for Merrick LID Grain Free dry (salmon duck or chicken); 2057941

AE Date	02/09/2018	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Died Euthanized
Breed	Retriever - Labrador		

Age	9 Years	
District Involved	PFR-New England DO	

#### **Product information**

Individual Case Safety Report Number: 2057941

Product Group: Pet Food

**Product Name:** Merrick LID Grain Free dry (salmon, duck, or chicken)

Description: DCM and CHF Euthanized for worsening heart failure and arrhythmia in September

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 Euthanized

Number of Animals Treated With Product: 1 Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Merrick LID Grain Free dry (salmon, duck, or chicken)		

#### **Sender information**

Lisa Freeman 200 Westboro Rd North Grafton, MA 01536 USA

# Owner information

**B6** 

To view this PFR Event, please click the link below: https://eon.fda.gov/eon//browse/EON-369322

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=386244

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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secret and confidential commercial information that you receive from the U.S. Food and Drug Administration from further disclosure. The information in the report is intended for situational awareness and should not be shared or acted upon independently. Any and all actions regarding this information should be coordinated through your local district FDA office.

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 <a href="mailto:FDAReportableFoods@fda.hhs.gov">FDAReportableFoods@fda.hhs.gov</a> immediately.

Report Details - EON-	369322		
ICSR:	2057941		
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 07:21:15 EDT		
Reported Problem:	Problem Description:	DCM and CHF Euth	anized for worsening heart failure and arrhythmia in
	Date Problem Started:	02/09/2018	
	Concurrent Medical Problem:	No	
	Outcome to Date:	Died Euthanized	
	Date of Death:	B6	
Product Information:	Product Name:	Merrick LID Grain Fr	ree dry (salmon, duck, or chicken)
	Product Type:	2	22 2.5 (cumon, acon, or omoron)
	Lot Number:	1 OCT OOG	
	Package Type:	BAG	
	Product Use Information:	Description:	Merrick for ~1 year Please see diet history for other foods and previous diets (Canidae LID grain free)
	Manufacturer /Distributor Information:		· · · · · · · · · · · · · · · · · · ·
	Purchase Location Information:		
Animal Information:	Name:	B6	
	Type Of Species:	L	
	5 (	Retriever - Labrador	
	Gender:	<del></del>	
	Reproductive Status:	4	
	3	47 Kilogram	
	<u> </u>	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:
			Phone: <b>B6</b>
			Emails
		Address:	B6
			United States
	Haalibaara Dari ii ii		
	Healthcare Professional Information:	Practice Name: Contact:	1
			Phone: (508) 887-4523  Email: lisa.freeman@tufts.edu

		Address:	200 Westboro Rd North Grafton Massachusetts 01536 United States
Sender Information:	Name:	Lisa Freeman	
		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:			
		B6 compiled reco	
		Compiled medical re	cord
	Type:	Medical Records	
		inedical (Cecords)	
		Tredical Necords	



## **Foster Hospital for Small Animals**

55 Willard Street North Grafton, MA 01536 (508) 839-5395

Client: Address: **B6** 

B6

All Medical Records

Patient: **B6** 

Breed: Labrador Retriever DOB: **B6** 

Species: Canine Sex: Male

(Neutered)

# Referring Information

**B6** 

#### **Initial Complaint:**

Emergency

#### SOAP Text Feb 9 2018 1:21PM - Clinician, Unassigned FHSA

#### Subjective

NEW VISIT (ER)

Doctor B6
Student: B6

Presenting complaint: Increased lethary and difficulty breathing since last night and this morning

Past pertinent medical history: On Dec 2, brought to rDVM for 2 weeks of diarrhea, coughing/gagging, wheezing lethary and decreased appetite. rDVM preformed bloodwork which came back esentially normal. At this time referred for an AUS which found dilated hepatic vessels along with a murmur, tachycardia, and heart enlargement. He was diagnosed with suspected "early CHF" and started on B6 , but due to concern for elevated kidney values, furosemide was discontinued after about 2 weeks of treatment. He had been doing well at

Client: <b>B6</b> Patient:	
home until the end of January where he started to have more at a lower dose (20 mg Q12h).	e coughing and gagging, so B6 was restarted, but
Medications currently administered at home:	
<b>B6</b>	
Dietary history:  Type of food: For the past month has been feeding mostly becommercial kibble (Blue Buffalo, Canidae) with added home  Travel: Born ir B6 and lived there for 2 years. Moved t	c <u>ooked meat (duc</u> k and bison)
/isit is a referral: Yes Bloodwork/Procedures completed prior to arrival: CBC/Chem Referred for specific test: Cardiology consult	า in December (see below)
BAR, BGS:	
nm slightly muddy, CRT <2 sec	
Objective (O)	
	6
DIAGNOSTICS:  B6	
12/13/17 (rDVM):	
Chem: <b>B6</b> remaining values WNL	

Client: Patient: <b>B6</b>
2/9/18 (Tufts): NOVA: <b>B6</b>
NOVA: B6  PCV/TS: B6 g/dL  EKG: initial concern for possible a-fib, but more consistent with frequent VPCs/bigeminy  TFAST/AFAST: no pleural, pericardial, or peritoneal effusion; moderate to marked left atrial enlargement with left ventricular dilation and decreased contractility; moderate coalescing B-lines (worse on the right)  Lateral thoracic radiograph: cardiomegaly, no significant pulmonary edema (taken after furosemide administration)
Assessment (A) A1: Dilated cardiomyopathy with left ventricular wall thinning and chamber dilation, left atrial enlargement, ventricula arrhythmias (frequent VPCs), and increased respiratory effort and muddy gums consistent with congestive heart failur - rule-out idiopathic vs. taurine deficiency vs. other
Plan (P)
<b>B6</b>
TGH following cardiology consult: ADD taurine, B6
<b>B6</b>
recheck with cardiology on 2/21 @ 3:30 pm - will recheck labwork at that time
Client Communication:
Discussed extensively with owner concern for heart failure - very bad MVD vs. more likely DCM given left ventricular dilation that I see and large breed status. Given some respiratory difficulty B6
B6 Prognosis with DCM is 6 months to 1 year depending on if/when arrhythmias develop -
risk for sudden death. Owner consented and echocardiogram was consistent with DCM B6 is fairly crazy and worker up in hospital. Could not place IVC despite sedation - no real effect on him. Pulmonary edema did no seem significant on radiograph, so recommended owner take him home which she was happy to do. Will supplement with taurine as it is relatively inexpensive and testing taurine levels is B6 Cardiology would like to recheck in a couple of weeks - owner ok with recheck time.
CPR status <b>B6</b>
SOAP completed by: ??? SOAP reviewed by: B6 , DVM, ECC Resident
Initial Complaint:  Recheck B6 consult done thru ER
SOAP Text Feb 21 2018 5:15PM - <b>B6</b>

#### **Initial Complaint:**

Nutrition Phone/In person

#### SOAP Text Feb 22 2018 2:31PM - Freeman, Lisa

#### **Subjective**

(See Diet History Form for additional details on diet)

History: DCM and CHF diagnosed Dec 2017, history of chronic intermittent diarrhea for years; evaluated by Tufts Cardiology 2/9/18 and recheck today

Meds: **B6** 

Current Diet: (See Diet History Form in Documents and comm log for additional information)
Canidae grain free (variable flavors) or Merrick LID grain free (variable flavors)

Approximately 40% of diet comes from other foods, rice, vaggins, most loggs, shoots, treats

Approximately 40% of diet comes from other foods - rice, veggies, meat, eggs, cheese, treats

Supplements: Taurine (from Tufts), **B6** 

Owner Goals: Optimal diet to help manage heart disease and diarrhea

Assessment: B6

Plan: Modify diet to lower sodium, more nutritional balanced; adjust supplements, treats, table food, medication administration, etc

#### **Initial Complaint:**

Emergency

#### SOAP Text Apr 9 2018 1:47PM - Clinician, Unassigned FHSA

#### Subjective

**NEW VISIT (ER)** 

Doctor: B6 V'18

Presenting complaint: possible arrhythmia

Referral visit? No

Diagnostics completed prior to visit

- Renal profile 4/6/18

HISTORY:

Signalment: 8 yo MN Lab  Current history: B6 was diagnosed in 12/2017 with DCM and CHF (sees cardio), has been managed since then on
B6 He has been increasingly less tolerant of walks at home, no coughing, not a lot
of gagging, but HR and RR have been very high at home. Since 3/27 addeq B6 to meds which seemed to have
been helping. Yesterday 4/8 after 15 min walk his HR seemed irregular, O was concerned he was having VPCs last night
and this morning. His RR this morning was up in the 40s-50s. The O is interested in whether he needs a holter
monitor/medication change/echo sooner than when scheduled in May. Had bloodwork at rDVM last week 4/6.
Prior medical history: No other medical issues
Current medications:
<b>B6</b>
Diet: Purina DCM cardiac diet, sometimes poor appetite so mixed with canidae chicken and rice; sometimes cooked
veggies
EXAM:
S: BAR, B6 S O: Wt B6
O: Wt B6
DCC/1 0\\ PC
BCS(1-9): <b>B6</b> MCS(normal,mild,moderate,severe): Normal
ivics(normal,mild,moderate,severe). Normal
Hydration: Euhydrated
Kh
<b>50</b>

ASSESSMENT:

A1: DCM

A2: Elevated BUN: r/o secondary to Lasix

PLAN:

P1: ECG

P2: TFAST - evidence of DCM, few small B-lines bilaterally, no PCE

Client: Patient:	<b>B6</b>		
Diagnostics c			
4/6/18 rDVM			
- Renal chem	: <b>B</b>	6	
- ECG: nsf			
Diagnostics p	ending:		
Recommende	ed cardiology		y, sinus arrhythmia but no concerning rhythms that we noticed. d chest x-rays. Offered day ECG monitoring as well. O declined and Dr. <b>B6</b>
Deposit & est	imate status	:	
Resuscitation	code (if adm	nitting to ICU):	
SOAP approv	ed (DVM to s	sign): B6 DVN	M
Initial Complement Recheck B6		ocol	
SOAP Text	Aug 17 2018	12:44PM <b>B6</b>	
Initial Compl. Nutrition Phon			
SOAP Text	Aug 27 2018	1:27PM - Freeman, Lisa	
Subjective			
Nutrition Pho		lotes I - NO EXAM PERFORME	ED**
(See Diet Hist	ory Form an	d information from refe	erring veterinarian in Documents for additional details)
Plan was to cafter starting	hange diet a	t last visit (2/22/18) but	rt failure, chronic intermittent diarrhea.  (B6) had CHF at that time and wouldn't eat (improved significantly ck LID/Grain Free salmon, duck, or chicken dry + 30-40% of calories eas, pasta, rice, etc
Meds:		B6	
Current Diet:	(See Diet His	story Form in Document	ts and comm log for additional information)
Supplements	:[		B6
Assessment:	DCM and CH	IF - need to change to n	non-BEG diet asap to see if any improvement in cardiac function is

Page 6/73

Client: **B6** 

possible. Also, need to manage GI signs, small kibble size.

Plan: Diet recommendations

\*\*PHONE CONSULTATION - NO EXAM PERFORMED\*\*

**Disposition/Recommendations** 



Lab Results Report

**Nova Full Panel-ICU** 

Α

NOVA SAMPLE

stringsoft.

Client:	В6	
Veterinarian	1:	
Patient ID:	B6	]
Visit ID:		

# Foster Hospital for Small Animals

55 Willard Street North Grafton, MA 01536 (508) 839-5395

Accession ID: B6

Patient:	B6
Species:	Canine
Breed:	Labrador Retriever
Sex:	Male (Neutered)
Age:	<b>B6</b> Years Old

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)	<b>B6</b>	12 - 28	mg/dL
CREAT (POC)		0.2 - 2.1	mg/dL
TCO2 (POC)		() - ()	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

2/9/2018 7:02:25 PM

B6

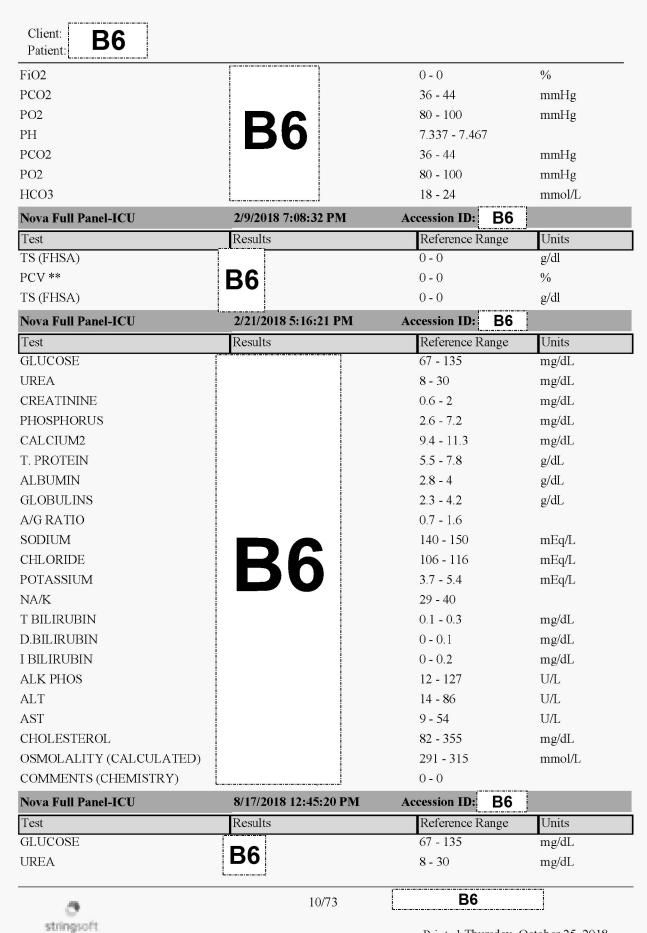
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Printed Thursday, October 25, 2018

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9/73



Printed Thursday, October 25, 2018

Client: <b>B6</b>			
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	DC	106 - 116	mEq/L
POTASSIUM	<b>B6</b>	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

stringsoft.

11/73 **B6** 

Printed Thursday, October 25, 2018

B4, B6

ME.

SHOW!

(subject)

Not below on hough a street a ball days may open

NAME OF TAXABLE

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(S) 35W/r

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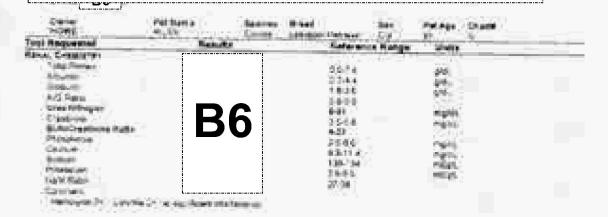
**B6** 

RDVN

**B4**, **B6** 

ab results 11/30/17-12/13/17

**B4, B6** 



B4, B6

0.1

RET THE OWNATED IN	
Fet Name	DC
Pet Last Home:	B6
Per Species/Breed	Dry / Labrador Satrayay
Pet's Color	Black
Pet's Withdate	B6
Pet's Sex	Male
Spayed or Neutered?	(a)
CONTINUOUS	
Circl State	
Cleen Address	DC
Clera Phone Ps	<b>B6</b>
Client Empl.	
Co-Owner States	
Co-Owner Phone	<u> </u>
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HIVM Fax	<u> </u>
(DVM Deal)	

Page 14/73





# **Clinical Mutation Service**

Foster Hospital for Small Asimusi 200 Westbord Road Hospi Grafton NA 01536 Phone: Dole 887-9690 ABN Hydritish Listion Pax. 506-867-4563 www.pethys/00ps/brg wetastribon/grafts/with



**B6** 

Midding Consultation.

**Nutrition appointment report 2-22-18** 



**B6** 

**Nutrition appointment report 2-22-18** 

**B6** 

Scripently,

Liss M. Freeman, DVM: PHD: GACVN Professor, Clinical Nutrition 508-887-4696 (Selephine) vetrus/recriff(s/fts odu (erros)) TOWN OF THE PARTY AND

3/6/18 e-mail from client with spreadsheet

Page 26/73

**B6** 

3/6/18 e-mail from client with spreadsheet

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3/6/18 e-mail from client with spreadsheet



B6 3/8/18-CBC/Chem

**B6** 

В6

abs 3/8/18-CBC/Chem

**B6** 

Clien Patie B6

**RDVM** В6 results 4/6/18 **B6**  rDVM

В6

labs 5/8/18

**B6** 

Pape 1

POME.

## Diet history 8/15/18

CARCIOLOGY DIET HISTORY FORM  Please answer the following questions about your pet						
t returns	B6	Sent Stance	В6	about the table 100 mg	Today's saw	6/15/18
How would	you resent yo	or persupposes? On a scan of t	10 eth 1 be	ing poor and 50-6	ming occimit	0.
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Province list connecting ex-	benne <u>ALL</u> pel ats: Petasse inci	Room, people fuse, invest, usack sate the board apoolic product.	durkal chevi nel failor so s	i, merrodes, and relative exactly o	any uther food a what you get is a	lons (their lythat pe saleing)
THE R. P. LEWIS CO., LANSING, MICH.		roduct and flavor. Form			o offen? Ouro snikovy to	Fed since t most term to
Food	include spec	the product and flower;	Forte	Amount	How otten?	Fed sance
	SEE BOTTON	FOR ADDITIONAL.	10	- 3305		
terror units	Croprodit (ACC) by	permitted fine a door seman, to fire a selection of the breet of lead, prevent the select restor	By By spends	11 VI fee 1 fee 3-4 procise	70/045 34/045 15-44/045	-SETELLI APRILL TREATMENT OF THE
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Wistonio Con	ndition Score:	normal proscin( ) mad inse	DE 1000 D	LOCOTTE SHIPPE	NESC) SIEVE	m minicie sons

## Clinical Nutrition Service

Fother Hospital for Small America. 200 Westborn Rose truth Grafter, MA 01506. Phone: 0096-857-4696 Albit Federion Littlers File: 508-857-4563 area 2605060000000000 wethubborn@sufficeds



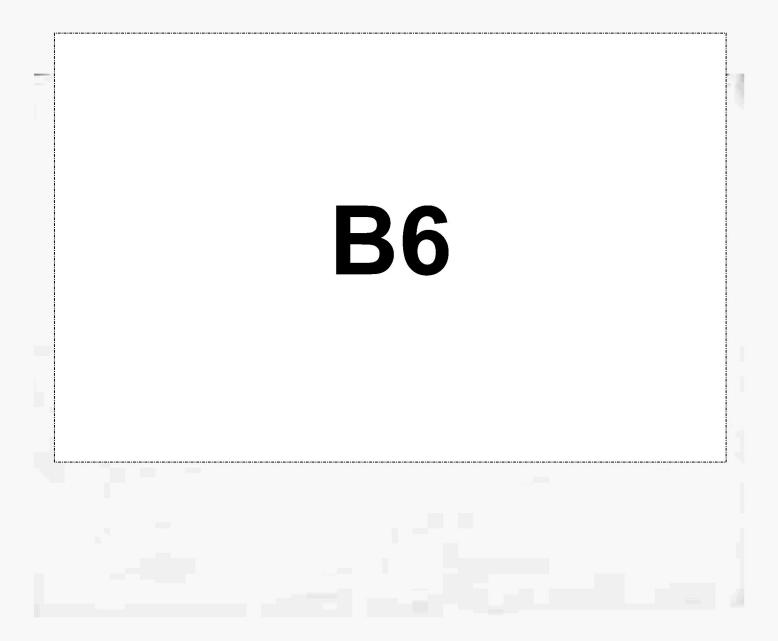
**B6** 

July attributions, 42 acres and third book.

**B6** 

Elecceptly,

Lisa M. Freeman, CVM, PhD, DACVN: Protessor, Caracal Substant 500:387-4590 (delephone) wathursion@subs esta (email) www.jattoodologe.org





Client: B6

RDVM/ В6 Practice Renal Profile 6/9/18 **B6 B6** 

Email from owner 9/11/18

**B6** 

Page 41/73

Email from owner 9/11/18

**B6** 

9

## Vitals Results

2/9/2018 3:12:22 PM 2/9/2018 3:12:23 PM 2/9/2018 3:12:24 PM 2/9/2018 3:12:25 PM 2/9/2018 3:41:50 PM 2/9/2018 3:52:17 PM 2/9/2018 4:29:58 PM 2/9/2018 6:21:42 PM 2/9/2018 6:31:58 PM 2/9/2018 6:57:57 PM 2/9/2018 7:55:28 PM 2/9/2018 7:57:28 PM 2/22/2018 5:37:36 PM 2/22/2018 5:37:37 PM 2/22/2018 5:37:38 PM 4/9/2018 1:30:52 PM 4/9/2018 1:30:53 PM 4/9/2018 1:30:54 PM 4/9/2018 1:30:55 PM 8/17/2018 12:16:11 PM 8/27/2018 1:27:16 PM 8/27/2018 1:27:17 PM

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**ECG** from Cardio

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2/9/2008 4:50/50 MI they to 4f it 7/4% between the the two Yes Commission received of the two

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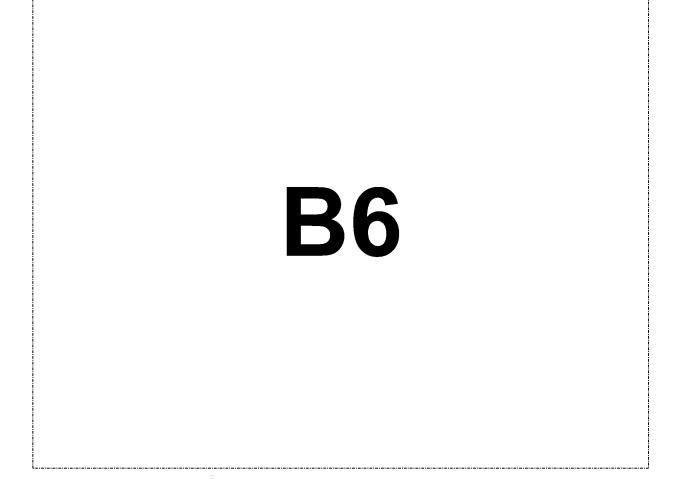
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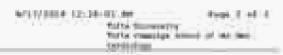


ECG 4/9/18

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### **Patient History**

Patient History	
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02/09/2018 07:15 PM	

Page 63/73

**Patient History** 02/09/2018 07:46 PM 02/09/2018 07:55 PM 02/09/2018 07:55 PM 02/09/2018 07:57 PM 02/09/2018 07:57 PM 02/18/2018 04:25 PM 02/21/2018 03:34 PM 02/21/2018 04:07 PM 02/21/2018 04:59 PM 02/21/2018 05:15 PM 02/21/2018 06:05 PM 02/22/2018 10:49 AM 02/22/2018 02:32 PM 02/22/2018 02:33 PM 02/22/2018 05:37 PM 02/22/2018 05:37 PM 02/22/2018 05:37 PM 02/23/2018 11:03 AM 02/23/2018 11:04 AM 03/02/2018 09:53 AM 04/09/2018 01:30 PM 04/09/2018 01:30 PM 04/09/2018 01:30 PM 04/09/2018 01:30 PM 04/09/2018 03:22 PM 04/09/2018 03:38 PM 04/09/2018 03:38 PM 04/09/2018 03:39 PM 04/10/2018 03:25 AM 05/04/2018 12:42 PM 05/04/2018 12:42 PM 08/08/2018 07:27 PM 08/17/2018 11:29 AM 08/17/2018 11:39 AM 08/17/2018 12:09 PM 08/17/2018 12:09 PM 08/17/2018 12:10 PM 08/17/2018 12:16 PM 08/17/2018 12:29 PM

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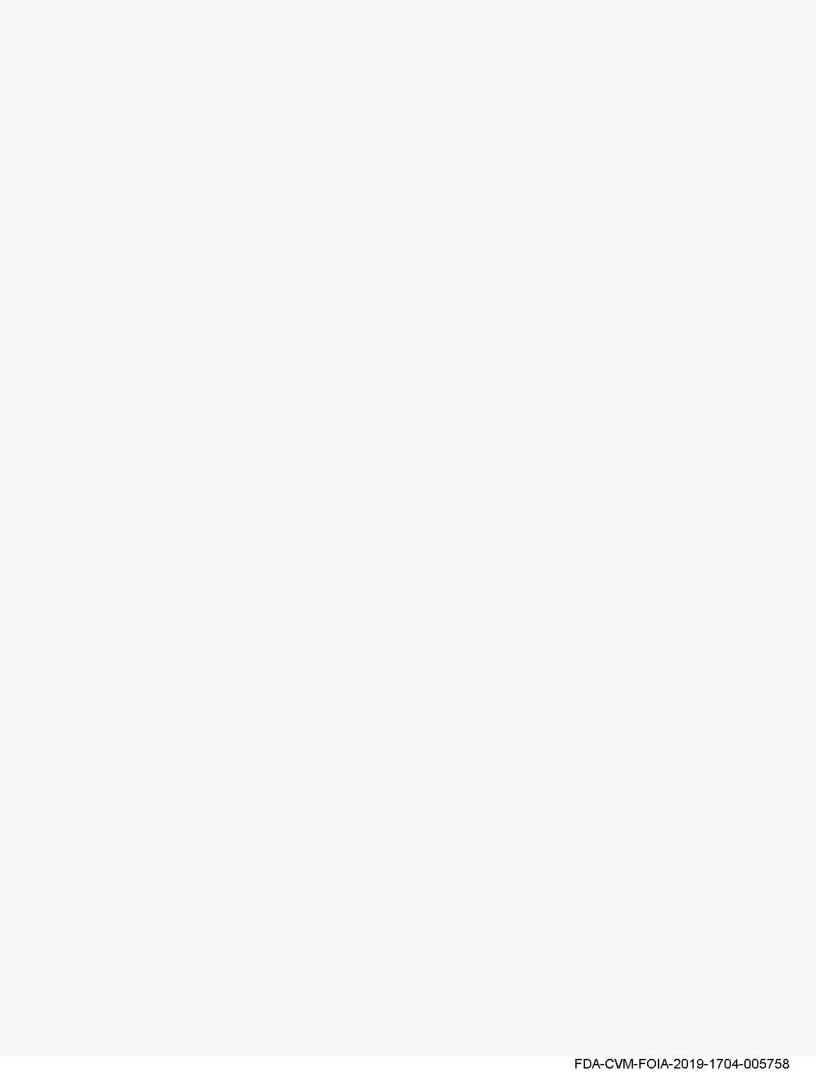
**B6** 

Page 64/73

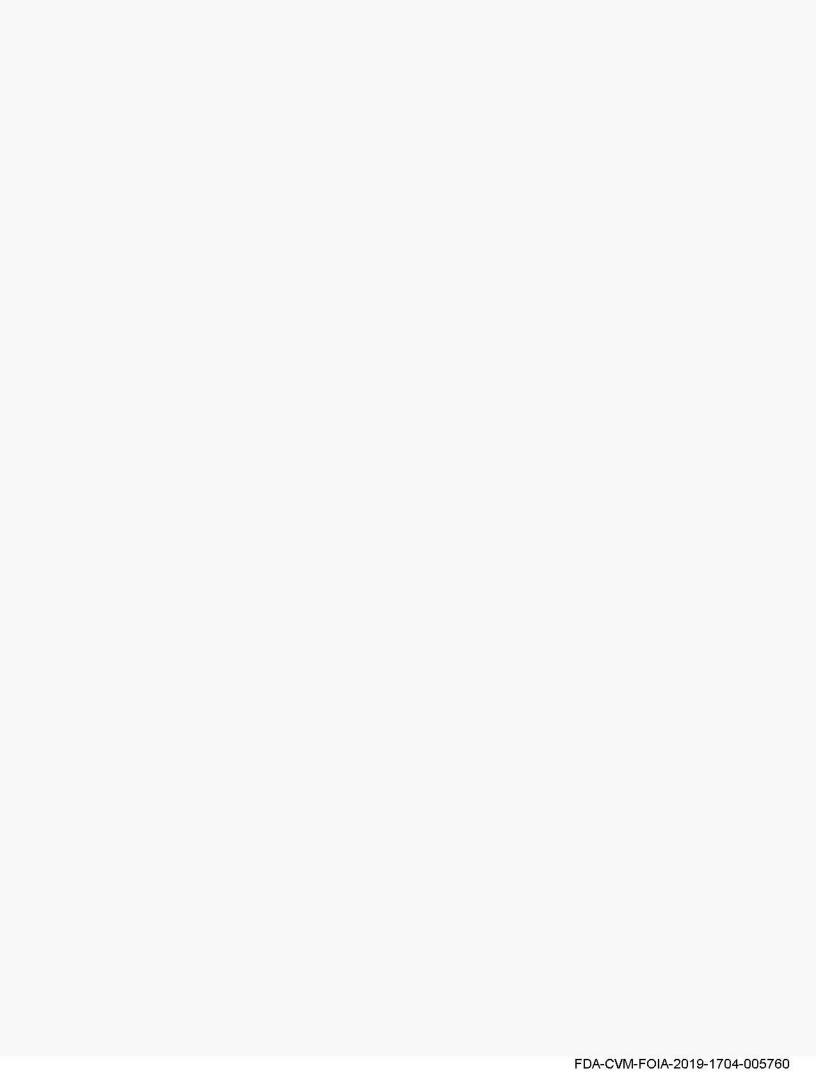
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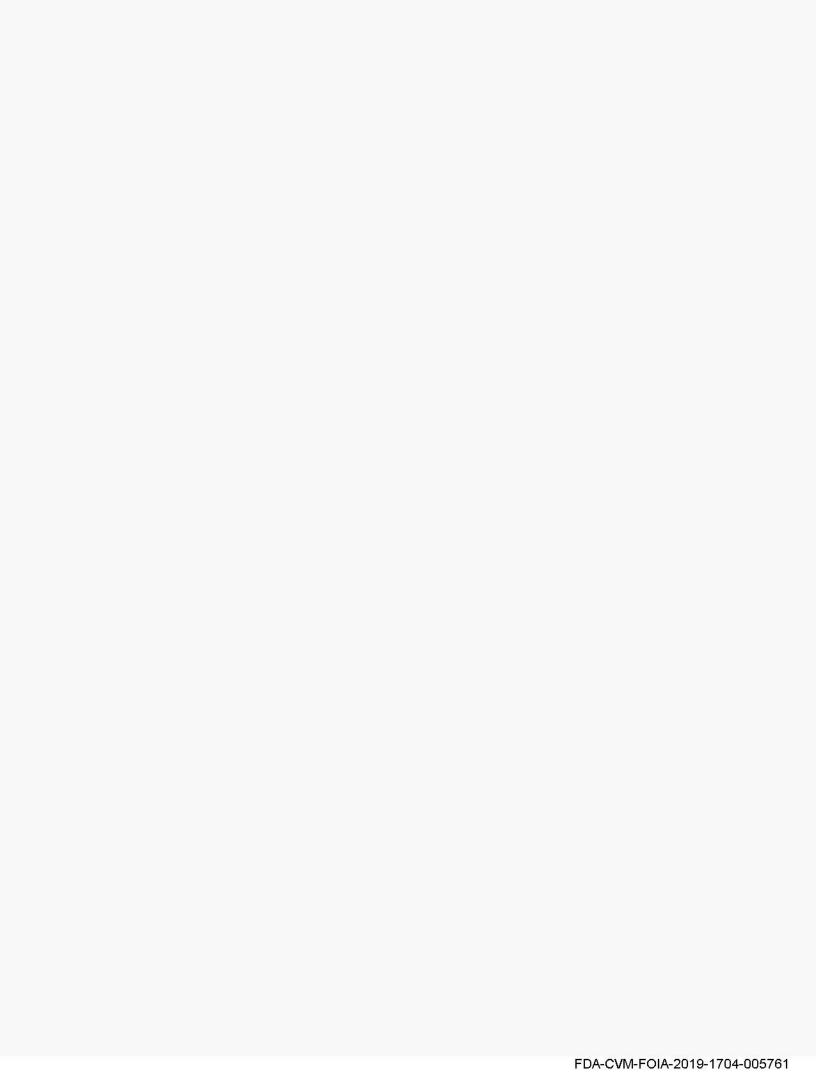
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Patient History	
08/17/2018 01:00 PM	
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08/27/2018 01:27 PM	
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08/27/2018 01:27 PM	
10/23/2018 03:01 PM	











Forter Hospital for Small Animals SS Willard Street Horth Grafton, MA 01516 Telephone (SGR) 839-5395 For (SGR) 839-7951 http://webmed.tufts.edu/

B6 Maie (Meutocod)
Control Labrador Petroleur Black

B6

**B6** 

Desar Dr. B6

Thank you for referring B6 with their pet B6

**B6** 

Please see attached decharge testructures for additional details as needed. If you have any questions, or concerns, please contact us at 508-887-4988.

Think you,

B6 (Resident, Emergency & Concal Care)



В6			
Desar Dr.	В6		
Thank yo	to far referring	В6	with the part B6
If you be	we any questions	er con	orms, pleane contact us at 500 882-4988
thank ye	4.		
B6	DVM, BACKEN	(Corded	ogy), PMD

Fonter Hospital for Small Amena's 25 Willard Street Horth Grafton, MA 01516 Telephone (SOR) \$3955295 For (SOR) \$397951 http://retined.bulls.edu/

B6 Mule (Heatered)
County Laborator Petrieves Black



Forter Hospital for Small Amena's SS Willard Street North Grafton, MA 01516 Telephone (SGR) 839-5395 For (SGR) 839-7951 http://webmed.tufts.edu/

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, Ca	andre:	Links	ador	Pictor	ever	Black
	<b>B6</b>					

В6		
Desar Dr.	B6	
Thank you for re	lonning B6	with their pel B6
Please see the a	taction deschary	e lettes:
If you have any	pestions, or con	como, pleane contact us at 500-882-4988
Thank you,		
В6	(SAM Retailing	letern)



**B6** 

Desar Dr. B6

Thank you for referring B6 with their per B6

If you have any questions, or concerns, pleans contact us at 500 887-4988.

Thank you,

B6 DVM, DACVIM (Condinlogy), PhD

Forter Hospital for Small Animals 25 Willard Street Horth Grafton, MA 01536 Telephone (SGR) 839-5395 For (SGR) 839-7951 http://vetmed.tufts.edu/

B6 Male (Restricted)
Country Entrandor Petricter Black
B6

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:** 10/25/2018 11:54:09 AM

Subject: B6 ase-FW: Taste of the Wild High Prairie: Lisa Freeman - EON-369325

**Attachments:** 2057945-report.pdf; 2057945-attachments.zip

David Rotstein, DVM, MPVM, Dipl. ACVP CVM Vet-LIRN Liaison
CVM OSC/DC/CERT
7519 Standish Place
B6 (BB)













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From: PFR Event cpfreventcreation@fda.hhs.gov>

Sent: Thursday, October 25, 2018 7:53 AM

To: Cleary, Michael \* < Michael. Cleary@fda.hhs.gov>; HQ Pet Food Report Notification

<HQPetFoodReportNotification@fda.hhs.gov>;

Subject: Taste of the Wild High Prairie: Lisa Freeman - EON-369325

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** 

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: <a href="https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jspa?decorator=none&e=0&issueType=12&issueId=386247">https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jspa?decorator=none&e=0&issueType=12&issueId=386247</a>

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Carey, Lauren </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP
(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F0226BD682844FA2B71EA3750D4FCB82-

LAUREN.CARE>

To: Rotstein, David; Ceric, Olgica; Glover, Mark; Jones, Jennifer L; Nemser, Sarah; Palmer, Lee

Anne; Peloquin, Sarah; Queen, Jackie L

**Sent:** 10/25/2018 7:10:28 PM

Subject: RE: B6 case-FW: Taste of the Wild High Prairie: Lisa Freeman - EON-369325

Dr. Freeman stated this might be a duplicate submission. I dug through the database and I don't find anything so I think this is an original report for this case.

From: Rotstein, David

From:

Sent: Thursday, October 25, 2018 7:54 AM

To: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Glover, Mark

- <Mark.Glover@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Nemser, Sarah
- <Sarah.Nemser@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Peloquin, Sarah
- <Sarah.Peloquin@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>; Rotstein, David
- <David.Rotstein@fda.hhs.gov>

Subject B6 case-FW: Taste of the Wild High Prairie: Lisa Freeman - EON-369325

David Rotstein, DVM, MPVM, Dipl. ACVP CVM Vet-LIRN Liaison CVM OSC/DC/CERT 7519 Standish Place B6 (BB)













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From: PFR Event cpfreventcreation@fda.hhs.gov

Sent: Thursday, October 25, 2018 7:53 AM

To: Cleary, Michael \* < Michael. Cleary@fda.hhs.gov>; HQ Pet Food Report Notification

<HQPetFoodReportNotification@fda.hhs.gov>; usha.gulati@doveltech.com

Subject: Taste of the Wild High Prairie: Lisa Freeman - EON-369325

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

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& issueld=386247

\_\_\_\_\_\_

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From:	Freeman, Lis	a <lisa.freeman@< th=""><th>)tufts.edu&gt;</th><th></th><th></th></lisa.freeman@<>	)tufts.edu>		
To:	Jones, Jennif	fer L			
CC:	Reimschuess				
Sent:	7/20/2018 11		, , , , , , , , , , , , , , , , , , ,		
Subject:	RE: 800.267-	·FDA Case Investig	gation for <b>B6</b> (	EON-358523)	
PS – I have food sam	oles for	В6	and <b>B6</b>		
Lisa M. Freeman, DVI Professor Cummings School of V Friedman School of N Tufts Clinical and Tran	Veterinary Medutrition Science	dicine ce and Policy			
Tufts University www.petfoodology.org					
From: Freeman, Lisa Sent: Friday, July 20, To: Jones, Jennifer L Cc: Reimschuessel, F Subject: RE: 800.267	<jennifer.jone Renate <renat< td=""><td>es@fda.hhs.gov&gt; te.Reimschues<u>se</u></td><td>l@fda.hhs.gov&gt;</td><td>523)</td><td></td></renat<></jennifer.jone 	es@fda.hhs.gov> te.Reimschues <u>se</u>	l@fda.hhs.gov>	523)	
Hi Jen and Renate  I'll get permission fron <b>B6</b> owners b Lisa	n all 3 owners ased on upda		s. I might wait ano	ther week before	calling <b>B6</b> and
<u>Updates:</u> For <u>B6</u> , WB were planning to pts to	<u></u>		L	<b>B6</b> was having	ı trouble breathing, they
For B6 died on B6 so no					a message that <b>B6</b> ditional info.
For <b>B6</b> <b>B6</b> No autopsy done. Not	where w	e had him put to	collapsed twice on sleep ırine was plasme	ii	home and again at
Lisa M. Freeman, DVI Professor	M, PhD, DAC\	/N			
Cummings School of '	Veterinary Med	dicine			
Friedman School of N Tufts Clinical and Trar	utrition Scienc	e and Policy			
Tufts University www.petfoodology.org					
From: Jones, Jennife Sent: Friday, July 20,			<u>ov</u> >		

To: Freeman, Lisa < lisa.freeman@tufts.edu >

Cc: Reimschuessel, Renate < Reimschuessel@fda.hhs.gov > Subject: RE: 800.267-FDA Case Investigation for B6 (EON-358523)

Good morning Lisa, Yes, we got the reports you previously submitted and recorded the information for our database. Will you please forward any medical records for:  • B6 are you able to send any updates on the Taurine testing or echocardiogram (if done?) • B6 Also was an autopsy done? Thank you in advance and for your time to report all the cases! 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: Friday, July 20, 2018 8:06 AM  To: Reimschuessel, Renate < Renate.Reimschuessel@fda.hhs.gov >  Cc: Jones, Jennifer L < Jennifer.Jones@fda.hhs.gov >  Subject: RE: 800.267-FDA Case Investigation for B6 (EON-358523)
Dear Renata and Jennifer That seems reasonable. I was never contacted about the other cases that I submitted. There was some confusion about the way I submitted them so I want to be sure you actually got them ( B6 ). I'm sure you're all getting slammed with reports (and there will probably be even more coming now) but just wanted to check to be sure they got recorded. Thanks Lisa
From: Reimschuessel, Renate [mailto:Renate.Reimschuessel@fda.hhs.gov]  Sent: Friday, July 20, 2018 7:55 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-358523)
Dear Lisa Thanks for gathering the information. I think, since we are getting so many reports since our CVM update, we should pass on the <b>B6</b> case as it is not clear-cut.
I think Jen is more familiar with the <b>B6</b> case, so I'll let her respond regarding that one. Thank you again for all your work on this investigation.

Renate Reimschuessel V.M.D. Ph.D. Director Vet-LIRN

Phone 1- 240-402-5404

Fax 301-210-4685

 $\underline{http://www.fda.gov/AnimalVeterinary/ScienceResearch/ucm247334.htm}$ 

From: Freeman, Lisa [mailto:Lisa.Freeman@tufts.edu]

**Sent:** Thursday, July 19, 2018 5:59 PM

**To:** Reimschuessel, Renate < Reimschuessel@fda.hhs.gov >

Subject: RE: 800.267-FDA Case Investigation for **B6** (EON-358523)

Dear Renate In looking back through this case, I'm not sure this is a completely clear-cut one. The dog has degenerative mitral valve disease and CHF but also has reduced cardiac contractility so might be a combination.  Do you still want me to collect the info below?
Also, I have an update on B6 who died at home last week. I do have food from the owner if you want that.  Thanks Lisa
Lisa M. Freeman, DVM, PhD, DACVN 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: Reimschuessel, Renate < Renate.Reimschuessel@fda.hhs.gov > Sent: Tuesday, July 17, 2018 11:48 AM To: Freeman, Lisa < lisa.freeman@tufts.edu > Subject: 800.267-FDA Case Investigation for B6 (EON-358523)
Dear Dr. Freeman, Thank you for submitting your consumer complaint to FDA. I'm sorry to hear about B6 illness.  As part of our investigation, we'd like to request:  • Full Medical Records  • Please email (preferred) or fax (301-210-4685) a copy of B6 entire medical history (not just this event), including any referral diagnostics.  • Phone interview about B6 diet and environmental exposures  • Please confirm permission to contact the owner.  • The interview generally lasts 30 minutes.  I attached a copy of our Vet-LIRN network procedures. The procedures describe how Vet-LIRN operates and how veterinarians help with our case investigations.  Please respond to this email so that we can initiate our investigation.
Thank you kindly, especially for submitting multiple cases, Dr. Reimschuessel
Renate Reimschuessel V.M.D. Ph.D.  Director: Vet-LIRN  (Veterinary Laboratory Investigation and Response Network)  Center For Veterinary Medicine, FDA,  8401 Muirkirk Road, Laurel, MD 20708  Phone 1- 240-402-5404 Fax 301-210-4685  EMAIL: renate.reimschuessel@fda.hhs.gov
Vet-LIRN  http://www.fda.gov/AnimalVeterinary/ScienceResearch/ucm247334.htm

Phish-Pharm

 $\underline{http://www.fda.gov/AnimalVeterinary/ScienceResearch/ToolsResources/Phish-Pharm/default.htm}$ 

 $\underline{http://www.fda.gov/AnimalVeterinary/ScienceResearch/ResearchAreas/ucm130892.htm}$ 

Client B6 Patient B6 IDEXX Reference Laboratories

IDEXX VetConnect 1-888-433-9987

Client: B6 Patient: B6 Species:CANINE Breed:GREAT\_DANE Gender:MALE Age: 8Y

Date: 02/21/2018 Requisition # 366354 Accession # B6 Ordered by: B6 TUFTS UNIVERSITY 200 WES TBORO RD NORTH GRAFTON, Massachusetts 01536-1828 508-839-7936

Account #80735

CARDIOPET P	roBNP - CANINE				
T est		Reference Range			igh
CARDIOPET pro	BNP B6	0 - 900 pmol/L	HIGH	В6	
Comments					
		B	6		

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 di 1

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

Patient ID: B6

B6 Canine
B6 Fears Old Male Great Dane
Fawn BW: Weight(bs) 0.00

**B6** 

### **Cardiology Inpatient**

— — — — — — — — — — — — — — — — — — —
<b>Date:</b> 2/20/2018 <b>Weight:</b> Weight(lbs) 82kg
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: collapse, lethargy, hyporexia, suspected A-fib at rDVM
Current medications and doses: one dose of lasix IV yesterday, no other meds
Key indication for consultation: suspect DCM, A-fib, RCHF
Questions to be answered from the Consult: confirm above, long term prognosis
<b>Is your consult time-sensitive</b> ? (e.g., anesthesia today, owner waiting, trying to get biopsy today)  ☑ Yes (explain) - owners waiting ☐ No
*STOP - remainder of form to be filled out by Cardiology*
Physical Examination
B6

Muscle	e condition:		
	Normal	Moderate cachexia	
1	Mild muscle loss	Marked cachexia	
Carolin	wascular Physical Exam		
	ur Grade:		
	None .	■ IV/VI	
	I/VI	□ v/vi	
	II <b>/</b> VI	□ vi∧i	
	III/VI	_ • • • • • • • • • • • • • • • • • • •	
Murm	ur location/description: systolic left	apical	
Jugula	rvein:		
	Bottom 1/3 of neck	■ Top 2/3 of neck	
1	Middle 1/3 of neck		
	11		
Arteria 2	al pulses: Weak	□ p	
	<del></del>	Bounding	
	Fair	Pulse deficits	
	Good	Pulsus paradoxus	
-	Strong	Other (describe):	
Arrhyt	hmia:		
	None	■ Bradycardia	
	Sinusarrhythmia	☑ Tachycardia, irregular	
	Premature beats		
Gallop			
	Yes	■ Pronounced	
	No	Other:	
	Intermittent	— — — ·	
_			
Pulmo	nary assessments:	m	
	Eupneic	Pulmonary Crackles	
	Mild dyspnea	Wheezes	
	Marked dyspnea	Upper airway stridor	
	Normal BV sounds	Other auscultatory findings:	
Abdon	ninal exam:		
	Normal	Abdominal distension	
	Hepatomegaly	Mild ascites	
Februar	ardiogram Findings:		
General/2-D findings:			
Echocardiogram performed with patient standing			
		D6	
		<b>B6</b>	

Docoler findings:		
R6		
В		
Mittal inflow: B6		
ECG findings:		
	B6	
Radiographic findings:		
Ideally recommend obtaining		
Assessment and recommendations:		
	moderate secondary IAE, and EKG reveals atrial fibri	llation
with rapid ventricular response rate. Char	nges are consistent with CHF being the cause for effus	sions and
trouble breathing. The collapse episode o	ould be related to CHF or intermittent more severe arr B6	hythmia.
B6 . Recommend	B6	
	be hospitalized for monitoring with telemetry and titr	
	g baseline blood work, and ideally thoracic radiograph d). Recheck renal values, digoxin level 6-8 hours post	-
	o/fluid check in "3 months, or sooner if clinical sign o	
as increased RR/RE, cough, collapse, or ex	rercise intolerance.	
Addendum: Patient appears more comfor	rtable, but HR is still elevated. Recommend increasing	DC
ER to 150mg PO BID.		B6
Diet Tarto of the Wild High Prairie Shuffe	alo/lamb/chicken). Owners plan to change diet.	
Diet - Taske Of the Wild High France (bull)	noylamby chickery. Owners plan to change thet	
Treatment plan:		
	<b>B6</b>	
Final Diagnosis:		
DCM, CHF		
Atrial fibrillation with rapid ventricular res	sponse rate	
Heart Failure Classification Score:		
ISACHC Classification:	_	
□ la □ L	IIIIa ☑ IIIIb	
Ш Ib	IIIb	

П **ACVIM CHF Classification: 1** Α ■ D **B1 B2** M-Mode **IVSd** am LVIDd an LVPWd an **IVSs** cm. LVIDs an **LVPWs** an % %FS Ao Diam an LA Diam an LA/Ao **B6** Max LA an **EPSS** an M-Mode Normalized  $\{0.29 - 0.52\}$ IVSdN LVIDdN {1.35 - 1.73}!  $\{0.33 - 0.53\}$ LVPWdN  $\{0.43 - 0.71\}!$ **IVSsN** LVIDsN  $\{0.79 - 1.14\}!$ **LVPWsN**  $\{0.53 - 0.78\}$ !  $\{0.68 - 0.89\}!$ Ao Diam N LA Diam N  $\{0.64 - 0.90\}$ ! 2D SA LA an Ao Diam an SA LA / Ao Diam **IVSd** an LVIDd an LVPWd am EDV(Teich) ml IVS<sub>5</sub> **CM B6 LVIDs** an **LVPWs** am ESV(Teich) ml EF(Teich) % %FS % SV(Teich) ml TAM TAX an **LVAJ LAX** an **LVEDV A-L LAX** ml **LVEDV MOD LAX** ml

LVIS LAX
LVAS LAX
LVESV A-L LAX
LVESV MOD LAX
HR
EF A-L LAX
LVEF MOD LAX
SV A-L LAX
SV MOD LAX
CO A-L LAX
CO MOD LAX

# <u>Doppler</u>

MR Vmax MR maxPG MV E Vel AV Vmax AV maxPG TR Vmax TR maxPG Time HR **B**6

om ml BPM % ml ml Vmin

an

**B6** 

m/s mmHg m/s m/s mmHg m/s mmHg ms

# Cummings Veterinary Medical Center

Cardiology Liaison: 508-887-4696

<b>B6</b>
Patient ID B6 Canine B6 Years Old Male Great Dane Fawn

# **Cardiology Appointment Report**

Date: 4/12/2018
Attending Cardiologist:  John E. Rush DVM, MS, DACVIM (Cardiology), DACVECC
<b>B6</b>
Cardiology Resident:
B6
Cardiology Technician:
B6
Student: B6 V'19
<u>Presenting Complaint:</u> Recheck visit for fluid check and kidney values. Owners had no new concerns.
Concurrent Diseases: DCM, CHF, A fib
General Medical History:
Diagnosed with DCM and CHF and A fib 02/20/18 following episode of collapse and increased respiratory rate
Doing really well - overall good energy, just normal old big dog slowing down. Jumps up into back of truck no problem.
Owner noticed slight bulging out of left flank. Slight tremor in the head and neck occasionally seen when
he lays down but is still holding his head up. HR 130-140 when resting at home, RR 12-14 when resting at home.
The 130-140 which results at home, he 12-14 which results at home.
<u>Diet and Supplements</u> : Old food - taste of the wild high prairie - about 5 cups daily (down from 8)
Also getting boiled chicken with his pills  When he eats more food, he gets soft stool (O asked for B6 script)
Nutro Blueberry Crunchies - dog treats

## Cardiovascular History:

Prior CHF diagnosis? Yes

Prior arrhythmia? Yes- A fib Cough? Occasional single cough first thing in the morning, but no other cough Shortness of breath or difficulty breathing? No. Snuffly sounding breathing more pronounced when he has Syncope or collapse? Yes - hx of collapse in February. None since then Sudden onset lameness? No. Just normal old great dane stiffness Exercise intolerance? No. Owners limit length of walks, good energy. Prior heart murmur? Yes-II/VI left apical systolic Current Medications Pertinent to CV System: **B6** Cardiac Physical Examination: **B6** Muscle condition: Normal | Moderate cachexia Mildmuscleloss Marked carbexia Cardiovascular Physical Exam: Murmur Grade: None **□** IV/VI **□** I/VI **□** v/vi II/VI **■** ₩/ 🔲 III/VI Murmur location/description: Left apical to mid-cardiac systolic Jugular vein: Bottom 1/3 of neck Top 2/3rd of neck

Prior ATE? No.

Middle 1/3 of neck

Arter <u>ia</u> l pulses:	
Weak	<b>Bounding</b>
☐ Fair	<b>☑</b> Pulse deficits
<b>☑</b> Good	Pulsus paradoxus
Strong	Other:
Arrhythmia:	
<b>—</b>	Descharanto
<b>■ None</b>	Bradycardia
Sinus arrhythmia	☑ irregular - A fib
Premature beats	
Gallop:	_
<b>≥</b> Yes	Pronounced
□ No	Other:
■ Intermittent	
Dulmonone acroscoportes	
Pulmonary assessments:	□ p.
<b>☑</b> Eupneic	Pulmonary craddes
Mild dyspnea	Wheeses
Marked dyspnea	Upper airway stridor
Mormal BV sounds	
Abdominal exam:	
✓ Normal	Mildascites
☐ Hepatomegaly	Marked ascites
Abdominal distension	in marker acries
Accominal distension	
e II post Cor a M	
<u>Problems</u> : DCM, hx of CHF, A fib	
Diagnostic plan:	_
Echocardiogram	☐ Dialysis profile
Chemistry profile	☐ Thoracicradiographs
ECG	■ NT-proBNP
Renal profile	Troponin I
Blood pressure	Othertests: Fluid check
— висирнемие	
Echocardiogram Findings:	
General/2-D findings:	
E	36
L	!
ECG findings:	
	B6
Assessment and recommendations:	
Patient is doing very well at home after some t	weaking of medications. B6
B6	and GI signs and his ventricular response rate
:	
	submitted today. REcommend continuing current
	n blood work. Recheck fluid check/brief echo in 2-4
months, or sooner if clinical signs occur at hom	e such as increased RR/RE, cough, collapse, abdominal
	ECGs at home or more often if there are clinical concerns.
- 1	
Final Diagnosis:	

# DCM History of biventricular CHF Atrial fibrillation

SV(Teich)

#### **Heart Failure Classification Score:** ISACHC Classification: 🔲 Illa 🔲 la ■ lb IIIb 1 **ACVIM Classification: ∠** C ■ B1 **■ B2** M-Mode **IVSd** am LVIDd am LVPWd am IVS<sub>5</sub> am **LVIDs** am **LVPWs** am %FS % **B6** Max LA am M-Mode Normalized $\{0.29 - 0.52\}!$ **IVSdN** LVIDAN (1.35 - 1.73)! **LVPWdN** $\{0.33 - 0.53\}$ **IVSsN** $\{0.43 - 0.71\}$ LVIDsN (0.79 - 1.14)!LVPWsN $\{0.53 - 0.78\}$ **2**D SA LA cm. Ao Diam am SA LA / Ao Diam **IVSd** am LVIDd am LVPWd am **B6** EDV(Teich) ml IVSs $\mathbf{cm}$ **LVIDs** cm : **LVPWs** am ESV(Teich) ml EF(Teich) % %FS %

ml

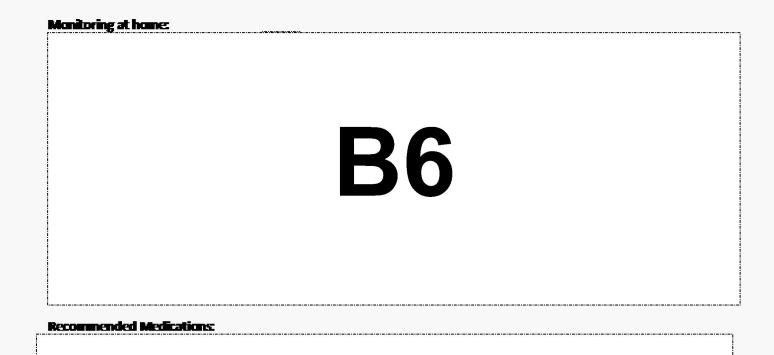


# Cummings Veterinary Medical Center

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

# Discharge Instructions

Patient Name: B6 Species: Canine Fawn Male Great Dane Birthdate: B6	Owner Name: B6 Address: B6	Patient E B6	
Attending Cardiologist:  John E. Rush DVM, MS, DACV  B6			
Cardioloev Resident:	B6		
Student: B6 V18 Cardioloev Technician: B6			
Admit Dates B6  Discharge Dates B6  Diagnoses: Dilated cardiomyopathy (	DOM) with congestive heart faik	lure; Atrial fibrillation	
Case summary: Thank you for brining B6 to Tufts for rhythm. B6 has been diagnosed with more common in large and giant bree pump function, and enlargement of the arrhythmias which can be life-threate which we believe caused his collapsing than convert that back to sinus rhythmeaning that fluid is backing up into the	r evaluation of his collapse epison haprimary heart muscle disease addogs and is characterized by the neupper chambers of the heart. ning and also require medical mage g events, and to help treat this a n. The heart enlargement has no he lungs or belly. Unfortunately ever we can use cardiac medical	ode, increased breathing effort, and irregular heart se called dilated cardiomyopathy (DOM). This diseas thirming of the walls of the heart, reduced cardiac t. Many dogs with DOM will also have significant nanagement. In B6 case, he has atrial fibrillation arrhythmia, wetry to reduce the heart rate rather low progressed to the point of congestive heart faily this is a progressive disease and we cannot reverse ations and some changes to the diet to make B6	e is n, ure
Diagnostic test results and findings:			
	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.ed	lu/heartsmart	/diet/)
---------------------	----------------------	---------------	---------

B6 usual diet may also have more sodium than recommended - we want him to continue to eat his normal diet for the first 7 to 14 days so we can make sure he is 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 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.

There have been some anecdotal reports of certain dog foods being associated with decreased contractile function in dogs. We would ideally want to avoid grain free diets or any diet that may have been associated with heart problems in dogs.

#### 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  $\begin{bmatrix} B6 \end{bmatrix}$  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 stremuous high energy activities (repetitive ball chasing, running fast off-leash, etc.) are generally not advised at this stage of heart failure.

	 	-
Rech		

NAME OF TAXABLE PARTY.
We would like Kenji to get bloodwork in 1-2 weeks to make sure he is tolerating his medications. We would like to check his
B6 levels and to assess his renal function. This blood sample needs to be taken 6-8 hours after his B6 is given.
We have scheduled you an appointment for Friday March 2nd at 3PM, but it B6 is doing well at home, you can get this
redheck done at your primary vet if more convenient. A recheck ECG is also recommended at that time.
We would like to see B6 back for a re-check echo in 3-4 months to re-assess his heart and the progression of his DOM.

Thank you for entrusting us with B6 scare. He is such a sweet and handsome boy! Please contact our Cardiology liaison, B6 or email us at cardiovet@fulls.edu for scheduling and non-emergent questions or concerns.

Please visit our HeartSmart website for more information http://vet.tufts.edu/heartsmart/

#### Prescription Refill Discloimer:

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 Triols:

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: <u>vet.tufts.edu/cvmc/dinical-studies</u>

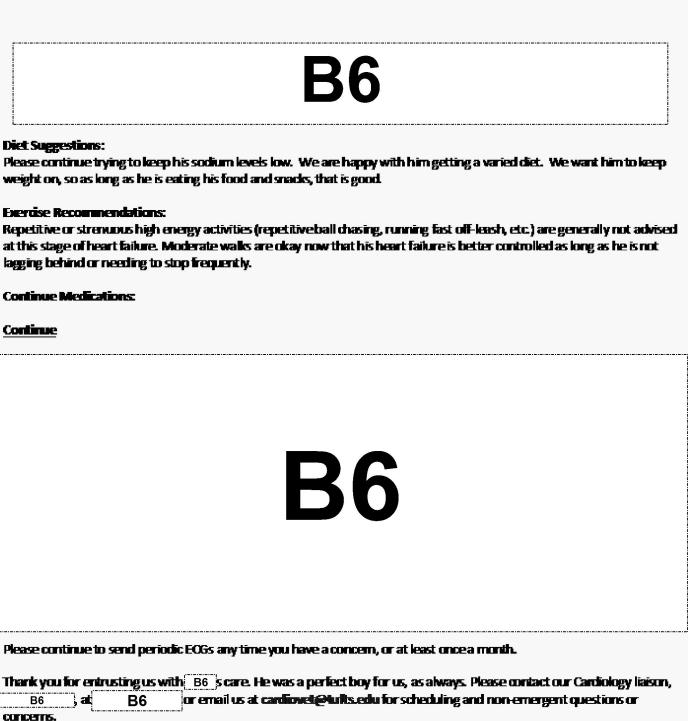
Case B6	Owner: B6	Discharge Instructions	

# Cummings Veterinary Medical Center

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

# Discharge Instructions

Name B6 Species: Canine Fawn Male Great Dane	Name: B6	
		Patient ID: B6
rawn male Great Dane	Address: B6	
<b>Birthdale:</b> B6		
Attending Cardiologist:  John E. Rush DVM, MS, DACVIM (Cardiology Resident:  B6  Student: B6 V*19  Cardiology Technician:	Cardiology), DACVECC	
B6		
Date: 4/12/2018	I	
Diagnoses: Dilated cardiomyopathy (DCM)  Clinical Findings: Thank you for bringi B6 o Tufts to red Today we did a brief ultrasound of his hear abdomen, and his hepatic vessels do not lo	heck how his heart is doing. He is such a s rt and abdomen today. He looks good - w	weet boy! sawno fluid around his heart or
		neight or tomormus when we get the
We also collected some blood today to che results back. We are so happy with how he		



Please visit our HeartSmart website for more information http://vet.tufts.edu/heartsmart/

#### Prescription Refill Discloimer:

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.

#### Orderino 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 Triols:

Clinical trials are studies in which our veterinary dactors 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/ovmc/dinical-studies

> Case **B6** Owner В6 Discharge Instructions

# Cummings Veterinary Medical Center

#### **Foster Hospital for Small Animals**

55 Willard Street North Grafton, MA 01536 (508) 839-5395

Client:	B6	
Veterinarian:	טט	
Patient ID:	В6	
Visit ID:	2477624	

Patient:	B6
Species:	Canine
Breed:	Great Dane
Sex:	Male
Age:	<b>B6</b> Years Old

### Lab Results Report

Chemistry 21 (Cobas)	1	6/5/2018 11:07:21 AM	Accession ID: B6	
Test	Resu	lts	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
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	В6		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)	i		0 - 0	
Slight hemolysis, Slight lipemia				







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

#### Radiology Request & Report

PERLECTIVE.	Owner		в В6
bane: B6	I	36	raucin.e.;
pecies: Canine	Address:	B6	Date of request: 2/20/2018
awn Male Great Dane	<u>i</u>		
<b>irthdate:</b> B6			
Attending Clinician: B6	VM (SAM Rotal	ting Intern)	Student:
	1		
Date of exam: 2/20/18			
Patient Location: Ward/C	age: ICU		Weight(lbs) 0.00
	_	•	
<b>☑</b> Inpatient	Se	edation BAG	
		OBAG	
Outpatient Time:			DD AV
Waiting		1/2 dose (	
Emergency			or/Butorphanol
		M Anesthesi	a to sedate/anesthetize
Examination Desired: CXR	(do standing in la	rge animal)	
	(B	-6	
Presenting Complaint and	<b>Clinical Question</b>	s you wish to	answer.
Emergency	_	-	
Pertinent History: collapse	episode, dx with	DCM, CHF, an	d A-fib
Findings			
		36	
		JU	

- Generalized cardiomegaly with mild to moderate left atrial enlargement. No clear evidence of

#### Radiologists

Condusions:

cardiogenic pulmonary edema on this limited exam.

Primary: B6 ), DVM
Reviewing: B6 DVM, DACVR

Dates

Reported: 2/20/18 Finalized: 2/21/18

# Cummings Veterinary Medical Center

Foster Hospital for Small Animals

55 Willard Street North Grafton, MA 01536 (508) 839-5395

Client:	DO
Veterinarian	<b>B</b> 6
Patient ID:	
Visit ID:	2477624

Patient:	B6	
Species:	Canine	
Breed:	Great Dane	
Sex:	Male	
Age:	<b>B6</b> Years Old	

## **Lab Results Report**

Taurine: Whole Blood Level	6/5/2018 11:06:00 AM	Accession ID: B6	
Test	Results	Reference Range	Units
TAURINE WB	B6	200 - 350	nmol/mL

1/1

From: To:	Freeman, Lisa <lisa.freeman@tufts.edu> Jones, Jennifer L</lisa.freeman@tufts.edu>
Sent: Subject:	8/22/2018 6:17:24 PM RE: B6
PS - <b>B6</b> died <b>B6</b>	
_isa M. Freeman, DVW Board Certified Veterin Professor	ary Nutritionist <sup>TM</sup>
	eterinary Medicine Itrition Science and Policy Islational Science Institute
From: Freeman, Lisa Sent: Wednesday, Aug To: Jones, Jennifer L < Subject:	gust 22, 2018 1:43 PM :Jennifer.Jones@fda.hhs.gov>
Hmm – that's strange. 'Il send those along Here's <b>B6</b> Lisa	
_isa M. Freeman, DVW Board Certified Veterin Professor Cummings School of V	ary Nutritionist <sup>TM</sup>
Friedman School of Nu	strition Science and Policy slational Science Institute
<b>Sent:</b> Wednesday, Aug	L < <u>Jennifer.Jones@fda.hhs.gov</u> > gust 22, 2018 12:54 PM a.freeman@tufts.edu>
Hi Lisa, don't have the report i rrack it down.	in our records from <b>B6</b> If she submitted one and has an ICSR number, we can
Also, I had our team ch to send those along wit	neck for reports for <b>B6</b> and <b>B6</b> but there weren't any. Are you also able th records?
	of your efforts gathing the records, getting permission for interviews with owners, and laints. You've been a great help to the investigation!!

Jennifer Jones, DVM Veterinary Medical Officer

Tel: 240-402-5421



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

HIJEN							
Actually,	В6	from <b>B</b>	6 submitted	B6	If you don't have	that one, let i	me know and l
can submit							
Owner would	be very hap	opy to talk t	o you				
Thanks							
Lisa							

Lisa M. Freeman, DVM, PhD, DACVN
Board Certified Veterinary Nutritionist<sup>TM</sup>
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 < <u>Jennifer.Jones@fda.hhs.gov</u>>

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

Lisa M. Freeman, DVM, PhD, DACVN
Board Certified Veterinary Nutritionist<sup>TM</sup>
Professor
Cummings School of Veterinary Medicine
Friedman School of Nutrition Science and Policy
Tufts Clinical and Translational Science Institute
Tufts University
<a href="https://www.petfoodology.org">www.petfoodology.org</a>

# Cummings Veterinary Medical Center

#### **Foster Hospital for Small Animals**

55 Willard Street North Grafton, MA 01536 (508) 839-5395

Client:	В6	
Veterinarian:	В6	
Patient ID:	В6	
Visit ID:	2477624	

Patient:	B6
Species:	Canine
Breed:	Great Dane
Sex:	Male
Age:	<b>B6</b> Years Old

## **Lab Results Report**

Taurine: Whole Blood Level	6/5/2018 11:06:00 AM	Accession ID: B6	
Test	Results	Reference Range	Units
TAURINE WB	B6	200 - 350	nmol/mL

stringsoft

1/1

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0A3B17EBFCF14A6CB8E94F322906BADD-

Rotstein, David </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

DROTSTEI>

To: Carey, Lauren; Ceric, Olgica; Glover, Mark; Jones, Jennifer L; Nemser, Sarah; Palmer, Lee

Anne; Peloquin, Sarah; Queen, Jackie L; Rotstein, David

**Sent:** 11/11/2018 1:15:58 PM

From:

Subject: DCM case-Tufts-- repeat submission EON-370776 and 370708

Attachments: Earthborn grain free weight management dry: Lisa Freeman - EON-370708; Earthborn Holistic

Weight Control (Grain Free) **B6** - EON-370776

Please note that these are for the same dog

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

**Sent:** 11/9/2018 10:08:47 PM

Subject: Earthborn grain free weight management dry: Lisa Freeman - EON-370708

Attachments: 2058678-report.pdf; 2058678-attachments.zip

A PFR Report has been received and PFR Event [EON-370708] has been created in the EON System.

A "PDF" report by name "2058678-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 "2058678-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

**EON Key:** EON-370708

ICSR #: 2058678

EON Title: PFR Event created for Earthborn grain free weight management dry; 2058678

AE Date	11/05/2018	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Stable
Breed	Doberman Pinscher		
Age	<b>B6</b> Years		
District Involved	PFR-New England DO		

#### **Product information**

**Individual Case Safety Report Number: 2058678** 

**Product Group:** Pet Food

**Product Name:** Earthborn grain free weight management dry

**Description:** Diagnosed with DCM, CHF, and atrial fibrillation 11/5/18. Currently hospitalized. Taurine submitted to UC Davis. Unclear if related to diet, given breed but eating boutique, grain-free diet. Only prior

history is traumatic injury in 2015.

**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
Earthborn grain free weight management 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-370708

To view the PFR Event Report, please click the link below:

 $\frac{https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jspa?decorator=none\&e=0\&issueType=12\&issueId=387677$ 

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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-	370708				
ICSR:	2058678				
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:	2018-11-09 16:57:32 EST				
Reported Problem:	Problem Description: Diagnosed with DCM, CHF, and atrial fibrillation 11/5/18. Currently hos Taurine submitted to UC Davis. Unclear if related to diet, given breed boutique, grain-free diet. Only prior history is traumatic injury in 2015.			diet, given breed but eating	
	Date Problem Started:	No n:			
	Concurrent Medical				
	Problem:				
	Outcome to Date:	Stable			
Product Information:	Product Name:	Earthborn grain free weight management dry			
	Product Type:	Pet Food	***************************************	***************************************	
	Lot Number:	7			TANA BANA BANA BANA BANA BANA BANA BANA
	Package Type:	BAG			
	Product Use Information:				
	Manufacturer				
	/Distributor Information:				
	Purchase Location Information:				
Animal Information:	Name:	B6			
	Type Of Species:	Ļ			
	7	Doberman Pinscher			
	Gender:	2 2		100000000000000000000000000000000000000	RAMAAA BAAA BAAAA BAAA BAAAA BAAAA BAAAA BAAAA BAAAA BAAAA BAAAA BAAAA BAAAA BAAAAA BAAAAA BAAAAAA
	Reproductive Status:	Neutered			***************************************
		45.2 Kilogram			
		<b>B6</b> Years		***************************************	ramanaanamaanaanaanaanaanaanaanaanaanaana
	Assessment of Prior	2			
	Health:	19 19 19 19 19 19			
	Number of Animals Given the Product:	1			
	Number of Animals Reacted:	1			
	Owner Information:	Owner Information provided:			
		Contact:	Name:	В6	
			Phone:	.ـــــــــــــــــــــــــــــــــــــ	
			Email:	B6	
		Address:	DA		
			<b>B6</b>		
		United States			
	Healthcare Professional Practice Name: Tufts Cummings		s School of Vet	erinary Medicine	
	Information:	Contact:	<u>,</u>	Lisa Freeman	
		Gomage:		(508) 887-4523	3
				lisa.freeman@t	
			⊏inali.	nsa.neeman@	tuito. GUU

		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:		5088874523 lisa.freeman@tufts.edu	
	Permission To Contact Sender:		<u> </u>	
	Preferred Method Of Contact:	Email		
Additional Documents:				
	Attachment:	compiled medical re	cord <b>B6</b> pdf	
		Medical records	C	
		Medical Records		

# Cummings Veterinary Medical Center AT TUFTS UNIVERSITY

#### **Foster Hospital for Small Animals**

55 Willard Street North Grafton, MA 01536 (508) 839-5395

	Medical Record for B6	
Client:	Patient: <b>B6</b>	
Address: <b>B6</b>	Breed: Doberman Pinscher	Species: Canine
	DOB: <b>B6</b>	Sex: Male
		(Neutered)
Home Phone: <b>B6</b>		
Work Phone: ( ) - Cell Phone:   <b>B6</b>		
Referring Information		
	B6	
		i
Client: B6		
1 duent.		
Initial Complaint:		

Emergency

#### SOAP Text Nov 5 2018 6:41PM - Clinician, Unassigned FHSA

#### **Subjective**

**NEW VISIT (ER)** 

**B6** Doctor: Student: **B6** V19 Presenting complaint: CHF Referral visit? yes

Diagnostics completed prior to visit: at rDVM 11/5

Bloodwork: **B6** 

Chest x-rays: Marked cardiomegaly, pulmonary edema

EKG: atrial fibrillation reported

HISTORY:

Signalment: 8 yo NM Doberman

#### Current history:

Patient presented as referral from rDVM for CHF and suspected DCM. Yesterday, owner noted that when playing fetch, patient yelped while running back and immediately went inside to lay down. Patient was lethargic remainder of evening, but went on 30 minute walk and was willing to eat dinner. Owners noticed he was intermittently breathing

heavier last night with a dry cough which owners mistook initially as him attempting to vomit. This morning, patient not willing to eat breakfast or go for walk. Maintains thirst.

Was evaluated by rDVM today, **B6**, for clinical signs. Radiographs showed cardiomegaly and an arrythmia was ausculted. ECG indicated atrial fibrillation. Patient was given 2 doses of furosemide (4mg/kg total) and referred here for cardiology workup.

Patient has no known history of heart disease, collapse, weakness, or respiratory changes. Patient diagnosed with idiopatic head shake 1 year ago.

Prior medical history: No known heart disease until today.

Current medications: Desaguin

Diet: earth borne grain free mixed with wellness diet wet food.

Vaccination status/flea & tick preventative use: HW and F&T preventatives.

Travel history: unknown

EXAM:

**B6** 

C/V: no murmur, Tachycardic, atrial fibrillation, poor femoral pulses

**B6** 

ASSESSMENT:

A1: CHF secondary to DCM

PLAN:

В6

Client: <b>B6</b>
Patient: [ BO ]
B6
Enroll in DCM diet study
<b>B6</b>
Diagnostics completed:
ECG on intake Atrial fibrilation
AFAST/TFAST no FF, enlargement of chambers, consistent with DCM NOVA no significant findings
PCV/TS- <b>B6</b>
· Landanianiani
Diagnostics pending:
BNP Taurine
Troponin
Client communication:
<b>B6</b>
Introduced o to Dr. Freemen, o intersted in being enrolled in DCM study.
Deposit & estimate status <b>R6</b>
Resuscitation code (if admitting to ICU) <b>B6</b>
SOAP approved (DVM to sign): B6 DVM
SOAP Text Nov 6 2018 7:16AM - Clinician, Unassigned FHSA
Subjective
History  B6 is an 8yo MN Dobie presented as referral yesterday for CHF and suspected DCM. Owner took to rDVM after a day
of lethargy, inappetance and possible coughing episode. Evaluated by rDVM 11/5 at that time radiographs showed
cardiomegaly and ECG indicated atrial fibrillation. Patient was given 2 doses o <b>B6</b> (4mg/kg total) and referred
here. Patient has no known history of heart disease, collapse, weakness, or respiratory changes. Patient diagnosed with
idiopatic head shake 1 year ago. Current diet: Earth borne grain-free mixed with wellness diet wet food. Medications include Dasequin, HW and F&T preventatives.
Overnight respiratory rate battucas 20.20 with parmal clight affort. Gives B6 W4.11.7-mg/kg dose) at
intake at 7 PM (ZAM dose d
B6 . EKG monitoring
Page 3/49

overnight showed persistent A-fib and tachycardia **B6** Had 2+ diarrhea overnight and vomited bile at 9 PM after quickly drinking water. Ate EN Proplan overnight. Interested in Dr. Freeman's study.

**B6** 

Heart: No murmurs/gallops ausculted, irregularly irregular rhythm ausculted, femoral pulses weak

**B6** 

Assessments [refined to the highest level; list Rule Outs if appropriate]

- A1: Enlarged heart- R/O- DCM (Dobie occult DCM vs. taurine-deficiency vs. BEG diet induced)
- A2: Atrial fibrillation- R/O- secondary to DCM
- A3. Wide complex QRS- R/O- atrial fibrillation w ashman's vs. VPC's vs. R on T
- A4. Mass on ventral neck- R/O- thyroid tumor (thymoma vs. carcinoma) vs. lipoma vs. soft tissue sarcoma
- A5. Neutrophila- R/O- stress leukogram
- A6. Elevated ALT/ALP- R/O: hepatic congestion vs. less likely primary liver disease (Doberman chronic hepatitis)

Plan **B6** 

Client:	D6
Patient:	DO

Subjective

**B6** 

SOAP completed by	. В6	V'19 اِ
SOAP reviewed by:		

SOAP Text Nov 7 2018 7:19AM - Clinician, Unassigned FHSA

**B6** 

Heart: Grade III/VI left apical systolic murmur, jugular pulses bottom 1/3 of neck, irregularly irregular heart beat,

femoral pulses variable,

Assessments [refined to the highest level; list Rule Outs if appropriate]

- A1: Enlarged heart- R/O- DCM (Dobie occult DCM vs. taurine-deficiency vs. BEG diet induced)
- A2: Atrial fibrillation- R/O- secondary to DCM
- A3. Grade III/VI- R/O- DMVD
- A4. Wide complex QRS- R/O- atrial fibrillation w ashman's vs. VPC's vs. R on T
- A5. Mass on ventral neck- R/O- thyroid tumor (thymoma vs. carcinoma) vs. lipoma vs. soft tissue sarcoma
- A6. Neutrophila- R/O- stress leukogram
- A7. Elevated ALT/ALP- R/O: hepatic congestion vs. less likely primary liver disease (Doberman chronic hepatitis)

rlan
<b>B6</b>
SOAP completed by: B6 V19 SOAP reviewed by:

**Disposition/Recommendations** 

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b	um	ШШ	IJi	)	
Ve	terina	ry Me	edica	al Ce	nter
	TUFTS	대신투 (이 원리원)			

#### Foster Hospital for Small Animals

55 Willard Street North Grafton, MA 01536 (508) 839-5395

Client:	В6
Veterinariar	1:
Patient ID:	В6
Visit ID:	

Patient:	B6
Species:	Canine
Breed:	Doberman Pinscher
Sex:	Male (Neutered)
Age:	B6 Years Old

## Lab Results Report

stringsoft

CBC, Comprehensive, Sm Animal	11/5/2018 8:12:13 PM	Accession ID: B6	
Test	Results	Reference Range	Units
MPV (ADVIA)		8.29 - 13.2	fl
RETICS (ABS) ADVIA		14.7 - 113.7	K/uL
HCT(ADVIA)		39 - 55	%
WBC (ADVIA)		4.4 - 15.1	K/uL
PLTCRT		0.129 - 0.403	%
PLT(ADVIA)		173 - 486	K/uL
MCV(ADVIA)	<b>B6</b>	64.5 - 77.5	fL
MCHC(ADVIA)	DU	31.9 - 34.3	g/dL
RDW (ADVIA)		11.9 - 15.2	
MCH(ADVIA)		21.3 - 25.9	pg
RETIC(ADVIA)		0.2 - 1.6	%
COMMENTS (HEMATOLOGY)		0 - 0	
HGB(ADVIA)		13.3 - 20.5	g/dL
RBC(ADVIA)		5.8 - 8.5	M/uL

Chemistry Profile - Small Animal (Pa	11/5/2018 8:12:13 PM	Accession ID B6	
Test	Results	Reference Range	Units
TRIGLYCERIDES	Do	30 - 338	mg/dl
CHOLESTEROL	B6	82 - 355	mg/dL
	iJ		_
<b>3</b>	8/49	B6 B6	j

Printed Friday, November 09, 2018

Client: <b>B6</b>				
SODIUM			140 - 150	mEq/L
CALCIUM2		Ġ	9.4 - 11.3	mg/dL
GLOBULINS			2.3 - 4.2	g/dL
POTASSIUM		1	3.7 - 5.4	mEq/L
I BILIRUBIN		(	0 - 0.2	mg/dL
ALK PHOS			12 - 127	U/L
PHOSPHORUS		,	2.6 - 7.2	mg/dL
T BILIRUBIN		(	0.1 - 0.3	mg/dL
MAGNESIUM 2+			1.8 - 3	mEq/L
ALBUMIN			2.8 - 4	g/dL
GLUCOSE		(	67 - 135	mg/dL
CK		2	22 - 422	U/L
CHLORIDE	В6		106 - 116	mEq/L
T. PROTEIN	DU		5.5 - 7.8	g/dL
GGT		(	0 - 10	U/L
ALT			14 - 86	U/L
tCO2 (BICARB)			14 - 28	mEq/L
AMYLASE		4	409 - 1250	U/L
D.BILIRUBIN		(	0 - 0.1	mg/dL
NA/K		2	29 - 40	
AGAP		8	8 - 19	
OSMOLALITY (CALCULATED)		2	291 - 315	mmol/L
AST		Ć	9 - 54	U/L
CREATININE		(	0.6 - 2	mg/dL
A/G RATIO		(	0.7 - 1.6	
UREA	<u>L</u>	1	8 - 30	mg/dL

Microscopic Exam of Blood Smean	• (A 11/5/2018 8:12:13 PM	Accession ID: B6	
Test	Results	Reference Range	Units
MONOS (ABS)ADVIA		0.1 - 1.5	K/uL
LYMPHS%		7 - 47	%
MONOS%	B6	1 - 15	%
SEGS%		43 - 86	%
LYMPHS (ABS)ADVIA		1 - 4.8	K/uL
WBC MORPHOLOGY	<b>Li</b>	0 - 0	
No Morphologic Abnormalities			
SEGS (AB)ADVIA	В6	2.8 - 11.5	K/ul
•	9/49	B6 B6	
stringsoft		Printed Friday, Nov.	vember 09-2018

Printed Friday, November 09, 2018

Client: **B6** Patient:

**B6** POIKILOCYTOSIS 0 - 0

Nova Full Panel-ICU	11/5/2018 8:12:13 PM	Accession ID: B6	
Test	Results	Reference Range	Units
nMG		0 - 0	mmol/L
CA (ionized)		1.17 - 1.38	mmol/L
BEecf		O - O	mmol/L
BEb		O - O	mmol/L
TCO2 (POC)		O - O	mmol/L
GLUCOSE (POC)		80 - 120	mg/dL
MG (POC)		0.1 - 0.4	mmol/L
HCT (POC)		38 - 48	%
CREAT (POC)		0.2 - 2.1	mg/dL
SO2%		94 - 100	%
K (POC)		3.6 - 4.8	mmol/L
FiO2		0 - 0	%
NOVA SAMPLE		0 - 0	
CA/MG	<b>B6</b>	0 - 0	mol/mol
BUN (POC)	טט	12 - 28	mg/dL
NA (POC)		140 - 154	mmol/L
LACTATE		0 - 2	mmol/L
GAP		0 - 0	mmol/L
nCA		0 - 0	mmol/L
CL(POC)		109 - 120	mmol/L
HB (POC)		12.6 - 16	g/dL
A		0 - 0	mmHg
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

None	11/5/2018 8:12:13	PM Accession ID: B6	
Test	Results	Reference Range U	nits
TS (FHSA)	D.C	0 - 0 g/o	dl
PCV **	В6	0 - 0 %	
	iJ		
<b>A</b>	10/49	B6 B6	
stringsoft		Printed Friday Novembe	- 00 201

Printed Friday, November 09, 2018

 Client: Patient:
 B6

 TS (FHSA)
 B6
 0 - 0
 g/dl

	11/5/2018 8:12:13 PM	Accession ID: B6	
Test	Results	Reference Range	Units
Troponin I (i-STAT) Cardiology - FHSA		0 - 0	ng/ml

Chemistry 21 (Cobas)	11/5/2	2018 8:12:13 PM	Acc	cession ID: B6	
Test	Results			Reference Range	Units
AST				9 - 54	U/I,
UREA				8 - 30	mg/dL
A/G RATIO				0.7 - 1.6	
CHOLESTEROL				82 - 355	mg/dL
NA/K				29 - 40	
T BILIRUBIN				0.1 - 0.3	mg/dL
D.BILIRUBIN				0 - 0.1	mg/dL
GLUCOSE				67 - 135	mg/dL
ALBUMIN				2.8 - 4	g/dL
CALCIUM2				9.4 - 11.3	mg/dL
T. PROTEIN	B6			5.5 - 7.8	g/dL
PHOSPHORUS				2.6 - 7.2	mg/dL
POTASSIUM				3.7 - 5.4	mEq/L
I BILIRUBIN				0 - 0.2	mg/dL
SODIUM				140 - 150	mEq/L
ALT				14 - 86	U/L
OSMOLALITY (CALCULATED)				291 - 315	mmol/L
ALK PHOS				12 - 127	U/L
CHLORIDE				106 - 116	mEq/L
GLOBULINS				2.3 - 4.2	g/dL
CREATININE				0.6 - 2	mg/dL

	1/5/2018 8:12:13 PM <b>Acc</b>	cession ID: B6	
Test Rest	lts	Reference Range	Units
TS (FHSA)		0 - 0	g/dl
PCV ** <b>B6</b>		0 - 0	%
TS (FHSA)		0 - 0	g/dl

,	Li		0	
٥	11/49	В6	В6	
<b>string</b> soft		Printed	Friday, November 09,	2018



IDEXX BNP - B6

IDEXX Reference Laboratories Clien B6 Patient B6

IDEXX VetConnect 1-888-433-9987

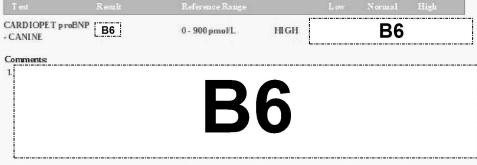
Client: B6 Patient! B6 Species CANINE Breed: DOBERMAN\_PINSCH Gender: MALE Ages 8Y

| Date: 11/06/2018 |
| Requisition #; JA |
| Accession # | B6 |
| Ordered by | B6 |

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

Account #88933

CARDIOPET proBNP - CANINE



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.

#### Vitals Results

Vitals Results	
11/5/2018 7:10:41 PM	Lasix treatment note
11/5/2018 7:15:25 PM	Heart Rate (/min)
11/5/2018 7:15:26 PM	Respiratory Rate
11/5/2018 7:15:27 PM	Temperature (F)
11/5/2018 7:15:28 PM	Weight (kg)
11/5/2018 8:50:18 PM	Amount eaten
11/5/2018 8:59:52 PM	Respiratory Rate
11/5/2018 9:00:02 PM	Cardiac rhythm
11/5/2018 9:00:03 PM	Heart Rate (/min)
11/5/2018 9:00:07 PM	Nursing note
11/5/2018 9:04:11 PM	Respiratory Rate
11/5/2018 9:41:42 PM	Respiratory Rate
11/5/2018 9:42:35 PM	Cardiac rhythm
11/5/2018 9:42:36 PM	Heart Rate (/min)
11/5/2018 11:05:47 PM	Cardiac rhythm
11/5/2018 11:05:48 PM	Heart Rate (/min)
11/5/2018 11:05:58 PM	Respiratory Rate
11/5/2018 11:27:54 PM	Eliminations
11/5/2018 11:28:35 PM	Eliminations
11/5/2018 11:28:49 PM	Catheter Assessment
11/6/2018 12:16:11 AM	Heart Rate (/min)
11/6/2018 12:16:12 AM	Cardiac rhythm
11/6/2018 12:16:24 AM	Respiratory Rate
11/6/2018 12:25:01 AM	Nursing note
11/6/2018 1:03:51 AM	Cardiae rhythm
11/6/2018 1:03:52 AM	Heart Rate (/min)
11/6/2018 1:04:30 AM	Respiratory Rate
11/6/2018 1:57:40 AM	Respiratory Rate
11/6/2018 1:58:50 AM	Cardiae rhythm
11/6/2018 1:58:51 AM	Heart Rate (/min)
11/6/2018 1:59:44 AM	Nursing note
11/6/2018 3:04:07 AM	Cardiac rhythm
11/6/2018 3:04:08 AM	Heart Rate (/min)
11/6/2018 3:06:27 AM	Respiratory Rate
11/6/2018 3:32:24 AM	Catheter Assessment
11/6/2018 3:34:43 AM	Amount eaten
11/6/2018 4:06:30 AM	Cardiac rhythm
11/6/2018 4:06:31 AM	Heart Rate (/min)
11/6/2018 4:06:49 AM	Respiratory Rate
11/6/2018 5:00:14 AM	Eliminations

Client: **B6** 

Vitals Results		
11/6/2018 5:24:57 AM	Cardiac rhythm	
11/6/2018 5:24:58 AM	Heart Rate (/min)	
11/6/2018 5:25:15 AM	Respiratory Rate	
11/6/2018 5:46:22 AM	Respiratory Rate	
11/6/2018 5:46:49 AM	Cardiac rhythm	
11/6/2018 5:46:50 AM	Heart Rate (/min)	
11/6/2018 6:31:20 AM	Cardiac rhythm	
11/6/2018 6:31:21 AM	Heart Rate (/min)	
11/6/2018 6:31:40 AM	Respiratory Rate	
11/6/2018 7:12:38 AM	Respiratory Rate	
11/6/2018 7:12:54 AM	Temperature (F)	
11/6/2018 7:13:08 AM	Cardiac rhythm	
11/6/2018 7:13:09 AM	Heart Rate (/min)	
11/6/2018 7:13:51 AM	Weight (kg)	
11/6/2018 7:13:59 AM	Catheter Assessment	
11/6/2018 7:16:21 AM	Body Condition Score (BCS)	
11/6/2018 7:16:22 AM	Muscle Condition Score (MCS)	
11/6/2018 7:16:23 AM	Pain assessment	
11/6/2018 9:19:06 AM	Respiratory Rate	
11/6/2018 9:36:24 AM	Cardiac rhythm	
11/6/2018 9:36:25 AM	Heart Rate (/min)	<b>B6</b>
11/6/2018 9:58:09 AM	Cardiac rhythm	
11/6/2018 9:58:10 AM	Heart Rate (/min)	
11/6/2018 10:06:41 AM	Lasix treatment note	
11/6/2018 10:07:04 AM	Catheter Assessment	
11/6/2018 10:15:59 AM	Eliminations	
11/6/2018 10:16:39 AM	Respiratory Rate	
11/6/2018 11:31:33 AM	Cardiac rhythm	
11/6/2018 11:31:34 AM	Heart Rate (/min)	
11/6/2018 11:33:55 AM	Respiratory Rate	
11/6/2018 11:37:52 AM	Eliminations	
11/6/2018 12:02:52 PM	Cardiac rhythm	
11/6/2018 12:02:53 PM	Heart Rate (/min)	
11/6/2018 12:03:56 PM	Respiratory Rate	
11/6/2018 1:11:16 PM	Respiratory Rate	
11/6/2018 1:13:44 PM	Cardiac rhythm	
11/6/2018 1:13:45 PM	Heart Rate (/min)	
11/6/2018 1:16:08 PM	Eliminations	
11/6/2018 1:38:13 PM	Respiratory Rate	
11/6/2018 1:51:30 PM	Cardiac rhythm	
11/6/2018 1:51:31 PM	Heart Rate (/min)	

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Client:
Patient:

**B6** 

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М	, 114		1100	ullo

Vitals Results	
11/6/2018 3:03:10 PM	Respiratory Rate
11/6/2018 3:10:58 PM	Cardiac rhythm
11/6/2018 3:10:59 PM	Heart Rate (/min)
11/6/2018 3:36:48 PM	Lasix treatment note
11/6/2018 3:37:03 PM	Catheter Assessment
11/6/2018 4:33:09 PM	Respiratory Rate
11/6/2018 4:33:31 PM	Cardiac rhythm
11/6/2018 4:33:32 PM	Heart Rate (/min)
11/6/2018 5:08:41 PM	Cardiac rhythm
11/6/2018 5:08:42 PM	Heart Rate (/min)
11/6/2018 5:18:43 PM	Respiratory Rate
11/6/2018 6:31:11 PM	Amount eaten
11/6/2018 6:31:46 PM	Cardiac rhythm
11/6/2018 6:31:47 PM	Heart Rate (/min)
11/6/2018 6:31:55 PM	Respiratory Rate
11/6/2018 6:32:03 PM	Eliminations
11/6/2018 9:01:47 PM	Respiratory Rate
11/6/2018 9:02:04 PM	Heart Rate (/min)
11/6/2018 9:02:15 PM	Cardiac rhythm
11/6/2018 9:32:43 PM	Catheter Assessment
11/6/2018 9:32:57 PM	Respiratory Rate
11/6/2018 9:33:11 PM	Cardiac rhythm
11/6/2018 9:33:12 PM	Heart Rate (/min)
11/6/2018 9:45:07 PM	Eliminations
11/6/2018 11:17:03 PM	Respiratory Rate
11/6/2018 11:18:05 PM	Cardiac rhythm
11/6/2018 11:18:06 PM	Heart Rate (/min)
11/6/2018 11:58:17 PM	Cardiac rhythm
11/6/2018 11:58:18 PM	Heart Rate (/min)
11/6/2018 11:59:06 PM	Respiratory Rate
11/7/2018 12:45:06 AM	Respiratory Rate
11/7/2018 12:45:29 AM	Cardiac rhythm
11/7/2018 12:45:30 AM	Heart Rate (/min)
11/7/2018 1:53:36 AM	Eliminations
11/7/2018 1:53:49 AM	Respiratory Rate
11/7/2018 1:54:14 AM	Cardiac rhythm
11/7/2018 1:54:15 AM	Heart Rate (/min)
11/7/2018 2:49:27 AM	Cardiac rhythm
11/7/2018 2:49:28 AM	Heart Rate (/min)
11/7/2018 2:50:03 AM	Respiratory Rate
11/7/2018 3:26:42 AM	Catheter Assessment

**B6** 

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Client: **B6** 

Vitals Results		
11/7/2018 4:00:38 AM	Cardiac rhythm	
11/7/2018 4:00:39 AM	Heart Rate (/min)	
11/7/2018 4:01:06 AM	Respiratory Rate	
11/7/2018 5:12:19 AM	Cardiac rhythm	
11/7/2018 5:12:20 AM	Heart Rate (/min)	
11/7/2018 5:12:33 AM	Respiratory Rate	
11/7/2018 5:19:34 AM	Nursing note	
11/7/2018 5:21:05 AM	Amount eaten	
11/7/2018 5:34:53 AM	Weight (kg)	
11/7/2018 5:35:01 AM	Eliminations	
11/7/2018 5:54:55 AM	Respiratory Rate	
11/7/2018 5:55:09 AM	Cardiac rhythm	
11/7/2018 5:55:10 AM	Heart Rate (/min)	
11/7/2018 6:27:18 AM	Cardiac rhythm	
11/7/2018 6:27:19 AM	Heart Rate (/min)	
11/7/2018 6:27:52 AM	Respiratory Rate	
11/7/2018 7:18:19 AM	Respiratory Rate	
11/7/2018 7:18:32 AM	Heart Rate (/min)	
11/7/2018 7:18:33 AM	Cardiac rhythm	
11/7/2018 7:19:29 AM	Temperature (F)	DC
11/7/2018 7:19:30 AM	Body Condition Score (BCS)	<b>B6</b>
11/7/2018 7:19:31 AM	Muscle Condition Score (MCS)	
11/7/2018 7:19:32 AM	Pain assessment	
11/7/2018 7:42:35 AM	Lasix treatment note	
11/7/2018 8:47:36 AM	Cardiac rhythm	
11/7/2018 8:47:37 AM	Heart Rate (/min)	
11/7/2018 8:47:47 AM	Respiratory Rate	
11/7/2018 8:50:11 AM	Catheter Assessment	
11/7/2018 9:09:21 AM	Respiratory Rate	
11/7/2018 11:08:26 AM	Cardiac rhythm	
11/7/2018 11:08:27 AM	Heart Rate (/min)	
11/7/2018 11:20:51 AM	Respiratory Rate	
11/7/2018 11:21:02 AM	Eliminations	
11/7/2018 12:06:15 PM	Cardiac rhythm	
11/7/2018 12:06:16 PM	Heart Rate (/min)	
11/7/2018 12:06:28 PM	Respiratory Rate	
11/7/2018 12:39:17 PM	Nursing note	
11/7/2018 1:03:57 PM	Cardiac rhythm	
11/7/2018 1:03:58 PM	Heart Rate (/min)	
11/7/2018 1:04:22 PM	Respiratory Rate	
11/7/2018 1:20:21 PM	Cardiac rhythm	

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Client:	D6
Patient:	DO

Vitals Results			
11/7/2018 1:20:22 PM	Heart Rate (/min)		
11/7/2018 1:20:59 PM	Respiratory Rate		
11/7/2018 1:21:06 PM	Eliminations		
11/7/2018 3:15:43 PM	Cardiac rhythm		
11/7/2018 3:15:44 PM	Heart Rate (/min)		
11/7/2018 3:16:26 PM	Respiratory Rate	Rh	
11/7/2018 3:48:16 PM	Respiratory Rate	L L U	
11/7/2018 3:48:26 PM	Cardiac rhythm		
11/7/2018 3:48:27 PM	Heart Rate (/min)		
11/7/2018 3:48:41 PM	Catheter Assessment		
11/7/2018 5:47:11 PM	Nursing note		

В6

11/6/2018 11:06:07 AM

Tufts University Tufts Cummings School of Vet Med Cardiology



B6

11/6/2018 11:06:48 AM

Page 1 of 2

Tufts University Tufts Cummings School of Vet Med Cardiology

B6

11/6/2018 11:06:48 AM

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Tufts University
Tufts Cummings School of Vet Med
Cardiology

В6

11/6/2018 11:07:04 AM

Tufts University Tufts Cummings School of Vet Med Cardiology

В6

11/6/2018 11:07:15 AM
Tufts University
Tufts Cummings School of Vet Med
Cardiology

### **Patient History**

·		
11/05/2018 07:05 PM	Prescription	
11/05/2018 07:07 PM	Prescription	
11/05/2018 07:10 PM	Vitals	
11/05/2018 07:15 PM	Vitals	
11/05/2018 07:23 PM	Purchase	
11/05/2018 07:23 PM	Purchase	
11/05/2018 07:23 PM	Purchase	
11/05/2018 08:12 PM	Purchase	
11/05/2018 08:12 PM	Purchase	
11/05/2018 08:13 PM	Purchase	
11/05/2018 08:36 PM	Labwork	
11/05/2018 08:38 PM	Treatment	
11/05/2018 08:50 PM	Treatment	
11/05/2018 08:50 PM	Treatment	
44/07/2040 00 70 70 7		
11/05/2018 08:50 PM	Treatment	
11/05/2018 08:50 PM	Vitals	
11/05/2018 08:59 PM	Treatment	
11/05/2018 08:59 PM	Vitals	Rh
11/05/2018 09:00 PM	Treatment	<b>B6</b>
11/05/2018 09:00 PM	Vitals	
11/05/2018 09:00 PM	Vitals	
11/05/2018 09:00 PM	Vitals	
11/05/2018 09:04 PM	Treatment	
11/05/2018 09:04 PM	Vitals	
11/05/2018 09:19 PM	Purchase	
11/05/2018 09:41 PM	Treatment	
11/05/2018 09:41 PM	Vitals	
11/05/2018 09:42 PM	Treatment	
11/05/2018 09:42 PM	Vitals	
11/05/2018 09:42 PM	Vitals	
11/05/2018 09:42 PM	Vitals	
11/05/2018 11:05 PM	Treatment	
11/05/2010 11:05 1 101	Houdiffellt	
11/05/2018 11:05 PM	Vitals	
11/05/2018 11:05 PM	Vitals	
11/05/2018 11:05 PM	Treatment	
11/05/2018 11:05 PM	Vitals	
11/05/2018 11:27 PM	Vitals	
11/05/2018 11:28 PM	Treatment	
11/05/2018 11:28 PM	Treatment	
		<u> </u>

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Client:	D6
Patient:	ВО

Patient History		
11/05/2018 11:28 PM	Vitals	
11/05/2018 11:28 PM	Treatment	
11/05/2018 11:28 PM	Vitals	
11/06/2018 12:16 AM	Treatment	
11/06/2018 12:16 AM	Vitals	
11/06/2018 12:16 AM	Vitals	
11/06/2018 12:16 AM	Treatment	
11/06/2018 12:16 AM	Vitals	
11/06/2018 12:25 AM	Vitals	
11/06/2018 01:03 AM	Treatment	
11/06/2018 01:03 AM	Vitals	
11/06/2018 01:03 AM	Vitals	
11/06/2018 01:04 AM	Treatment	
11/06/2018 01:04 AM	Vitals	
11/06/2018 01:57 AM	Treatment	
11/06/2018 01:57 AM	Vitals	
11/06/2018 01:58 AM	Treatment	
11/06/2018 01:58 AM	Vitals	
11/06/2018 01:58 AM	Vitals	
11/06/2018 01:59 AM	Vitals	
11/06/2018 03:04 AM	Treatment	<b>B6</b>
11/06/2018 03:04 AM	Vitals	
11/06/2018 03:04 AM	Vitals	
11/06/2018 03:06 AM	Treatment	
11/06/2018 03:06 AM	Vitals	
11/06/2018 03:31 AM	Treatment	
11/06/2018 03:32 AM	Treatment	
11/06/2018 03:32 AM	Vitals	
11/06/2018 03:34 AM	Treatment	
11/06/2018 03:34 AM	Vitals	
11/06/2018 03:34 AM	Vitals	
11/06/2018 04:06 AM	Treatment	
11/06/2018 04:06 AM	Vitals	
11/06/2018 04:06 AM	Vitals	
11/06/2018 04:06 AM	Treatment	
11/06/2018 04:06 AM	Vitals	
11/06/2018 05:00 AM	Treatment	
11/06/2018 05:00 AM	Vitals	
11/06/2018 05:24 AM	Treatment	
11/06/2018 05:24 AM	Vitals	
11/06/2018 05:24 AM	Vitals	
11/06/2018 05:25 AM	Treatment	
11/06/2018 05:25 AM	Vitals	

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Client:	DC
Patient:	DU

Patient History		
11/06/2018 05:46 AM	Treatment	
11/06/2018 05:46 AM	Vitals	
11/06/2018 05:46 AM	Treatment	
11/06/2018 05:46 AM	Vitals	
11/06/2018 05:46 AM	Vitals	
11/06/2018 06:31 AM	Treatment	
11/06/2018 06:31 AM	Vitals	
11/06/2018 06:31 AM	Vitals	
11/06/2018 06:31 AM	Treatment	
11/06/2018 06:31 AM	Vitals	
11/06/2018 07:12 AM	Treatment	
11/06/2018 07:12 AM	Vitals	
11/06/2018 07:12 AM	Treatment	
11/06/2018 07:12 AM	Vitals	
11/06/2018 07:13 AM	Treatment	
11/06/2018 07:13 AM	Treatment	
11/06/2018 07:13 AM	Vitals	
11/06/2018 07:13 AM	Vitals	
11/06/2018 07:13 AM	Treatment	
11/06/2018 07:13 AM	Treatment	<b>B6</b>
11/06/2018 07:13 AM	Vitals	
11/06/2018 07:13 AM	Treatment	
11/06/2018 07:13 AM	Vitals	
11/06/2018 07:14 AM	Treatment	
11/06/2018 07:16 AM	Vitals	
11/06/2018 07:16 AM	Vitals	
11/06/2018 07:16 AM	Vitals	
11/06/2018 08:10 AM	Purchase	
11/06/2018 08:38 AM	Purchase	
11/06/2018 08:44 AM	Purchase	
11/06/2018 08:44 AM	Purchase	
11/06/2018 09:19 AM	Treatment	
11/06/2018 09:19 AM	Vitals	
11/06/2018 09:33 AM	Deleted Reason	
11/06/2018 09:36 AM	Treatment	
11/06/2018 09:36 AM	Vitals	
11/06/2018 09:36 AM	Vitals	
11/06/2018 09:44 AM	Purchase	
11/06/2018 09:44 AM	Purchase	
11/06/2018 09:44 AM	Purchase	
11/06/2018 09:57 AM	Treatment	

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Client: **B6** 

P	atient	History

Patient History		
11/06/2018 09:58 AM	Treatment	
11/06/2018 09:58 AM	Vitals	
11/06/2018 09:58 AM	Vitals	
11/06/2018 10:06 AM	Vitals	
11/06/2018 10:07 AM	Treatment	
11/06/2018 10:07 AM	Treatment	
11/06/2018 10:07 AM	Vitals	
11/06/2018 10:15 AM	Treatment	
11/06/2018 10:15 AM	Vitals	
11/06/2018 10:16 AM	Treatment	
11/06/2018 10:16 AM	Vitals	
11/06/2018 10:19 AM	Purchase	
11/06/2018 10:43 AM	Prescription	
11/06/2018 11:03 AM	Purchase	
11/06/2018 11:25 AM	Purchase	
11/06/2018 11:31 AM	Treatment	
11/06/2018 11:31 AM	Vitals	<b>B6</b>
11/06/2018 11:31 AM	Vitals	
11/06/2018 11:33 AM	Treatment	
11/06/2018 11:33 AM	Vitals	
11/06/2018 11:37 AM	Treatment	
11/06/2018 11:37 AM	Vitals	
11/06/2018 12:02 PM	Treatment	
11/06/2018 12:02 PM	Vitals	
11/06/2018 12:02 PM	Vitals	
11/06/2018 12:03 PM	Treatment	
11/06/2018 12:03 PM	Vitals	
11/06/2018 12:55 PM	UserForm	
11/06/2018 12:57 PM	UserForm	
11/06/2018 12:58 PM	Treatment	
11/06/2018 01:10 PM	Treatment	
11/06/2018 01:11 PM	Treatment	
11/06/2018 01:11 PM	Vitals	
11/06/2018 01:13 PM	Treatment	
11/06/2018 01:13 PM	Vitals	
11/06/2018 01:13 PM	Vitals	
11/06/2018 01:16 PM	Treatment	
11/06/2018 01:16 PM	Vitals	

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	i
Client:	D6
Patient:	DU

P	atient	History

Patient History		
11/06/2018 01:30 PM	Treatment	
11/06/2018 01:30 PM	Treatment	
11/06/2018 01:38 PM	Treatment	
11/06/2018 01:38 PM	Vitals	
11/06/2018 01:43 PM	UserForm	
11/06/2018 01:51 PM	Treatment	
11/06/2018 01:51 PM	Vitals	
11/06/2018 01:51 PM	Vitals	
11/06/2018 03:03 PM	Treatment	
11/06/2018 03:03 PM	Vitals	
11/06/2018 03:10 PM	Treatment	
11/06/2018 03:10 PM	Vitals	
11/06/2018 03:10 PM	Vitals	
11/06/2018 03:36 PM	Vitals	
11/06/2018 03:37 PM	Treatment	
11/06/2018 03:37 PM	Treatment	
11/06/2018 03:37 PM	Vitals	
11/06/2018 04:33 PM	Treatment	
11/06/2018 04:33 PM	Vitals	
11/06/2018 04:33 PM	Treatment	
11/06/2018 04:33 PM	Vitals	<b>B6</b>
11/06/2018 04:33 PM	Vitals	LJU
11/06/2018 05:08 PM	Treatment	
11/06/2018 05:08 PM	Vitals	
11/06/2018 05:08 PM	Vitals	
11/06/2018 05:18 PM	Treatment	
11/06/2018 05:18 PM	Vitals	
11/06/2018 06:29 PM	Prescription	
11/06/2018 06:31 PM	Treatment	
11/06/2018 06:31 PM	Treatment	
11/06/2018 06:31 PM	Treatment	
11/06/2018 06:31 PM	Vitals	
11/06/2018 06:31 PM	Treatment	
11/06/2018 06:31 PM	Treatment	
11/06/2018 06:31 PM	Vitals	
11/06/2018 06:31 PM	Vitals	
11/06/2018 06:31 PM	Treatment	
11/06/2018 06:31 PM	Vitals	
11/06/2018 06:32 PM	Treatment	
11/06/2018 06:32 PM	Vitals	
11/06/2018 09:01 PM	Treatment	
	Page 27/49 [	
	1 age 27719	

FDA-CVM-FOIA-2019-1704-005831

### **Patient History**

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11/06/2018 09:01 PM	Treatment	
11/06/2018 09:01 PM	Vitals	
11/06/2018 09:02 PM	Vitals	
11/06/2018 09:02 PM	Vitals	
11/06/2018 09:32 PM	Treatment	
11/06/2018 09:32 PM	Treatment	
11/06/2018 09:32 PM	Treatment	
11/06/2018 09:32 PM	Vitals	
11/06/2018 09:32 PM	Treatment	
11/06/2018 09:32 PM	Vitals	
11/06/2018 09:33 PM	Treatment	
11/06/2018 09:33 PM	Vitals	
11/06/2018 09:33 PM	Vitals	
11/06/2018 09:44 PM	Treatment	
11/06/2018 09:45 PM	Treatment	
11/06/2018 09:45 PM	Vitals	
11/06/2018 11:17 PM	Treatment	
11/06/2018 11:17 PM	Vitals	
11/06/2018 11:18 PM	Treatment	
11/06/2018 11:18 PM	Vitals	<b>B6</b>
11/06/2018 11:18 PM	Vitals	
11/06/2018 11:58 PM	Treatment	
11/06/2018 11:58 PM	Vitals	
11/06/2018 11:58 PM	Vitals	
11/06/2018 11:59 PM	Treatment	
11/06/2018 11:59 PM	Vitals	
11/07/2018 12:45 AM	Treatment	
11/07/2018 12:45 AM	Vitals	
11/07/2018 12:45 AM	Treatment	
11/07/2018 12:45 AM	Vitals	
11/07/2018 12:45 AM	Vitals	
11/07/2018 01:11 AM	Treatment	
11/07/2018 01:53 AM	Treatment	
11/07/2018 01:53 AM	Vitals	
11/07/2018 01:53 AM	Treatment	
11/07/2018 01:53 AM	Vitals	
11/07/2018 01:54 AM	Treatment	
11/07/2018 01:54 AM	Vitals	
11/07/2018 01:54 AM	Vitals	
11/07/2018 02:49 AM	Treatment	
11/07/2018 02:49 AM	Vitals	

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	;;	
Client:	R6	t
Patient:	DO	

P	atient	His	tory
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Patient History		
11/07/2018 02:49 AM	Vitals	
11/07/2018 02:50 AM	Treatment	
11/07/2018 02:50 AM	Vitals	
11/07/2018 03:26 AM	Treatment	
11/07/2018 03:26 AM	Vitals	
11/07/2018 04:00 AM	Treatment	
11/07/2018 04:00 AM	Vitals	
11/07/2018 04:00 AM	Vitals	
11/07/2018 04:01 AM	Treatment	
11/07/2018 04:01 AM	Vitals	
11/07/2018 05:12 AM	Treatment	
11/07/2018 05:12 AM	Vitals	
11/07/2018 05:12 AM	Vitals	
11/07/2018 05:12 AM	Treatment	
11/07/2018 05:12 AM	Vitals	
11/07/2018 05:12 AM	Treatment	
11/07/2018 05:19 AM	Treatment	
11/0//2010 05.15 11/1	Tradition	
11/07/2018 05:19 AM	Vitals	
11/07/2018 05:20 AM	Treatment	
11/07/2018 05:21 AM	Treatment	<b>B6</b>
11/07/2018 05:21 AM	Vitals	Bn
11/07/2018 05:34 AM	Treatment	
11/07/2018 05:34 AM	Vitals	
11/07/2018 05:35 AM	Treatment	
11/07/2018 05:35 AM	Vitals	
11/07/2018 05:54 AM	Treatment	
11/07/2018 05:54 AM	Vitals	
11/07/2018 05:55 AM	Treatment	
11/07/2018 05:55 AM	Vitals	
11/07/2018 05:55 AM	Vitals	
11/07/2018 06:27 AM	Treatment	
11/0//2010 00.2/ 11/1	Troumon	
11/07/2018 06:27 AM	Vitals	
11/07/2018 06:27 AM	Vitals	
11/07/2018 06:27 AM	Treatment	
11/07/2018 06:27 AM	Vitals	
11/07/2018 06:59 AM	Purchase	
11/07/2018 07:18 AM	Treatment	
11/07/2018 07:18 AM	Vitals	
11/07/2018 07:18 AM	Treatment	
11/07/2018 07:18 AM	Vitals	
11/07/2018 07:18 AM	Vitals	
11/07/2018 07:19 AM	Vitals	
11.07,2010 07.19 1111	Teals	

Page 29/49

Client:	D6
Patient:	DU

	P	atient	History
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1 attent History		
11/07/2018 07:19 AM	Vitals	
11/07/2018 07:19 AM	Vitals	
11/07/2018 07:19 AM	Vitals	
11/07/2018 07:42 AM	Vitals	
11/07/2018 07:42 AM	Treatment	
11/07/2018 08:47 AM	Treatment	
11/07/2018 08:47 AM	Vitals	
11/07/2018 08:47 AM	Vitals	
11/07/2018 08:47 AM	Treatment	
11/07/2018 08:47 AM	Vitals	
11/07/2018 08:48 AM	Treatment	
11/07/2018 08:50 AM	Treatment	
11/07/2018 08:50 AM	Vitals	
11/07/2018 08:56 AM	Treatment	
11/07/0010 00 00 13 5	T	
11/07/2018 09:09 AM	Treatment	
11/07/2018 09:09 AM	Vitals	
11/07/2018 11:08 AM	Treatment	
11/07/2018 11:08 AM	Vitals	
11/07/2018 11:08 AM	Vitals	
11/07/2018 11:20 AM	Treatment	
11/07/2018 11:20 AM	Vitals	
11/07/2018 11:21 AM	Treatment	<b>B6</b>
11/07/2018 11:21 AM	Vitals	
11/07/2018 12:06 PM	Treatment	
11/07/2018 12:06 PM	Vitals	
11/07/2018 12:06 PM	Vitals	
11/07/2018 12:06 PM	Treatment	
11/07/2018 12:06 PM	Vitals	
11/07/2018 12:39 PM	Vitals	
11/07/2018 01:03 PM	Treatment	
11/07/2018 01:03 PM	Vitals	
11/07/2018 01:03 PM	Vitals Vitals	
11/07/2018 01:04 PM	Treatment	
11/07/2018 01:04 PM	Vitals	
11/07/2018 01:04 PM	Treatment	
11/07/2018 01:20 PM	Treatment	
11/07/2018 01:20 PM	Vitals	
11/07/2018 01:20 PM	Vitals	
11/07/2018 01:20 PM	Treatment	
11/07/2018 01:20 PM	Vitals	
11/07/2018 01:21 PM	Treatment	
11/07/2018 01:21 PM	Vitals	
11/07/2018 02:53 PM	Purchase	
11/07/2018 03:15 PM	Treatment	

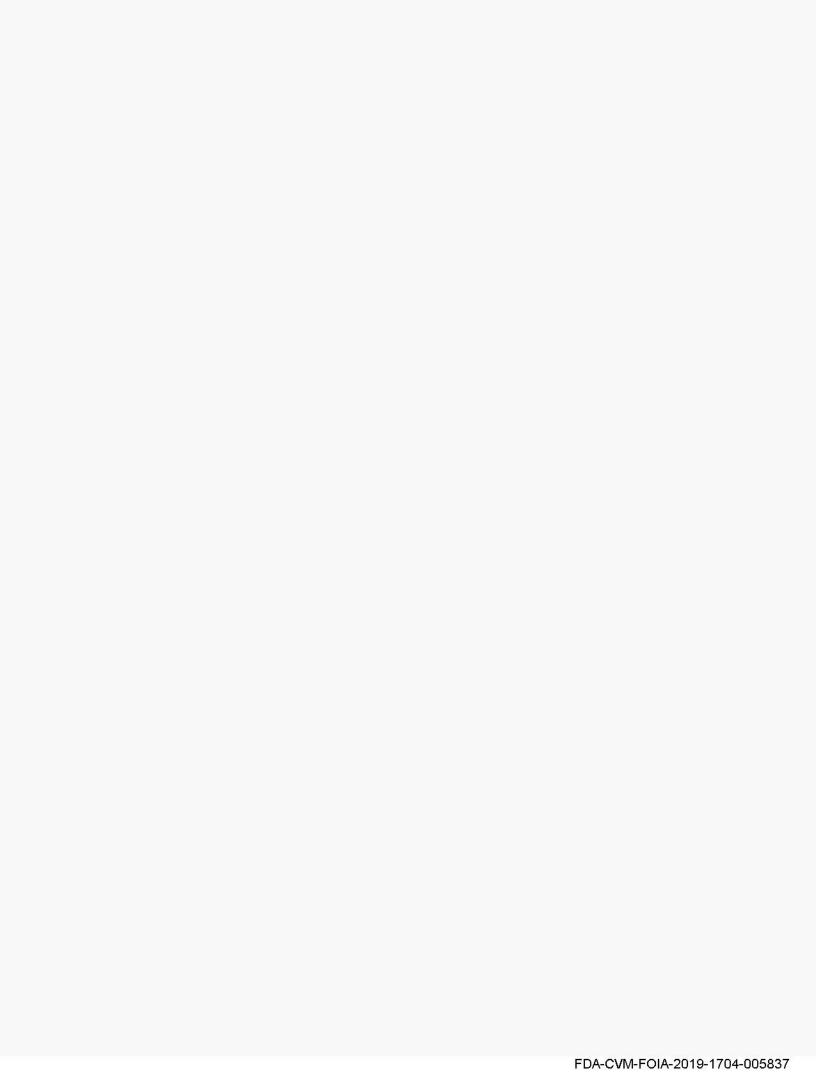
Page 30/49

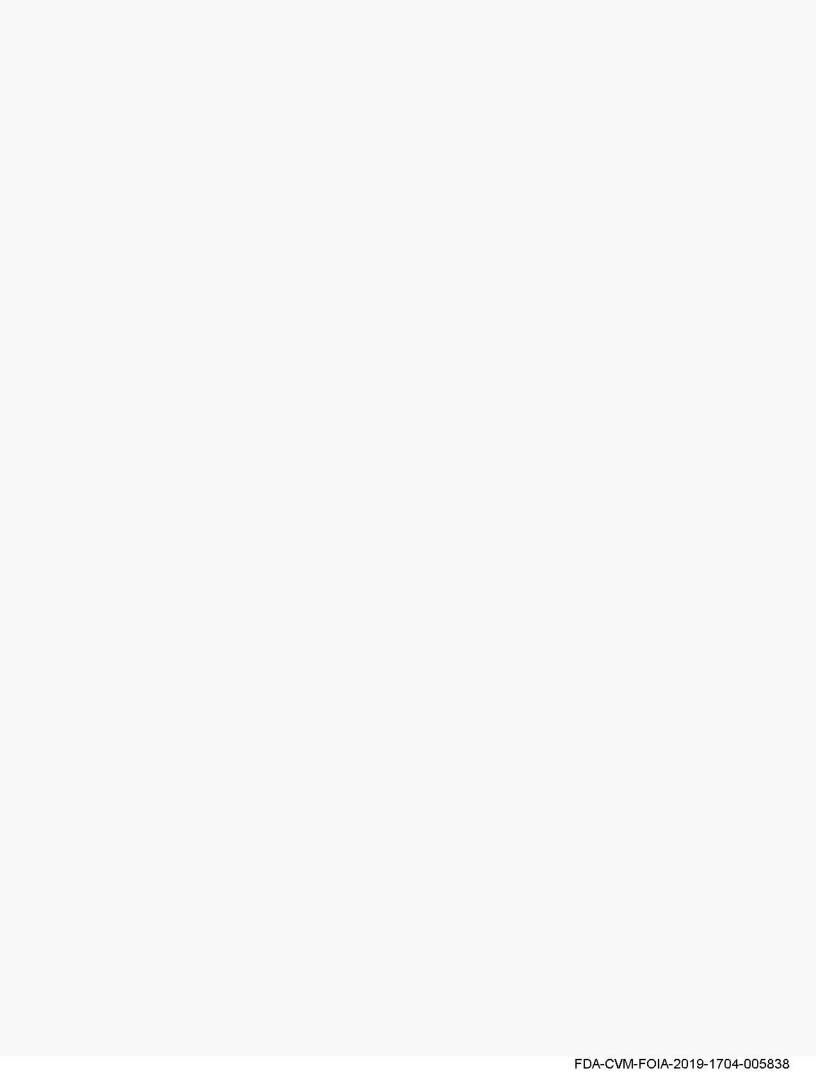
Client:	B6
Patient:	В

Patient	History
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11/07/2018 03:15 PM	Vitals	
11/07/2018 03:15 PM	Vitals	
11/07/2018 03:16 PM	Treatment	
11/07/2018 03:16 PM	Vitals	
11/07/2018 03:40 PM	Labwork	
11/07/2018 03:48 PM	Treatment	
11/07/2018 03:48 PM	Vitals	
11/07/2018 03:48 PM	Treatment	
11/07/2018 03:48 PM	Vitals	
11/07/2018 03:48 PM	Vitals	
11/07/2018 03:48 PM	Treatment	<b>B6</b>
11/07/2018 03:48 PM	Vitals	
11/07/2018 04:45 PM	Prescription	
11/07/2018 04:45 PM	Prescription	
11/07/2018 04:47 PM	Prescription	
11/07/2018 04:47 PM	Prescription	
11/07/2018 04:48 PM	Prescription	
11/07/2018 05:47 PM	Treatment	
11/07/2018 05:47 PM	Treatment	
11/07/2018 05:47 PM	Treatment	
11/07/2018 05:47 PM	Vitals	







## Cummings Veterinary Medical Center

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

PERESTR.	CHART	B6		
Name B6	Name:		Patient II): B6	
Species: Canine	Address	<b>B6</b>	Date of request:	B6
Black/Tan Male (Neutered)	<u> </u>			
Doberman Pinscher				
<b>Birthdate:</b> B6				
Attending Clinician B	6 DVM (Resider	nt - Cardiology)	Student:	
Date of exam: 11/7/18				
Patient Location: Ward	I/Cage:		Weight (kg) 45.20	
	S	iedation		
Inpatient		BAG		
Outpatient Time:		■ OBAG		
■ Waiting	· <b>-</b>	■ 1/2 dose O	AG.	
Emergency		DexDomitor		
= unagany			to sedate/anesthetize	
		■ Aresulesia	io seualeyanesinelize	
Examination Desired: 1	view thoracic radio	graph (lateral) -	to be done standing in	large animal, please.
Presenting Complaint a	nd Clinical Questio	ns you wish to a	NWO.	
Emergency				
Pertinent History: B6 DCM. Evaluated by rDV	., h	_		
ECG indicated atrial fibr	illation Patient wa	søiven 2 dasesa	B6	and referred
here. 1 dose of B6	narriaht	Senci zaosco		, alarconca
INIC TOUSEO, DO	, wanight			
Findings:				
THORAX, SINGLE LATER	AT VIEW TWO INAA	CFC (commoned +	n DFWM ctude dated 11	/5/18 in CC).
		<del>_</del>	<del>-</del>	
Evaluation of the cardia		-		
of the ventral portion o				
of the caudal cardiac bo	rder. The pulmona	ry vessels are wit	hin normal limits. The p	reviously seen

marked perihilar interstitial pattern appears markedly improved, however the lung fields are not

abdomen is within normal limits. No osseous abnormalities are detected.

completely evaluated. A small amount of gas is seen within the thoracic esophagus. The imaged cranial

### Condusions:

- Resolving pulmonary edema and unchanged cardiomegaly consistent with diagnosed DCM. A complete thoracic series may be considered for full evaluation.

Radiologists

Primary: B6 DVM

Reviewing: B6 DVM, DACVR

Dates

Reported: 11/6/18 Finalized: 11/7/18

### Cummings Veterinary Medical Center

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

### Discharge Instructions

<u>Patient</u>	Owner	ļ.=.=.=.=
Name: B6	Maine: B6	Patient ID: B6
Species: Canine Black/Tan Male (Neutered) Doberman Pinscher	Address: B6	
Attending Cardiologist:  John E. Rush DVM, MS, DACVIM (4	Cardiology), DACVECC	
Cardiology Resident:		
B6	<b>5</b>	
Cardiology Technician:		
B6		
Student: B6 V*19		

Admit Date: 11/5/2018 6:19:57 PM Discharge Date: 11/6/2018

### Diagnoses:

- 1. Dilated cardiomyopathy (DCM) with congestive heart failure
- 2. Atrial fibrillation with ventricular beats
- 3. Mild degenerative mitral valve disease

### Case summary:

Thank you for bringing B6 into Tufts! He is a lovely boy!

On presentation, B6 was quiet but alert. His heart rate was elevated and irregular, and an EKG confirmed atrial fibrillation as well. He was on telemetry (continuous EKG) and received supportive care in the KU and was started on cardiac medications in order to help decrease his heart rate and pump better.

An echocardiogram (ultrasound of the heart) revealed dilation and thirming of the walls of his heart consistent with a disease called dilated cardiomyopathy (DCM). On his EKG in addition to his atrial fibrillation, he had ventricular beats (presented as couplets and triplets) which can be concerning as they can lead to life-threatening arrhythmias. We also repeated chest x-rays on  $\begin{bmatrix} BG \end{bmatrix}$  which showed impovement in the congestion in his lung. His bloodwork showed normal kidney value but slightly elevated liver enzymes. We suspect this is secondary to his heart disease but is sumething we will monitor through bloodwork in the future. His ventricular arrhythmia improved overnight and he continued to breathewell. We feel he is ready to go home with you for continued care and monitoring.

B6 has been diagnosed with a primary heart musde disease called dilated cardiomyopathy (DCM). This disease is

more common in large and giant breed dogs and is characterized by thirming of the walls of the heart, reduced cardiac pump function, and enlargement of the upper chambers of the heart. Doberman pinschers are predisposed to developing this disease. Many dogs with DOM will also have significant arrhythmias which can be life-threatening and also require medical management. The heart enlargement has now 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 and some changes to the diet to make your dog comfortable and have him breathing easier.

B6

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/)

Your dog's usual diet may also have more sodium than recommended - we want him/her to continue to eat his/her normal diet for the first 7 to 14 days so we can make sure he is 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 5050, etc.). Hopefully you can find a diet on the list that your dog likes to eat. As you have been trying to reduce B6 weight, we recommend Purina Pro Plan Adult Weight Management as it is a good weight management diet that is low in sodium. If you would like to put a small amount of wet food to entice him to eat, there are cannot food recommendations below as well.

- O 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.
- Werecommend switching Bode to commercial diet made by a well-established company that is not grain-free and does not contain any exotic ingredients, such as langaroo, duck, lamb, venison, lentils, peas, beans, buffalo, tapioca, barley, and chidqueas.
- O The FDA issued a statement regarding this issue (https://www.fda.gov/AnimalVeterinary/NewsEvents/CVM/Updates/uom613305.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:

Purina Pro Plan Adult Weight Management.

### 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 Carrin Mature 8+

### 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  $\begin{bmatrix} B6 \end{bmatrix}$  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 stremuous 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 and liver values. 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@tults.edu for scheduling and non-emergent questions or concerns.

### Please visit our HeartSmart website for more information http://vet.tulits.edu/heartsmart/

### Prescription Refill Discloimer:

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/dinical-studies

Caree: B6	Owner B6	Discharge Instructions	



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

### Alivecor/Kardia Handout

If you have an iPhone or Android, you may want to explore the option of purchasing an AliveCor/Kardia. ECG monitor which will allow you to record and email your pet's heart rate and rhythm at home.

The device (Kardia) can be purchased at <u>www.alivecor.com</u> or <u>www.amazon.com</u>. The app for your phone is free.

### If you have an iPhone:

- Search for 'Veterinary AliveECG' app in the Apple Store
- You will need to sign-up for an account.
- O Make sure to have your pet's name in the information so we know whom it is from
- If the app asks for permission to access headphone port/speaker portal, say 'OK/allow'

### If you have an Android:

- Search for 'Kardia' app in the Google Playstore
- You will need to sign-up for an account.
- O Make sure to have your pet's name in the information so we know whom it is from
- O If the app asks for permission to access headphone port/speaker portal, say 'OK/allow'
- Once downloaded, it will require you to send a "test ECG" for activation of the app. Just place your fingers on the sliver sensors and let it record
- O If the test ECG is unable to record, try again, with less movement. If it still fails, then your phone is not compatible with the device

### Recording an BCG:

- Apply rubbing alcohol (soaked cotton ball will work) to the chest region behind your pet's elbow (where you can feel the heartbeat)
- Enough to wet the regions where both silver boxes will touch the animal
- O If your pet is fluffy, you may have to clip a small patch of fur to allow for better contact.
- O Hold the device against your pet's chest with the silver areas being up and down (vertical) in contact with the animal
- With the app open, hold your phone near (within a few inches) the device.
- O There is a signal bar in the upper left corner of the app to show whether it detects the device.
  If there are no bars then move your phone around/get closer to the device until they appear.
- Once you see a recording, hold everything in place for at least 30 seconds if possible.
- O The human Kardia app will attempt to interpret the ECG; just ignore this as it is not always accurate.
- O The heart rate that the apps report is also not always accurate.

### Saving an ECG:

- The app will automatically save the ECG as long as the recording is long enough (>20seconds).
- You can click on the ID (box with pencil icon) in the Veterinary AliveECG app to add your pet's name

### **Emailing an ECG:**

- O If you are in the recording screen on the Veterinary AliveECG app, click on 'ECGs' to see the list of saved ECGs
- Of If you are in the home screen on the Kardia app, click **'History'**.
- O Select the ECG you wish to send. Go to "Share". Select "Email PDF". SKIP the Password protect feature and select the email app you wish to send it by (Gmail, outlook, yahoo, etc). You must have a working email on your phone for this to work.
- O Select an ECG that you wish to send
- O Click the mail icon (either a box with arrow or a letter symbol), and select "Email"
- Email to: <u>cardiovet@tufts.edu</u> (only monitored Monday-Friday 9AM-5PM)

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

Murmur location/description: left apical systolic

B6

B6 Canine

B6 Years Old Male (Neutered)

Doberman Pinscher

Black/Tan BW: Weight (kg) 45.20

### **Cardiology Inpatient**

Date: 11/6/2018	
Weight: Weight (kg) 45.20	
region inc.gin (45) iones	
Attending Cardiologist:	
John E. Rush DVM, MS, DACVIM (C	ardiology) DACVECC
B6	
<b>D</b> 0	
Cardiclosy Resident:	
B6	
БО	
<u> </u>	i
Thoracic radiographs available for review	?
Yes - in SS	
Yes - in PACS	
□ No	
Presenting complaint and important cond	current diseases:
DCM, CHF, a-fib	
*STOP - remainder o	of form to be filled out by Cardiology*
Physical Examination	
	<b>B6</b>
Muscle condition:	
Mormal Normal	Moderate cachexia
■ Mild muscle loss	Marked cachexia
Cardiovascular Physical Exam	
Murmur Grade:	
None	□ IV/VI
<b>⊠</b> I∕VI	<b>□ v/v</b> i
<b>□</b> II <b>/</b> VI	
□ 11/VI	□ vi∕vi

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  Good Strong	<ul> <li>■ Bounding</li> <li>✓ Pulse deficits</li> <li>■ Pulsus paradoxus</li> <li>■ Other (describe):</li> </ul>
Arrhythmia: None Sinus arrhythmia Premature beats	<ul><li>■ Bradycardia</li><li>✓ Tachycardia - atrial fibrillation</li></ul>
Gallop: ☐ Yes ☑ No ☐ Intermittent	Pronounced Cther:
Pulmonary assessments:  Eupneic  Mild dyspnea  Marked dyspnea  Normal BV sounds	<ul> <li>Pulmonary Crackles</li> <li>Wheezes</li> <li>Upper airway stridor</li> <li>Other auscultatory findings:</li> </ul>
Abdominal exam:  Normal  Hepatomegaly	Abdominal distension Mild ascites
	<b>B6</b>
Doppler findings:	
Mitual inflow:  Summated Normal Delayed relaxation	Pseudonormal Restrictive
Blood Pressure (mmHg): Cuff size: Limb:	
<b>B6</b>	

Assessment and recommendations: Findings consistent with active congestive heart failure due to dilated cardiomyopathy (DCM) and atrial fibrilaltion. Considering breed predisposition, unclear whether DCM is a primary cause or this is diet induced (patient has been on grain free diet for years). Patients on DCM with CHF demands lifelong treatment in order to improve systolic function and avoid fluid accumulation. However, recommend Taurine suplemmentation as some patients can benefit from it. Atrial fibrillation with fast ventricular rate worsens systolic function, which makes prognosis and life. expectancy lower than in animals without the arrhythmia. Thus decrease HR is necessary and **B6** is recommended. Patient should be under telemetry monitoring during hospitalization and doses were administered over the past 24 hours, kidney and electrolytes values should be **as** monitored during hospitalization. Recommend switch diet to a normal large breed diet, such as Pro Plan Weight Management. Echocardiogram should be repeated in 3 months or sooner in case patient develops clinical signs consistent with worsening of the disease.

Treatment plan:

**B6** 

-			
20.0	м		11

ACCICION					
11/7/2018 - Patient improved respir	atory ra	te overnight but	had frequent ventricu	lar arrhythmias	
(multimorphic VPCs, couplets and tr	riplets)	that can potenti	ally be life treatening.	B6	BIE
for 7 days and then SID is recomme	nded. B	ood work revea	led normal kidney fund	tion and mild eleva	tion
on liver enzymes and hypokalemia	B6	/L). Recommend	B6	D and supplement	
potassium 2mEq orally BID.					
B6 - Respiratory rate is with	in nom	nal limits with sli	ght effort. Ventricular	arrhythmias are les	25
frequent and rara episodes of coupl	lets and	l no triplets was	visualized. Blood work	stable and potassi	um
levels improved B6 /L). Patient	: was di:	scharged from ti	he hospital		

### Final Diagnosis:

Dilated cardiomyopathy - r/o primary vs. diet induced. Congetsive heart failure Atrial fibrillation

entricular arrhythmias.	
leart Failure Classification Score:	
ACHC Classification:	
■ la	🔲 IIIa
■ lb	🔲 IIIb
<b>☑</b>	
CVIM CHF Classification:	
□ A	✓ C



Foster Hospital for Small Animals 95 Willard Street North Grafton, MA 01536 Telephone (508) 839-5395 Fax (508) 839-7951 http://wetmed.turks.edu/ Referring Vet Direct Line 508-887-4988

### **Notice of Patient Admit**

Date: 11/5/2018 6:19:57 PM	Case ∎o: B6
Referring Doctor: B6	<u> </u>
Client II ame: B6	
Patient II ame: B6	
Dear B6	
Your patient presented to our Emergen communication with our team.	cy service. Please make note of the following information to facilitate
The attending doctor is: B6	
The reason for admission to the FH	
If you have any questions regarding the	ic narticular carn, please call 500,007,4000 to much the Carticleau Consiss

Information is updated daily, by noon.

Thank you for your referral to our Emergency Service.





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

B6 Male (Neutered)
Canine Doberman Pinscher
Black/Tan
B6

### Daily Update From the Cardiology Service

Today's date: 11/8/2	018	
Dear	В6	
Thank you for referring University.	ig patients ti	o the Foster Hospital for Small Animals at the Cummings School of Tufts
Your patient B6	wasa	dmitted and is being cared for by the Cardiology Service.
Today, B6		
is in stable co	ndition	
is still in the o	xygen cage	
is critically ill		
discharged fro	om the hospi	ital 11/7/2018
Today's treatments in	clude:	
bloodwork pla	nned/pendi	ng
echocardiogra		
cardiac cathe	-	
treatment for		•
ongoing treat		
■ ongoing treat	ment for arr	hythmia (atrial fibrillation)
Additional plans:		
	ness days for	r reports to be finalized upon patient discharge.
	•	
Please call (508) 887-4 Thank you!	4696 before	5pm or email us at <b>cardiovet@tufts.edu</b> if you have any questions.
Attending Clinician:	B6	DVM (Resident - Cardiology)
Faculty Clinician:	В6	DVM,DACVIM
Senior student:		



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

**Sent:** 11/11/2018 2:32:25 AM

Subject: Earthborn Holistic Weight Control (Grain Free): **B6** - EON-370776

Attachments: 2058702-report.pdf

A PFR Report has been received and PFR Event [EON-370776] has been created in the EON System.

A "PDF" report by name "2058702-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report:

**EON Key:** EON-370776

ICSR #: 2058702

EON Title: PFR Event created for Earthborn Holistic Weight Control (Grain Free); 2058702

AE Date	<b>B</b> 6	Number Fed/Exposed	1
Best By Date	11/09/2019	Number Reacted	1
Animal Species	Dog	Outcome to Date	Stable
Breed	Doberman Pinscher		
Age	9 Years		
District Involved	PFR-New England DO		

### **Product information**

**Individual Case Safety Report Number: 2058702** 

Product Group: Pet Food

**Product Name:** Earthborn Holistic Weight Control (Grain Free)

**Description:** Diagnosed and treated for DCM at Cummings Medical Center at Tufts. Have fed Earthborn Holistic Weight Mamagement Grain Free diet for about 5 years. Read FDA Study Report and decided to report experience. I wrote a comprehensive description of what happened twice and got timed out both times. Call if I

can be of further help. **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
Earthborn Holistic Weight Control (Grain Free)		11/09/2019

**Sender information** 

**B6** 

**USA** 

To view this PFR Event, please click the link below: <a href="https://eon.fda.gov/eon//browse/EON-370776">https://eon.fda.gov/eon//browse/EON-370776</a>

To view the PFR Event Report, please click the link below:

 $\underline{https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jspa?decorator=none\&e=0\&issueType=12\&issueId=387745$ 

\_\_\_\_\_

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.

The information is provided as part of the Federal-State Integration initiative. As a Commissioned Official and state government official, you are reminded of your obligation to protect non-public information, including trade secret and confidential commercial information that you receive from the U.S. Food and Drug Administration from further disclosure. The information in the report is intended for situational awareness and should not be shared or acted upon independently. Any and all actions regarding this information should be coordinated through your local district FDA office.

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-	370776						
ICSR:	2058702						
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:	2018-11-10 21:21:30 EST						
Reporter is the Animal Owner:	Yes						
Reported Problem:	Problem Description:	Earthborn Holistic W FDA Study Report a	ed for DCM at Cummings Medical Center at Tufts. Have fed /eight Mamagement Grain Free diet for about 5 years. Read nd decided to report experience. I wrote a comprehensive happened twice and got timed out both times. Call if I can be				
	Date Problem Started:	11/04/2018					
	Concurrent Medical Problem:						
	Outcome to Date:	e: Stable					
Product Information:	Product Name:	Earthborn Holistic W	/eight Control (Grain Free)				
	Product Type:	?					
	Lot Number:	111111111111111111111111111111111111111					
	IIPC-						
	Package Type:						
	Package Size:						
	Purchase Date:						
	Number Purchased:						
	Possess Unopened Product:	No t: Yes					
	Possess Opened Product:						
	Storage Conditions:	s: In sealable bag that it came in in dry room					
		DOODI PUOII.	Kibbles fed along with Wellness wet food				
		First Exposure Date:					
		Last Exposure Date:	11/05/2018				
		Time Interval between Product Use and Adverse Event:	6 Hours				
		Product Use Stopped After the Onset of the Adverse Event:	Yes				
		Adverse Event Abate After Product Stop:	No				
		Product Use Started Again:	Unknown				
		Perceived Relatedness to Adverse Event:	Possibly related				
		Other Foods or Products Given	Yes				

		to the Animal			out of the same
		<b>During This Time</b>	Periodicular		
		Period:			onnonen energen
	Manufacturer	Name:	Eartborn Holistiv		
	/Distributor Information:	Type(s):	Manufacturer		- Contraction
		(h. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1.	United States		50000 00000 00000
		Contact:			000
		Possess One or	Yes		anguena.
		More Labels from			
		This Product:			harman
	Purchase Location	Name:	Amazon		
	Information:	Address:	United States		000
A	<u> </u>	D6 1	11.		
Animal Information:	Name:	B6			
	Type Of Species:				500000
	<u>}</u>	Doberman Pinscher			
	Gender:				2000
	Reproductive Status:	Neutered			nonnon
		100 Pound			
	Age:	9 Years			
	Assessment of Prior	Excellent			SARAGON
	Health:				0000000
	Number of Animals Given the Product:	1			200000000000000000000000000000000000000
	Number of Animals Reacted:	1			THE PROPERTY OF THE PARTY OF TH
	Owner Information:				20000000
	Healthcare Professional	Practice Name:	E	36	
	Information:	Contact:	Name:	B6	
			Phone:	B6	0000 0000 0000 0000
			Other Phone:	B6	000000000000000000000000000000000000000
			ł		955
	<u> </u>	∆ddress:			
		Address:	D6		50000000000000000000000000000000000000
		Address:	<b>B6</b>		000000000000000000000000000000000000000
		Address:	B6		200 C C C C C C C C C C C C C C C C C C
			B6 United States		100 mm m m m m m m m m m m m m m m m m m
		Type of	B6 United States Primary/regular v	/eterinarian	100 mm m m m m m m m m m m m m m m m m m
		Type of Veterinarian:	Primary/regular v	veterinarian	
		Type of Veterinarian: Date First Seen:	Primary/regular v	veterinarian	
		Type of Veterinarian:	Primary/regular v	veterinarian	
		Type of Veterinarian: Date First Seen: Permission to Release Records	Primary/regular v 11/05/2018 Yes	veterinarian inary Medical Center at Tufts University	
		Type of Veterinarian: Date First Seen: Permission to Release Records to FDA: Practice Name:	Primary/regular v  11/05/2018  Yes  Cummings Veter		
		Type of Veterinarian: Date First Seen: Permission to Release Records to FDA: Practice Name:	Primary/regular v 11/05/2018 Yes Cummings Veter Name:		
		Type of Veterinarian: Date First Seen: Permission to Release Records to FDA: Practice Name:	Primary/regular v  11/05/2018  Yes  Cummings Veter  Name: Phone:		
		Type of Veterinarian: Date First Seen: Permission to Release Records to FDA: Practice Name: Contact:	Primary/regular v  11/05/2018  Yes  Cummings Veter  Name: Phone: Other Phone:		
		Type of Veterinarian: Date First Seen: Permission to Release Records to FDA: Practice Name:	Primary/regular v  11/05/2018  Yes  Cummings Veter  Name: Phone: Other Phone:		
		Type of Veterinarian: Date First Seen: Permission to Release Records to FDA: Practice Name: Contact:	Primary/regular v  11/05/2018  Yes  Cummings Veter  Name: Phone: Other Phone:  55 Willard St North Grafton Massachusetts		
		Type of Veterinarian: Date First Seen: Permission to Release Records to FDA: Practice Name: Contact:	Primary/regular v  11/05/2018  Yes  Cummings Veter  Name: Phone: Other Phone:  55 Willard St North Grafton Massachusetts 01536		
		Type of Veterinarian: Date First Seen: Permission to Release Records to FDA: Practice Name: Contact:	Primary/regular v  11/05/2018  Yes  Cummings Veter  Name: Phone: Other Phone:  55 Willard St North Grafton Massachusetts 01536 United States	inary Medical Center at Tufts University	300000000000000000000000000000000000000
		Type of Veterinarian: Date First Seen: Permission to Release Records to FDA: Practice Name: Contact:	Primary/regular v  11/05/2018  Yes  Cummings Veter  Name: Phone: Other Phone:  55 Willard St North Grafton Massachusetts 01536	inary Medical Center at Tufts University	
		Type of Veterinarian: Date First Seen: Permission to Release Records to FDA: Practice Name: Contact: Address:	Primary/regular v  11/05/2018  Yes  Cummings Veter  Name: Phone: Other Phone:  55 Willard St North Grafton Massachusetts 01536 United States  Referred veterina	inary Medical Center at Tufts University	

		Permission to Yes Release Records	
		to FDA:	
Sender Information:	Name:	В6	
	Address:	<b>B6</b> United States	
	Contact		1
	Contact:	hone: B6 Other Phone: B6	
		Email: B6	
	Permission To Contact Sender:	es	
	Preferred Method Of Contact:	hone	
Additional Documents:			



### Chem 3/14/19



### Tufts Cummings School Of Veterinary Medicine

200 Westboro Road North Grafton, MA 01536

### DUPLICATE

Amylase

Osmolality (calculated)

Comments (Chemistry)

			-
Name/DOB: B6	Sex: CM	Provider. B6 Order Location: V320559: Investigation into	
Phone number:	Age: 9	Sample ID: 1903140161	
Collection Date: 3/14/2019 4:02 PM	Species: Canine	Contractor • Programme Contractor	
Approval date: 3/14/2019 6:30 PM	Breed: Doberman Pinscher		

### Research Chemistry Profile - Small Animal (Cobas)

DNOYES Glucose Urea Creatinine Phosphorus Calcium 2 Magnesium 2+ Total Protein Albumin Globulins A/G Ratio Sodium Chloride Potassium tCO2(Bicarb) AGAP NA/K Total Bilirubin Alkaline Phosphatase GGT ALT AST Creatine Kinase Cholestero1 Triglycerides

Ref. Range/Males 67-135 mg/dL 8-30 mg/dL 0.6-2.0 mg/dL 2.6-7.2 mg/dL 9.4-11.3 mg/dL 1.8-3.0 mEq/L 5.5-7.8 g/dL 2.8-4.0 g/dL 2.3-4.2 g/dL 0.7-1.6 140-150~mEq/L106-116 mEq/L 3.7-5.4 mEq/L 14-28 mEq/L8.0-19.0 29-40 0.10-0.30 mg/dL 12-127 U/L 0-10 U/L 14-86 U/L 9-54 U/L 22-422 U/L 82-355 mg/dL 30-338 mg/dl 409-1250 U/L

291-315 mmol/L

Sample ID: 1903140161/1 REPRINT: Orig. printing on 3/14/2019 (Final)

Reviewed by: \_\_

### **Diet Hx 3/14/19**

CARDIOLOGY D		A 100 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0		
ot's name B6 Owner's name :	<b>B6</b>		_ Today's date:	3/14/19
How would you assess your pet's appetite? (mark the point Example: Poor	nt on the line be		resents your pe ellent	t's appetite)
Poor		Exc	ellent	
Have you noticed a change in your pet's appetite over the DEats about the same amount as usual DEats less the DESeems to prefer different foods than usual DOther	last 1-2 weeks? han usual	? (check all that a □Eats more than		
Over the last few weeks, has your pet (check one)  □Lost weight □Gained weight Stayed about the s	ame weight 🛭	Don't know		
Please list below <u>ALL</u> pet foods, people food, treats, snac currently eats. Please include the brand, specific product.	and flavor so w	e know exactly w	hat you pet is e	ating.
Examples are shown in the table - please provide enough		could go to the st	ore and buy the How often?	exact same foo
Food (include specific product and flavor)	Form dry	1 1/2 cup	2x/day	Jan 2018
Nutro Grain Free Chicken, Lentil, & Sweet Potato Adult	microwaved	3 oz	1x/week	Jan 2015
85% lean hamburger	treat	3 0Z 1/3	1x/week	Aug 2015
Pupperoni original beef flavor			1x/week	Dec 2015
Rawhide	treat	6 inch twist	2 American	THE STATE
BENEFIT PROME THEO MORE		<b>-3</b> 40		
Salmoni pice			2x diy	101 pp 20/
Churken   Rich	NEW TOTAL STREET		<i></i>	1000 2018
T3-6-6-6-12-11				Jan 2019
oci Nautile Datus Dieta	ingless and the second	26	axday	Febraco Codys
Prode for anting sweet potators	(Docsntwant	VICE anymor	<b>U</b>	Peb11, 2019
I we calmon - superpolate	カで	1/20	1 ax day	*
appretited desipped by	a hit-	Α		
		00 d -	L	<u> </u>
*Any additional diet information can be listed on the back	of this speet —	I can mail a	e deate i time i	EXOLET TOWN
Do you give any dietary supplements to your pet (for examplements)?  DYes No If yes, please list which Brand/C	mple: vitamins, c	المرابع على المرابع ا	y acids, or any to ounts:	ouneF Go+WoW ount per day
Carnitine DYes DNo				
Antioxidants DYes DNo			. 41	
Multivitamin DYes DNo				
Fish oil DYes DNo				
Coenzyme Q10				
Other (please list):	Nature's Bounty		500 mg tablets – 1 per day	
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):  HE never takes the HEL AM T alw	e the	hicken o	( Plant =	Butter
HE never lates to	erm in aus hui 2	PIII poc but pul p	Kets - Vacketig	Lown three

When we took B6 home unitally he rejused to est! We find the dry food and Hills Camed food as prescribed -He ste NOTHING! We tried to give him his ald tood- he resused By the 4th day I got worried - tried chicken broad a No!

He refused to eat - I could get him to take

100 cebes & strink water only 
100 cebes & strink water only 
100 cebes & strink water only prescribed the nedicine "Entyce". By the 5th day home - and after the Entyes he finally. ate & can of vigent care hills diet it smelled like Out food & came in the same small can-\* He then rejected the proscribed diet of dog food against and began eating - Salmon/Rice or chekin/ RIU/ or Bey (Rice) or Strambled Eggs! Then my husband ordered Dr. Marky's - for about 3 weeks he ate this then he began rejecting then and is regularly rating People food- cheken-carrots, potatoes-Bug Salmon - he No longer wants rice - ZC - 2x daily in the bast 3 days 3/11/19- his appetite has dropped off - he is only eating Ix a day I keep a deskilled have with record from the day B6 came home with exactly what he has eaten/how many times he pees/or pophs-/his walks/

### Notes from owner 3/14/19

MEMORANDUM
то; В6 ;
TUFTS UNIVERSITY - Cummings School of Veterinary Medicine
Re: B6 - Cummings Patient ID No B6 Doberman Pinscher b. B6
EXPERIENCE WITH PROTOCOL FOR DILATED CARDIOMYOPATHY (DCM)
RESEARCH REVIEW VOLUNTEER
Antecedents - On Sunday, 11\4\2018, B6 came running back to me retrieving a tennis ball and let ou a yelp for no apparent reason. He dropped the ball and walked around somewhat disoriented - an apparent hypoxic event. We brought him into the house and kept a close watch on him with no signs o distress. The next morning when he seemed somewhat lethargic, I put a stethoscope on him and was surprised that his heart rate was very rapid. I also detected a gurgle in his abdomen. We took him to our local vet B6 , diagnosed him as having DCM and recommended that he be taken to Tufts. As we had had him at Tufts before, we immediately agreed and our vet made contact with Tufts and told us that they would be expecting us.
I might also note, retrospectively that approximately six months earlier, he was running in the backyard and let out an "idiopathic yelp", but without any disorientation or unusual behavior.
In the intervening six months and perhaps some months before he had numerous incidents of head tremors which were described by our vet as benign and idiopathic - but perhaps are not idiopathic and may be symptomatic of cardiovascular output issues.
B6 was admitted to Tufts on 11.05.2018 and spent 1-1/2 days in the ICU with our interfacing with Dr.  B6 A modicinal rooting was put in place (with minor modifications over the first few weeks in consultation with B6 The current dosages are as follows:
B6 We left runs with a prognosis of a 4-8 month potential survival with reasonable quality of life, but with
sudden death a possibility at any time. We were also told that while DCM can be managed for an ndeterminate period it is not a reversible condition.
lis heart rate remained very high B6 for most of the first two months as did his resting respiration rate (mid 20's to mid 30's). Over the past two months his respiration rate has been quite

normal and his heart rate has not been visibly rapid (although I was surprised at the heart rate shown on the Kardia ecg app when I recorded it today at B6

#### BEHAVIORAL CHANGES.

There have been numerous behavioral changes.

- He sleeps a lot more than pre-incident.
- 2. His appetite has diminished considerably and B6 has had to be very creative to assure adequate nutrition. We started him out on the diet recommended by the Nutrition Dept consisting of Purina Pro Plan Adult Weight Management and Hill's Science Diet Adult Beef & Barley Entree. He basically refused this diet after our trying various ways to entice him to eat this. He also refused his prior diet of Earthborn Holistic Adult Weight Management Kibbles and Wellness grain free Beef, Chicken, Lamb, or Turkey. He kept losing weight and after consulting with B6 , he suggested we feed him whatever it takes to maintain body mass. We started out with roasted chicken and rice. Whatever we fed him he seemed to lose interest in rather quickly. At one point we resorted to Hills Science Urgent Care a/d to stimulate his appetite. We now tend to feed him baked salmon, hamburger, steak, turkey, pork, halibut, etc. It is generally difficult to get him to eat other that at our dinner hour when he indicates he'll have the same thing we are having. We have also had some intermittent success with Dr. Marty's freeze dried raw meat, fish, poultry and eggs.

This is a dog that lived for food and exercise. He ate anything that we put in front of him with gusto and always had his head on my arm at meal time. He always wanted a dog biscuit when he came in from outside. Now he often has no interest in such a treat or will refuse 3 choices hoping to get what might be his current favorite.

- 3. We have had and continue to have considerable trouble with diarrhea. He'll be good for a few days then bad for a few days - but quite difficult to permanently stabilize.
- He is not as assertive as he was pre-treatment as instead of bounding out the door and running around the property being a watchdog, he now walks out the door and waits to be sure I am with him.

#### QUALITY OF LIFE

I would say that once his respiration stabilized and his apparent heart rate appeared non burdensome, he has had a good quality of life. He thoroughly enjoys his walks and we take him out for 15 minute to 45 minute walks when the weather is reasonably comfortable. On colder days, if he stops walking due to me chatting with somebody, he will start shivering after a few minutes; but as long as he is moving he is fine. When a vehicle pulls into the driveway he goes into watch dog mode and barks loudly - although he misses some of the delivery trucks that do not ring the bell (which he never missed before). He maintains his very gentle charming self when not sleeping and enjoys a little ball playing in the house. He bounds up to the second floor bedroom as if everything is just fine.

B6

#### MANAGEMENT

The two biggest management issues have been (1) diet and diarrhea and (2) frequent urination around the clock. B6 stays up with him until 12:00 - 2:00 a.m. and I get the graveyard shift with a wake-up generally between 2:00 and 4:00 a.m. where I accompany him outside for five to ten minutes with perhaps a wind chill of 10 degrees below zero. This is a feature of the B6 which has kept his lungs clear and his respiratory rate comfortable.

#### QUESTIONS

We are most interested in your evaluation and any suggestions that you might have for us.

Would any of the supplements that are prescribed for humans such as CoQ10, magnesium or arginine be of any value?

Would a raw food diet be of any benefit?

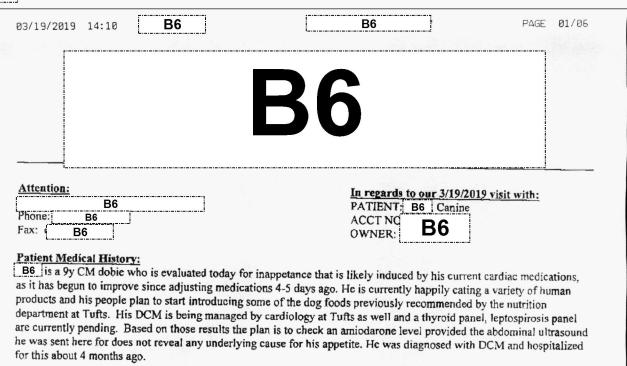
We are very grateful for the **B6** days we have had with our pal. We were not sure he would last until we got back to **B6** when we left Cummings. **B6** was very responsive to any questions and suggested modifications to the protocol based on conditions presented once we were home. All the staff that we interacted with at Tufts were top notch.

#### IDEXX BNP - 3/14/2019

Client B6 Patient B6 IDEXX Reference Laboratories IDEXX VetConnect 1-888-433-9987 Client B6
Patient B6
Species CANINE
Breed: DOBERMAN\_PINSCH
Gender: MALE NEUTERED Date: B6 TUFTS UNIVERSITY 200 WES TBORO RD NORTH GRAFTON, Massachusetts 01536 Requisition#:1A
Accession# B6
Ordered by B6 508-839-5395 Age: 9Y Account #88933 CARDIOPET proBNP - CANINE CARDIOPET proBNP B6 0 - 900 pmol/L HIGH **B6** Comments: 1. 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.

Client: B6

B6 records



**B6** 

B6

B6

B6 records

N3/19/2N19 1	4:10	B6	B6 PAGE	02/06

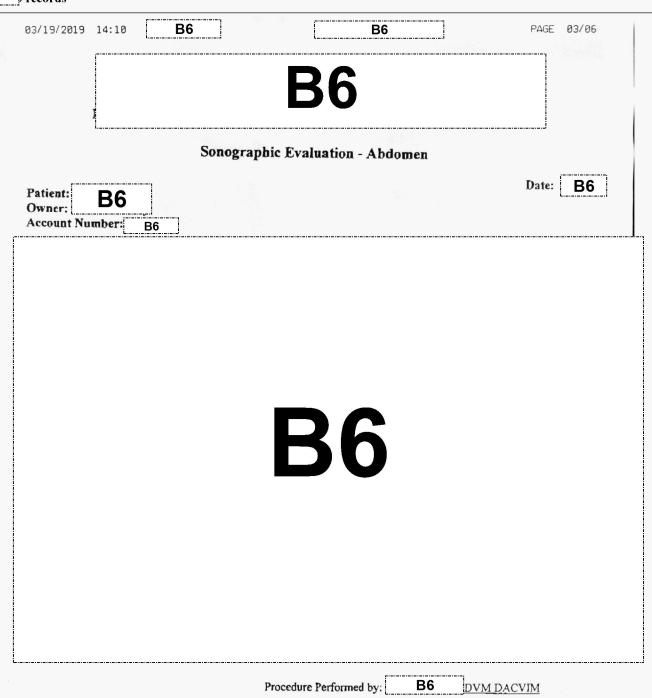
# Client Instructions:

We love your sweet boy and are happy not to have seen anything concerning in his abdomen today! We agree with the suspicion that his cardiac medications have led to the reduced appetite which has already started to improve. We discussed the concern for deficiencies in his current dict of a variety of healthy human food and you have reached out to the nutritionist at Tufts to discuss a supplement. You are also cautiously optimistic that he will eat some dog food with his improvement and will start to try and introduce the dicts recommended by Tufts.

Please continue with his cardiac medications as pr	eviously directed.
Please let B6 know how things are going	with him and if there is anything else we can help with for his carel
	Thank you for letting us assist you in B6 care.
	Sincerely, B6 DVM DACVIM
httachments: u/s report, discharge instruction	Transcription; B6 Edits B6

If	В6	is scheduled to return to E	36 for furth	er services, pleas	e forward	d any new
	medica	al history and lab work to	В6	or fax to	В6	]

Patient:	records		
Client:	R6		



DVM DACVIM

Client: B6

B6 records

03/19/2019 14:10

**B6** 

**B6** 

PAGE 04/06

**B6** 

Medical Discharge Instructions

**B6** 

#### Patient Update:

B6 is a 9y CM dobie who is evaluated today for inappetance that is likely induced by his current cardiac medications as it has begun to improve since adjusting medications 4-5 days ago. He is currently happily eating a variety of human products and his people plan to start introducing some of the previously recommended dog foods by the nutrition department at Tufts. His DCM is being managed by cardiology at Tufts as well and a thyroid panel, leptospirosis panel are currently pending. Based on those results the plan is to check an amiodarone level provided the abdominal ultrasound he was sent here for does not reveal any underlying cause for his appetite. He was diagnosed with DCM and hospitalized for this about 4 months ago.

**B6** 

#### Discharge Instructions:

We love your sweet boy and are happy not to have seen anything concerning in his abdomen today! We agree with the suspicion that his cardiac medications have led to the reduced appetite which has already started to improve. We discussed the concern for deficiencies in his current diet of a variety of healthy human food and you have reached out to the nutritionist at Tufts to discuss a supplement. You are also cautiously optimistic that he will cat some dog food with his improvement and will start to try and introduce the diets recommended by Tufts.

**B6** 

**B6** 

Client: Patient:	В6			
В6	records			
	03/19/2019 14:10	В6	B6	PAGE <b>05</b> /06
J	Please continue with his ca	ardiac medications as previously	directed.	
1	Plcase let B6 kno	ow how things are going with hir	n and if there is anything clse we can help with	for his care!
1	Please call our office at	B6 I if you have any ques	tions or concerns before your next scheduled p	rogress exam. If you have a

medical emergency outside of our normal office hours, please contact your regular veterinarian, or consult the list of emergency clinics

below.

B6

В6

DVM, DACVIM

**B6** 

**B6** 

6 records			
03/19/2019 14:	10 <b>B6</b>	B6	PAGE <b>06</b> /06
B6			
Urinalysis		- B6	
Date: B6	_ Cysto	Hurthday:	8.7 lbs
Doctor: B6	Catheter	Birthday: B6 Age:	₹
Gross Examination	on: Color: 5/raw Pellet:	Appearance: Clear  Specific Gravity: 1.014	
Strip Reading:	Urobili (mg/dL): normal	□ <sub>2</sub> □ <sub>4</sub> □ <sub>8</sub>	
	Glucose (mg/dL): negative	□ 50 □ 100 □ 250 □ 500	□1000
	Ketone (mg/dL): negative	□ trace □15(+) □40(++) □80(+++	160(++++)
	Bilirubin:	O++ O+++	
	Protein (mg/dL): □ negative	Ørace □30(+) □100(++) □300(+-	++) D2000(++++)
	Blood: Inegative Non-Hemolyz	olyz ed	e (++) 🖫 large(+++)
	рН: 🗆 5 🕽 🕻 С 6 6 5	o7 o8 o9	
	BE WBC: Mare RBC	: none Bacteria: none	

Page 16/71

Notes:\_\_

Client: **B6** 

B6 Records - 3/21/2019

03/21/2019 3:39:07 PM -0400 B6

PAGE 1 OF 1

**B6** 

B6 **B6** 

#### REPORT OF LABORATORY EXAMINATION

Client:

B6

Owner:

В6

Rovd Date:

3/19/2019 3:40:00 PM

Admitted By: B6
Ordered By: N/A
Encounter: 02617248
CR#: AP

Animal: Species: Age: Tag/Reg ID:

Other ID:

B6 Canine 8 years

MRN: 37181

Breed: Doberman Pinscher Gender: Male, Castrated

# Pending Order Summary

Received Date Order Name

03/18/2019 Endocrinology Interpretation

Status Ordered

# Endocrinology

### **Endocrine Results**

(If Provided)	03/18/2019 11:00:00		
Procedure		Ref Range	Units
Total Thyroxine (TT4) (RIA)		[11-60]	nmol/L
Total Triiodothyronine (TT3) (RIA) *		[0.8-2.1]	nmol/L
Free T4 by dialysis (RIA)		[6-42]	pmol/L
T4 Autoantibody (RIA)	B6	[0-20]	%
T3 Autoantibody (RIA)		[0-10]	%
Thyroid Stimulating Hormone (CLIA)		[0.00-0.58]	ng/mL
Thyroglobulin Autoantibody (ELISA) *		[0-35]	%

**B6** 

L = Low Result, H = High Result; @ = Critical Result; ^ = Corrected Result, \* = Interpretive Data; # = Result Footnote

Print Date/Time: 3/21/2019 3:39 PM

**B6** /Records - 3/21/2019

# **B6**

#### **Final Report** Case#: B6 Accessioned: 03/20/19 Report Generated: 03/20/19 @ 3:35 PM by AS1 Results Last Modified: 03/20/19 @ 3:35 PM **B6** ardia B6 Case ID Owner B6 B6 Breed Species Age B6 Years Sex / Fixed Canine (dog) Doberman Pinscher Male - Neutered / Microbiology Lepto Titer Verified: 03/20/19 3:27 PM by B6 Lean Lerie B6 Animal Lautumn Lbrat

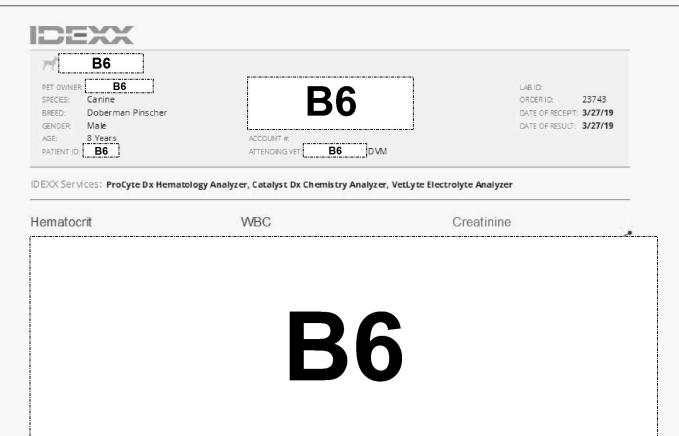
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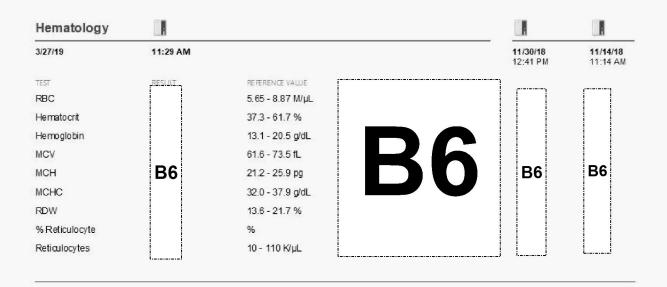
B6

Page 1 of 1

**B6** 

B6 - 3/27/2019

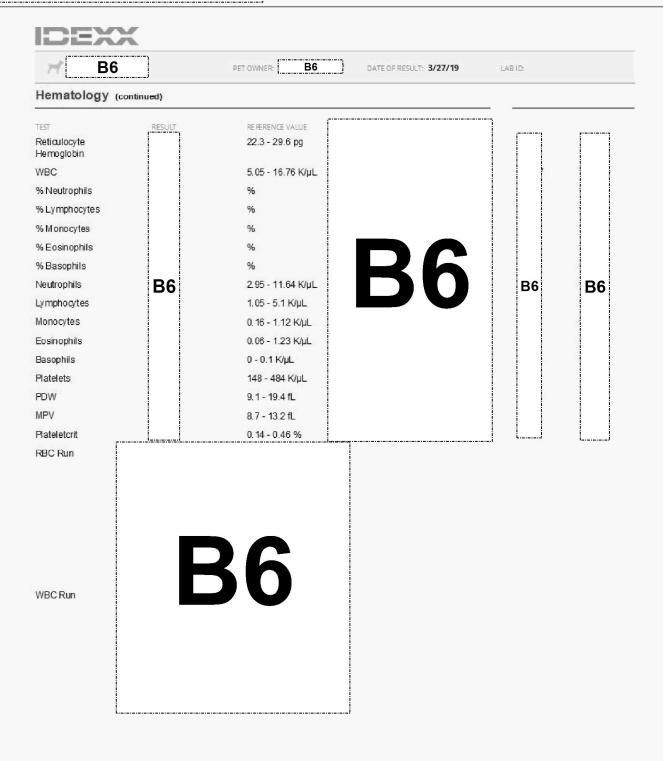




Page 24/71

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Page 1 of 3



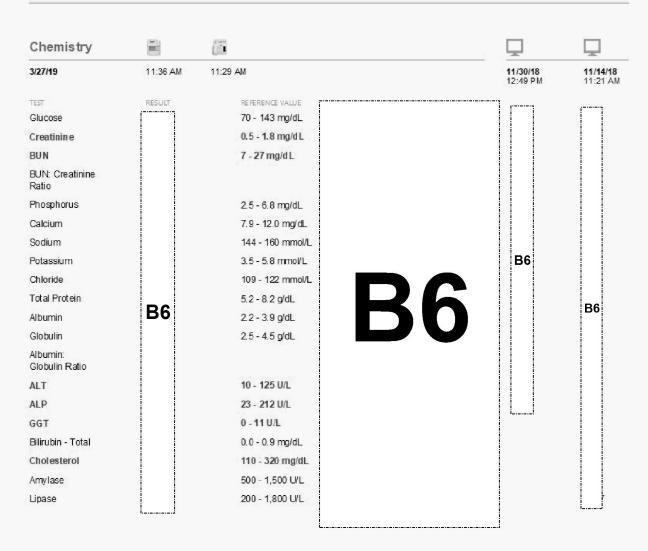
Generated by VetConnect® PLUS March 27, 2019 11:46 AM

Page 2 of 3

B6 - 3/27/2019







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Page 3 of 3

Client: **B6** 

B6 - 4/6/2019

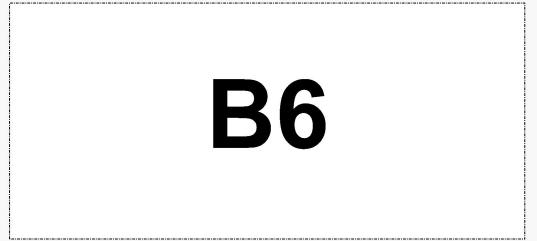
Client: B6
Patient Name: B6
Species: Canine

Breed:

Gender: Male/Castrated Weight: Age: 8 Years Doctor:

**B6** 

Test	Results	Reference Interval	LOW	NORMAL	HIGH	
ProCyte Dx (	April 6, 2019 1	0:18 AM)				3/27/19
RBC		5.65 - 8.87				
HCT		37.3 - 61.7				
HGB		13.1 - 20.5				
MCV		61.6 - 73.5				
MCH		21.2 - 25.9				
MCHC		32.0 - 37.9				
RDW		13.6 - 21.7				
%RETIC		X-1 = X - X				
RETIC		10.0 - 110.0				
RETIC-HGB		22.3 - 29.6				
WBC		5.05 - 16.76		36		
%NEU	DO					B6
%LYM	B6					DO
%MONO						
%EOS		ł				
%BASO						
NEU		2.95 - 11.64 HIGH				
LYM		1.05 - 5.10 LOW				
MONO		0.16 - 1.12				
EOS		0.06 - 1.23				
BASO		0.00 - 0.10 HIGH				
PLT		148 - 484				
MPV		8.7 - 13.2				
PDW		9.1 - 19.4				
PCT		0.14 - 0.46				



Printed: April 6, 2019 10:26 AM

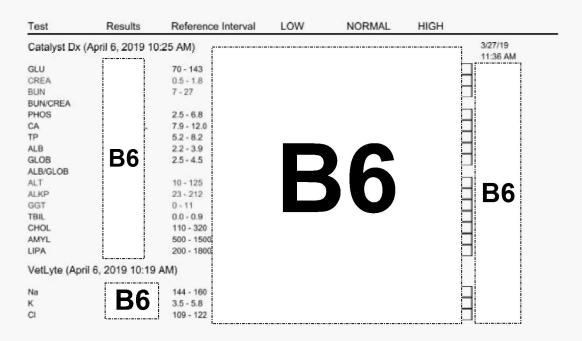
Page 1 of 2



Client: B6

B6 - 4/6/2019

Client: B6 Gender: Male/Castrated
Patient Name: B6 Weight:
Species: Canine Age: 8 Years
Breed: Doctor:



Printed: April 6, 2019 10:26 AM

Page 2 of 2

# Troponin 4/4/19



Comments:

# 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			
B6 Tufts University-Clinical Pathology Lab Attn: B6 200 Westboro Road North Grafton, MA 01536 USA	Owner Specie	I Name: Name:	B6 B6 B6 Canine Apr 04, 2019
Clinical Pathology Tracking Number: 329174		GI Lab Ac	cession B6
Test Ultra-Sensitive Troponin I Fasting	Result <b>B6</b>	Control Range ≤0.06	Assay Date 04/05/19
	36		

#### Troponin 4/4/19

#### Important Notices:

Internal Medicine Conference

Join us for a unique continuing education event in Phuket, Thailand Oct 7th - 11th, 2019. For details see <a href="http://texasimconference.tamu.edu">http://texasimconference.tamu.edu</a>

#### 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 in formation.

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.

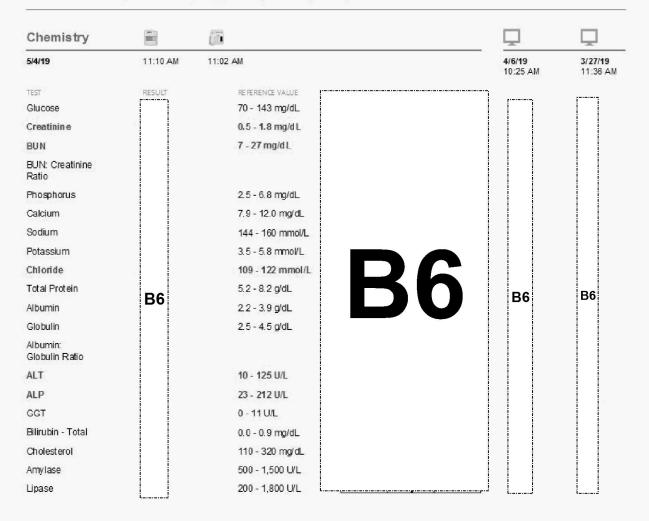
#### GI Lab Contact Information

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





ID EXX Services: Catalyst Dx Chemistry Analyzer, VetLyte Electrolyte Analyzer



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Page 1 of 1

NC State Genetics 6/5/2019

# NC State College of Veterinary Medicine

# Veterinary Cardiac Genetics Laboratory

1060 William Moore Dr., RB 326 Raleigh, NC 27607 vcgl@lists.ncsu.edu (919) 513-3314



To request swab collection kits, please visit: https://cvm.ncsu.edu/genetics/cheek-swab-request/

#### Doberman Pinscher Dilated Cardiomyopathy (DCM) Genetic Testing

Dilated cardiomyopathy mutation (DCM) is a form of heart disease in the Doberman pinscher dog. It is an inherited disease, and our laboratory has identified two mutations responsible for the development of DCM. Dogs that are positive for both mutations are at the highest risk of developing DCM

Owner Name: B6

NCSU Doberman DCM1 (PDK4) Result:

Dog's Name: B6

NCSU Doberman DCM2 Result:

NCSU Doberman DCM2 Result:

Below is an explanation for each possible test result so you can better understand all the possible results and make informed breeding decisions:

Negative Result for both DCM1 and DCM2:	The absence of both mutations in a Doberman indicates that the risk of developing DCM is low. It is still possible for a dog to develop heart disease. However, a negative result for both DCM1 and DCM2 indicates that a dog does not have either mutation known to cause DCM.		
Positive result for NCSU DCM1 only:	About 10 70 of dogs with this induded will develop bein bogs and are positive for or		
Breeding recommendations:	Dogs are positive for DCM1 should NEVER be bred to a dog that is positive for NCSU DCM 2 since this will lead to dogs that are highest risk of developing DCM. Dogs that are positive homozygous for DCM1 should ideally not be bred.		
Positive Result for NCSU DCM2 only:	About 50% of dogs with this mutation will develop DCM. Dogs that are positive for only DCM2 will not necessarily develop significant heart disease.		
Breeding recommendations:	Dogs are positive for DCM2 should NEVER be bred to a dog that is positive for NCSU DCM1 (PDK4) since this will lead to dogs that are highest risk of developing DCM. Dogs that are positive homozygous for DCM2 should ideally not be bred.		
Positive result for both NCSU DCM1 and NCSU DCM2 :	Dogs that positive for BOTH DCM1 & DCM2 are at a very HIGH risk of developing DCM and should be carefully monitored by your veterinarian for signs of disease. Annual evaluation by a cardiologist with an echocardiogram and Holter monitor after 3 years of age is recommended.		
Breeding recommendations:	Dogs that are positive for both DCM1 & DCM2 are at the HIGHEST risk of developing DCM and should ideally not be bred since they can pass both traits on. They should never be bred to a dog that is positive for either test.		



As always, breeding decisions should be made carefully. Removal of a significant number of dogs from the breeding population could be very bad for the Doberman Pinscher breed. Remember that dogs that carry this mutation may also carry other important good genes that we do not want to lose from the breed.



# **Cummings** Veterinary Medical Center

AT TUFTS UNIVERSITY

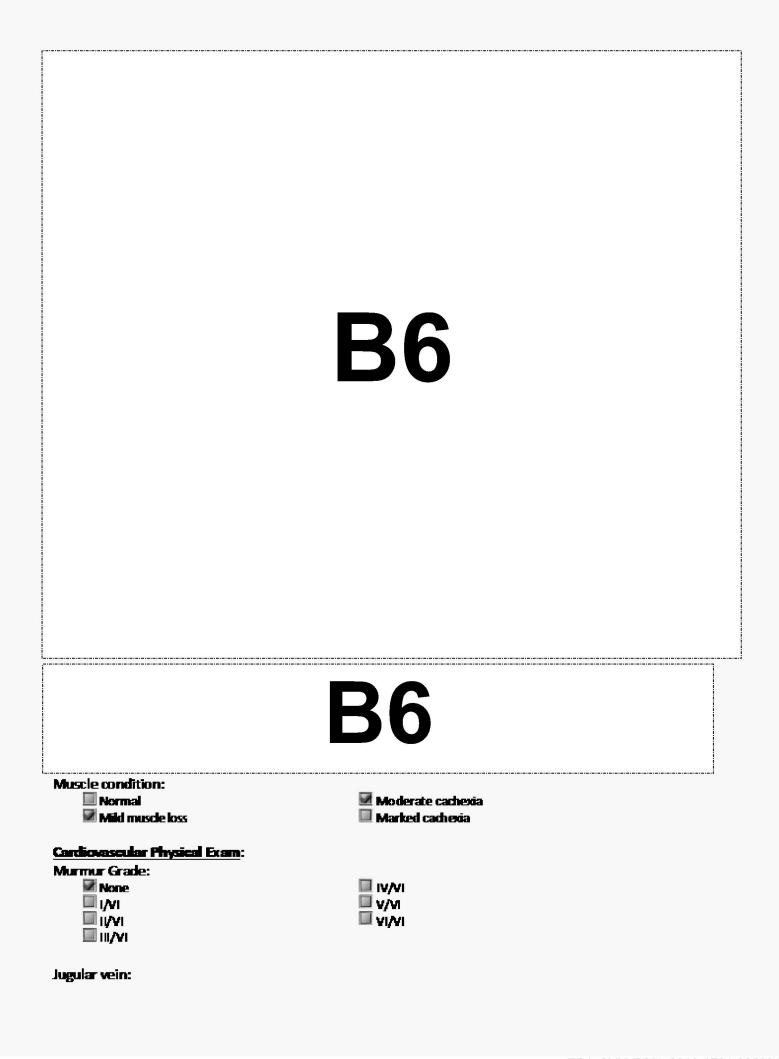
Cardiology Liaison: 508-887-4696

**B6** 

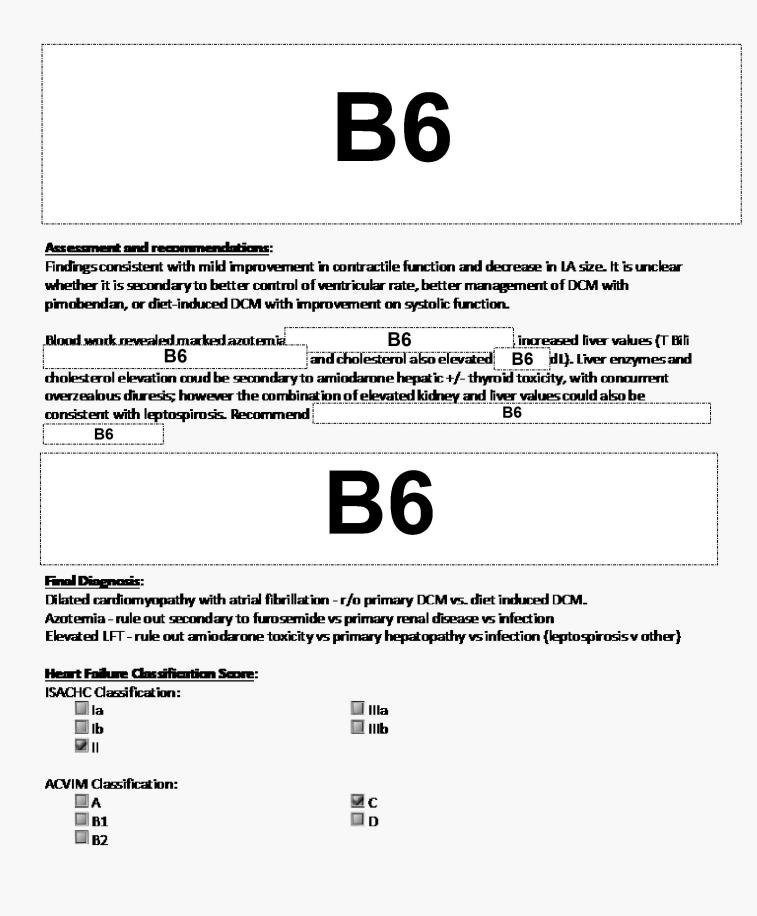
Patient ID: B6
B6 Camine
B6 Years Old Male (Neutered) Doberman
Pinscher
Black/Tan

Cardiology Appointment Report ENROLLED IN DCM DIET STUDY

Date: B6	
Attending Cardiologist	- h I - ) pagings
B6	raininga. DACACC.
Cardiology Technician:	B6
B6	
Presenting Complaint: recheck DCM	
Concurrent Diseases: B6	
	<b>B6</b>



☑ Bottom 1/3 of the neck ☐ Middle 1/3 of the neck	<ul><li>1/2 way up the neck</li><li>Top 2/3 of the neck</li></ul>	
Arterial pulses:  Weak Fair  Good Strong	Bounding Pulse deficits Pulsus paradoxus Other:	
Arrhythmia: slow afib? 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 ainway stridor	
Abdominal exam:  Normal Hepatomegaly Abdominal distension	Mild ascites Marked ascites	
Problems: -DCM  Diagnostic plan:		
Echocardiogram Chemistry profile ECG Renal profile Blood pressure	Dialysis profile Theracic radiographs NT-proBNP Troponin   Other tests:	
	<b>B6</b>	
Mitral inflow:  E waves present only-AFib		
<b>B6</b>		



M Modo		
M-Mode IVSd		cm
LVIDd		om
LVPWd		om
IVSs		
LVIDs		om om
LVPWs		om
EDV(Teich)		ml
ESV(Teich)	<b>B6</b> ′	ml
EF(Teich)		%
%FS		%
SV(Teich)		ml
Max IA		om
TAPSE		om
EPSS		om
LI 33	<u>                                     </u>	u.i
M-Mode Normalized		
IVSdN		(0.290 - 0.520)
LVIDdN		(1.350 - 1.730)
LVPWdN	DC	(0.330 - 0.530)
IVSsN	B6	(0.430 - 0.710)
LVIDsN		(0.790 - 1.140) !
LVPWsN		(0.530 - 0.780)
24. 11.21	<b>4</b>	(about alroa)
<u>2D</u>		
SALA		cm
Ao Diam		cm
SA LA / Ao Diam		
IVSd		cm
LVIDd		cm
LVPWd		om
EDV(Teich)		ml
IVSs		cm
LVIDs		cm
LVPWs		cm
ESV(Teich)		ml
EF(Teich)	D6	%
%FS	<b>B6</b>	%
SV(Teich)		ml
IVSd		cm
LVIDd		cm
EDV(Teich)		ml
LVPWd		om
I <b>V</b> Ss		cm
LVIDs		cm .
ESV(Teich)		ml
EF(Teich)		%
ESV(Cube)		ml
EF(Cube)		%

%FS % SV(Teich) ml SI(Teich) ml/m SV(Cube) ml SI(Cube) ml/m **LVPWs** an LV Major an LV Minor an Sphericity Index **LVLd LAX** am **LVAJ LAX** am **LVEDV A-L LAX** ml **LVEDV MOD LAX** ml **LVL5 LAX B6** an LVAs LAX an **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 **/min** CO A-L IAX CO MOD LAX **//min** R-R ms BPM HR CO A-LIAX **//min** CO MOD LAX l/min <u>Doppler</u> m/s E S' m/s **B6 IVRT** ms **AV Vmax** m/s AV maxPG mmHg

{						
Report Details - EON-	390034					
ICSR:	2067994					
Type Of Submission:	Followup					
Report Version:	FPSR.FDA.PETF.V.V1	)A.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 11:03:47 EDT					
Initial Report Date:	11/09/2018					
Parent ICSR:	2058683					
Follow-up Report to FDA Request:	Yes					
Reported Problem:	Problem Description:	has been eating the reduced cardiac con started taurine supp	agnosed with DCM and CHF. Screening B6 because he same diet. Does not have clearcut DCM on echo but has tractility. Taurine pending and owner has changed diet and lementation			
	Date Problem Started:	11/07/2018				
	Concurrent Medical Problem:	No				
	Outcome to Date:	Better/Improved/Red	covering			
Product Information:	Product Name:	Zignature trout & sa	mon dry			
	Product Type:	Pet Food				
	Lot Number:					
	Package Type:	BAG				
	Product Use Information:	Description:	B6, is four and was born on B6. He ate Zignature trout & salmon from 09/30/15-10/01/18. 1.25 cups twice daily of Zignature. The primary cookies he ate was Earthborn Holistic Grain-Free, all varieties, and he might have had 3-4 cookies per day. The only other cookies he would have eaten were misc. varieties brought by misc. delivery people (propane, UPS, etc.) and not regularly. If we ever had to give medication, we always used the Greenies Pill Pockets.			
	Manufacturer /Distributor Information:					
	Purchase Location Information:					
Animal Information:	Name:	B6				
	Type Of Species:	Dog				
	?)	Retriever - Labrador				
	Gender:	<u></u>				
	Reproductive Status:	Neutered				
		25.9 Kilogram				
		3 Years				
	Assessment of Prior Health:	7				
	Number of Animals Given the Product:	3				
	Number of Animals Reacted:	2				
	Owner Information:	Owner Information provided:				
		Contact:	Name: B6 Phone: B6			

			Email	B6	
		Address:	·	i	
			United States		
	Healthcare Professional	Practice Name:	Tufts Cumming	s School of Veterinary Me	dicine
	Information:	Contact:		Lisa Freeman	
			Phone:	(508) 887-4523	
			Email:	lisa.freeman@tufts.edu	
		Address:	200 Westboro 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@t	ufts.edu	
	Permission To Contact Sender:	Yes			
	Preferred Method Of Contact:				
	Reported to Other Parties:	None			
Additional Documents:					
	Attachment:	Med Records pt 2.pd	df		
		Medical Records  Medical Records			
	Attachment:	Med Records pt 1.pd	1f		
		Medical Records	AI .		
		Medical Records			

From: Carey, Lauren </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F0226BD682844FA2B71EA3750D4FCB82-

LAUREN.CARE>

To: Rotstein, David; Ceric, Olgica; Glover, Mark; Jones, Jennifer L; Nemser, Sarah; Palmer, Lee

Anne; Peloquin, Sarah; Queen, Jackie L

**Sent:** 11/13/2018 8:56:20 PM

Subject: RE: DCM cases- Lisa Freeman and/or Tufts-related- 11/10/18

To stay on the same page: EON-370713 and EON-370715 are 2 pets from the same household reported by Dr. Freeman. EON-370762 is the owner report for this household.

From: Rotstein, David

Sent: Saturday, November 10, 2018 8:56 PM

To: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Glover, Mark

<Mark.Glover@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Nemser, Sarah

<Sarah.Nemser@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Peloquin, Sarah

<Sarah.Peloquin@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>; Rotstein, David

<David.Rotstein@fda.hhs.gov>

Subject: DCM cases- Lisa Freeman and/or Tufts-related- 11/10/18

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













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From: Carey, Lauren </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F0226BD682844FA2B71EA3750D4FCB82-

LAUREN.CARE>

To: Rotstein, David; Ceric, Olgica; Glover, Mark; Jones, Jennifer L; Nemser, Sarah; Palmer, Lee

Anne; Peloquin, Sarah; Queen, Jackie L

**Sent:** 11/19/2018 11:49:14 AM

**Subject:** RE: DCM cases 11/16/2018 1500

EON-371239 is the 2<sup>nd</sup> report for this dog, the 4<sup>th</sup> report for this household. Dr. Freeman submitted a report for each dog (EON-370713 and EON-370715) and the owner has now submitted a report for each dog (EON-370762 and EON-371239).

From: Rotstein, David

Sent: Friday, November 16, 2018 2:59 PM

To: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Glover, Mark

<Mark.Glover@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Nemser, Sarah

<Sarah.Nemser@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Peloquin, Sarah

<Sarah.Peloquin@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>; Rotstein, David

<David.Rotstein@fda.hhs.gov>

Subject: DCM cases 11/16/2018 1500

Please note for (EON370762) EON-371239-Zignature, that there was a report for another dog in the household.

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
CVM OSC/DC/CERT
7519 Standish Place
B6 BB)





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

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

11/9/2018 10:52:44 PM

Subject: Zignature trout & salmon dry: Lisa Freeman - EON-370715

Attachments: 2058683-report.pdf; 2058683-attachments.zip

A PFR Report has been received and PFR Event [EON-370715] has been created in the EON System.

A "PDF" report by name "2058683-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 "2058683-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

**EON Key:** EON-370715

ICSR #: 2058683

**EON Title:** PFR Event created for Zignature trout & salmon dry; 2058683

AE Date	11/07/2018	Number Fed/Exposed	3
Best By Date		Number Reacted	2
Animal Species	Dog	Outcome to Date	Stable
Breed	Retriever - Labrador		
Age	3 Years		
District Involved	PFR-New England DO		

### **Product information**

**Individual Case Safety Report Number: 2058683** 

**Product Group:** Pet Food

**Product Name:** Zignature trout & salmon dry

**Description:** Older housemate diagnosed with DCM and CHF. Screening **B6** because he has been eating the same diet. Does not have clearcut DCM on echo but has reduced cardiac contractility. Taurine pending and owner

has changed diet and started taurine supplementation

**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: 3 Number of Animals Reacted With Product: 2

Product Name	Lot Number or ID	Best By Date
Zignature trout & salmon dry		

# **Sender information**

Lisa Freeman 200 Westboro Rd North Grafton, MA 01536 USA

Owner information	
<b>B</b> 6	
B6	USA

To view this PFR Event, please click the link below: https://eon.fda.gov/eon//browse/EON-370715

To view the PFR Event Report, please click the link below: <a href="https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jspa?decorator=none&e=0&issueType=12&issueId=387684">https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jspa?decorator=none&e=0&issueType=12&issueId=387684</a>

\_\_\_\_\_

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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-	370715			
ICSR:	2058683			
Type Of Submission:	Initial			
Report Version:	FPSR.FDA.PETF.V.V1			
Type Of Report:	Adverse Event (a symptom,	reaction or disease a	associated with the product)	
Reporting Type:	Voluntary			
Report Submission Date:	2018-11-09 17:46:50 EST			
Reported Problem:	Problem Description:	has been eating the	agnosed with DCM and CHF. Screening B6 because he same diet. Does not have clearcut DCM on echo but has tractility. Taurine pending and owner has changed diet and ementation	
	Date Problem Started:	11/07/2018		
	Concurrent Medical Problem:	No		
	Outcome to Date:	Stable		
Product Information:	Product Name:	Zignature trout & sal	mon dry	
	Product Type:			101111111111111111111111111111111111111
	Lot Number:	7		
	Package Type:	BAG		
	Product Use Information:	Description:	trout & salmon from 09/30/15-10/01/18. 1.25 cups twice daily of Zignature. The primary cookies he ate was Earthborn Holistic Grain-Free, all varieties, and he might have had 3-4 cookies per day. The only other cookies he would have eaten were misc. varieties brought by misc. delivery people (propane, UPS, etc.) and not regularly. If vever had to give medication, we always used the Greenies	we
			Pill Pockets.	
	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:	25.9 Kilogram		
	Age:	3 Years		
	Assessment of Prior Health:	Excellent		
	Number of Animals Given the Product:	3		
	Number of Animals Reacted:	2		
	Owner Information:	Owner Information provided:	Yes	
		Contact:	Name: B6	
			Phone: B6	70000000000000000000000000000000000000
			Email: B6	000 000 000 000 000 000 000
		Address:		
			<b>B6</b>	000 000 000 000 000 000 000 000
				000000000000000000000000000000000000000

Address: 200 Westboro Rd North Grafton Massachusetts 01536 United States  Contact: Phone: 5088874523 Email: lisa.freeman@tufts.edu  Permission To Contact Sender: Preferred Method Of Contact: Email	Healthcare Professional Information:  Practice Name: Tufts Cummings School of Veterinary Medicine  Name: Lisa Freeman Phone: (508) 887-4523 Email: lisa freeman@tufts.edu  Address: 200 Westboro Rd North Grafton Massachusetts 01536 United States  Phone: 200 Westboro Rd North Grafton Massachusetts 01536 United States  Phone: 5088874523 Email: lisa.freeman@tufts.edu  Permission To Contact: Sender: Preferred Method Of Contact:  Preferred Method Of Contact: Preferred Method Of Contact: Radditional Documents:  Additional Documents: Additional Documents: Preserved Method Of Contact: Compiled medical record.pdf Records	Healthcare Professional Information:    Contact:   Name:   Lisa Freeman   Phone:   (508) 887-4523   Email:   lisa.freeman@tufts.edu	
Information:   Contact:   Name:   Lisa Freeman   Phone: (508) 887-4523   Email:   lisa.freeman@tufts.edu	Information:   Contact:   Name:   Lisa Freeman   Phone: (508) 887-4523   Email:   lisa.freeman@tufts.edu	Information:   Contact:   Name:   Lisa Freeman   Phone: (508) 887-4523   Email:   lisa. freeman@tufts.edu	
Information:   Contact:   Name:   Lisa Freeman   Phone: (508) 887-4523   Email:   lisa.freeman@tufts.edu	Information:   Contact:   Name:   Lisa Freeman   Phone: (508) 887-4523   Email:   lisa.freeman@tufts.edu	Information:   Contact:   Name:   Lisa Freeman   Phone: (508) 887-4523   Email:   lisa.freeman@tufts.edu	/ledicine
Phone: (508) 887-4523   Email:   sa.freeman@tufts.edu	Phone: (508) 887-4523   Email:   sa.freeman@tufts.edu	Phone: (508) 887-4523   Email:   lisa.freeman@tufts.edu	
Address:   Sender Information:   Address:   200 Westboro Rd   North Grafton   Massachusetts   01536   United States      Name:   Lisa Freeman   200 Westboro Rd   North Grafton   Massachusetts   01536   United States	Address:   Sender Information:   Address:   200 Westboro Rd   North Grafton   Massachusetts   01536   United States      Name:   Lisa Freeman   200 Westboro Rd   North Grafton   Massachusetts   01536   United States	Address:   200 Westboro Rd North Grafton Massachusetts 01536 United States    Name:   Lisa Freeman	
Address: 200 Westboro Rd North Grafton Massachusetts 01536 United States  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: Preferred Method Of Contact: Preferred Method Of Contact: Remail: Resorts Remail: Resorts Remail: Resorts Reso	Address: 200 Westboro Rd North Grafton Massachusetts 01536 United States  Name: 200 Westboro Rd North Grafton Massachusetts 01536 United States  Address: 200 Westboro Rd North Grafton Massachusetts 01536 United States  Contact: Phone: 5088874523 Email: lisa.freeman@tufts.edu  Permission To Contact Sender: Preferred Method Of Contact: Email  Additional Documents: Attachment: compiled medical record.pdf Description: Records	Address: 200 Westboro Rd North Grafton Massachusetts 01536 United States  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: Preferred Method Of Contact: Contact: Email  Additional Documents:  Attachment: compiled medical record.pdf Description: Records	
Address: 200 Westboro Rd North Grafton Massachusetts 01536 United States  Contact: Phone: 5088874523 Email: lisa.freeman@tufts.edu  Permission To Contact Sender: Preferred Method Of Contact: Email  Additional Documents:  Attachment: compiled medical record.pdf Description: Records	Address: 200 Westboro Rd North Grafton Massachusetts 01536 United States  Contact: Phone: 5088874523 Email: lisa.freeman@tufts.edu  Permission To Contact Sender: Preferred Method Of Contact:  Preferred Method Of Contact: Email  Additional Documents: Attachment: compiled medical record.pdf Description: Records	Address: 200 Westboro Rd North Grafton Massachusetts 01536 United States  Contact: Phone: 5088874523 Email: lisa.freeman@tufts.edu  Permission To Contact Sender: Preferred Method Of Contact: Email  Additional Documents:  Attachment: compiled medical record.pdf Description: Records	
North Grafton Massachusetts 01536 United States  Contact: Phone: 5088874523 Email: lisa.freeman@tufts.edu  Permission To Contact Sender: Preferred Method Of Contact:  Additional Documents:  Attachment: compiled medical record.pdf Description: Records	North Grafton Massachusetts 01536 United States  Contact: Phone: 5088874523 Email: lisa.freeman@tufts.edu  Permission To Contact Sender: Preferred Method Of Contact:  Additional Documents:  Attachment: compiled medical record.pdf Records	North Grafton   Massachusetts   01536   United States	
Permission To Contact Sender:   Yes   Preferred Method Of Contact:   Preferred Method Of Co	Email:   lisa.freeman@tufts.edu	Permission To Contact Sender: Preferred Method Of Contact:  Additional Documents:  Attachment: compiled medical record.pdf Description: Records	
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Type:   Medical Records	Type: Medical Records	Type: Medical Records	



# Foster Hospital for Small Animals

55 Willard Street North Grafton, MA 01536 (508) 839-5395

All	Medical	Records

Client: Address: **B6**  Patient: **B6**Breed: Golden Retriever
DOB: **B6** 

Species: Canine
Sex: Male
(Neutered)

Home Phone: B6
Work Phone: -Cell Phone: B6

Referring In	formation
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 		<b>B6</b>	
 · - · - · - · - · - · - · - · - · - · -	•		

Client: **B6** 

#### **Initial Complaint:**

Scanned Record

## **Initial Complaint:**

New - **B6** - DCM study

SOAP Text B6 12:08PM - B6

#### **Disposition/Recommendations**

Cummings	
Veterinary Medical	Center

Client:	B6	
Veterinaria	n:	•
Patient ID:	В6	
Visit ID:		

## Lab Results Report

## Foster Hospital for Small Animals

55 Willard Street North Grafton, MA 01536 (508) 839-5395

Patient:	B6
Species:	Canine
Breed:	Golden Retriever
Sex:	Male (Neutered)
Age:	B6 Years Old

	11/7/2018 1:29:30 PM Ac	cession ID: B6	
Test	Results	Reference Range	Units
Troponin I Research - FHSA	B6	0 - 0.08	mg/dl

3/22 **B6 B6** 

Printed Friday, November 09, 2018

Client: **B6** Patient: В6 RDVM records **B6 B6** 

Client: **B6** Patient: RDVM B6 records **B6 B6** 

Prop 3 H B

Client: **B6** Patient: RDVM **B6** records **B6 B6** 

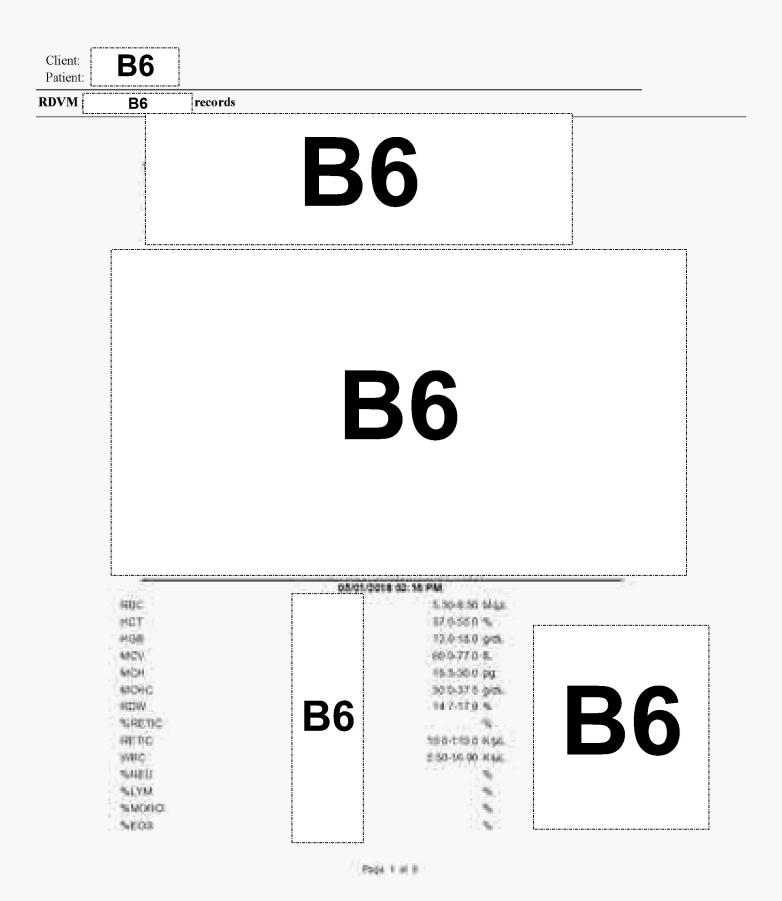
Page 3 at 8

Client: **B6** Patient: **B6** RDVM records **B6 B6** 

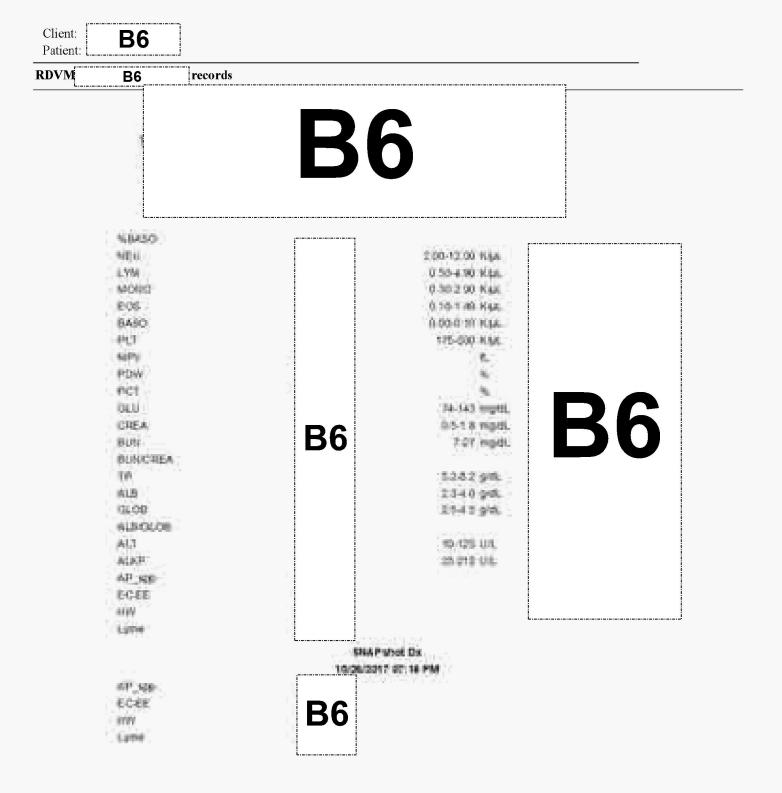
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Client: **B6** Patient: RDVM В6 records **B6 B6** 

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Page 9/22



Page II in B

Page 10/22

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Client: <b>B6</b> Patient:
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RDVM B6 records

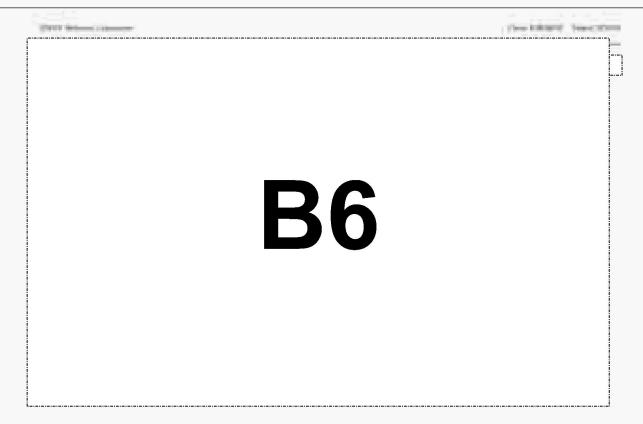
B6  Appearation  Appearation  Local Centile pellon  Base Committee		FECAL AMALY	SIS: (In House)		
		CONTRACTOR	The Armstein		
	В6			7077	
		te lamb lee			**************************************
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	Fecal Co.	diffequitor as well as			
	Okett Sa			z    	
	Parasites				
		9, <b>B</b>			
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	80 :				

Client: **B6** Patient: **RDVM** В6 records 30/18/2016 02:30 PW OLL 34-543 (-44). BUN. 727 mgm. CREA 854 Kingdt **B6** DUNCHEA Dr. :5342 gra. MLS 2340 pm. **B6** (4.08) 2540 例如: ALB/CICOR 10-125 UIL AUL ALKE 25-212-04. AP NO ECEE +110

Page 9 at 8

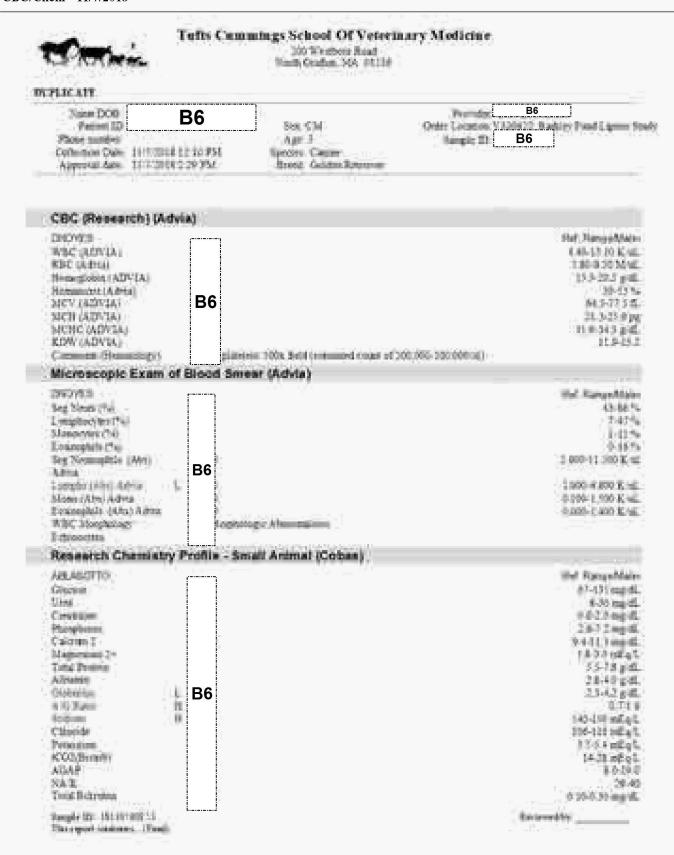
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Section.

#### CBC/Chem - 11/7/2018



Page 16/22

## **CBC/Chem - 11/7/2018**

C. Corne	Tefts Cen	mings School Of Veteri 300 Western Road Smit Grafus, 304 #121#	nary Medicine
OCPLICATE.			
Name DOB Patient ID Phone sundivi Collection Outs Approval Asse	B6 B6 1H NORTH AT 10 FSI 1H HORTH 2 29 FSL	Sick CM Age: 3 Species Course Breed Golden Represent	Great Location VISINE Balling Free Ligner St. Hampis: III B6
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Client: <b>B6</b>		
Vitals Results		
11/7/2018 11:32:13 AM	Weight (kg)	D6

**B6** 



**B6** 

ECG from cardio

**B6** 



**B6** 

ECG from cardio

В6



**B6** 

## **Patient History**

11/05/2018 10:46 AM	Appointment	
11/05/2018 12:36 PM	Appointment	
11/07/2018 10:07 AM	UserForm	
11/07/2018 10:48 AM	UserForm	
11/07/2018 10:53 AM	Treatment	<b>B6</b>
11/07/2018 11:32 AM	Vitals	
11/07/2018 12:08 PM	Purchase	
11/07/2018 12:18 PM	UserForm	
11/07/2018 01:29 PM	Labwork	
11/07/2018 01:30 PM	Purchase	
11/07/2018 01:30 PM	Purchase	
11/07/2018 01:30 PM	Purchase	

From:	PFR Event <pfreventcreation@fda.hhs.gov></pfreventcreation@fda.hhs.gov>		
То:	Cleary, Michael *; HQ Pet Food Report Notification B6		
Sent:	1/1/2019 9:48:33 PM		
Subject:	Orijen grain free original dry: Lisa Freeman - EON-375114	Orijen grain free original dry: Lisa Freeman - EON-375114	
Δttachments	2060741-report pdf: 2060741-attachments zin		

A PFR Report has been received and PFR Event [EON-375114] has been created in the EON System.

A "PDF" report by name "2060741-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 "2060741-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

**EON Key:** EON-375114

ICSR #: 2060741

**EON Title:** PFR Event created for Orijen grain free original dry; 2060741

AE Date	12/28/2018	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Stable
Breed	Doberman Pinscher		
Age	9 Years		
District Involved	PFR-New England DO		

## **Product information Individual Case Safety Report Number: 2060741** Product Group: Pet Food Product Name: Orijen grain free original dry **Description:** DCM and CHF diagnosed 12/28/18 at emergency clinic. Started on B6 Seen by Tufts cardiology 12/31/18. Eating Orijen grain free original dry so unclear if just genetically associated DCM or if diet associated.

**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
Orijen grain free original 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-375114

To view the PFR Event Report, please click the link below:

 $\underline{https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jspa?decorator=none\&e=0\&issueType=12\&issueId=392123$ 

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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.

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.



## **Foster Hospital for Small Animals**

55 Willard Street North Grafton, MA 01536 (508) 839-5395

Client: Address:	B6  Home Phone:	!	Species:	Canine Male
Referring	Work Phone: ( Cell Phone: ( _ Information			
Client:		B6		
Patient:	<b>B6</b>			
4/5/2017 12::  Doctor  Student:  Presenting co	56:09 PM NEW  B6 B6 bomplaint: B6			
HISTORY:				
Current histo jump. Owner gabapentin). one point and not interested	ry: Owner heard took patient to Patient has been I seems painful a I in his food star	jor history; owner mentioned that patient has an enlarged prostate	n (trama atient ye r event.	adol and elped again at Patient was
		B6 some table scraps		
	status/flea & ticl	x preventative use: UTD vaccines; no flea, tick. On heartgard.		
EXAM:		····		
S: O	B6			

Client: <b>B6</b>	
BCS B6  Hydration: B6	
Tryutation: [	
	<b>B6</b>
ASSESSMENT: A1: A2:	B6
PLAN: P1	
Diagnostics completed:	B6
Diagnostics pending:	
Client communication:	B6 B6
DVM summary:	
Deposit & estimate status:	
Resuscitation code (if admitting to ICU):	
SOAP approved (DVM to sign): <b>B6</b>	
4/5/2017 3:48:11 PM: <b>B6</b>	
4/5/2017 3:51:02 PM Prescribed - B6 - FHSA	A (10) urs WITH FOOD for 5 days - Expires: 4/5/2018 No Refills

## **Initial Complaint:**

Emergency

SOAP Text Dec 31 2018 12:26PM - B6	
<b>B6</b> 9yo MC Doberman, presenting for Cardio consult for recent DCM diagnosis	
History: referral for cardiology consult. increased respiratory effort and rate on Friday r who owner reports saw fluid in chest, started on cardio meds for DCM. Patient has bee starting medications.	
Current medications: B6	}
B6 (received all meds this morning)	
Diet: Orijen grain free	
No major previous medical history	
Subjective:	
B6	

C/V: II/VI systolic murmur, tachycardic with irregular rhythm

**B6** 

Assessment:

A1: DCM - r/o genetic vs. diet induced

A2: CHF - r/o secondary to A1

A3: Atrial fibrillation - secondary to A1

Plan:

#### CARDIO CONSULT/CHEST RADIOGRAPH FINDINGS:

Echocardiogram reveals DCM with marked LA enlargement, active CHF, and atrial fibrillation with fast ventricular rate. Since the patient is a Doberman we are more inclined to believe that the origin of the DCM is genetic although the patient is on a grain free diet which could potentially contribute to the markedly decreased systolic function. The patient was officially enrolled in Dr. Freeman's study today and blood was pulled for all of the required test. Chest radiographs revealed persistence of the previously diagnosed CHF and the ventricular rate is still relatively fast.

**B6** 

also be started and the patient should be switched diet. Recheck BW including a digoxin level (especially since the current dose is still on the higher end) and ECG is recommended in 7-10 days. 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 intolerance, or syncope.

Medications:

**B6** 

Taurine supplementation - 1000mg PO BID Diet change - sent home with multiple samples

Recheck exam/BW and EKG in 7-10 days with Cardio

B6 VMD

**Disposition/Recommendations** 

Cummings	
Veterinary Medical	Center

Client:	B6		
Veterinarian:			
Patient ID:	В6		
Visit ID:			

# Foster Hospital for Small Animals

55 Willard Street North Grafton, MA 01536 (508) 839-5395

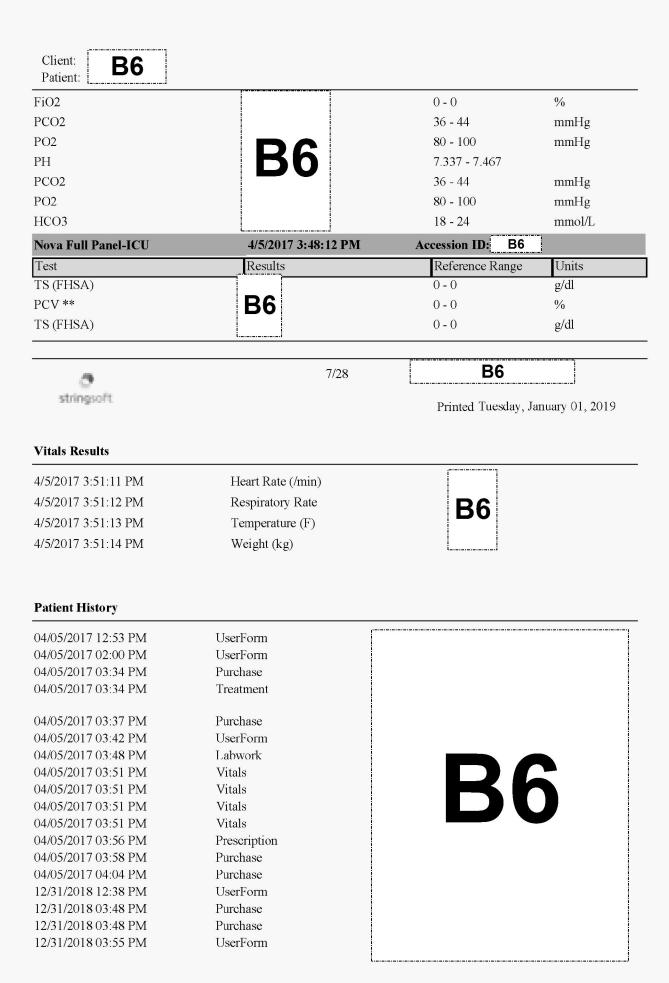
Patient:	B6
Species:	Canine
Breed:	Doberman Pinscher
Sex:	Male
Age:	<b>B6</b> Years Old

# Lab Results Report Age: B6 Years Old Nova Full Panel-ICU 4/5/2017 3:37:25 PM Accession ID: B6 Test Results Reference Range SO2% 94 - 100 HCT (POC) 38 - 48

Units % % HB (POC) 12.6 - 16 g/dL NA (POC) 140 - 154 mmol/L K (POC) 3.6 - 4.8 mmol/L 109 - 120 CL(POC) mmol/L CA (ionized) 1.17 - 1.38mmol/L MG (POC) 0.1 - 0.4mmol/L GLUCOSE (POC) 80 - 120mg/dL LACTATE 0 - 2mmol/L **B6** 12 - 28 BUN (POC) mg/dL CREAT (POC) 0.2 - 2.1mg/dL TCO2 (POC) () - () mmol/L nCA 0 - 0 mmol/L nMG 0 - 0mmol/L GAP 0 - 0 mmol/L CA/MG 0-0 mol/mol **BEecf** 0 - 0mmol/L BEb 0 - 0 mmol/L 0-0 mmHg NOVA SAMPLE 0 - 0

6/28 **B6** 

Printed Tuesday, January 01, 2019



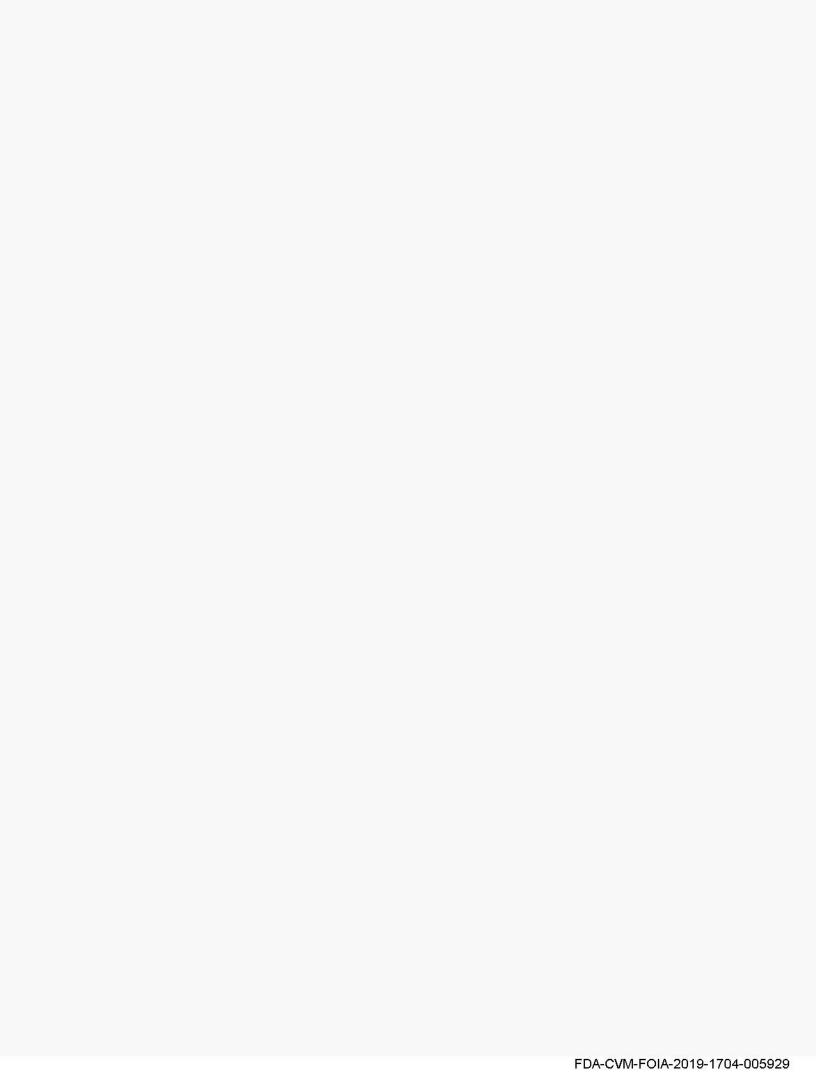
Page 7/28

Client:
Patient:

**B6** 

## **Patient History**

12/31/2018 04:07 PM 12/31/2018 04:07 PM	Treatment Purchase	
12/31/2018 04:13 PM 12/31/2018 05:01 PM	Treatment  Prescription	
12/31/2018 05:04 PM 12/31/2018 05:05 PM 12/31/2018 05:14 PM	Prescription Purchase Deleted Reason	<b>B6</b>
12/31/2018 05:16 PM 01/01/2019 05:31 AM	Purchase UserForm	
01/01/2019 05:36 AM	Email	





**B6** 

**B6** 

Caraine Doberman Prescher BladyTan

Partient ID: B6

#### STANDARD CONSENT FORM

Lamithe owner, or agent for the owner, of the above described animal and have the authority to execute consent. It hereby authorize the Cummings School of Veterinory Medicine at Tults 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 visterinary medical care as they deem researable and appropriate under the circumstances.

Commings School and its officers, agents, and imployers will use all resconding rare in the treatment of the above mentioned animal, but will not be liable for any loss or accident that may occur or any discuse that may develop as a result of the care and treatment provided.

Funderstand that the above identified onimal may be treated by Cummings School students under the supervision and assistance of Cummings School staff members.

in menuting this form, I hardry expressly advowledge 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 threatment without an opportunity for discussion and consideration by me, in the case of the development of any life threatment as required. I make and understand that results cannot be government.

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 againment that may occur.

agreeto pick up the animal when motified that it is musty for related:

in the event the animal is not picked up, and if ten (18) days have expired since a registered letter was sent to the address given above, not flying me to call for the animal, the animal may be sold or otherwise deposed of in a humane manner and the processes applied to the diverges 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 hearby grant to the Cummings School of Weierbury Medicine at Tuffs University, its officers and employees (collectively referred to herein as Cummings School), and its agents and assigns (the Grantees) the irrevolable rights to photographs and images for, and in connection with, a Grantee's medical, scientific, educational, and publicity purposes, by any moses, methods and medic (print and electronic) now known or, in the Misses, developed that the Grantee downs appropriate (provided that each photographs and images may not be used in for profit commercials, unless such commercials are publicating educational programs at Cummings School). As medical and surgical treatment necessitates the removal of treats, cells, fluids or body parts of my animal, I authorite the Grantees to dispose of or use these tissues, cells, fluids or body parts for scientific and educational purposes. funderstand that a FINANCE CHANCE will be applied to all accounts unpoid after 30 days. The FINANCE CHANCE is computed on a morthly rate of L33% per morthly which is an armusi percentage rate of 16% applied to the average daily before constanding, with a minimum less of SSB.

I do further agree that should any payment, or the full amount of the sum stated above, become owndumence than 20 days from the above agreed upon time of payment or payments, the entire bolance shall be considered in default and become due and payable. I further agree to be responsible for any or all collection agreey and/or attorney free secretary to collect the full amount.

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

I have read, understand, and agree to accept the terms and overlitens hereis.

Caratina a	В6	<b>0</b> В6
Osent's address.		B6
	B	6

**Take** 

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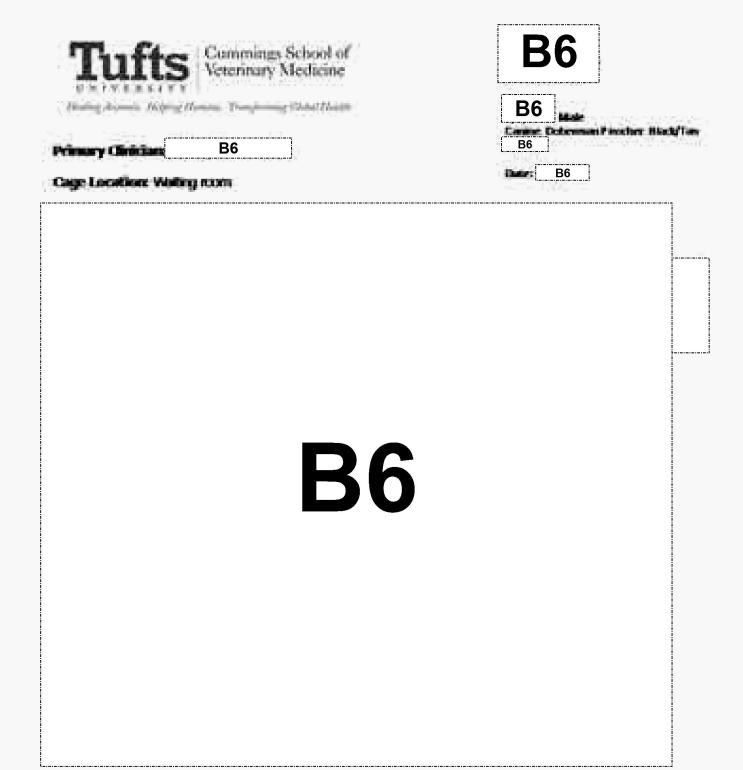
Town/City

If the individual admitting the animal is someone other than the legal cones,

Cketar

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# Cummings Veterinary Medical Center

Emergency & Critical Care. Lamon: (500) 887-4745

Foster Hospital for Small Animals 55 Willard Street Horth Grafton, MA 01536 Telephone (SOS) 839-5375 Fan (SOS) 839-8739 Milty://witnesd.fulls.colu/

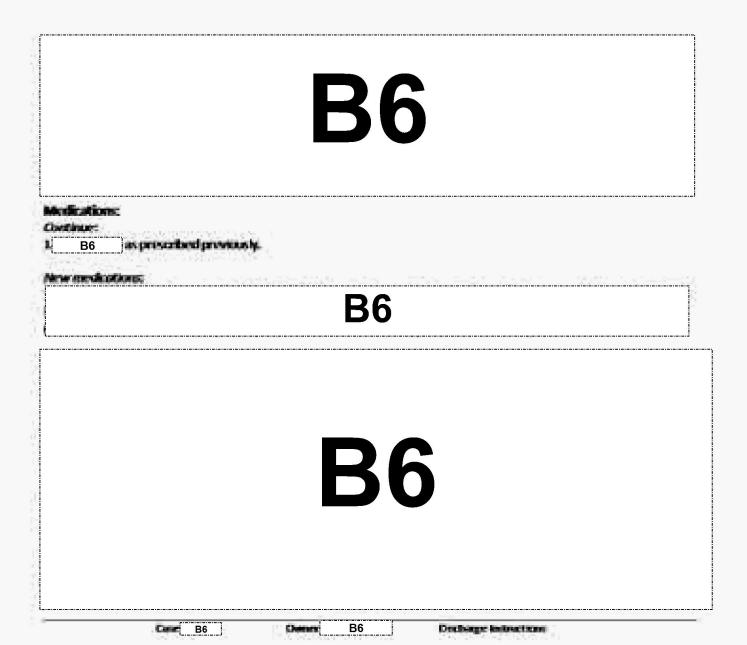
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Emergency Clinicians Consulting Clinicians	В6	marabed \$	any gracy and Oil	
ER Samor säxor:				
		<b>B6</b>		

### Discharge Instructions

Admit Date: 4/5/2017 12:52:11 PM Check Out Date: 4/5/2017

Case Summary Diagnosis:

**B6** 





Forter Hospital for Small Animals 55 Willard Street North Grafton, MA 02526 Telephone (508) 839-5095 Fax (508) 839-7951 Mtp://volumed.kelbs.edu/

### Radiology Request & Report

Putint O	uner:	, <sub>1</sub>
B6 M	B6	Patient Et. B6
The state of the s	Mress B6	Date of request: B6
Blady fan Male Onberman Prostus	<u> </u>	400
B6		
Murraing Chicianc B6 MO	(Intern B6 st.	dut
Date of experc 12/21/18		
Potient Location: Word/Cage: Ex	en room 13	Weight (kg) 43.60
2	Sedition	
Impatient	III BAG	
Outpot lent Time:	I OBAG	group.
Waiting	■ 1/2 dose 0	
in Enurgency		r/Butorphunol
	III Anesthesia	to sedate/anesthetion
Examination Desired: 1 lateral radi	ograph (can do standing	)
Presenting Complaint and Clinical	Questions you wish to a	mwa:
Emergency - r/o OF		
Pertinent History: DCM, had echoo	ardiogram today.	
Findings:		
Conskisions		
Radiologists		
Primary:		
Reviewing		
Dates		
Reported:		



Patient Ct B6
B6 Control
B6 Priors Old Male Dobermon Proches
Block/lan BW World (kg) 43.60

## Cardiology Consultation ENROLLED IN DOM STUDY

Date: 17/31/2018			
Weight: Weight (kg) 43.60			
Requesting Clinician B6	VMD (Intern B6		
Attending Cardiologist			
	DACVIM (Cardiology), DACVE	oc.	
im parit is reast from many	The same test manager, the sec	MAN .	
	<b>B6</b>		
Curdiology Resident:	erionz necessies	<u></u> i	
<b>B6</b>			
Thurnese endingraphs available	e for review?		
W Yes - in SS	AND CONTRACTOR OF		
Wes-in PACS			
III No.			
Petient location: Exam room			
Presenting complaint and imprespiratory effort and rate on chest, started on cardio meds	Friday night (12/28), saw Bosto	on Road who owner reports s	aw fluid in
		RE	<u> </u>
COTTOR INCOLLEGOES INCOME	K		erreadh.
	B6		
At-home diet: (name, form, ar	nount, frequency) Orijen dry d	og food	
Key indication for comultatio	n: (murmur, arthythmia, need	s fluids, etc.) arrbythmia, DC	м
Quantizes to be answered on	y changes to medications/tree	atment plan moving forward	

is your consult time semilive? (c., Tes (coplain):  Who	g., anesthesia today, owner waiting, trying to get biopsy today				
"STOP - comb	"STOP - remainder of form to be filled out by Cardiology"				
Physical Exemination	<u> </u>				
Heart rate: 184	Respiratory rate: Parting				
MIM Color and CRT: Pink, <2sec	BC5 (1-9): 7-8				
Muscle condition:					
M Normal	Moderate cachesia				
Mild muscle lass.	Marked cachesia				
Ourdiovascular Physical Essen					
Murrour Grade:	222/V 1.01				
□ None	□ v/vi				
I⊒ (M	<b>■v/vi</b>				
₩ II/MI	₩ vvv				
□ n(vi					
Moreor location/description: Left	apical systolic				
ugular 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:					
III Weak	□ founding				
iiii Fair	Pulse deficits				
Good	Pulsus paradonus				
Strong	Other (describe):				
Verhythmia: Irregularly irregular	985 N C				
None:	Hradycantia				
Sinus arrhythmia	Tachycardia				
Premature beats					
Sallop:	learn.				
W Yes	Pronounced				
₩ No	Other:				
intermittent					
Vilnouary assessments:	<u>-5</u>				
Tuprick:	Pulmonary Craddles				
Mild dyspness (for a Dobie)	₩heses				
Marked dyspnea	Upper airway strider				
Mormal BV sounds	Other ausoultatory findings:				

# Abdominal exami Mormal Abdominal distansion Mid agains Hepatomegaly **B6** Mittal inflow: Atrial fibrillation Summuted Prostoromal Normal: Restrictive: Delayed resusation **B6** Assessment and recommendations: Echocardiogram reveals OCM with marked LA enlargement, active CHF, and atrial fibrillation with fast

Echocardiogram reveals OCM with marked LA enlargement, active CHF, and atrial fibrillation with fast ventricular rate. Since the patient is a Doberman we are more inclined to believe that the origin of the DCM is genetic although the patient is on a grain free diet which could potentially contribute to the markedly decreased systolic function. The patient was officially enrolled in Dr. Freeman's study today and blood was pulled for all of the required test. Chest radiographs revealed persistence of the previously diagnosed CHF and the ventricular rate is still relatively fast. Recommend making the

**B6** 

Recheck BW including a digotin level (especially since the current dose is still on the higher end) and ECG is recommended in 7-10 days. Recheck echocardiogram is 3 months or sooner if the patient develops clinical signs consistent with worsening heart disease such as increased RR/RE, cough, exercise into learning, or syncope.

Section in Section 1	Mark Company	- side or	and the self-	line or
		100.0		
L ALICE	-			ш.

- DOM with marked reduced contractile functionand active CRF r/o genetic vs. diet related
- Atrial fibrillation with fast wentricular rate

Heart Failure Clausfication Score: ISAO IC Classification:		
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iii b	<b>जि ग</b> र्क	
⊒u		
ACVIM CHF Classification:	ital.	
W A	₩c	
∰ 81	□ p	
∰ 82		



Foster Hospital for Small Annuals SS Willard Street North Graften, MA 01536 Telephone (SOR) 839-5395 Fan (SOR) 839-7951 http://writned.buks.edu/

### Discharge Instructions

Patient	Ow	mar.	
B6	Mar	B6	Patient III B6
Species: Carrier		*** B6	
Black/Tan Male Doberman P	restree		
Bethder B6	222 204 1	THE SECTION SHAPE	
Abeil Date: 12/81/2018 11:2	229 AM		
Obcharge Dates 1/1/2019			
Diagnoses: Dilated cardiomy	opathy (DCM) with c	orgestive heart felure	
Case summary:		erenyere onenn generalen bestellt.	NG CONTRACTOR AND CONTRACTOR AND CONTRACTOR
The state of the s			edonyopathy (DCM). This dease is more
			ols of the heart, reduced cardiocyump OOM will also have significant antischmus
			enlargement has now progressed to the
			Unfortunately this is a progressive disease
			rdiac medications and some dranges to the
des to make your dog comfo	table and have him	breathing cooler.	
Manharine at home			
MERCHANIS ALTONO			
		<b>B6</b>	
Medications:			
		R6	



**B6** 

Royal Carrin Borer
Royal Carrin Borer
Purina Pro Plan Adult Weight Management
Purina Pro Plan Bright Mind Adult Small Breed Formula
Carried Food Options:

Hill's Science Des Adult Beef and Barley Entree: Hill's Science Des Adult 1 & Healthy Curine Rombed Chicken, Carrot, and Spinach Slew

Rosal Caran Mature 8+

We have also sent you have with Taurine for oral supplementation. Pieces give 1000ing by mouth twice shilly.

Larrice Recommendations:

Dry Fond Optome:

For the first 7 to 10 days after starting medications for heart failure we recommend very limited activity. Leach walking or
is ideal, and short walks to start. Oricethe heart failure is better controlled, then slightly lenger 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 wa
are advised in the luture. Repetitive or strengtus high energy activities (repetitive buildhaving, running fast off leach, etc.
are generally not solved at this stage of heart failure.
Recheck Visites
A recheck visit is recommended in 7-bit days for recheck bloodwork and electrocardiagram. At this visit we will check your
doe's breathing effort and heart function, do a blood test to ordreck kidney values, and probably recheck a blood pressure
Ared eak eahocardiagram is resommended in 34 months.
Thank you for entrusting up with B6 care. Plants contact our Cardiology has an at 6003 887-4976 or email us at
codinet(Ptubusku karsakulary and non-emresent questions or concerns.
Company of the control of the contro
Please visit our HoartSmart website for more information
https://sex.tufts.ork/fesortsmont/
Progription to fill Dischings:
For the safety and well-being of our patients, your pet most have had an examination by one of our exteriorrisms within the past
year in order to obtain prescription medications.
Ordering Feed:
Please check with your primary retrementan to purchase the recommended deligit. If you wish to purchase your fixed from or,
please and 7-10 days in advance (508-887-4629) to resure the food a in stock. Alternatively, veteriousy diets can be ordered from
anline retailine with a prescription/interinary approval.
Challed Trible: 11 Sept. 1995. Sept. 1995. Sept. 1995. Sept. 1995. Sept. 1995. Sept. 1995.
Chairol trials are studies in which our veteriousy diction work with you and your pet to investigate a specific disease process or a
promising new test or lieutesent. Please see our website, yet high edufavory/distant shades
Canal B6 Deces: B6 Declarage instructions
2 (4 (4 (4 (4 (4 (4 (4 (4 (4 (4 (4 (4 (4





Forter Hooptal for Small Animals SS Willard Street Horth Grafton, MA 01516 Telephone (SGR) 839-5395 For (SGR) 839-8730 http://setmed.tufts.edu/

В	6
В6	Oobennan Prescher
Black	Conc
B6	

В6	].	
Desar	B6	
significa	ot harb neserolo	scable right-sided neck poin. B6 was inconsistent on ER and Meurology economotises. No peol problems were identified. HOVA was normal. O/c corpories, decontinued transactal, seek appear 2 weeks.
If you be	we any questio	m, or concern, please contact us at 588-887-4988.
Thank ye		
	B6	(Entropincy and Critical Com Parathert)





1/1/2019

Forter Hospital for Small Amena's SS Willard Street North Grafton, MA 01516 Telephone (SGR) 839-5395 For (SGR) 839-7951 http://webmed.tufts.edu/

B6	Main
B6 n	obennan Freuher
Black/Car	į.
B6	

Desar	B6				
Thank you fo	or referring	В6	with their pet	В6	Please see attached client declarge instantions.
If you have	ny quedient	er cook	arno, please cost	ad us	at 500 887-4981.
Thank you.					
B6					