Darcy Adin <dbadin@ncsu.edu>

To: Jones, Jennifer L 2/27/2018 3:36:45 AM Sent:

blr0004.1.pdf Subject: Attachments: blr0004.1.pdf

Hi Jennifer,

From:

B4, B5 Here is

The talk of grain free related DCM is exploding on our list serve. One question people have is related to data collection and I thought I would get your input. Should we as a group:

Thanks for your thoughts! Darcy

From: To: CC: Sent: Subject: Attachments:	Freeman, Lisa <lisa.freeman@tufts. -="" 11:26:51="" 2018="" 27="" 4="" 4-27-18="" adin;="" anne;="" cases="" darcy="" david;="" dcm="" delan="" diet="" external.doc<="" form="" history="" jennifer="" jones,="" joshua="" l;="" norris,="" pm="" proposed="" rotstein,="" th=""><th>a A Stern; Fries, Ryan C; cey, Siobhan; Ceric, Olgica</th><th>B5, B6</th></lisa.freeman@tufts.>	a A Stern; Fries, Ryan C; cey, Siobhan; Ceric, Olgica	B5, B6
Hi everyone	dist history Comp.	B5	į
I'm attaching a proposed	B5		
	u have any comments – I know this is py patterns as well as provide information		
	B\$	_	
Once I get some input fro	om you, I can make into a fillable form	so we can send out electronica	dly.
Our group also discussed	a	B5	
Thanks Lisa			
Lisa M. Freeman, DVM, Professor Cummings School of Vet Friedman School of Nutr Tufts Clinical and Transla Tufts University www.petfoodology.org	erinary Medicine ition Science and Policy		
Sent: Friday, April 20, 20	@ncsu.edu>; Freeman, Lisa <lisa.free< th=""><th></th><th>ern <jstern@ucdavis.edu>;</jstern@ucdavis.edu></th></lisa.free<>		ern <jstern@ucdavis.edu>;</jstern@ucdavis.edu>
Cc: Rotstein, David <da <siobhan.delancey@fda<="" td=""><th>i vid.Rotstein@fda.hhs.gov&gt;; Norris, Ar .hhs.gov&gt;; Ceric, Olgica <olgica.ceric ith Dr. Adin re: DCM cases</olgica.ceric </th><th>9</th><th>v&gt;; DeLancey, Siobhan</th></da>	i vid.Rotstein@fda.hhs.gov>; Norris, Ar .hhs.gov>; Ceric, Olgica <olgica.ceric ith Dr. Adin re: DCM cases</olgica.ceric 	9	v>; DeLancey, Siobhan
My apologies for the repe just email me a spreadshe	eat email. After further internal discusset with the data.	ion, in lieu of submitting Cons	umer Complaints, you can
Jennifer Jones, DVM Veterinary Medical Officer Tel: 240-402-5421	«Sage»		
U.S. FOOD & DRUG			
From: Jones, Jennifer L Sent: Friday, April 20, 20	018 1·19 PM		
To: 'Darey Adin' < dbadin	n@ncsu.edu>; Freeman, Lisa < <u>lisa.free</u>		ern < <u>jstern@ucdavis.edu</u> >;
Fries, Ryan C < rfries@ill	inois.eau>;	B5, B6	

Cc: Rotstein, David < <u>David.Rotstein@fda.hhs.gov</u>>; Norris, Anne < <u>Anne.Norris@fda.hhs.gov</u>>; DeLancey, Siobhan < <u>Siobhan.Delancey@fda.hhs.gov</u>>; Ceric, Olgica < <u>Olgica.Ceric@fda</u>.hhs.gov>

Subject: RE: hold-call with Dr. Adin re: DCM cases

Thank you again for joining us on the call and providing the information about your cases. To help us catalogue and potentially act on these adverse events, please file an official consumer complaint. Instructions on how to report a pet food report can be found at: https://www.fda.gov/AnimalVeterinary/SafetyHealth/ReportaProblem/ucm182403.htm. The complaint can be submitted through the Safety Reporting Portal: https://www.safetyreporting.hhs.gov. You can attach documents already created that compile your case data. We will review the data and may contact you for possible follow-up.

In the meantime, if you have a dog with DCM on a grain free diet that dies or is euthanized, please do not dispose of the animal's body or any remaining food. Please submit an individual consumer complaint for that dog, and mention that you have been instructed to submit the report by Vet-LIRN. We will review the complaint for potential follow-up and may be able to offer a necropsy. I attached a copy of our Vet-LIRN network procedures that describe how we operate. I also included a version for animal owners.

Please email or call me with any questions. Thank you again for your time and expertise, Jen

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



From: Darcy Adin [mailto:dbadin@ncsu.edu] **Sent:** Thursday, April 19, 2018 11:00 AM

To: Freeman, Lisa < lisa.freeman@tufts.edu>; Joshua A Stern < jstern@ucdavis.edu>; Fries, Ryan C < rfries@illinois.edu>; B5, B6 Jones, Jennifer L

<<u>Jennifer.Jones@fda.hhs.gov</u>>

Cc: Rotstein, David <David Rotstein@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancev, Siobhan

<Siobhan.Delancey@fda.hhs.gov>

Subject: Fwd: hold-call with Dr. Adin re: DCM cases

Dear Dr. Jones,

Drs. B5, B6 Freeman B5, B6 Fries and Stern - the call details are in the forwarded email below.

Just a brief introduction for the FDA group:

**B6** 

Dr. Lisa Freeman is a Professor of Clinical Nutrition at Tufts University, College of Vet Med

**B5**, **B6** 

Dr. Ryan Fries is a Clinical Assistant Professor of Cardiology at Illinois, College of Vet Med Dr. Josh Stern is an Associate Professor of Cardiology at UC Davis, College of Vet Med

Thank you everyone for making time in your schedule! I am looking forward to this.

Sincerely,

 Forwarded	message	

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

Date: Thu, Apr 19, 2018 at 7:16 AM

Subject: hold-call with Dr. Adin re: DCM cases

To: "Rotstein, David" < <u>David.Rotstein@fda.hhs.gov</u>>, "Norris, Anne" < <u>Anne.Norris@fda.hhs.gov</u>>, "DeLancey,

Siobhan" <Siobhan.Delancey@fda.hhs.gov>, Darcy Adin <dbadin@ncsu.edu>

-- Do not delete or change any of the following text. --

# Join WebEx meeting

Meeting number (access code) **B6**Meeting password: **B6** 

## Join by phone

B6 US Toll US Toll Free

Global call-in numbers | Toll-free calling restrictions

Can't join the meeting?

If you are a host, go here to view host information.

IMPORTANT NOTICE: Please note that this WebEx service allows audio and other information sent during the session to be recorded, which may be discoverable in a legal matter. By joining this session, you automatically consent to such recordings. If you do not consent to being recorded, discuss your concerns with the host or do not join the session.

\_.

Darcy B. Adin, DVM, DACVIM (Cardiology) Clinical Assistant Professor of Cardiology North Carolina State University NC State Veterinary Hospital 1060 William Moore Drive Raleigh, NC 27607 919-513-6032 From: PFR Event <pfreventcreation@fda.hhs.gov>

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

Sent: 8/5/2018 1:32:12 AM

Subject: Acana Pork and Squash: B6 EON-361371

Attachments: 2053236-report.pdf

A PFR Report has been received and PFR Event [EON-361371] has been created in the EON System.

A "PDF" report by name "2053236-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report:

**EON Key:** EON-361371

ICSR #: 2053236

EON Title: PFR Event created for Acana Pork and Squash; 2053236

AE Date	04/12/2016	Number Fed/Exposed	2
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Unknown
Breed	Retriever - Golden		
Age	4 Years		
District Involved	PFR- <b>B6</b> DO		

### **Product information**

**Individual Case Safety Report Number: 2053236** 

Product Group: Pet Food

Product Name: Acana Pork and Squash

**Description:** This is not an event that suddenly occurred. My dog was diagnosed with dilated cardiomyopathy at 2 years old. I enrolled him in the taurine deficient study done by Dr. Joshua Stern at UC Davis. He was eating Acana Pork & Squash since he was a puppy. His taurine was tested (4-18) and his whole blood is 135 and plasma 28. Since his taurine level is low, I was told to supplement him with taurine and take him off the current dog food. I was told his food could cause taurine deficient dilated cardiomyopathy. He will be re-tested in the upcoming months. It is not know at this time if the dog food contributed to his disease or caused it. The study is still on going.

**Submission Type:** Initial

**Report Type:** Adverse Event (a symptom, reaction or disease associated with the product)

Outcome of reaction/event at the time of last observation: Unknown

Number of Animals Treated With Product: 2 Number of Animals Reacted With Product: 1

Sender information

Product Name	Lot Number or ID	Best By Date
Acana Pork and Squash		

Schuci midimution
<b>B6</b>
USA
USA
To view this PFR Event, please click the link below:
B6
<b>D0</b>
To view the PFR Event Report, please click the link below:
20 Mar 2012 - San Salpan, Pranta and Mar 2010 M.

**B6** 

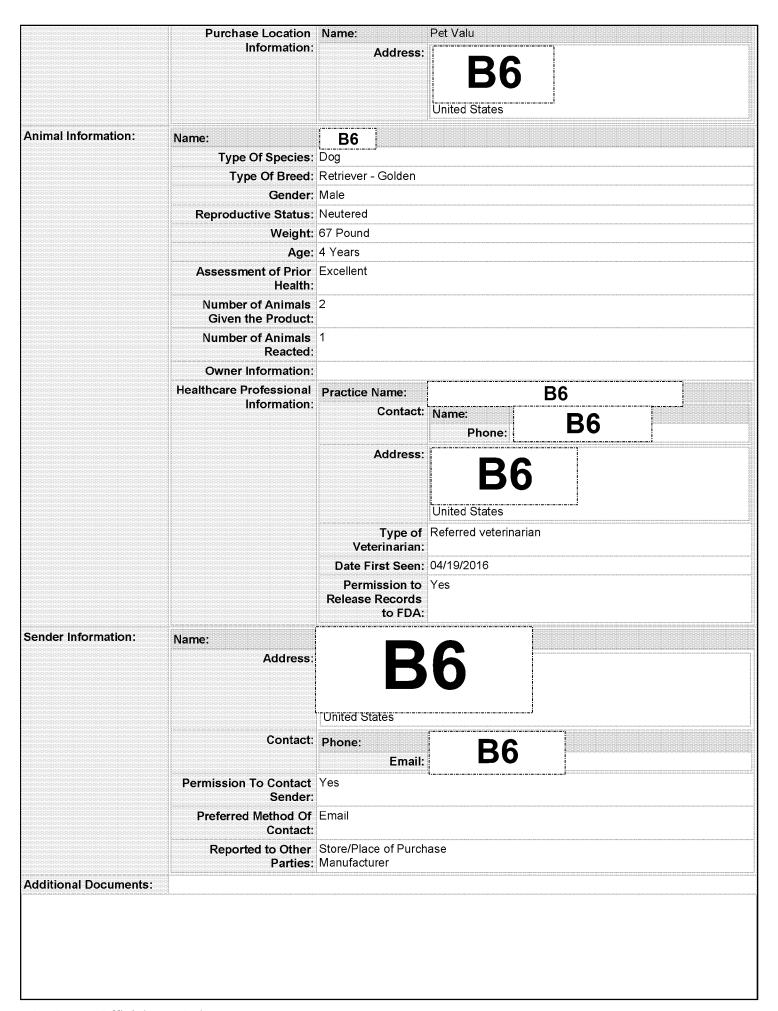
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Report Details - EON-	361371				
ICSR:	2053236				
Type Of Submission:	Initial				
Report Version:	FPSR.FDA.PETF.V.V1				
Type Of Report:	Adverse Event (a symptom,	reaction or disease a	associated with the product)		
Reporting Type:	Voluntary				
Report Submission Date:	2018-08-04 21:25:50 EDT	an naan nakaa a naa a kiraa n maa ka naa a naasi a naa a naasi a naa a nasi a			
Reporter is the Animal Owner:	Yes				
Reported Problem:	Problem Description:	This is not an event that suddenly occurred. My dog was diagnosed with dilated cardiomyopathy at 2 years old. I enrolled him in the taurine deficient study done by Dr. Joshua Stern at UC Davis. He was eating Acana Pork & Squash since he was a puppy. His taurine was tested (4-18) and his whole blood is 135 and plasma 28. Since his taurine level is low, I was told to supplement him with tauring and take him off the current dog food. I was told his food could cause taurine deficient dilated cardiomyopathy. He will be re-tested in the upcoming months. It is not know at this time if the dog food contributed to his disease or caused it. The study is still on going.			
	Date Problem Started:	: 04/12/2016			
	Concurrent Medical Problem:				
	Outcome to Date:	Unknown			
Product Information:	Product Name:	Acana Pork and Squash  duct Type: Pet Food			
	Product Type:				
	Lot Number:	ot Number:			
	Package Type:	: BAG			
	Package Size:				
	Purchase Date:				
	Number Purchased:	1			
	Possess Unopened Product:				
	Possess Opened Product:	77 77 77 77 77 77			
	}	The product is stored	d in it's original bag and then placed in a air tight container.		
	Product Use	Description:	The product was feed 2xs per day.		
	Information:	Last Exposure Date:			
		Product Use Stopped After the Onset of the Adverse Event:	Yes		
		Adverse Event Abate After Product Stop:	Unknown		
		Product Use Started Again:	No		
		Perceived Relatedness to Adverse Event:	Possibly related		
		Other Foods or Products Given to the Animal During This Time Period:	Yes		
	Manufacturer /Distributor Information:				



Report Details - EON-	367777			
ICSR:	2055744			
Type Of Submission:	Initial			
Report Version:	FPSR.FDA.PETF.V.V1			
Type Of Report:	Both			
Reporting Type:	Voluntary			
Report Submission Date:	.) 			
Reporter is the Animal Owner:	Yes			
Reported Problem:	Problem Description:	taken to the emerger misdiagnosis. On they performed Chesheart was enlarged a of Lasix, and placed cardiologist. On Emergency Vet Hosp Vet Cardiologist, unc Diagnosed with Dilat was related to the gr for treatment and oxporting up the next day recommended transf	ncy vet and B6 he was at X-ray and and he was on 3 medica 6 his sym bital and wa lerwent a hi ed Cardiom ain free diet ygen. He en or. The next i erring to the	was diagnosed with Kennel Cough, which was a as seen by his vet, B6 in B6 where bloodwork and it was determined that B6 in Congestive Heart Failure. He was given a shot ations and I was told he should be seen by a ptoms worsened and he was take. Back to the skept over night. On B6 he saw B4, B6 story and an echocardiogram where he was yopathy and the vet reported that he believed it. He kept him in the hospital in B4, B6 overnight couraged me to buy Taurine and L-Carnitine and morning, B6 B6 was worse and they a ICU at B4, B6 On B6 thanized as he was not responding to treatments.
	Date Problem Started:	29;	i s	
	Concurrent Medical Problem:	}l		
	Pre Existing Conditions:	He has seasonal and indoor allergies and was on Apoquel and Allergy injections. He may have had food allergies. He was placed on the grain free food 3-4 years ago. He was health and active. He was on ACANA SINGLES LIMITED INGREDIENT LAMB AMD APPLE AND SOMETIMES DUCK AND PEAR FOR THE PAST 3-4 YEARS EXCLUSIVELY.		
	Outcome to Date:	Died Euthanized		
	Date of Death:	B6		
Product Information:	Product Name:	Acana Singles Limite	d Ingredien	t Lamb and Apple 25 pound bag
	Product Type:	;	o migrouron	, Zamb and Apple Zo pound 20g
	Lot Number:			
	Package Type:	BAG		
	Package Size:	<u></u>		
	Purchase Date:	<u> </u>		
	Number Purchased:	<u></u>		
	Possess Unopened Product:	4		
	Possess Opened Product:	Yes		
	Storage Conditions:			tight and waterproof container in the basement. A an airtight container on the kitchen.
	Product Use Information:	Description:  Last Exposure Date:	B6 ate B6	1 1/4 cup divided into two meals per day.
		Time Interval between Product Use and Adverse Event:		
		Product Use Stopped After the Onset of the Adverse Event:	Yes	

		Adverse Event	Not Applicable
		Abate After	
		Product Stop:	
		Product Use Started Again:	
		Perceived	Definitely related
		Relatedness to Adverse Event:	
		Other Foods or Products Given	No
		to the Animal During This Time Period:	
	Manufacturer		
	/Distributor Information:		
	Purchase Location	Name:	Perflow.com
	Information:	Address:	United States
Animal Information:	Name:	B6	
	Type Of Species:	Dog	
	Type Of Breed:	Spaniel - Cocker Am	nerican
	Gender:	Male	
	Reproductive Status:	Neutered	
	Weight:	28 Pound	
	Age:	5 Years	
	Assessment of Prior Health:	Excellent	
	Number of Animals Given the Product:	1	
	Number of Animals Reacted:	1	
	Owner Information:		
	Healthcare Professional Information:		
Sender Information:	Name:	B6	
	Address:		
		<b>B6</b>	
		United States	
	Contact:	Phone:	B6
		Other Phone:	
		Email:	B6
	Permission To Contact Sender:	Yes	
	Preferred Method Of Contact:	Phone	
	Reported to Other Parties:	Other	
Additional Decimands	Falues.		
Additional Documents:			

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

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

DROTSTEI>

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

Anne; Peloquin, Sarah; Queen, Jackie L; Rotstein, David

 Sent:
 10/26/2018 12:30:01 PM

 Subject:
 DCM cases 10/26/2018 0827

Attachments: Blue Wilderness: B6 - EON-369415; Nov 2015-Nov 2017: Nature's Variety Instinct

Limited Ingredient Lamb-Nov 2017- Aug 2018: Blue Buffalo Basics Grain Free-Aug 2018-Oct 2018: American Journey Lamb and Sweet Potato: B6 - EON-369375; taste of the wild

grain free pacific stream-taste of the wild prey trout limited ingredients: B6

EON-369346; Taste of the Wild High Prairie: Lisa Freeman - EON-369325; WELLNESS CORE

GRAIN FREE: **B6** - EON-369373

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





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From: PFR Event <pfreventcreation@fda.hhs.gov>
To: Cleary, Michael \*; HQ Pet Food Report Notification; B6 .com
Sent: 10/26/2018 11:32:24 AM
Subject: Blue Wilderness: B6 - EON-369415

A PFR Report has been received and PFR Event [EON-369415] has been created in the EON System.

2058021-report.pdf

A "PDF" report by name "2058021-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report:

**EON Key:** EON-369415

Attachments:

ICSR #: 2058021

EON Title: PFR Event created for Blue Wilderness; 2058021

AE Date	01/01/2016	Number Fed/Exposed	1
Best By Date		Number Reacted	1
<b>Animal Species</b>	Dog	Outcome to Date	Died Euthanized
Breed	Retriever - Labrador		
Age	11 Years		
District Involved	PFR <b>B6</b> DO		

### **Product information**

**Individual Case Safety Report Number: 2058021** 

Product Group: Pet Food

**Product Name:** Blue Wilderness

**Description:** When the dog was 9 years old she started limping periodically. Had some gas. I looked for a grain free, soy free food with glucosamine. We decided on Blue Wilderness. In two years the dog had to be Euthanized for a grain grant feeture.

for a enlarged heart/congestive heart failure.

**Submission Type:** Initial

Report Type: Both

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

<b>Product Name</b>	Lot Number or ID	Best By Date
Blue Wilderness		

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

<u>Sender</u>	infor	<u>mation</u>
	R	6

USA

	B6			
To view the PFR E	vent Report, pleas	e click the link below:		
		B6	 	
		Ъ	 	

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Report Details - EON-	369415				
ICSR:	2058021				
Type Of Submission:	Initial				
Report Version:	FPSR.FDA.PETF.V.V1				
Type Of Report:					
Reporting Type:	Both				
	Voluntary				
	2018-10-26 07:25:05 EDT				
Reporter is the Animal Owner:	Yes				
Reported Problem:	Problem Description:	looked for a grain free	years old she started limping periodically. Had some gas. I e, soy free food with glucosamine. We decided on Blue ears the dog had to be Euthanized for a enlarged heart ure.		
	Date Problem Started:				
	Concurrent Medical Problem:	Unknown			
	Outcome to Date:	Died Euthanized			
	Date of Death:	preservation and the second second			
Product Information:	Product Name:	Blue Wilderness			
	Product Type:				
	Lot Number:				
	Package Type:				
	Package Size:	}			
	Possess Unopened Product:	No			
	Possess Opened Product:	No			
	Storage Conditions:	Dog food container			
	Product Use		Fed 2x's per day total of 4 cups		
	Information:	[ [	Probably related		
	Manufacturer /Distributor Information:	£			
	Purchase Location Information:				
Animal Information:	Name:	В6			
	Type Of Species:	·			
	3}	Retriever - Labrador			
	Gender:	) }			
	Reproductive Status:				
	2)	70 Pound			
	3	: 70 Pound : 11 Years			
	Assessment of Prior Health:	<b>r</b> Good			
	Number of Animals Given the Product:	1			
	Number of Animals Reacted:	1			
	Owner Information:	4			
	Healthcare Professional Information:				
Sender Information:	Name:	B6			

	Address:	DC		
		<b>B6</b>		
		United States		
	Contact:	Phone:	B6	
		Email:	B6	
	Reporter Wants to Remain Anonymous:	No		
	Permission To Contact Sender:			
	Preferred Method Of Contact:	Email		
	Reported to Other Parties:	None		
Additional Documents:				

From: PFR Event creation@fda.hhs.gov> To: Cleary, Michael \*; HQ Pet Food Report Notification; com **B6** Sent: 10/25/2018 8:01:06 PM Nov 2015-Nov 2017: Nature's Variety Instinct Limited Ingredient Lamb-Nov Subject: 2017- Aug 2018: Blue Buffalo Basics Grain Free-Aug 2018-Oct 2018: American Journey Lamb and Sweet Potato: В6 - EON-369375 Attachments: 2057993-report.pdf; 2057993-attachments.zip

A PFR Report has been received and PFR Event [EON-369375] has been created in the EON System.

A "PDF" report by name "2057993-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 "2057993-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

**EON Key:** EON-369375

ICSR #: 2057993

**EON Title:** PFR Event created for Nov 2015-Nov 2017: Nature's Variety Instinct Limited Ingredient Lamb Nov

2017- Aug 2018: Blue Buffalo Basics Grain Free Aug 2018-Oct 2018: American Journey Lamb and Sweet

Potato; 2057993

AE Date	10/02/2018	Number Fed/Exposed	1
Best By Date		Number Reacted	1
<b>Animal Species</b>	Dog	Outcome to Date	Stable
Breed	Mixed (Dog)		
Age	4 Years		
District Involved	PFR <b>B6</b> DO		

#### Product information

**Individual Case Safety Report Number: 2057993** 

**Product Group:** Pet Food

**Product Name:** Nov 2015-Nov 2017: Nature's Variety Instinct Limited Ingredient Lamb Nov 2017- Aug 2018:

Blue Buffalo Basics Grain Free Aug 2018-Oct 2018: American Journey Lamb and Sweet Potato

Description: 02 Oct 2018 - presented for routine exam. A new grade II/VI murmur was noted. 13 Oct 2018 -

presented to a different veterinarian for 2nd opinion for the heart murmur. Chest rade no signs of heart failure. A limited cardiac ultrasound revealed dilatation of all 4 heart myocardial contractility. Suspected grain free diet DCM. Changed diet to Purina Pro L-Carnitine 1 g BID, Taurine 500 mg BID and referred to B6 for further work II/VI left apical systolic murmur ausculted; no arrhythmias. Echocardiogram revealeright atria, moderately dilated left ventricle, decreased LV systolic function. Elevated on doppler. Blood pressure, thyroid panel, platelet count and troponin levels all norm taurine level sent to B6 still pending 25 Oct 2018. Diagnosis: Dilated Cardion Submission Type: Initial Report Type: Both  Outcome of reaction/event at the time of last observation: Stable Number of Animals Treated With Product: 1  Number of Animals Reacted With Product: 1	ort chambers with Plan Lamb and Pup. 17 Oct 2018 and mildly dilated the left filling pressonal. Blood submi	poor Rice. Rx: : Grade left and sures based
Product Name	Lot Number or ID	Best By Date
Nov 2015-Nov 2017: Nature's Variety Instinct Limited Ingredient Lamb Nov 2017- Aug 2018: Blue Buffalo Basics Grain Free Aug 2018-Oct 2018: American Journey Lamb and Sweet Potato		
Sender information  B6		
Owner information  B6  USA		
To view this PFR Event, please click the link below:  B6		
To view the PFR Event Report, please click the link below:		

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Report Details - EON	_369375		
ICSR:	2057993		
Type Of Submission:	Initial		
Report Version:	Initial FPSR.FDA.PETF.V.V1		
Type Of Report:	Both		
Reporting Type:	Voluntary		
Report Submission Date			
Reported Problem:		02 Oat 2019 presented for routing every A new grade IIA/I murrous was noted	
Reported Problem.	Problem Description:	02 Oct 2018 - presented for routine exam. A new grade II/VI murmur was noted. 13 Oct 2018 - presented to a different veterinarian for 2nd opinion for the heart murmur. Chest rads revealed cardiomegaly but no signs of heart failure. A limited cardiac ultrasound revealed dilatation of all 4 heart chambers with poor myocardial contractility. Suspected grain free diet DCM. Changed diet to Purina Pro Plan Lamb and Rice. Rx: L-Carnitine 1 g BID, Taurine 500 mg BID and referred to B6 for further work up. 17 Oct 2018: Grade II/VI left apical systolic murmur ausculted; no arrhythmias. Echocardiogram revealed mildly dilated left and right atria, moderately dilated left ventricle, decreased LV systolic function. Elevated left filling pressures based on doppler. Blood pressure, thyroid panel, platelet count and troponin levels all normal. Blood submitted for taurine level sent to B6 still pending 25 Oct 2018. Diagnosis: Dilated Cardiomyopathy.	
	Date Problem Started:	10/02/2018	
	Concurrent Medical Problem:	No	
	Outcome to Date:	Stable	
Product Information:	Product Name:	Nov 2015-Nov 2017: Nature's Variety Instinct Limited Ingredient Lamb Nov 2017-Aug 2018: Blue Buffalo Basics Grain Free Aug 2018-Oct 2018: American Journey Lamb and Sweet Potato	
	Product Type:	Pet Food	
	Lot Number:		
	Package Type:	BAG	
	Package Size:	14 Pound	
	Possess Unopened Product:	No	
	Possess Opened Product:	A contract of the contract of	
	Storage Conditions:	Room temperature in kitchen pantry	
	Product Use Information:	Description: Oral administration  Perceived Probably related  Relatedness to Adverse Event:	
	Manufacturer /Distributor Information:		
	Purchase Location Information:		
Animal Information:	Name:	B6	
	Type Of Species:	ļ <b>t</b>	
	Type Of Breed:	Mixed (Dog)	
	Gender:	Female	
	Reproductive Status:	Neutered	
	Weight:	15.9 Kilogram	
	Age:	4 Years	
	Assessment of Prior Health:	Excellent	
	Number of Animals Given the Product:	1	

	Owner Information:	Owner Information provided:	Yes
		Contact:	Name: B6  Phone: B6  Email: B6
		Address:	
			United States
ŀ	Healthcare Professional	Practice Name:	B6
	Information:	Contact:	
		Type of	Primary/regular veterinarian
		Veterinarian:	
		Permission to Release Records to FDA:	Yes
Sender Information:	Name:	В6	
	Address:		B6
		United States	
	Contact:	Phone: Email:	B6 B6
	Reporter Wants to Remain Anonymous:	No	1
	Permission To Contact Sender:	Yes	
	Preferred Method Of Contact:	Email	
	Reported to Other Parties:	None	
Additional Documents:			
1	Attachment:	<b>B6</b> 10.21.2018.pd	
		All medical records  Medical Records	

**B6** 

PENDING DIAGNOSTIC TESTS:

**B6** 

ASSESSMENT:

Thank you for entrusting us with <u>B6</u> care today. Today, <u>B6</u> was diagnosed with dilated cardiomyopathy (DCM). DCM is a disease that affects the muscle of the heart and causes a decrease in the contractility (pumping ability) of the heart. Because the heart is unable to pump with enough force to move blood adequately forward into circulation, a volume overload occurs and the heart dilates to accommodate it. Subsequently, the chambers of the heart become enlarged and the <u>mitral</u> valve leaflets are pulled slightly apart, resulting in back-flow of blood (mitral regurgitation) and the heart murmur ausculted on <u>B6</u> physical exam. <u>B6</u> echocardiogram today showed mild to moderate dilation of her heart chambers, mild mitral valve regurgitationm and mild to moderately diminished pumping ability of her heart.

While the exact mechanism of DCM is currently unknown, dietary deficiencies in the amino acids taurine and carnitine, genetics, infectious and inflammatory conditions, and toxins have all been linked to DCM. Since **B6** is an atypical breed to develop primary (hereditary) DCM and has been on a grain-free diet for the last 3 years, we are concerned for a possible diet associated DCM. This is a diagnosis of exclusion, so to rule out other causes, blood was drawn today for a troponin level and for thyroid testing. Troponin is a biomarker for damage to the muscle of the heart and is elevated in cases of myocardiitis, which can be caused by many things including infectious or inflammatory disease. **B6** troponin level was normal, so an infectious or inflammatory cause of her DCM is unlikely. Thyroid testing was also submitted today, as hypothyroidism can be another cause of DCM.

There has been recent unpublished data suggesting a link between some grain-free diets and cardiomyopathy. Although some of these cases seem related to taurine/carnitine deficiency, others do not, and the reason for this link is not yet clear. Although the mechanism has not been confirmed, one hypothesis is that phytic acid, produced by legumes and lentils (common ingredients in grain-free diets) decreases the absorption of taurine and other essential nutrients from the intestines into the bloodstream. Some animals will show reversibility of their heart disease with supplementation of taurine and carnitine and initiation of a grain-containing diet.

**B6** 

INSTRUCTIONS FOR CARE

**B6** 

# B4, B6

Owner/Agent

Clinicians:

Clinicians:

Clinicians:

Clinical Technicians:

Client Services:

B4, B6

Research Technician

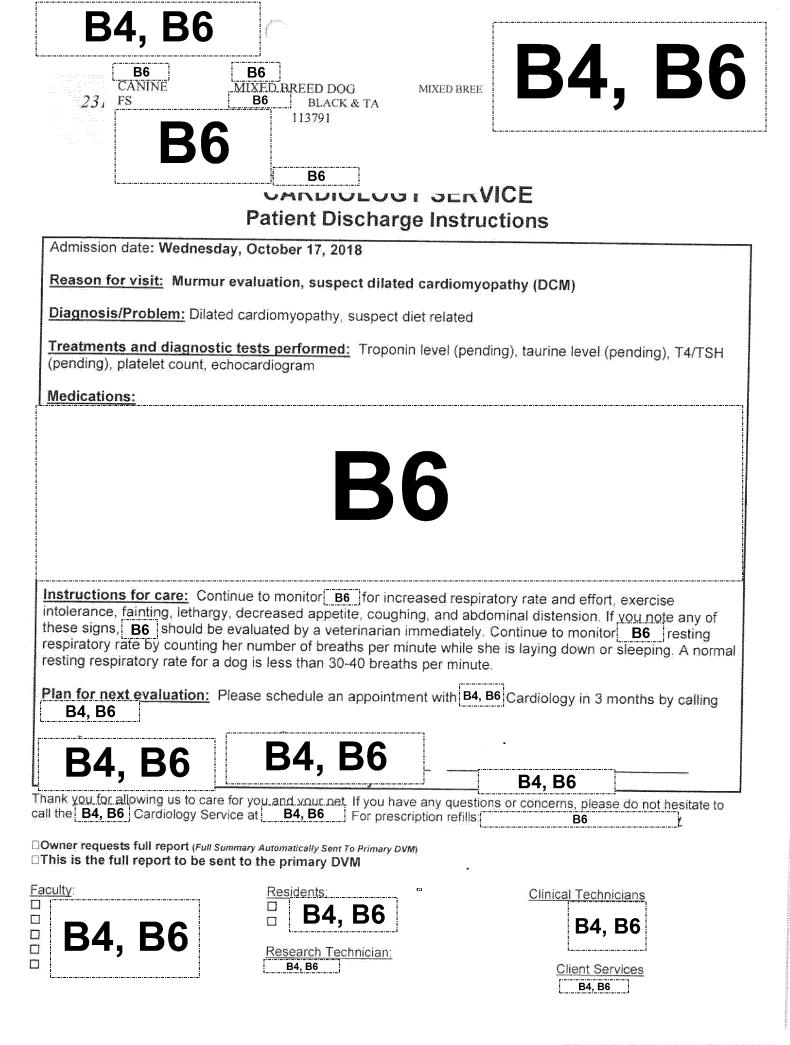
B4, B6

In order to help expedite medication refills, please visit us online at

B4, B6

and select Pet Owners, Pharmacy Refills.

B6



**B4**, **B6** 

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Client:

**B6** 

Owner:

**B6** 

Rovd Date:

10/18/2018 4:31:00 PM

Admitted By:

Not, Provided

Ordered By: Encounter:

CR#

02540503

N/A AP

Animal: Species.

Age:

Other ID:

В6 Canine

3 years

Tag/Reg ID:

MRN:

B6

Breed: Dog Mixed Breed Gender, Female, Spayed

Endocrinology

**Endocrine Results** 

Collected Date/Time

(If Provided)

10/17/2018 16:39:00

Procedure.

Endocrinology Interpretation

Ref Range Units [11-60] nmol/L 0.8-2.1 nmol/L [9-39] pmol/L [0-20] [0-10][0.00-0.58] ng/mL

0,0

[0-35]

See Below

**B6** 

L = Low Result; H = High Result; @ = Critical Result; \*= Corrected Result; \*= Interpretive Data; # = Result Footnote

Print Date/Time: 10/23/2018 10:31 AM

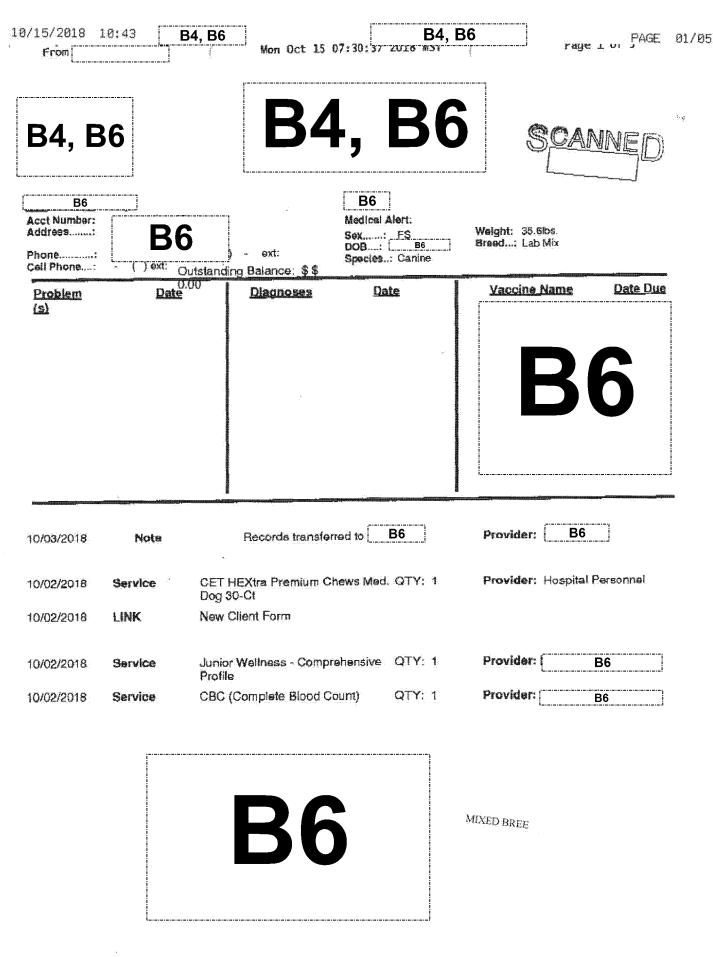
Page 1 of 1

Cardiology Pet Diet History  231020 CANINE MIXED BREED DOG MIXED BREE  B6  Current diet:  B6  Current diet:
Date: 10/16/18  CANINE MIXED BREED DOG MIXED BREE 12/24/14 BLACK & TA 113791  CANINE MIXED BREED DOG MIXED BREE BLACK & TA 113791  B6  Current diet:
Current diet:
and American Tours 100 100
Brand American Journey Lamb & Sucet Potato
Variety Limited Ingredient Grain-Free
Is this diet Grain-free? Yes
How long has your pet eaten this food? 3 months (Aug 18-Oct 18)  Are there other pets in your house eating this food? Yes, puppy version for 5 mo.  Goldendoodle, B6
Other diets eaten in the last 3 years and dates:  (Nov17 - Ava 18) Blue But Color discourse to the control of the potato
5 DIVE DUFFAID aither Chit Versions of basic, lifesoura & fradom (mostly basics)
(Nov 15-Nov17) Nature's Variety Instinct Limited Ingredient Lamb
First zmonths after adoption tried z or 3 foods that caused major diarrhea avomi so claimed allergic to chicken and started on Grain-free, chicken-free diet. No more DorV. Other food (treats, rawhides, table food):
No rawhides. Not too many treats. Occasional table food (rare).
Have given Better Belly chews, dental chews (milk bone, pentastix, Nylabone Nutri Dent)
Supplements (e.g. fish oil, CoQ10, vitamins etc) > all very fewand for between.
None -

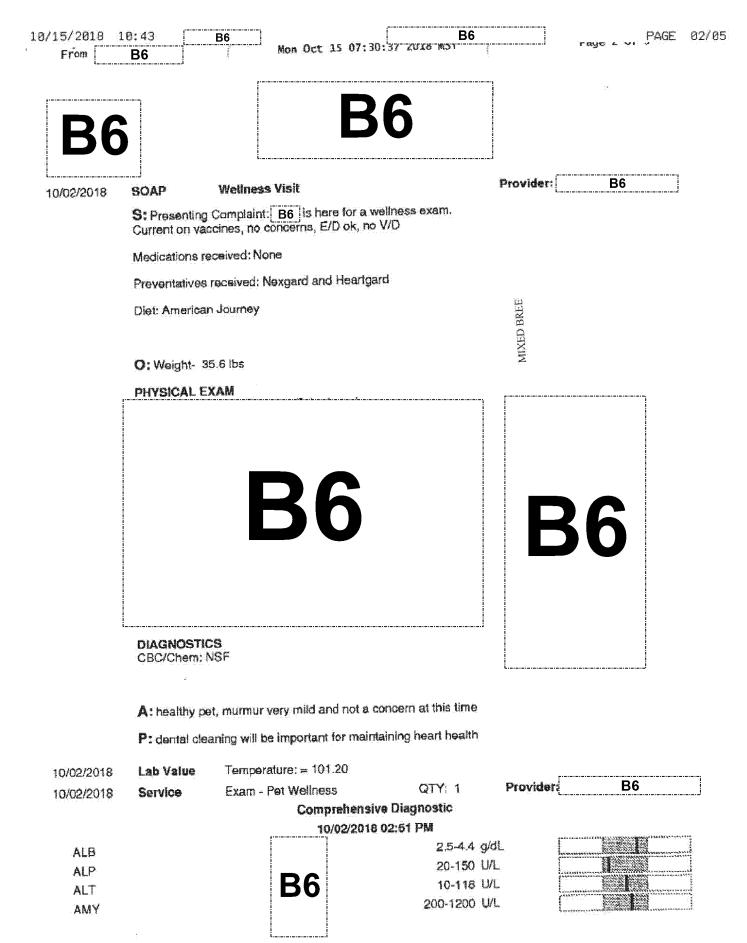
Patient History Report	B6 10/15/2018
Clinic:  B6 Client: B6	Patient: B6  ID: B6  Tag: Species: Canine, Mixed breed Sex: female/spayed. Age: 4 yrs, DOB: B6  Weight: 35.7 Lbs  Color: Black/tan markings Last visit: 10/13/2018  Referred By:
Home Phone   <b>B6</b>   Work Phone   <b>B6</b>   Keell   ID   <b>B6</b>   File #: 386	Tel: / Fax:
Medical Record Entries: 10/15/2018	Referral - SW B6 fit into redslot- 1 month  -save diet and bring it in to appointment. CHange diet to one with grain in it  Taurine- 40mg/kg 640mg/day (250 and 500ok too)  L-carnitine- ???  does O need to call ( B6
10/15/2018	See Attachments - Blood Work Downtown B6 Animal Hospital B6
10/13/2018	Consultation with specialist - Sent to B6 Cardiology:  Would like referral for echocardiogram at B6 ASAP- suspect grain-free diet related DCM. Client amenable to referral. On grain free diet past 3-4 years. New heart murmur first noted last week at a different veterinary office. Seen today by our hospital first time for second opinion. Grade 2-3/6 L systolic murmur, NSR. Respiratory: WNL, no crackles/wheezes. Eupnic. Does not appear to be in CHF. Not currently on any medications aside from Nexguard and Heartguard. Advised Taurine 500mg PO BID and L carnitine-1gram PO BID and change to diet containing grains while awaiting echo. Discussed monitoring for signs of impending CHF and when to seek emergency care.
	Chest rads- Generalized moderate to severe cardiomegaly. Lungs appear WNL. Brief cardiac US (by me)- All 4 chambers appear subjectively enlarged/dilated. Myocardium appears subjectively thin with POOR contractility. No pericardial effusion detected. Suspect DCM. Bloodwork performed recently by another vet hospital- WNL per owner (Copies unavailable today- Saturday).  - Earliest appointment client can be seen? - Additional medications or changes in dosages of supplements to prevent CHF while
	awaiting referral? -Rads and video of cardiac US will be sent by email on Monday (when support staff available).  B6
10/13/2018	Ultrasound Consult Fee - Cardiac US- All 4 chambers appear subjectively
	Patient History Report - 10/15/2018 - B6 Owner B6 Page 1 of 2

	enlarged/duated. Myocardium appears subjectively thin with poor contractility. No pericardial effusion detected. Suspect DCM B6
10/13/2018	Radiographs-Two Views - 3 view thorax- Generalized moderate to severe cardiomegaly.  Lungs appear WNL. Suspect DCM B6
10/13/2018	Weight in lbs (35.7) B6
10/13/2018	Examination/Office Call - B6 Chief Complaint: second opinion, heart murmur History: 2nd opinion- heart murmur. Adopted approx. 3 years ago, think she was around 9 months at time of adoption. Pretty healthy past few months- had diarrhea occasionally in first year, improved once she eliminated chicken and grains from the diet. 1 week ago-diagnosed with a heart murmur for the first time at B6 Prior to that, has been to multiple vets and they have never mentioned a heart murmur. Occassionally coughs, mostly when excited (when pulling on the leash/collar, but also sometimes when playing off leash).  Diet- American Journey Salmon and sweet potato (grain free). Has always been on a grainfree diet.  On Heartguard and Nexquard, O gives every month, regularly.
	<b>B6</b>
В	6 MIXED BREE

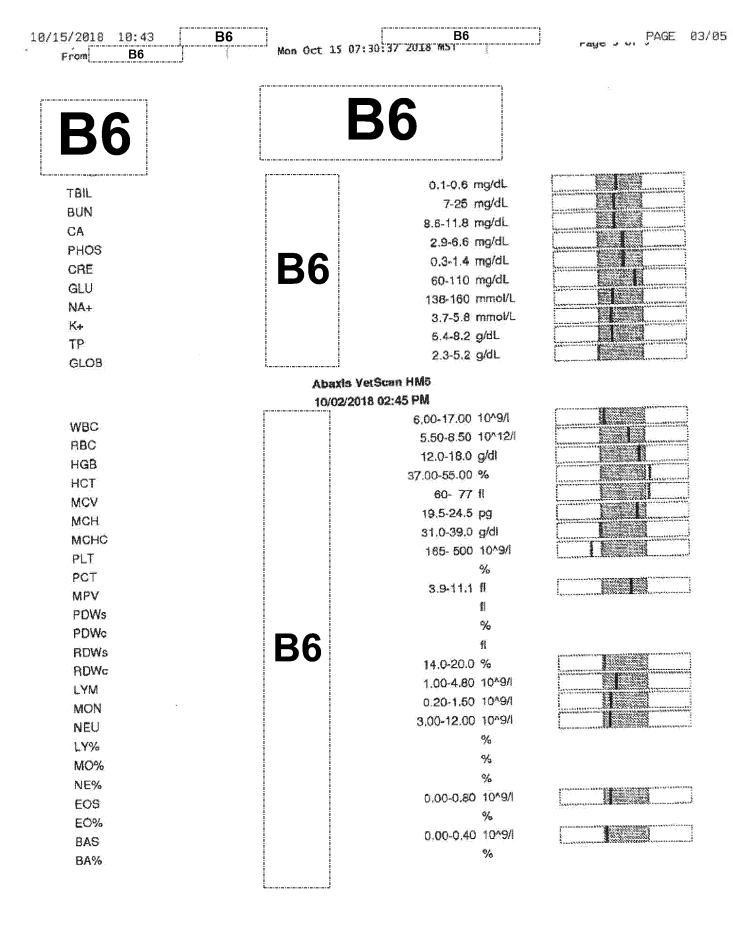
Patient History Report - 10/15/2018 - B6 Owner: B6 - Page 2 of 2



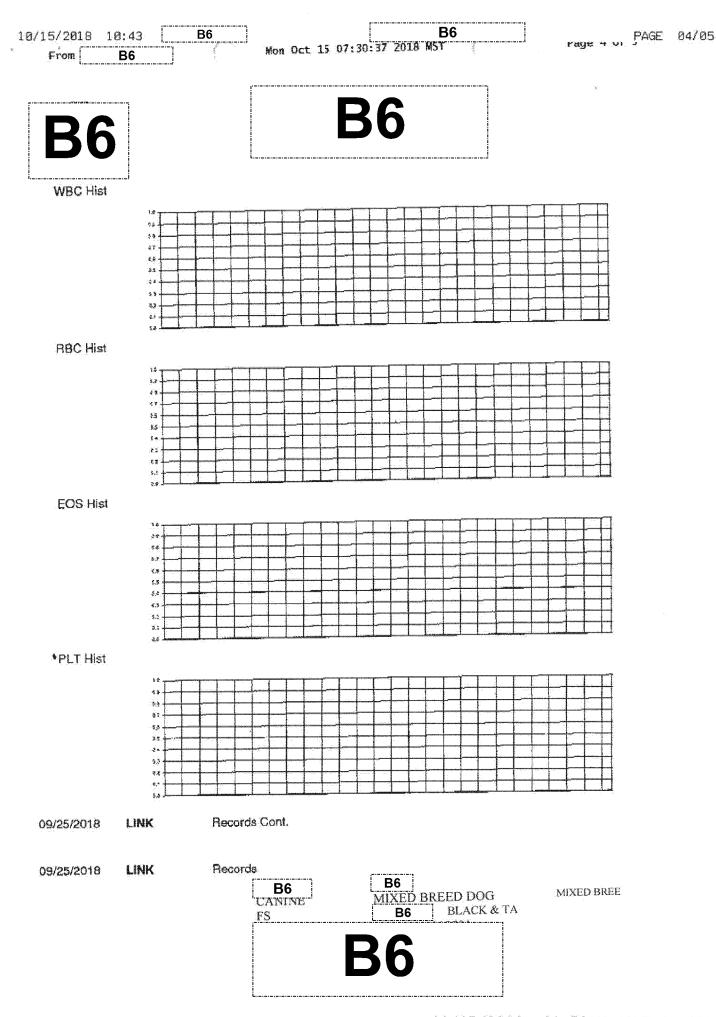
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Page 2 of 5



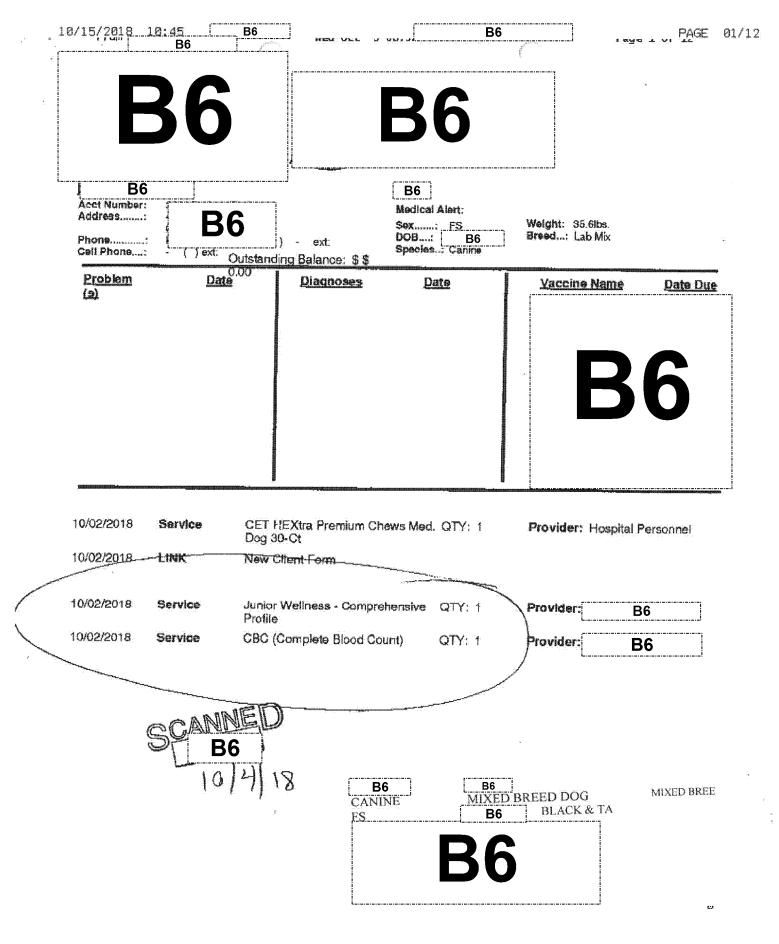
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**B6** 

INEO BREE

Laboration in terror discovery Page 5 of 5



intermether to Lors Move Page 1 of 2

For any questions on B6 health, please call B6

Client: Phone: Address:	Е	36		В6	Breed: Sex:	Mixed Spayed Female
Date Type	> Staff	History			4	
7/30/2018 P	(DC)					
	B6			<b>B</b> 6		
7/27/2018 P	B6					
7/27/2018 P	B6	c				
7/23/2018 TC	B6	Signed Conser	nts - TENTATIVE			
7/23/2018 TC	B6	Signed Estimat	e/Drop Off - TEN	TATIVE	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	
/20/2018 TC	B6 CINES &	PDVM - TENTA	ase type be	B6 Iow when va	ccines	or tests were
ually Give	nat B6	- Not Whe	n they are c	<u>lue **</u>		
TES VACC	ines Giv	/EN:	B6	d to history, E:Example 21		IN PDVM OF
espondence, T.Images	C. LC. Lauranea	B6 ; ANINE	MAKED BREE	ED DOG BLACK & TA	MIXED BR	37 PM
			<b>3</b> 6			

·*		Patie	ent History Re	port		
Client: Phone: Address:	В		Patient: Can Species: Can Age: 3 Yr Color: Blac	B6 ine s. 8 Mos.	Breed: Sex:	Mixed Spayed Female
Date Type	Staff	History		6-55-00-00-00-00-00-00-00-00-00-00-00-00-		Account of the second of the s
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10/15/2018 10:45 From 86 raye , ., PAGE 05/12

Patient History Report

Client: Phone: Address:

**B6** 

Patient: B6 Species: Canine Age: 3 Yrs. 8 Mos.

Color: Black/Tan

**B6** 

Breed: Mixed

Sex: Spayed Female

Date Type

Staff

History

Temp/Pulse/Resp: 101.8 / 130 / 40

**B6** 

B6 B6 CANINE MIXED BREED DOG

36

MIXED BRE

TA

7/19/2018 P

B6

**B6** 

B.Billing, C:Med note, CB:Cell back, CK:Check-In, CM:Communications, D:Diagnosis, DH:Declined to history, E:Examination, ES:Estimates, ED-powting instr. Lilab result, M:Image cases, P:Prescription, PA:PVL Accepted, PB:problems, PP:PVL Performed, PR:PVL Recommended, R:Correspondence, T:Images, TC:Tentative medi note, V:Vital signs

**B6** 

Page 4 of 9

Date: 8/29/2018 6:37 PM

**B6** 

Page 5 of 9

Date: 8/29/2018 6:37 PM

			Patient History Report
Client: Phone: Address:	В	6	Patient: B6 Species: Canine Breed: Mixed Age: 3 Yrs. 8 Mos. Sex: Spayed Female Color: Black/Tan
Date Type	Staff	History	
8/1/2016 C	B6	RR-FIN	AL 08/01/2016
7/30/2016 C	B6	Canine E	xam - CLOSED 08/29/2016 Canine Exam
	Patien	t Name:	B6 DVM Technician B6
our pet having any	problems?	Mithiel Manness of Since Mannes of States	All things are good. O wants Bravecto for P. O will do vx towards end of S 2016. Current on Tri-heart. Nature's Variety lamb/pea dry food.
tory (Subjective): our pet having any	problems?		All things are good. O wants Bravecto for P. O will do vx towards end of S 2016. Current on Tri-heart. Nature's Variety lamb/pea dry food.
our pet having any	problems?	A CONTRACTOR OF THE PROPERTY O	All things are good. O wants Bravecto for P. O will do vx towards end of S 2016. Current on Tri-heart. Nature's Variety lamb/pea dry food.
our pet having any	d by DVM		All things are good. O wants Bravecto for P. O will do vx towards end of S 2016. Current on Tri-heart. Nature's Variety lamb/pea dry food.    Mouth/Teeth/Gum
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be completed m (Objective): e and Throat formal Did Not sbnormal Ears formal Did Not	d by DVM  Exam  Exam  Exam  Examine		2016. Current on Tri-heart. Nature's Variety lamb/pea dry food.  Mouth/Teeth/Gurn  Normal  Did Not Exam Abnormal Remarks:  Coat and Skin  Normal  Did Not Exam

	Patie	e <u>nt History</u> Rep	оп	
Client: Phone: Address:	<b>B6</b>	Patient: Species: Cani Age: Color: Black	DU STA.	Mixed Spayed Female
Date Type Si	aff History			
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I Tract/Abdomen Normal Did Not Exa Expressed Anal Glands	mine Abnormal Remarks:	Urinary and G	Did Not Examine	**************************************
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В6

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<b>Va.</b>		Datio	nt History	Report			
Client:			Patient:	B6			in .
Phone: Address:		<b>36</b>		3 Yrs. 8 Mos. Black/Tan	Breed: N	Aixed Spayed Female	
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CANINE V		5 Booster <b>⊘</b> i1	Vane Clayer	e Califfornia			
DHPP Date G	tiven: - Bo	oster 1 Year 3 oster 1 Year 3 oster 1 Year 3	Year W/Le	pto			
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LEPTO Date (		r					
▼ BORDETELLA BORDETELLA	Date Given:_0 Date Given:_	9/24/2015 ☐ Intrar - ☐ Intranasal ☐ O	asal [_]Oral   ral [_]Injectabl	njectable			
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7/30/2016 Ck	В6					L	
7/30/2016 V	В6			<b>B</b> 6			
7/30/2016 B 7/30/2016 B	B6 B6						
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B6		Pa	ge 8 of 9	Date:	3/29/2018 6:	37 PM	

**Patient History Report** 

Client: Phone: Address:

**B6** 

Patient: B6 Species: Canine

Age: 3 Yrs. 8 Mos. Color: Black/Tan

**B6** 

Breed: Mixed

Sex: Spayed Female

Date Type

History

7/30/2016 B 7/30/2016 B 7/30/2016 B 7/18/2016 V

В6

Staff

**B6** 

Weight

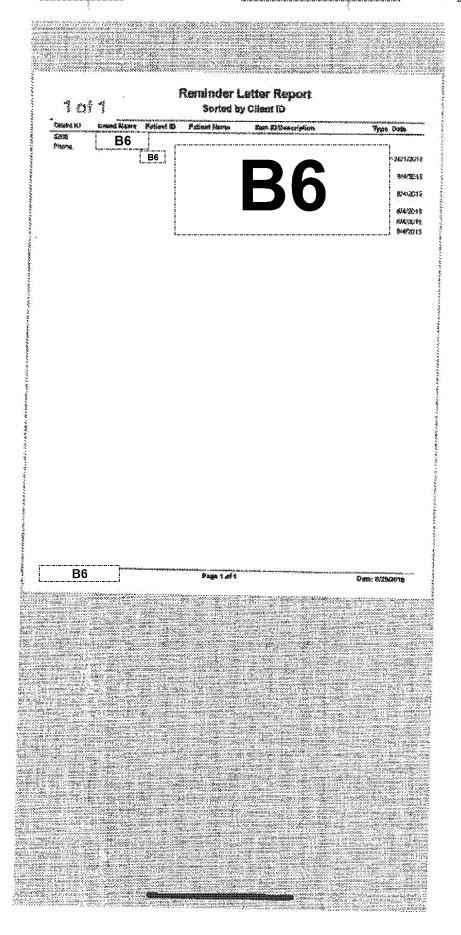
1 35.00 pounds

B.Billing, C.Med note, CB:Call back, CK:Check-in, CM:Communications, D:Diagnosis, DH:Declined to history, E:Examination, ES:Estimates, EDeparting Instr., LLab result, M.Image cases, P:Prescription, PA:PVL Accepted, PB:problems, PP:PVL Performed, PR:PVL Recommended, R:Correspondence, T:Images, TC:Tentative medi note, V:Vital signs

**B6** 

Page 9 of 9

Date: 8/29/2018 6:37 PM



**B4**, **B6** 

**B4**, **B6** 

# Canine Echocardiography Report

Patient Name:	В6		Date of Exam:	B6
Medical Rec #:	231020		Breed:	Mixed breed
DOB:	B6		Weight:	16 kg
Age:	3 years		BSA:	0.64 m²
Sex:	Fs		HR:	
Sonographer:	B4, B6	DVM, DACVIM	BP-sys:	
	(CA) DACVECC			

Report Status: READ

Suspect Grain Free Diet Associated DCM, Decreased left ventricular systolic function; Diagnosis:

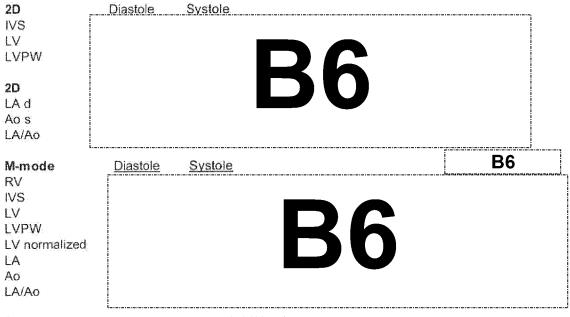
Left ventricular dilation

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

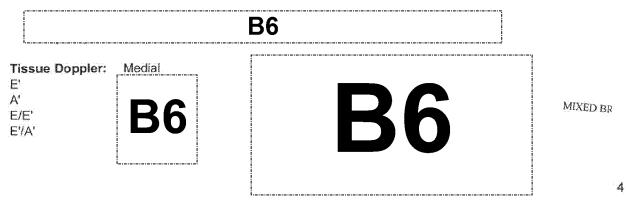
patient was awake.

### **Additional Comments:**

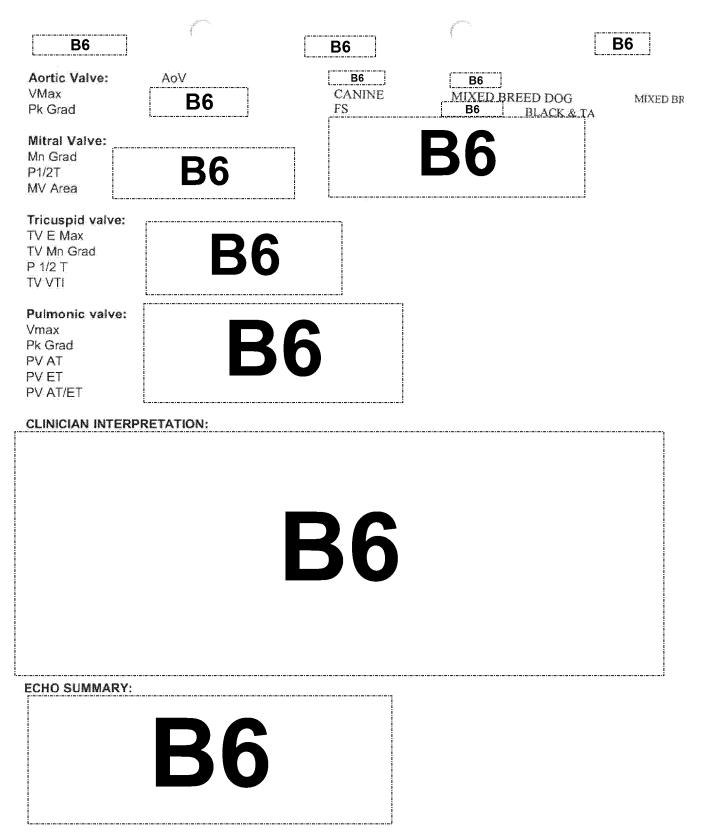
Dog presents for asymptomatic heart murmur.



Normal Canine M-mode values (in cm) for 15 kg dogs.



Final



### CV Exam:

Cardiac auscultation revealed a systolic murmur of grade II-III/VI intensity loudest at the left apex. Radiographs:

RDVM radiographs. No evidence of pulmonary edema. Left sided cardiomegaly.

**Recommendations:** Cause of dog's murmur is Mitral valve insufficiency due to MV annular stretch. MV anatomy is normal.

**B6** 

Since B6 is an atypical breed for DCM and has been on grain free diet for last 3 years, we are concerned for possible diet associated DCM. Other causes are possible such as idiopathic, infectious/inflammatory, ischemic or hypothyroidism. Cardiac troponin and thyroid testing are pending. Blood for infectious disease has been banked if troponin is markedly elevated. Taurine concentrations are also pending but dog has been on new diet and taurine for last 4-5 days.

Recommend continuing with taurine 40 mg/kg per day and carnitine. Suggest adding pimobendan 5 mg am, 2.5 mg pm and recheck echo in 3 months. If changes are reversible then diet associated DCM is likely cause

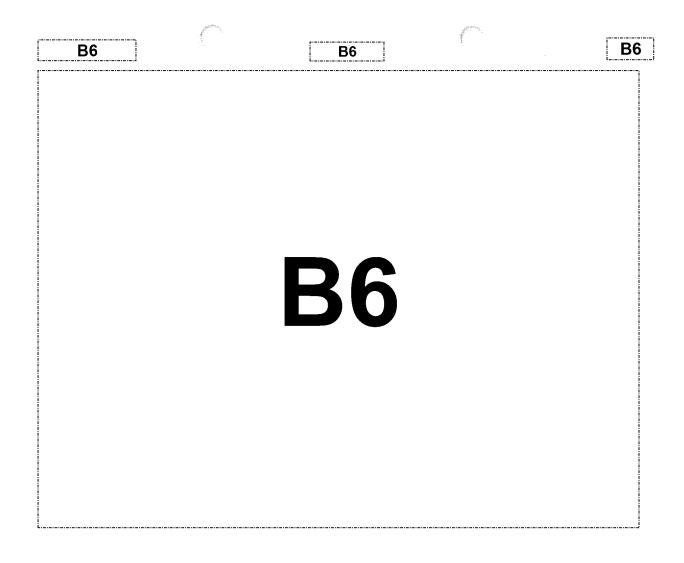
B4, B6 DVM, DACVIM (CA), DACVECC
Electronically signed on B6 on 2:07:37 PM

**B6** 

B6 B6 MIXED BREED DOG B6 B1 ACK A TA

MIXED BR

Page 3 of 4



**B6** 



From:	PFR Event <pfreventcreation@fda.hhs.gov></pfreventcreation@fda.hhs.gov>
То:	Cleary, Michael *; HQ Pet Food Report Notification; B6
Sent:	10/25/2018 5:16:28 PM
Subject:	taste of the <u>wild grain free</u> pacific stream-taste of the wild prey trout limited ingredients: <b>B6</b> - EON-369346
Attachments:	2057985-report.pdf; 2057985-attachments.zip

A PFR Report has been received and PFR Event [EON-369346] has been created in the EON System.

A "PDF" report by name "2057985-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 "2057985-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

**EON Key:** EON-369346

ICSR #: 2057985

EON Title: PFR Event created for taste of the wild grain free pacific stream taste of the wild prey trout limited

ingredients; 2057985

AE Date	B6	Number Fed/Exposed	3
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Stable
Breed	Dogue de Bordeaux		
Age	8 Years		
District Involved	PFR <b>B6</b> DO		

### **Product information**

**Individual Case Safety Report Number: 2057985** 

Product Group: Pet Food

**Product Name:** taste of the wild grain free pacific stream taste of the wild prey trout limited ingredients **Description:** B4, B6 . Has been eating Taste of the wild grain free for about 5 years. B6 had to be rushed to cardiologist and diagnosed with dcm dilated cardiomyopathy. Have full vet report and findings. He is still not recovered and we are unsure where this is going to end up

C. I. . . . TE. T. '.' 1

**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: 1** 

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

Product Name	Lot Number or ID	Best By Date
taste of the wild grain free pacific stream taste of the wild prey trout limited ingredients		

Sender information	
<b>B6</b>	
USA	-

To view the PFR Event Report	, please click the link below:	
	B6	

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Report Details - EON-						
ICSR:	2057985					
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 13:10:59 EDT					
Reporter is the Animal Owner:	Yes					
Reported Problem:	Problem Description:  B6  .Has been eating Taste of the wild grain free for a  /18 had to be rushed to cardiologist and diagnosed with dcm cardiomyopathy. Have full vet report and findings. He is still r are unsure where this is going to end up					
	Date Problem Started	B6				
	Date of Recovery:	10/24/2018				
	Concurrent Medical Problem:	No				
	Outcome to Date:	Stable				
Product Information:	Product Name:	taste of the wild graingredients	n free pacific stream taste of the wild prey trout limited			
	Product Type:	Pet Food				
	Lot Number:					
	Package Type:	::::::::::::::::::::::::::::::::::::::				
	Purchase Date:					
	Number Purchased:					
	Possess Unopened	No				
	Product:	st. No				
	Possess Opened Product:					
	Storage Conditions:	Cool dry place				
	Product Use	Description:	Recommeded feeding for all three of our dogs			
	Information:	First Exposure Date:	10/03/2018			
		Last Exposure Date:				
		Time Interval between Product Use and Adverse Event:	5 Years			
		Product Use Stopped After the Onset of the Adverse Event:	Yes			
		Adverse Event Abate After Product Stop:	Not Applicable			
		Product Use Started Again:	No			
		Perceived Relatedness to Adverse Event:	Probably related			
		Other Foods or Products Given to the Animal During This Time Period:	Yes			

	Manufacturer /Distributor Information:						
	Purchase Location Information:	Name:	В6				
	information.	Address:	United States	5			
Animal Information:	Name:	B6					
	Type Of Species:	i					
		Dogue de Bordeaux					
	Gender:	199					
	Reproductive Status:						
		: 8 Years					
	Assessment of Prior Health:	:					
	Number of Animals Given the Product:						
	Number of Animals 1 Reacted:	1					
	Owner Information:						
	Healthcare Professional	Practice Name:	В6				
	Information:	Contact:	l	B6			
			Phone	<u> </u>	<u></u>		
			Emai		B6		
			Liliai	····	D0	i	
		Address:	<b>B6</b>				
			United States	 S			
		Type of Veterinarian  Veterinarian:					
		Date First Seen: 10/24/2018					
		Permission to Release Records to FDA:	Yes				
Sender Information:	Name:	B6					
	Address:						
		B6 United States					
	Contact:		- BA				
	Contact.	r none.	B6	20	·-·•		
		Email	E	36			
	Reporter Wants to Remain Anonymous:	No					
	Permission To Contact Sender:	Yes					
	Preferred Method Of Contact:	Email					
Additional Documents:							
	Attachment:	<b>B6</b> 102418_5.pdf					
	Description:	I					
		Article					
	Attachment:	<b>B6</b> 102418_4.pdf					
	Description:	vet findings					
	Туре:	Article					

Attachment:	<b>B6</b> 102418_1.pdf
Description:	B6 102418_1.pdf vet findings
Туре:	Article

경영 하는 사람들은 사람들은 사람들은 가는 사람들이 되었다.

Thanks for allowing me to consult on this case. Please feel free to contact me regarding this or any other case.

Respectfully, B4, B6 DVM, MS, DACVIM-CA, DECVIM-B4, B6

Print Date: 10/24/2018

# B4, B6

# B4, B6

Date/Time B6 2:4	4:01pm	Weight (lb)	Heart 6	Rate	Attitude QAR
** PLEASE DO	O NOT RUN OUT OF MEDIC	ATIONS ***			
Date/Time	Drug Name	Qty Instructions		Prescrib	ed By
В6				B4, B DACVIM, I	6 DVM, M: DECVIM
В6				B4, B	6 DVM, M
				DACVIM,	DECVIM
В6		<b>B6</b>		B4, E	6 DVM, M
				DACVIM, 1	DECAIM

### ECG - Electrocardiogram - 10 lead (Ref: US10393-DR6381)

Normal sinus rhythm No evidence of supra and ventricular arrhythmia Left ventricle enlargement pattern

A Diagnostic Result

## Echocardiogram by cardiologist (Ref: US10393-DR6377)

Decreased systolic function, dilated Left Ventricle
Mild to moderate Mitral Valve Regurgitation due to dilatation, with mild left atrial enlargement
Mild triscuspid regurgitation with mild right atrial enlargement and no pulmonary hypertension
No Pericardial effusion

Report Details - EON-	369325		
ICSR:	2057945		
Type Of Submission:	Initial		
Report Version:	FPSR.FDA.PETF.V.V1		
Type Of Report:	Adverse Event (a symptom,	reaction or disease a	ssociated with the product)
Reporting Type:	Voluntary		
Report Submission Date:	2018-10-25 07:45:50 EDT		
Reported Problem:			rillation WB taurine = 260 Dog's diet previously submitted to be a duplicate submission
	Date Problem Started:	02/20/2018	
	Concurrent Medical Problem:	No	
	Outcome to Date:	Died Naturally	
	Date of Death:	B6	
Product Information:	Product Name:	Taste of the Wild Hig	ıh Prairie
	Product Type:	Pet Food	
	Lot Number:		
	Package Type:	BAG	
	Product Use Information:		
	Manufacturer /Distributor Information:		
	Purchase Location Information:		
Animal Information:	Name:	B6	
	Type Of Species:	Dog	
	Type Of Breed:	Great Dane	
	Gender:	Male	
	Reproductive Status:	Intact	
	Weight:	74 Kilogram	
	Age:	9 Years	
	Assessment of Prior Health:	Excellent	
	Number of Animals Given the Product:	1	
	Number of Animals Reacted:	1	
	Owner Information:	Owner Information provided:	
		Contact:	Name: B6
			Phone: B6
			Email: B6
		Address:	B6
			United States
	Healthcare Professional	Practice Name:	B4, B6
	Information:	Contact:	\
	1		Phone: (508) 887-4523
			Email: lisa.freeman@tufts.edu
	1		THAIR 199.119911QUARE COM

		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:		
	Preferred Method Of Contact:	Email	
Additional Documents:			
	Attachment:	B6 compiled reco	rds.pdf
	Description:	L	
	Type:	Medical Records	

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

**Sent:** 10/25/2018 7:36:40 PM

Subject: WELLNESS CORE GRAIN FREE: **B6** - EON-369373

Attachments: 2057992-report.pdf

A PFR Report has been received and PFR Event [EON-369373] has been created in the EON System.

A "PDF" report by name "2057992-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report:

**EON Key:** EON-369373

ICSR #: 2057992

EON Title: PFR Event created for WELLNESS CORE GRAIN FREE, NULO GRAIN FREE, BLUE

BUFFALO GRAIN FREE; 2057992

AE Date	10/22/2018	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Stable
Breed	Schnauzer - Miniature		
Age	10.5 Years		
District Involved	PFR <b>B6</b> DO		

### **Product information**

**Individual Case Safety Report Number: 2057992** 

Product Group: Pet Food

Product Name: WELLNESS CORE GRAIN FREE, NULO GRAIN FREE, BLUE BUFFALO GRAIN FREE

**Description:** CHEST RADIOGRAPHS REVEALED AN ENLARGED HEART

**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
BLUE BUFFALO GRAIN FREE		
WELLNESS CORE GRAIN FREE		
NULO GRAIN FREE		

Sender information	
<b>B6</b>	
USA	
Owner information	
<b>B6</b>	USA
<u> </u>	
To view this PFR Event, please c	lick the link below:
	<u></u>
To view the PFR Event Report, p	lease click the link below:
	<b>B</b> 6

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Report Details - EON-	369373		
ICSR:	2057992		
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 15:26:17 EDT		
Reported Problem:	Problem Description:	CHEST RADIOGRA	PHS REVEALED AN ENLARGED HEART
	Date Problem Started:	10/22/2018	
	Concurrent Medical Problem:	No	
	Outcome to Date:	Stable	
Product Information:	Product Name:	BLUE BUFFALO GF	RAIN FREE
	Product Type:	Pet Food	
	Lot Number:		
	Package Type:	BAG	
	Possess Unopened Product:	Unknown	
	Possess Opened Product:	Unknown	
	Storage Conditions:	UNKNOWN	
	Product Use Information:	Description: Product Use	ORALLY
		Stopped After the Onset of the Adverse Event:	Uliknown
		Perceived Relatedness to Adverse Event:	Possibly related
	Manufacturer /Distributor Information:		
	Purchase Location Information:		
	Product Name:	NULO GRAIN FREE	
	Product Type:	Pet Food	
	Lot Number:	D.4.C.	
	Package Type:		
	Possess Unopened Product:		
	Possess Opened Product:		
	Storage Conditions:	<del></del>	
	Product Use Information:	Description:	ORALLY
	information.	Product Use Stopped After the Onset of the Adverse Event:	Unknown
		Perceived Relatedness to Adverse Event:	Possibly related
	Manufacturer /Distributor Information:		
	Purchase Location Information:		

	Product Name:	WELLNESS CORE	GRAIN FREE
	Product Type:	Pet Food	
	Lot Number:		
	Package Type:	BAG	
	Possess Unopened Product:		
	Possess Opened Product:	Unknown	
	Storage Conditions:	UNKNOWN	
	Product Use	Description:	ORALLY
	Information:	Product Use	Unknown
		Stopped After the Onset of the Adverse Event:	
		Relatedness to Adverse Event:	Possibly related
		Other Foods or Products Given to the Animal During This Time Period:	Unknown
	Manufacturer		
	/Distributor Information:		
	Purchase Location Information:		
Animal Information:	Name:	B6	
	Type Of Species:	Dog	
		Schnauzer - Miniatu	re
	Gender:	Female	
	Reproductive Status:	Neutered	
	2)	16.3 Pound	
		10.5 Years	
	Assessment of Prior Health:	Good	
	Number of Animals Given the Product:	1	
	Number of Animals Reacted:	1	
	Owner Information:	Owner Information provided:	Yes
		Contact:	Name: B6 Phone: B6
		Address:	<b>B6</b>
			United States
	Healthcare Professional Information:		United States
Sender Information:	Name:	B6	
	Address:	· · · · · · · · · · · · · · · · · · ·	
	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	<b>B</b> 6	

		United States			 	
	Contact	Phone:	В6			
		Other Phone: Email:	В6	De De	 	
	Reporter Wants to Remain Anonymous			B6		
	Permission To Contact Sender:	Yes			 	
	Preferred Method Of	Email				
	Contact:	None				
itional Docume	Parties:				 	
itional Docume	ents:	ntaran tara di nica di		nannanantanannanananananananana	 	

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:** 12/6/2018 3:20:09 AM **Subject:** DCM cases 12/5/2018 2200

Attachments: Acana dog food. Varying diet/formulas over the past **B6** years.: **B6** EON-372923;

Earthborn Meadow Feast dry: Lisa Freeman - EON-372804; Earthborn Meadow Feast dry: Lisa Freeman - EON-372828; Earthborn Meadow Feast dry: Lisa Freeman - EON-372831; Earthborn Meadow Feast dry: Lisa Freeman - EON-372834; Earthborn Meadow Feast dry: Lisa Freeman - EON-372842; Kirkland Signature Nature's Domain Salmon Meal & Sweet Potato Formula for Dogs: \_\_\_\_\_\_ EON-372864; Pure Vita Holistic Pet Foods Turkey and Sweet Potato

Entree: **B6** - EON-372846; The Honest Kitchen Grain Free Chicken Recipe **B6** B6 EON-372839; Wellness Core Natural Grain Free Dry Dog Food Ocean Whitefish: **B6** 

**B6** EON-372851

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

B6 BB)





From:

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То:	Cleary, Michael *; HQ Pet Food Report Notification;
Sent:	12/5/2018 4:44:22 PM
Subject:	Acana dog food. Varying diet/formulas over the past <b>B6</b> years. <b>B6</b>
Attachments:	2059678-report.pdf

ΑI

A "PDF" report by name "2059678-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report:

**EON Key:** EON-372923

ICSR #: 2059678

**EON Title:** PFR Event created for Acana dog food. Varying diet/formulas over the past B6 years.; 2059678

AE Date	09/01/2018	Number Fed/Exposed	3
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Died Euthanized
Breed	Mastiff		
Age	B6 Years		
District Involved	PFR <b>B6</b> DO		

<b>Individual Case</b>	Safety Report No	umber: 2059678
D 1 4 C	D + E 1	

**Product Group:** Pet Food

Product information

**Product Name:** Acana dog food. Varying diet/formulas over the past **B6** years.

**Description:** Since approximately Sept 2018, we noticed **B6** had an occasional cough/throat clearing noise. We mentioned this during vet visits, but our vets didn?t seem concerned. On we rushed

**B6** to the emergency vet due to weakness and inability to stand and while there he had chest X-rays taken which showed ?an extremely large heart?. The on duty vet performed an ultrasound and noted how hard his heart was working to pump blood. He inquired about the food we feed him and if it was grain free. After finding out it was, he alerted us to new findings regarding grain free diets and dilated cardiomyopathy. He suggested we contact the FDA to report the findings. Unfortunately, **B6** did not recover and passed away early **B6** 

**B6** 

Submission Type: Initial

**Report Type:** Adverse Event (a symptom, reaction or disease associated with the product)

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

Number of Animals Treated With Product: 3 Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Acana dog food. Varying diet/formulas over the past <b>B6</b> years.		

Sender information	
<b>B6</b>	

To view this PFR	Event, please click	the link below:
	B6	

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

<b>B</b> 6	
	•

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Report Details - EON-	372923		
ICSR:	2059678		
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		······································
	2018-12-05 11:36:30 EST		
Reporter is the Animal Owner:	Yes		
Reported Problem:	Problem Description:	/throat clearing noise concerned. On to weakness and ina which showed an ex and noted how hard food we feed him an new findings regardi	Sept 2018, we noticed B6 had an occasional cough by We mentioned this during vet visits, but our vets didnt seem B6 we rushed B6 to the emergency vet due stillity to stand and while there he had chest X-rays taken tremely large heart. The on duty vet performed an ultrasound his heart was working to pump blood. He inquired about the diffit was grain free. After finding out it was, he alerted us to ng grain free diets and dilated cardiomyopathy. He suggested to report the findings. Unfortunately, B6 blid not recover arly B6
	Date Problem Started: Concurrent Medical Problem:	<u> </u>	
	Pre Existing Conditions:	Prednisone	
	Outcome to Date:	3	
	Date of Death:		
Product Information:		<u> </u>	
Product information.	Product Name: Product Type: Lot Number:	Pet Food	rying diet/formulas over the past B6 years.
	Package Type:	<del>}</del>	
	Package Size:	4	
	Storage Conditions:	Sealed container	
	Product Use Information:	First Exposure Date:	
		Last Exposure Date:	Probably related
		Relatedness to Adverse Event:	
		Other Foods or Products Given to the Animal During This Time Period:	
	Manufacturer /Distributor Information:		*
	Purchase Location Information:		
Animal Information:	Name:	B6	
	Type Of Species:	3	
	Type Of Breed: Gender:	4	
	Reproductive Status:	:4 □	
	- 3 }	200 Pound	
		B6 Years	
	Assessment of Prior		
	Assessment of Prior	- C000	

	Health:					
	Number of Animals Given the Product:	3				
	Number of Animals Reacted:	1				
	Owner Information:					
	Healthcare Professional	Practice Name:	В6 ,			
	Information:	Contact:		<b>B6</b>		
			Phone:	DU		00000
		Permission to	Yes			<sup>©</sup>
		Release Records to FDA:				
Sender Information:	Name:					
	Address:	<b>B</b> 6				
	i	United States	<u></u> !			
	Contact:	Phone:	B6			
		Email:	В			
	Permission To Contact Sender:	Yes				
	Preferred Method Of Contact:	Phone	recent resident a constant form a constant account constant account a constant account a constant account a co	annitaanna antinaanna alkuus		том авинов а пото вытов пово выполняющих повод пово
	Reported to Other Parties:	None			a n 111 a 181	
Additional Documents:						

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

**Sent:** 12/4/2018 10:17:32 PM

Subject: Earthborn Meadow Feast dry: Lisa Freeman - EON-372804

Attachments: 2059619-report.pdf; 2059619-attachments.zip

A PFR Report has been received and PFR Event [EON-372804] has been created in the EON System.

A "PDF" report by name "2059619-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 "2059619-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

**EON Key:** EON-372804

ICSR #: 2059619

**EON Title:** PFR Event created for Earthborn Meadow Feast dry; 2059619

AE Date	11/21/2018	Number Fed/Exposed	5
Best By Date		Number Reacted	4
Animal Species	Dog	Outcome to Date	Stable
Breed	Boxer (German Boxer)		
Age	3 Years		
District Involved	PFR <b>B6</b> DO		

### **Product information**

**Individual Case Safety Report Number: 2059619** 

**Product Group:** Pet Food

Product Name: Earthborn Meadow Feast dry

**Description:** Littermate diagnosed with reduced cardiac contractility Eating BEG diet (Earthborn) so screened all housemates Echo within normal limits but elevated NT-proBNP and cardiac troponin I Taurine pending

Owner changing diet and will recheck in 3 months

**Submission Type:** Initial

**Report Type:** Adverse Event (a symptom, reaction or disease associated with the product)

Outcome of reaction/event at the time of last observation: Stable

**Number of Animals Treated With Product: 5 Number of Animals Reacted With Product: 4** 

Product Name	Lot Number or ID	Best By Date
Earthborn Meadow Feast dry		

### **Sender information**

Lisa Freeman 200 Westboro Rd North Grafton, MA 01536 USA

Owner	inforn	nation
		<del></del> -

**B6** 

To view this PFR Event, please click the link below: **B6** 

To view the PF	R Event Report, please	click the link below:		 	
		<b>B6</b>	Ď		

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Report Details - EON	-372804					
ICSR:	2059619					
Type Of Submission:	Initial					
Report Version:	FPSR.FDA.PETF.V.V1					
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)					
Reporting Type:	Voluntary					
Report Submission Date	: 2018-12-04 17:08:36 EST					
Reported Problem:	Problem Description:	Littermate diagnosed with reduced cardiac contractility Eating BEG diet (Earthborn) so screened all housemates Echo within normal limits but elevated NT-proBNP and cardiac troponin I Taurine pending Owner changing diet and will recheck in 3 months				
	Date Problem Started:	11/21/2018				
	Concurrent Medical Problem:	Yes				
	Pre Existing Conditions:	History of resection of jejunum and ileum due to intussusception as puppy				
	Outcome to Date:	<del></del>				
Product Information:	Product Name:	Earthborn Meadow Feast dry				
	Product Type:					
	Lot Number:					
	Package Type:					
	Product Use	Description: See diet history				
	Information:	First Exposure 02/01/2018				
		Date:				
	Manufacturer /Distributor Information:					
	Purchase Location Information:					
Animal Information:	Name:	B6				
	Type Of Species:	<u>i</u>				
		Boxer (German Boxer)				
	Gender:					
	Reproductive Status:					
	Pregnancy Status:					
	Lactation Status:					
		: 27.4 Kilogram				
		3 Years				
	Assessment of Prior Health:	Excellent				
	Number of Animals Given the Product:					
	Number of Animals Reacted:	4				
	Owner Information:	Owner Yes Information				
		provided:				
		Contact: Name:				
		Phone: BO				
		Email:				
		Address:				
		Bø				
		United States				



AT TUFTS UNIVERSITY

Client: **B6** Address: Home Phone: Work Phone: Cell Phone: (

**All Medical Records** 

Patient: **B6** Breed: Boxer DOB: **B6** 

Species: Canine Female Sex:

#### **Referring Information**

#### **Initial Complaint:**

Scanned Record

SOAP Text Nov 20 2018 12:24PM - Clinician, Unassigned B6

#### **Initial Complaint:**

DCM study

SOAP Text Nov 20 2018 1:12PM -

**B6** 

**Disposition/Recommendations** 

## Cummings Veterinary Medical Center

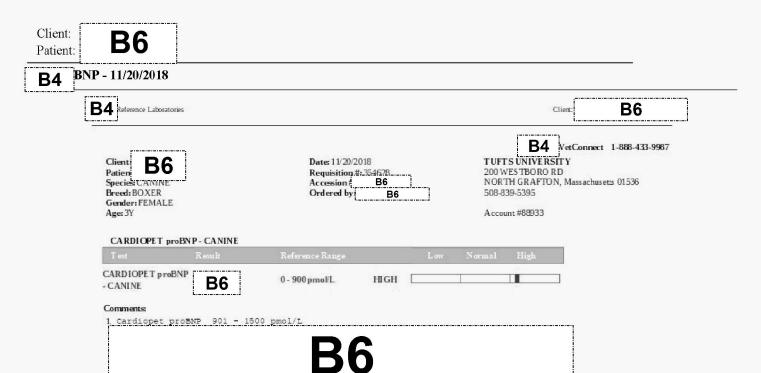
Client: **B6** Veterinarian: Patient ID: 345628 Visit ID:

Patient:	B6
Species:	Canine
Breed:	Boxer
Sex:	Female
Age:	<b>B6</b> Years Old

#### Lab Results Report

	11/20/2018 5:45:57 PM	Accession ID: B6
Test	Results	Reference Range Units
Troponin I Research -	В6	0 - 0.08 mg/dl
	3/12	B6
stringsoft		Drintad Tuasday Dagambar 04, 2018

Printed Tuesday, December 04, 2018



Please note: Complete interpretive comments for all concentrations of Cardiopet proBNP are available in the online directory of services. Serum specimens received

at room temperature may have decreased NT-proBNP concentrations.

Page 1 of 1

#### Gastrointestinal Lab Texas A&M 11/20/18



#### Gastrointestinal Laboratory

Dr. J.M. Steiner

### Department of Small Animal Clinical Sciences Texas A&M University 4474 TAMU

College Station, TX 77843-4474

Website User ID: clinpath@tufts.edu

GI Lab Assigned Clinic ID: 11405



B6	Phone:	508 887 4669
Tufts University-Clinical Pathology Lab	Fax:	9 508 839 7936
Attn: B6   200 Westboro Road	Animal Name:	DC
North Grafton, MA 01536	Owner Name:	B6
USA	Species:	Canine
	Date Received:	Nov 27, 2018
Tuffe University Clinical Pathology Lah	GLIah	Accession: R6

Tracking Number: 1811200085			L
Test	Result	Reference Interval	Assay Date
Ultra-Sensitive Troponin I Fasting	B6	≤0.06	11/27/18
Interpretation:	B6		
	<b>B6</b>		

Comments:

B6

345528 Canine
11/20/2018 1:14 PM
CARDIAC TROPONIN/TEXGI

GI Lab Contact Information

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

#### Gastrointestinal Lab Texas A&M 11/20/18



### Gastrointestinal Laboratory Dr. J.M. Steiner Department of Small Animal Clinical Sciences

College Station, TX 77843-4474

ent of Small Animal Clinical Sciences
Texas A&M University

4474 TAMU



Important Notices: Ongoing studies

B4, B6

GI Lab Contact Information

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

ļ	nı	CARDIOLOGY ase answer the follogen			net	
et's name:	<b>B6</b>	Owner's name	В	6	Today's date	20100/201
How would y		et's appetite? (mark the po	oint on the line be	elow that best rep		
					ellent	
Eats about	the same amount	your pet's appetite over the as usual □Eats less ds than usual □Other	than usual	? (check all that a DEats more that		
Over the last	few weeks, has y t □Gained weig	our pet (check one) tht Stayed about the	same weight	IDon't know		
currently eats	s. Please include t	s, people food, treats, sna he brand, specific product le – please provide enoug	t, and flavor so w	ve know exactly v	vhat you pet is e	ating.
	0.000		WORLD BETT CERCICAL TO			
		roduct and flavor) til, & Sweet Potato Adult	Form dry	Amount 1 ½ cup	How often?	Fed since
85% lean har		iii, & Sweet Foldto Addit	microwaved	3 oz	2x/day 1x/week	Jan 2018 Jan 2015
Pupperoni or	iginal beef flavor		treat	1/2	1x/day	Aug 2015
Rawhide	girrar boor mayor		treat	6 inch twist	1x/week	Dec 2015
	COADM - US	DEFAST		-11/2C	Zxday	FEB 2016
*Any addition	al diet information	can be listed on the back	of this sheet			
Do you give a supplements)	?		ch ones and give concentration	brands and amo	ounts:	other
Taurine	□Yes □N	0				
Carnitine	□Yes □N	0				
Antioxidants Multivitamin		0				
Fish oil	□Yes □N					
	10 DYes DN					
Other (please Example: Vita SUPPLEM	e list): amin C		ure's Bounty	ent	500 mg table	ets - 1 per day
						1-27
☐ I do not giv	administer pills to y	3				
☐ I put them I	in my pet's dog/ca in a Pill Pocket or		5- Ch 2-	م.		

**ECG** from Cardio

**B6** 

11/20/2018 2:45:12 PM

Tufts University Tufts Cummings School of Vet Med Cardiology

**B6** 

**ECG** from Cardio

**B6** 

11/20/2018 2:45:12 PM
Tufts University
Tufts Cummings School of Vet Med
Cardiology

**B6** 

#### **Patient History**

Patient History	/=====================================
09/27/2018 02:02 PM	
11/14/2018 05:13 PM	
11/19/2018 06:05 PM	
11/20/2018 12:38 PM	
11/20/2018 01:10 PM	
11/20/2018 04:05 PM	<b>B6</b>
11/20/2018 04:05 PM	
11/20/2018 04:06 PM	
11/20/2018 04:56 PM	
11/20/2018 05:46 PM	
11/20/2018 05:46 PM	
11/21/2018 11:19 AM	
11/26/2018 11:33 AM	

# Cummings Veterinary Medical Center



**B6** 

11/22/2018



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

Thank you,

**B6** DVM, DACVIM (Cardiology) To: Cleary, Michael \*; HQ Pet Food Report Notification B6

**Sent:** 12/4/2018 11:04:49 PM

**Subject:** Earthborn Meadow Feast dry: Lisa Freeman - EON-372828

Attachments: 2059621-report.pdf; 2059621-attachments.zip

A PFR Report has been received and PFR Event [EON-372828] has been created in the EON System.

A "PDF" report by name "2059621-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 "2059621-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

**EON Key:** EON-372828

ICSR #: 2059621

EON Title: PFR Event created for Earthborn Meadow Feast dry; 2059621

AE Date	11/20/2018	Number Fed/Exposed	5
Best By Date		Number Reacted	4
Animal Species	Dog	Outcome to Date	
Breed	Boxer (German Boxer)		
Age	3 Years		
District Involved	PFR <b>B6</b> DO		

#### **Product information**

**Individual Case Safety Report Number: 2059621** 

**Product Group:** Pet Food

Product Name: Earthborn Meadow Feast dry

**Description:** Eating BEG diet (Earthborn) Echo had subjectively reduced contractility; elevated NT-proBNP and

cardiac troponin I Taurine pending Owner changing diet and will recheck in 3 months

Submission Type: Initial

**Report Type:** Adverse Event (a symptom, reaction or disease associated with the product)

Outcome of reaction/event at the time of last observation: Stable

**Number of Animals Treated With Product: 5** 

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

Product Name	Lot Number or ID	Best By Date
Earthborn Meadow Feast dry		

#### **Sender information**

Lisa Freeman 200 Westboro Rd North Grafton, MA 01536 USA

Owner	inform	ation
Owner	miorm	auon



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

**B6** 

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Report Details - EON	-372828					
ICSR:	2059621					
Type Of Submission:	Initial					
Report Version:	FPSR.FDA.PETF.V.V1					
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)					
Reporting Type:	Voluntary					
Report Submission Date	: 2018-12-04 17:59:30 EST					
Reported Problem:	Problem Description:	Eating BEG diet (Earthborn) Echo had subjectively reduced contractility; elevated NT-proBNP and cardiac troponin I Taurine pending Owner changing diet and will recheck in 3 months				
	Date Problem Started:	11/20/2018				
	Concurrent Medical	No				
	Problem:					
	Outcome to Date:	e: Stable				
Product Information:	Product Name:	Earthborn Meadow F	<sup>=</sup> east dry			
	Product Type:	Pet Food				
	Lot Number:					
	Package Type:	BAG				
	Product Use Information:	Description:	See diet history in records for more details			
	Manufacturer /Distributor Information:					
	Purchase Location Information:					
Animal Information:	Name:	B6				
	Type Of Species:	71				
	Type Of Breed:	Boxer (German Box	er)			
	Gender:	Female				
	Reproductive Status:	Intact				
	Pregnancy Status:	Not pregnant				
	Lactation Status:	Not lactating				
	Weight:	30.3 Kilogram				
	Age:	3 Years				
	Assessment of Prior Health:	Excellent				
	Number of Animals Given the Product:	5				
	Number of Animals Reacted:	4				
	Owner Information:	Owner Information provided:	Yes			
		Contact:	Name: DG			
			Phone: B6			
		Address:				
		, iddiess,	<b>B6</b>			
			United States			
	Healthcare Professional	Practice Name:	Tufts Cummings School of Veterinary Medicine			
	Information:	Contact:	7			

			Phone:	(508) 887-4523
			Email:	lisa.freeman@tufts.edu
		Address:	200 Westboro North Grafton Massachusetts 01536 United States	
ender Information:	Name:	Lisa Freeman		
	Address:	200 Westboro Rd North Grafton Massachusetts 01536 United States		
	Contact:	Phone:	5088874523	
		Email:	lisa.freeman@t	tufts.edu
	Permission To Contact Sender:	Yes		
	Preferred Method Of Contact:	Email		
Additional Documents:				
	Attachment:	rpt_medical_record_	preview.pdf	
		Medical records		
	Туре:	Medical Records		

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

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

Sent: 12/4/2018 11:12:44 PM

Subject: Earthborn Meadow Feast dry: Lisa Freeman - EON-372831

Attachments: 2059622-report.pdf; 2059622-attachments.zip

A PFR Report has been received and PFR Event [EON-372831] has been created in the EON System.

A "PDF" report by name "2059622-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 "2059622-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

**EON Key:** EON-372831

ICSR #: 2059622

**EON Title:** PFR Event created for Earthborn Meadow Feast dry; 2059622

AE Date	11/15/2018	Number Fed/Exposed	5
Best By Date		Number Reacted	4
Animal Species	Dog	Outcome to Date	Stable
Breed	Boxer (German Boxer)		
Age	3 Years		
District Involved	PFR <b>B6</b> DO		

#### **Product information**

**Individual Case Safety Report Number: 2059622** 

**Product Group:** Pet Food

Product Name: Earthborn Meadow Feast dry

**Description:** Daughter diagnosed with reduced cardiac contractility ( **B6** is mother of **B6** and **B6** Eating BEG diet (Earthborn) so screened all housemates Echo within normal limits but elevated

NT-proBNP and cardiac troponin I Taurine pending Owner changing diet and will recheck in 3 months

**Submission Type:** Initial

**Report Type:** Adverse Event (a symptom, reaction or disease associated with the product)

Outcome of reaction/event at the time of last observation: Stable

**Number of Animals Treated With Product: 5 Number of Animals Reacted With Product: 4** 

Product Name	Lot Number or ID	Best By Date
Earthborn Meadow Feast dry		

#### **Sender information**

Lisa Freeman 200 Westboro Rd North Grafton, MA 01536 USA

Owner	inforr	nation

**B6** 

To view this PFR Event, please click the link bel	ow
<b>B6</b>	

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

<b>B6</b>	
	i

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Report Details - EON-	5				
ICSR:	2059622				
Type Of Submission:	Initial				
Report Version:	FPSR.FDA.PETF.V.V1				
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)				
Reporting Type:	Voluntary				
Report Submission Date:	2018-12-04 18:08:14 EST				
Reported Problem:	Problem Description:	B6 nousemates Ecno w	with reduced cardiac contractility ( B6 is mother of Eating BEG diet (Earthborn) so screened all within normal limits but elevated NT-proBNP and cardiac ending Owner changing diet and will recheck in 3 months		
	Date Problem Started:	11/15/2018			
	Concurrent Medical Problem:	No			
	Outcome to Date:	Stable			
Product Information:	Product Name:	Earthborn Meadow I	Feast dry		
	Product Type:	Pet Food			
	Lot Number:				
	Package Type:	BAG			
	Product Use Information:	Description:	See diet history in medical record for more info		
	Manufacturer /Distributor Information:				
	Purchase Location Information:				
Animal Information:	Name:	В6			
	Type Of Species:	i: Dog			
	Type Of Breed:	Boxer (German Box	er)		
	Gender:	Female			
	Reproductive Status:	Intact			
	Pregnancy Status:	<del>-</del>			
	Lactation Status:				
		29.1 Kilogram			
		3 Years			
	Assessment of Prior Health:	Excellent			
	Number of Animals Given the Product:	5			
	Number of Animals Reacted:	4			
	Owner Information:	Owner Information	Yes		
		provided:			
		Contact:	Phone: B6		
		Address:	Email:		
			B6		
			United States		
	Healthcare Professional Information:	Practice Name: Contact:	Tufts Cummings School of Veterinary Medicine  Name: Lisa Freeman		

Address: 200 Westboro Rd North Grafton Massachusetts 01536 United States  Sender Information: Name: Lisa Freeman   Address: 200 Westboro Rd North Grafton Massachusetts 01536 United States  Contact: Phone: 5088874523 Email: lisa.freeman@tufts edu  Permission To Contact Yes Sender: Preferred Method of Contact: The Contact Sender: Preferred Method of Contact: Medical Records  Additional Documents: Type: Medical Records  Attachment: rpt_medical_record_preview B6 pdf  Description: Medical Records				Phone: (508) 887-4523
North Grafton   Massachusetts   O1536   United States				Email: lisa.freeman@tufts.edu
Address: 200 Westboro Rd North Grafton Massachusetts 01536 United States  Contact: Phone: 5088874523 Email: lisa.freeman@tuffs.edu  Permission To Contact Sender: Preferred Method Of Contact: Pmail  Additional Documents:  Attachment: rpt_medical_record_preview B6 odf Description: Medical records			Address:	North Grafton Massachusetts 01536
North Grafton   Massachusetts   01536   United States	Sender Information:	Name:	Lisa Freeman	
Email:   lisa.freeman@tufts.edu		Address:	North Grafton Massachusetts 01536	
Email:   lisa.freeman@tufts.edu		Contact:	Phone:	5088874523
Sender: Preferred Method Of Contact:  Additional Documents:  Attachment: rpt_medical_record_preview B6 pdf Description: Medical records				lisa.freeman@tufts.edu
Additional Documents:  Attachment: rpt_medical_record_preview B6 pdf Description: Medical records			Yes	
Attachment: rpt_medical_record_preview B6 pdf  Description: Medical records			Email	
Description: Medical records	Additional Documents:			
Type: Medical Records		Attachment:	rpt_medical_record_	preview <b>B6</b> pdf
		Description:	Medical records	preview <b>B6</b> pdf
		Description:	Medical records	preview <b>B6</b> pdf

Report Details - EON-	372834			
ICSR:	2059624			
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	TCUCKION OF GISCUSC C	330clated with the producty	
Report Submission Date:	:5 :			
Reported Problem:	Problem Description:	Littermate diagnosed with reduced cardiac contractility Eating BEG diet (Earthborn) so screened all housemates Subjectively reduced contractility on echo and elevated NT-proBNP and cardiac troponin I Taurine pending Owner changing diet and will recheck in 3 months		
	Date Problem Started:	11/20/2018		
	Concurrent Medical Problem:	No		
	Outcome to Date:	Stable		
Product Information:	Product Name:	Earthborn Meadow F	east dry	
	Product Type:			
	Lot Number:	1 1 1 1 1 1 1 1		
	Package Type:	BAG		
	Product Use Information:	Description:	See diet history in medical record for more info	
	Manufacturer /Distributor Information:			
	Purchase Location Information:			
Animal Information:	Name:	B6		
	Type Of Species:	<u>[i</u>		
	Type Of Breed:	Boxer (German Boxe	er)	
	Gender:	Male		
	Reproductive Status:	Neutered		
	Weight:	30.3 Kilogram		
	Age:	3 Years		
	Assessment of Prior Health:	Tends Tends Tends		
	Number of Animals Given the Product:			
	Number of Animals Reacted:	4		
	Owner Information:	Owner Information provided:	,	
		Contact:	Name:	
			Phone: B6	
			Email:	
		Address:	<b>B6</b>	
			United States	
	Healthcare Professional	Practice Name:	Tufts Cummings School of Veterinary Medicine	
	Information:	Contact:		
			Phone: (508) 887-4523	
			Email: lisa.freeman@tufts.edu	

		۰ ـ ـ ـ ـ ـ ـ ـ ـ ـ ـ ـ ـ ـ ـ ـ ـ ـ ـ ـ	000 14/ 11 - 5 1
		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:		5088874523
		Email:	lisa.freeman@tufts.edu
	Permission To Contact Sender:	Yes	
	Preferred Method Of Contact:	Email	
Additional Documents:			
	Attachment:		ecords.pdf
		Medical records	
	Type:	Medical Records	



AT TUFTS UNIVERSITY

**B6** 

#### **All Medical Records**

	В6	
Breed:	Boxer	•
	В6	

Species: Canine Sex: Male

(Neutered)

#### **Referring Information**

**B6** 

#### **Initial Complaint:**

Scanned Record

SOAP Text Nov 20 2018 12:22PM -

**B6** 

#### **Initial Complaint:**

DCM Study

SOAP Text Nov 20 2018 1:10PM -

**B6** 

#### **Disposition/Recommendations**

## Cummings Veterinary Medical Center

AT TUFTS UNIVERSITY

B6	
Veterinarian:	
B6	
Visit ID:	 •

### Lab Results Report

В	36
Species:	Canine
Breed:	Boxer
Sex:	Male (Neutered)
Age:	B6 Years Old

	11/20/2018 5:45:23 PM	Accession ID: 448860	
Test	Results	Reference Range Units	
Troponin I Research - FHSA	В6	0 - 0.08 mg/dl	

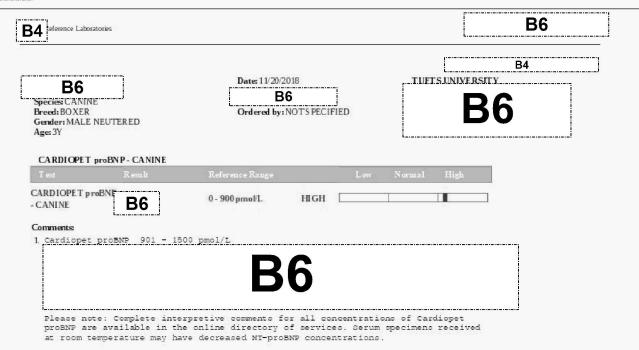
**B4** 

**B6** 3/13

Printed Tuesday, December 04, 2018

B4

· 11/20/2018



Page 1 of 1

#### CARDIAC TROPONIN/TEXGI SST 11/20/18



#### **Gastrointestinal Laboratory**

Dr. J.M. Steiner

#### Department of Small Animal Clinical Sciences Texas A&M University

4474 TAMU

College Station, TX 77843-4474



Website User ID: clinpath@tufts.edu

GI Lab Assigned Clinic ID: 11405

Ci Eus Assigned Chinic ID: 11405			
B6 Tufts University-Clinical Pathology Lab Attn: B6 200 Westboro Road North Grafton, MA 01536 USA		В	6
COA		Species:	Canin
		Date Received:	Nov 27, 2018
Tufts University-Clinical Pathology Lab Tracking Number: 1811200093		GI Lab Ac	cession B6
Test	Result	Reference Interval	Assay Date
Ultra-Sensitive Troponin I Fasting	В6	≤0.06	11/27/18
E	36		
Comments:	<del></del>		

GI Lab Contact Information

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

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



Gastrointestinal Laboratory
Dr. J.M. Steiner

Department of Small Animal Clinical Sciences
Texas A&M University

4474 TAMU

College Station, TX 77843-4474



Important Notices:

B4, B6

GI Lab Contact Information

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

How would you assess your pet's appetite? (mark the point on the line below that best represents your pet's appetite. Poor				ving questions	ise answer the follow	Plea	
Excellent  Poor	NOV ZO	Today's date: ZO		B6			
Excellent  Poor	ppetite)	sents your pet's apr	w that best repres	nt on the line bel	appetite? (mark the po	u assess your pet's	How would you
Haye you noticed a change in your pet's appetite over the last 1-2 weeks? (check all that apply)    Deats about the same amount as usual						Poor	Example:
Haye you noticed a change in your pet's appetite over the last 1-2 weeks? (check all that apply)    Case		lent	Fxcell				
DEats about the same amount as usual □Eats less than usual □Seems to prefer different foods than usual □Cther_  Over the last few weeks, has your pet (check one) □Lost weight □Don't know  Please list below ALL pet foods, people food, treats, snack, dental chews, rawhides, and any other food item to currently eats. Please include the brand, specific product, and flavor so we know exactly what you pet is eating to the same shown in the table – please provide enough detail that we could go to the store and buy the examples are shown in the table – please provide enough detail that we could go to the store and buy the examples are shown in the table – please provide enough detail that we could go to the store and buy the examples are shown in the table – please provide enough detail that we could go to the store and buy the example. See an hamburger  Food (include specific product and flavor)  Nutro Grain Free Chicken, Lentil, & Sweet Potato Adult  dry 1 ½ cup 2x/day 2x/day 35% lean hamburger  microwaved 3 oz 1x/week 30 1			4-20011			20 10 10 10 10 10 10 10 10 10 10 10 10 10	
Please list below ALL pet foods, people food, treats, snack, dental chews, rawhides, and any other food item the currently eats. Please include the brand, specific product, and flavor so we know exactly what you pet is eating the samples are shown in the table – please provide enough detail that we could go to the store and buy the examples are shown in the table – please provide enough detail that we could go to the store and buy the examples are shown in the table – please provide enough detail that we could go to the store and buy the examples of the store and buy the exampl				than usual C	s usual	he same amount as	Eats about the
Examples are shown in the table – please provide enough detail that we could go to the store and buy the exa  Food (include specific product and flavor)  Form  Amount  How often?  Form  Nutro Grain Free Chicken, Lentil, & Sweet Potato Adult  dry  1 ½ cup  2x/day  302  1x/week  9x/day  4x/day  4x/day  7x/day		3. Over the last few weeks, has your pet (check one) □Lost weight □Gained weight □Stayed about the same weight □Don't know					
Food (include specific product and flavor)  Nutro Grain Free Chicken, Lentil, & Sweet Potato Adult  Any 1 1/4 cup 2x/day 2x/day 3x/day 4x/day	g.	at you pet is eating.	know exactly wha	and flavor so we	brand, specific product	Please include the	currently eats. F
Nutro Grain Free Chicken, Lentil, & Sweet Potato Adult dry 1 ½ cup 2x/day 35% lean hamburger microwaved 3 0z 1x/week 2pupperoni original beef flavor treat ½ 1x/day ARawhide treat 6 inch twist 1x/week DEACTHROON - MEADOWPEAST OLD VIJ2C + 2x DAY TEACTHROON - MICROSOPIC STREET OLD VIJ2C + 2x DAY	ct same foo	e and buy the exact	uld go to the store	h detail that we co	<ul> <li>please provide enoug</li> </ul>	shown in the table -	Examples are s
#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   Taurine   Taurine   Carnitine   Any additional gives   No   Multivitamin   Yes   No   Multivitamin   Tyes   No   Coenzyme Q10   Coenzyme Q10   Cother (please list):   Example: Vitamin C  Nature's Bounty  Multivis   Mawhide   Itreat   Microwaved   3 oz   1x/week   1x/day   A  1x/week   Connet the ack of this sheet  Do you give any dietary supplements to your pet (for example: vitamins, glucosamine, fatty acids, or any other supplements)?   Brand/Concentration   Amount  Amount   Amount   Carnitine   Coenzyme Q10   Coenzyme Q10   Coenzyme Q10   Coenzyme Q10   Coenzyme Coenzy	ed since	How often? Fe	Amount I	Form	duct and flavor)	clude specific pro	Food (incl
Pupperoni original beef flavor  Rawhide  treat 6 inch twist 1x/week  EARTHROWN - MEADOWPEAST  OLY  *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  Brand/Concentration  Taurine  Yes No  Camitine  Yes No  Antioxidants  Yes No  Multivitamin  Yes No  Coenzyme Q10  Yes No  Other (please list):  Example: Vitamin C  SUPPLEMENT  Nature's Bounty  SOO mg tablets -	Jan 2018	2x/day Ja	1 ½ cup	dry	& Sweet Potato Adult		
*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	Jan 2015		The first section of the section of	microwaved			
*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)?	Aug 2015		1.70	treat		inal beef flavor	
*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)?	Dec 2015			The state of the s			
Do you give any dietary supplements to your pet (for example: vitamins, glucosamine, fatty acids, or any other supplements)?    Yes	382016	1x DAY FEE	11/20 + 3	DEY	PEAST	N - MEADOW	EARTHBORN
Do you give any dietary supplements to your pet (for example: vitamins, glucosamine, fatty acids, or any other supplements)?    Yes							
Do you give any dietary supplements to your pet (for example: vitamins, glucosamine, fatty acids, or any other supplements)?    Yes							
Do you give any dietary supplements to your pet (for example: vitamins, glucosamine, fatty acids, or any other supplements)?							
Supplements)?				of this sheet	an be listed on the back	l diet information ca	*Any additional
Antioxidants DYes DNo Multivitamin DYes DNo Fish oil DYes DNo Coenzyme Q10 DYes DNo Other (please list):  Example: Vitamin C SUPPLEMENT Nature's Bounty 500 mg tablets -		acids, or any other nts: Amount pe	ands and amoun	h ones and give I oncentration	If yes, please list which Brand/C	Yes •No	supplements)?
Multivitamin DYes DNo Fish oil DYes DNo Coenzyme Q10 DYes DNo Other (please list):  Example: Vitamin C SUPPLEMENT NURRO - DOC SUPPLEMENT  500 mg tablets - 176		-				□Yes □No_	
Fish oil		i		<del>-</del>		DYes DNo_	
Fish oil		1,				DVos DNo	
Coenzyme Q10							
Other (please list):  Example: Vitamin C  SUPPLEMENT  NURD - DOC SUPPLEMENT  SCOOP - 1 TF		9				0 DYes DNo	
Example: Vitamin C SUPPLEMENT NUPPO - DOC SUPPLEMENT SCOOP (~ ) TR		S <del></del>				list):	Other (please lis
SUPPLEMENT NUPRO - DOG SUPPLEMENT 1 SCOOP (~ 1)TH	- 1 per day	500 mg tablets - 1		ire's Bountv	Nati	nin C	Example: Vitam
	250) 1-2 x	1 Score /~ I TRS		LPOI EMENT	NUPRO - DOGS		
How do you administer pills to your pet?	29120						
How do you administer pills to your pet?							
		·-			ir net?	Iminieter nille to you	How do you adn
□ I do not give any medications □ I put them directly in my pet's mouth without food					nouth without food	any medications irectly in my pet's m	☐ I do not give a ☐ I put them dire
□ 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): Pol DGWA CHEESE					ood milar product	n my pet's dog/cat for a Pill Pocket or sin	□ I put them in a

В6

11/20/2018 3:27:51 PM Tufts University

Tufts University Tufts Cummings School of Vet Med Cardiology



11/20/2018 3:28:15 PM

Page 1 of 2

Tufts University
Tufts Cummings School of Vet Med
Cardiology



11/20/2018 3:28:15 PM

Page 2 of 2

Tufts University
Tufts Cummings School of Vet Med
Cardiology

**B6** 

#### **Patient History**

11/20/2018 11:45 AM

11/20/2018 12:23 PM
11/20/2018 01:11 PM
11/20/2018 04:04 PM
11/20/2018 04:04 PM
11/20/2018 04:55 PM
11/20/2018 05:45 PM
11/20/2018 05:46 PM
11/21/2018 11:25 AM

# Cummings Veterinary Medical Center

B6
Male (Neutered) xrer Fawn

11/22/2018
------------

В6				
Thank you for referring	В6	with their	В6	
If you have any questions	, or concern	s, please contact	us a	В6
Thank you,				
	B6			

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

**Sent:** 12/5/2018 12:00:38 AM

Subject: Earthborn Meadow Feast dry: Lisa Freeman - EON-372842

Attachments: 2059630-report.pdf; 2059630-attachments.zip

A PFR Report has been received and PFR Event [EON-372842] has been created in the EON System.

A "PDF" report by name "2059630-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 "2059630-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

**EON Key:** EON-372842

ICSR #: 2059630

**EON Title:** PFR Event created for Earthborn Meadow Feast dry; 2059630

AE Date	11/29/2018	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Stable
Breed	Mixed (Dog)		
Age	8 Years		
District Involved	PFR <b>B6</b> DO		

#### **Product information**

**Individual Case Safety Report Number: 2059630** 

**Product Group:** Pet Food

Product Name: Earthborn Meadow Feast dry

**Description:** DCM and CHF (cough developed earlier but diagnosed 11/29/18) Eating BEG diet Taurine pending

Owner changing diet and we will recheck Note: listed as **B6** in medical record

**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 Meadow Feast 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:

**B6** 

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

**B6** 

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Report Details - EON-	372842				
ICSR:	2059630				
Type Of Submission:	Initial				
Report Version:	FPSR.FDA.PETF.V.V1				
Type Of Report:		reaction or disease a	associated with the product)		
Reporting Type:	Voluntary		r /		
Report Submission Date:					
Reported Problem:	Problem Description:		gh developed earlier but diagnosed 11/29/18) Eating BEG diet ner changing diet and we will recheck Note: listed as <b>B6</b>		
	Date Problem Started:	ļ			
	Concurrent Medical Problem:	Yes			
	Pre Existing Conditions:	Hypothyroidism			
	Outcome to Date:	id			
Product Information:	Product Name:	Earthborn Meadow F	Feast dry		
	Product Type:	·			
	Lot Number:				
	Package Type:	BAG			
	Product Use Information:	Description:	See diet history in medical record for more info I have bag of food if interested in sample		
	Manufacturer /Distributor Information:				
	Purchase Location Information:				
Animal Information:	Name:	В6			
	Type Of Species:				
	Type Of Breed:	:/			
	Gender:	Female			
	Reproductive Status:	Neutered			
	Weight:	19.9 Kilogram			
	Age:	8 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>		
			Email:		
		Address:			
		Address.	<b>B6</b>		
			United States		
	Healthcare Professional	Practice Name:	Tufts Cummings School of Veterinary Medicine		
	Information:	Contact:	;;		
			Phone: (508) 887-4523		

			Email: lisa.freeman@tufts.edu
		Address:	200 Westboro Rd North Grafton Massachusetts 01536 United States
ender Information:	Name:	Lisa Freeman	
	Address:	200 Westboro Rd North Grafton Massachusetts 01536 United States	
	Contact:	Phone:	5088874523
			lisa.freeman@tufts.edu
	Permission To Contact Sender:	Yes	
	Preferred Method Of Contact:	Email	
dditional Documents:			
	Attachment:	rpt_medical_record_	preview.pdf
		Medical records	
	Туре:	Medical Records	

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

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

Sent: 12/5/2018 1:37:23 AM

Subject: Kirkland Signature Nature's Domain Salmon Meal & Sweet Potato Formula for Dogs: B6 - EON-372864

Attachments: 2059643-report.pdf

A PFR Report has been received and PFR Event [EON-372864] has been created in the EON System.

A "PDF" report by name "2059643-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report:

**EON Key:** EON-372864

ICSR #: 2059643

EON Title: PFR Event created for Kirkland Signature Nature's Domain Salmon Meal & Sweet Potato Formula

for Dogs; 2059643

AE Date	09/01/2018	Number Fed/Exposed	2
Best By Date		Number Reacted	2
Animal Species	Dog	Outcome to Date	Worse/Declining/Deteriorating
Breed	Poodle - Miniature		
Age	13 Years		
District Involved	PFR- <b>B6</b> DO		

#### **Product information**

**Individual Case Safety Report Number: 2059643** 

**Product Group:** Pet Food

**Product Name:** Kirkland Signature Nature's Domain Salmon Meal & Sweet Potato Formula for Dogs **Description:** B6 started coughing and passing out. The vet found that he has an enlarged heart.

**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:** Worse/Declining/Deteriorating

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

Product Name	Lot Number or ID	Best By Date
Kirkland Signature Nature's Domain Salmon Meal & Sweet Potato Formula for Dogs		

Sender information			
<b>B</b> 6			
USA			

To view this PFR Event, please click the link below: **B6** 

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

B6

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Report Details - EON-	372864				
ICSR:	2059643				
Type Of Submission:	Initial				
Report Version:	FPSR.FDA.PETF.V.V1				
Type Of Report:	Adverse Event (a symptom,	reaction or disease	associated with the product)		
Reporting Type:	Voluntary				
Report Submission Date:	2018-12-04 20:27:27 EST				
Reporter is the Animal Owner:	Yes				
Reported Problem:	Problem Description: B6 started coughing and passing out. The vet found that he has an enlarged neart.				
	Date Problem Started:	09/01/2018			
	Concurrent Medical Problem:	No			
	Outcome to Date:	Worse/Declining/De	teriorating		
Product Information:	Product Name:	Dogs	lature's Domain Salmon Meal & Sweet Potato Formula for		
	Product Type:	Pet Food			
	Lot Number:				
	Package Type:	BAG			
	Package Size:	35 Pound			
	Purchase Date:				
	Number Purchased:				
	Possess Unopened Product:				
	Possess Opened Product:				
	Storage Conditions:	In a cool garage in the bag in a plastic bin and in a metal covered container, in the house.			
	Product Use	Description:	Feed to the dogs, sometimes with a little water.		
	Information:	Last Exposure Date:			
		Product Use Stopped After the Onset of the Adverse Event:			
		Perceived Relatedness to Adverse Event:	Probably related		
		Other Foods or Products Given to the Animal During This Time Period:			
	Manufacturer				
	/Distributor Information:				
	Purchase Location	Name:	Costco		
	Information:	Address:	B6		
			LUnited States		
Animal Information:	Nome	DE T			
Ammar miormadon.	Name:	B6			
	Type Of Species:	::::::::::::::::::::::::::::::::::::::			
	Type Of Breed:	d: Poodle - Miniature			

	Gender:	Male			
	Reproductive Status:	Neutered			
	Weight:	10 Pound			
	Age:	13 Years			
	Assessment of Prior Health:	Excellent	100 0 100 0 100 0 100 100 100 100 100 1		
	Number of Animals Given the Product:	2			
	Number of Animals Reacted:	2			
	Owner Information:				
	Healthcare Professional	Practice Name:		B6	
	Information:	Contact:	Name:	gravaravaravarararararararar	
			Phone:	<b>B6</b>	G : 6 : 6 : 6 : 6 : 6 : 6 : 6 : 6 : 6 :
		Address:		B6	
			United States	DU	
0 1 10 2					52
Sender Information:	Name:	B6			
	Address:	B6			
		DU			
		United States	j		
	011	[ L			
	Contact:	Phone: Email:	<b>B6</b>		
	Reporter Wants to Remain Anonymous:	No	L		
	Permission To Contact Sender:	Yes			
	Preferred Method Of Contact:	Email			
	Reported to Other Parties:				
Additional Documents:	Falles				
Additional Documents:					

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

**Sent:** 12/5/2018 12:16:14 AM

Subject: Pure Vita Holistic Pet Foods Turkey and Sweet Potato Entree **B6** 

EON-372846

Attachments: 2059634-report.pdf

A PFR Report has been received and PFR Event [EON-372846] has been created in the EON System.

A "PDF" report by name "2059634-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report:

**EON Key:** EON-372846

ICSR #: 2059634

EON Title: PFR Event created for Pure Vita Holistic Pet Foods Turkey and Sweet Potato Entree; 2059634

AE Date	05/05/2018	Number Fed/Exposed	2
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Stable
Breed	Retriever - Golden		
Age	6 Years		
District Involved			

#### **Product information**

**Individual Case Safety Report Number: 2059634** 

Product Group: Pet Food

**Product Name:** Pure Vita Holistic Pet Foods Turkey and Sweet Potato Entree

**Description:** Sudden collapse witnessed in May 2018. Seen by veterinarian same day. Canine cardiologist diagnosed Dilated Cardiac Myopathy. Cardiologist strongly suspected grain free diet. Dog had been on grain free

diet since 1 year of age. Prognosis 2 - 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: 2** 

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

Product Name	Lot Number or ID	Best By Date
Pure Vita Holistic Pet Foods Turkey and Sweet Potato Entree		

Sender	infor	mation

**B6** 

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

**B6** 

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

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

**Sent:** 12/4/2018 11:33:18 PM

Subject: The Honest Kitchen Grain Free Chicken Recipe: **B6** 

EON-372839

Attachments: 2059627-report.pdf

A PFR Report has been received and PFR Event [EON-372839] has been created in the EON System.

A "PDF" report by name "2059627-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report:

**EON Key:** EON-372839

ICSR #: 2059627

EON Title: PFR Event created for The Honest Kitchen Grain Free Chicken Recipe; 2059627

AE Date	06/01/2018	Number Fed/Exposed	
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Stable
Breed	Other Canine/dog		
Age	8 Years		
District Involved	PFR <b>B6</b> 00		

#### **Product information**

**Individual Case Safety Report Number: 2059627** 

Product Group: Pet Food

**Product Name:** The Honest Kitchen Grain Free Chicken Recipe

**Description:** June 2018- Seen by vet (dehydration) Around September 2018 - Seen by vet for rabies and batella shot September 2018 - Seen by Vet multiple times for dehydration, coughing and weekends. This went on for a month. Heart murmur detected. October 2018 - Seen by vet for dehydration, coughing. X-ray taken. Heart murmur confirmed. Placed on two heart medicines. Told she must take for remainder of her life.

**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 Reacted With Product: 1**

Product Name	Lot Number or ID	Best By Date
The Honest Kitchen Grain Free Chicken Recipe		

Sender information		
	<b>B6</b>	

To view this PFR Event, please	click the link below:
<b>B6</b>	

B6	
	J

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Report Details - EON-	372839				
ICSR:	2059627				
Type Of Submission:	Initial				
Report Version:	FPSR.FDA.PETF.V.V1				
Type Of Report:	Adverse Event (a symptom,	reaction or disease	associated with the p	roduct)	
Reporting Type:	Voluntary				
Report Submission Date:	2018-12-04 18:23:32 EST				
Reporter is the Animal Owner:	Yes				
Reported Problem:	Problem Description:	June 2018- Seen by vet (dehydration) Around September 2018 - Seen by vet for rabies and batella shot September 2018 - Seen by Vet multiple times for dehydration, coughing and weekends. This went on for a month. Heart murmur detected. October 2018 - Seen by vet for dehydration, coughing. X-ray taken. Heart murmur confirmed. Placed on two heart medicines. Told she must take for remainder of her life.			
	Date Problem Started:	06/01/2018			
	Date of Recovery:	11/01/2018			
	Concurrent Medical Problem:	No			
	Outcome to Date:	Stable			
Product Information:	Product Name:	The Honest Kitchen	Grain Free Chicken	Recipe	
	Product Type:	Product Type: Pet Food			
	Lot Number:	4			
	Package Type:	: BAG			
	Purchase Date:				
	Number Purchased:	1			
	Possess Unopened Product:				
	Possess Opened Product:	No			
	Storage Conditions:	In bag in Kitchen			
	Product Use	Description:	Feed to my dog		
	Information:	Time Interval between Product Use and Adverse Event:			
		Product Use Stopped After the Onset of the Adverse Event:	Yes		
		Adverse Event Abate After Product Stop:	3 3 3 3 3 3 3 3 3 3		
		Product Use Started Again:	4		
		Perceived Relatedness to Adverse Event:	Definitely related		
		Other Foods or Products Given to the Animal During This Time Period:			
	Manufacturer /Distributor Information:				
	Purchase Location	Name:	B6		

	Information:	Address:	<b>B</b> 0
			<b>B6</b>
			United States
Animal Information:	Name:	В6	
	Type Of Species:	L	
		Other Canine/dog	
	Gender:		
	Reproductive Status:	Intact	
	Pregnancy Status:	Not Pregnant	
	Lactation Status:	Not lactating	
	Weight:	8 Pound	
	Age:	8 Years	
	Assessment of Prior Health:	Excellent	
	Number of Animals Reacted:	1	
	Owner Information:	n maran nakara a maran minara n maran ka maran maran na maran makara.	
	Healthcare Professional Information:		
Sender Information:	Name:	В6	
	Address:	i	
		R6	
		DU	
		United States	i
	Contact:	- Indiana di Amerikana di Ameri	
	Joniaot.	Email:	B6
	Reporter Wants to Remain Anonymous:	NO	
	Permission To Contact Sender:	Yes	
	Preferred Method Of Contact:	Phone	
	Reported to Other Parties:	None	
Additional Documents:			

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

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

Sent: 12/5/2018 12:32:29 AM

Subject: Wellness Core Natural Grain Free Dry Dog Food Ocean Whitefish **B6** 

EON-372851

Attachments: 2059636-report.pdf

A PFR Report has been received and PFR Event [EON-372851] has been created in the EON System.

A "PDF" report by name "2059636-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report:

**EON Key:** EON-372851

ICSR #: 2059636

**EON Title:** PFR Event created for Wellness Core Natural Grain Free Dry Dog Food Ocean Whitefish Herring &

Salmon; 2059636

AE Date	01/01/2016	Number Fed/Exposed	6
Best By Date		Number Reacted	2
Animal Species	Dog	Outcome to Date	Worse/Declining/Deteriorating
Breed	Chihuahua		
Age	15 Years		
District Involved	PFR- <b>B6</b> 00		

#### Product information

**Individual Case Safety Report Number: 2059636** 

Product Group: Pet Food

Product Name: Wellness Core Natural Grain Free Dry Dog Food Ocean Whitefish, Herring & Salmon

**Description:** 2 years ago my dog was diagnosed with canine dilated cardiomyopathy. All of my pets had been on

wellness grain fee food because the vet said it was good for their skin.

**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: Worse/Declining/Deteriorating

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

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

Product Name	Lot Number or ID	Best By Date
Wellness Core Natural Grain Free Dry Dog Food Ocean Whitefish, Herring & Salmon		

Sender information	
<b>B6</b>	
USA	
To view this PFR Event, please click the link below: <b>B6</b>	
To view the PFR Event Report, please click the link below:	
<b>B6</b>	

This email and attached document are being provided to you in your capacity as a Commissioned Official with

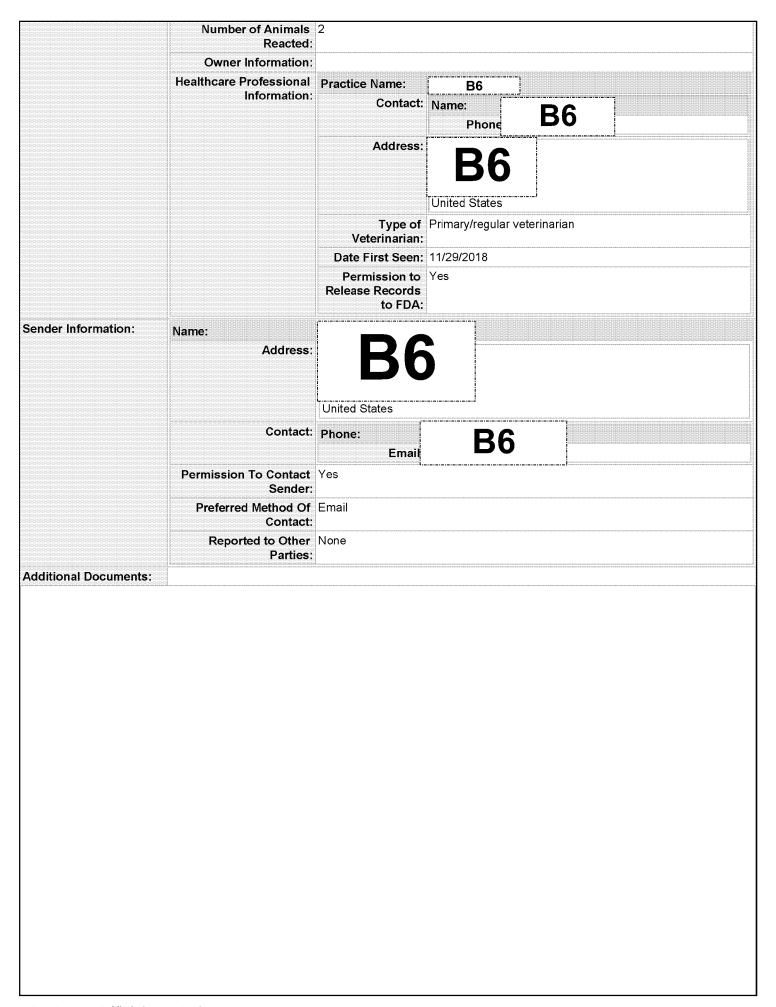
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Report Details - EON-	372851			
ICSR:	2059636			
Type Of Submission:	Initial			
Report Version:	FPSR.FDA.PETF.V.V1			
Type Of Report:	Adverse Event (a symptom,	reaction or disease a	associated with the product)	
Reporting Type:	Voluntary		,	
Report Submission Date:	) 			
Reporter is the Animal Owner:	Yes			
Reported Problem:	Problem Description:	2 years ago my dog was diagnosed with canine dilated cardiomyopathy. A pets had been on wellness grain fee food because the vet said it was goo their skin.		
	Date Problem Started:	01/01/2016		
	Concurrent Medical Problem:	No		
	Outcome to Date:	Worse/Declining/Det	eriorating	
Product Information:	Product Name:	Wellness Core Natur Salmon	ral Grain Free Dry Dog Food Ocean Whitefish, Herring &	
	Product Type:	Pet Food		
	Lot Number:			
	Package Type:	BAG		
	Package Size:	26 Pound		
	Purchase Date:	01/01/2017		
	Number Purchased:	1		
	Possess Unopened Product:			
	Possess Opened Product:			
	Storage Conditions:	Stored in dog food c	ontainer	
	Product Use Information:	Description: Perceived Relatedness to Adverse Event:	Fed daily to pets Definitely related	
		Other Foods or Products Given to the Animal During This Time Period:	No	
	Manufacturer /Distributor Information:	3		
	Purchase Location Information:	Name: Address:	Chewy.com United States	
Animal Information:	Name:	B6		
	Type Of Species:	i		
	Type Of Breed:			
	::{:	r. Mixed Population of Female and Male		
	Reproductive Status:			
	3	t: 6 Pound		
		e: 15 Years		
	Assessment of Prior Health:	Good		
	Number of Animals Given the Product:	6		



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:** 11/11/2018 1:55:59 AM

Subject: DCM cases- Lisa Freeman and/or Tufts-related- 11/10/18

Attachments: Earthborn grain free weight management dry: Lisa Freeman - EON-370708; Nutro Ultra adult dry

dog food the superfood plate (chicken: Lisa Freeman - EON-370712; Pure Balance Salmon and Pea dry: Lisa Freeman - EON-370760; Rachel Ray peak open range recipe (beef: Lisa Freeman - EON-370720; Zignature trout & salmon dry: Lisa Freeman - EON-370715; Zignature Trout &

Salmon Meal Limited Ingredient Formula Grain-Free Dry Dog Food: B6

EON-370762; Zignature trout and salmon dry: Lisa Freeman - EON-370713

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





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

 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

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.

2058678-report.pdf; 2058678-attachments.zip

Below is the summary of the report:

**EON Key:** EON-370708

Attachments:

ICSR #: 2058678

**EON Title:** PFR Event created for Earthborn grain free weight management dry; 2058678

AE Date	B6	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 <b>B6</b> 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 **B6** 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



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

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

**B6** 

**B6** 

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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 a	ssociated 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 <b>B6</b> Currently hospital Taurine submitted to UC Davis. Unclear if related to diet, given breed but a boutique, grain-free diet. Only prior history is traumatic injury in 2015.		
	Date Problem Started: Concurrent Medical Problem:	No		
	Outcome to Date:			
Product Information:	Product Name:	Earthborn grain free	weight management dry	
	Product Type:	Pet Food		
	Lot Number:			
	Package Type:	BAG		
	Product Use			
	Information:			
	Manufacturer /Distributor Information:			
	Purchase Location Information:			
Animal Information:	Name:	В6		
	Type Of Species:	Dog		
	Type Of Breed:	Doberman Pinscher		
	Gender:	Male		
	Reproductive Status:	Neutered		
	Weight:	45.2 Kilogram		
	Age:	B6		
	Assessment of Prior	Excellent		
	Health:			
	Number of Animals Given the Product:			
	Number of Animals Reacted:	1		
	Owner Information:	Owner Information provided: Contact:	Name:	
			Phone: B6	
			Email:	
		Address:		
			<b>B</b> 6	
	Healthcare Professional	Practice Name:	Tufts Cummings School of Veterinary Medicine	
	Information:			
		Contact:		
			Phone: (508) 887-4523	
			Email: lisa.freeman@tufts.edu	

Sender Information:  Address: Address:  Address:  Address:  Address:  Contact: Permission To Contact: Sender: Preferred Method Of Contact:  Additional Documents:  Attachment: Description: Description: Medical records Type: Medical Records			Address: 200 Westboro Rd North Grafton Massachusetts 01536 United States
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 Description: Medical records	Sender Information:	Name:	Lisa Freeman
Permission To Contact Sender: Preferred Method Of Contact:  Additional Documents:  Attachment:  Description:    Email:   lisa.freeman@tufts.edu		Address:	North Grafton   Massachusetts   01536
Sender: Preferred Method Of Contact:  Additional Documents:  Attachment: compiled medical record B6 pdf Description: Medical records		Contact:	
Additional Documents:  Attachment: compiled medical record B6 pdf  Description: Medical records			
Attachment: compiled medical record B6 pdf  Description: Medical records			
Description: Medical records	Additional Documents:		
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**B6** 

Medical Record for B6

Patient B6

Breed: Doberman Pinscher

DOB: B6

Species: Canine Sex: Male (Neutered)

Referring Information

**B6** 

**Initial Complaint:** 

Emergency

SOAP Text

**B6** 

6:41PM - Clinician, Unassigned FHSA

**Subjective** 

**NEW VISIT (ER)** 

**B6** 

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 or 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





ASSESSMENT:

A1: CHF secondary to DCM

PLAN:

Diagnostics completed:

ECG on intake-- Atrial fibrilation
AFAST/TFAST-- no FF, enlargement of chambers, consistent with DCM
NOVA-- no significant findings
PCV/TS-- 65/7

Diagnostics pending:

**B6** 

#### Client communication:

Confirmed history with owners. Discussed that on presentation arrythmia is still present. Recommended hospitalization with bloodwork, monitoring, initiating medications, and echocardiogram. O ok with plan. Discussed resuscitation code, o hesistant but settled on red code. Discussed that new dr would take over in AM and that no updates between now and then is good news.

Introduced o to Dr. Freemen, o intersted in being enrolled in DCM study.

Deposit & estimate status: 2500

Resuscitation code (if admitting to ICU): Red

SOAP approved (DVM to sign): **B6** DVM

**SOAP Text** 

**B6** 

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 B6 at that time radiographs showed cardiomegaly and ECG indicated atrial fibrillation. Patient was given 2 doses of furosemide (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.



**B6 B6 B6 B6 SOAP Text** 7:19AM - Clinician, Unassigned FHSA Subjective **B6** 



 ${\bf Disposition/Recommendations}$ 

## Cummings Veterinary Medical Center

**B6** 

B6		
Veterinarian:		
В6	·	
Visit ID:		

E	36
Species:	Canine
Breed:	Doberman Pinscher
Sex:	Male (Neutered)
Age:	<b>B6</b> Years Old

### Lab Results Report

CBC, Comprehensive, Sm Animal	<b>B6</b> 3:12:13 PM	В6	
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)	DC	64.5 - 77.5	fL
MCHC(ADVIA)	<b>B6</b>	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		B6	
Test	Results	Reference Range	Units
TRIGLYCERIDES	<b>D</b> 0	30 - 338	mg/dl
CHOLESTEROL	B6	82 - 355	mg/dL

**B4** 

8/49

**B6** 

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SODIUM		140 - 150	mEq/L
CALCIUM2		9.4 - 11.3	mg/dL
GLOBULINS		2.3 - 4.2	g/dL
POTASSIUM		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
СК		22 - 422	U/L
CHLORIDE	6	106 - 116	mEq/L
CHLORIDE T. PROTEIN	O	5.5 - 7.8	g/dL
GGT		0 - 10	U/L
ALT		14 - 86	U/L
tCO2 (BICARB)		14 - 28	mEq/L
AMYLASE		409 - 1250	U/L
D.BILIRUBIN		0 - 0.1	mg/dL
NA/K		29 - 40	
AGAP		8 - 19	
OSMOLALITY (CALCULATED)		291 - 315	mmol/L
AST		9 - 54	U/L
CREATININE		0.6 - 2	mg/dL
A/G RATIO		0.7 - 1.6	
UREA		8 - 30	mg/dL
i	!		

Microscopic Exam of Blood Smear (A	B6	3:12:13 PM	В6	
Test	Results		Reference Range	Units
MONOS (ABS)ADVIA			0.1 - 1.5	K/uL
LYMPHS%			7 - 47	%
MONOS%			1 - 15	%
SEGS%	DC		43 - 86	%
LYMPHS (ABS)ADVIA	<b>B6</b>		1 - 4.8	K/uL
WBC MORPHOLOGY			0 - 0	
No Morphologic Abnormalities				
SEGS (AB)ADVIA			2.8 - 11.5	K/ul
L.				

9/49 **B6** 

POIKILOCYTOSIS

Occasional

0 - 0

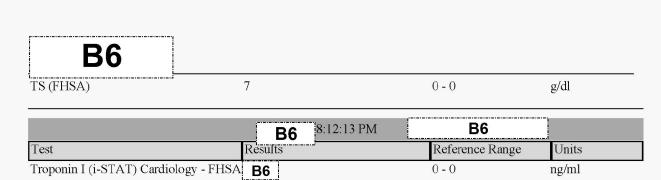
Nova Full Panel-ICU	<b>B6</b> 3:12:13 PM	В6	
Test	Results	Reference Range	Units
nMG		0 - 0	mmol/L
CA (ionized)		1.17 - 1.38	mmol/L
BEecf		0 - 0	mmol/L
BEb		0 - 0	mmol/L
TCO2 (POC)		0 - 0	mmol/L
GLUCOSE (POC)		80 - 120	mg/dL
MG (POC)		0.1 - 0.4	mmol/L
HCT (POC)		38 - 48	%
CREAT (POC)		0.2 - 2.1	mg/dL
SO2%		94 - 100	%
K (POC)		3.6 - 4.8	mmol/L
FiO2		0 - 0	%
NOVA SAMPLE		0 - 0	
CA/MG	DC	0 - 0	mol/mol
BUN (POC)	<b>B6</b>	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
РН		7.337 - 7.467	
PCO2		36 - 44	mmHg
PO2		80 - 100	mmHg
HCO3		18 - 24	mmol/L

None	<b>B6</b> 8:12:13 PM	В6	
Test	Results	Reference Range	Units
TS (FHSA)	DC	0 - 0	g/dl
PCV **	B6	0 - 0	%
L.			

**B4** 

10/49

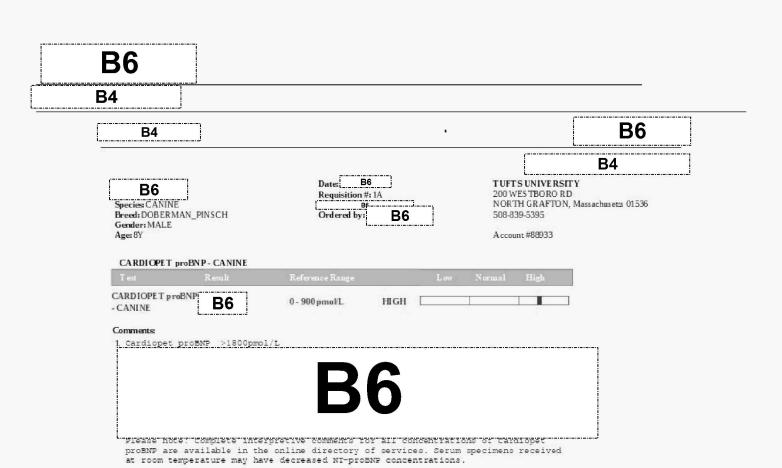
В6



Chemistry 21 (Cobas)	<b>B6</b> 3:12:13 PM	Accession ID: B6	-
Test	Results	Reference Range	Units
AST		9 - 54	U/L
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	<b>B6</b>	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

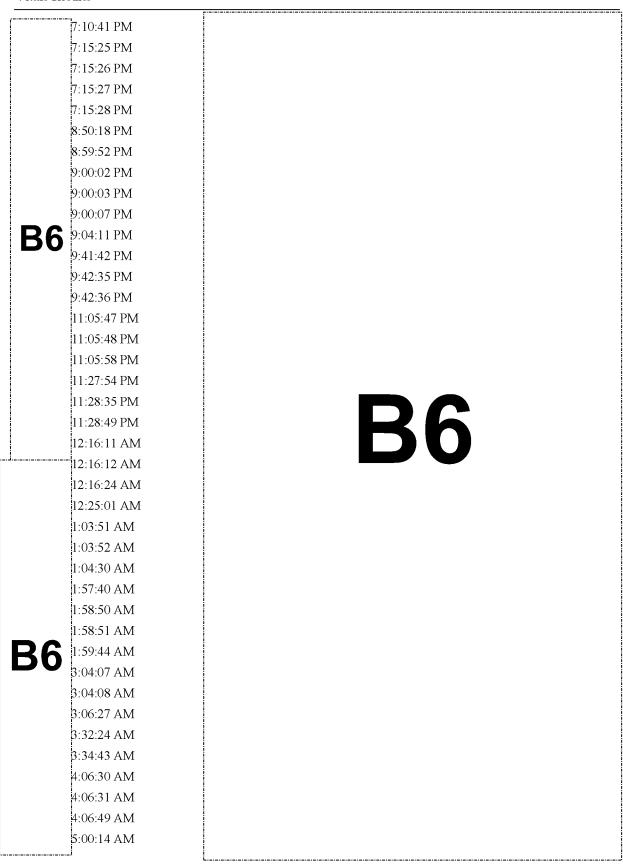
None	<b>B6</b> 8:12:13 PM	B6	
Test	Results	Reference Range	Units
TS (FHSA)		0 - 0	g/dl
PCV **	B6	0 - 0	%
TS (FHSA)		0 - 0	g/dl

**B4** 11/49 **B4** 



Page 1 of 1

#### Vitals Results



Page 13/49

Vitals Results 5:24:57 AM 5:24:58 AM 5:25:15 AM 5:46:22 AM 5:46:49 AM 5:46:50 AM 6:31:20 AM 6:31:21 AM 6:31:40 AM 7:12:38 AM 7:12:54 AM 7:13:08 AM 7:13:09 AM 7:13:51 AM 7:13:59 AM 7:16:21 AM 7:16:22 AM 7:16:23 AM 9:19:06 AM **B6** 9:36:24 AM **B6** 9:36:25 AM 9:58:09 AM 9:58:10 AM 10:06:41 AM 10:07:04 AM 10:15:59 AM 10:16:39 AM 11:31:33 AM 11:31:34 AM 11:33:55 AM 11:37:52 AM 12:02:52 PM 12:02:53 PM 12:03:56 PM 1:11:16 PM 1:13:44 PM 1:13:45 PM 1:16:08 PM 1:38:13 PM 1:51:30 PM 1:51:31 PM

Vitals Results

3:03:10 PM 3:10:58 PM 3:10:59 PM 3:36:48 PM 3:37:03 PM 4:33:09 PM 4:33:31 PM 4:33:32 PM 5:08:41 PM 5:08:42 PM 5:18:43 PM 6:31:11 PM 6:31:46 PM 6:31:47 PM 6:31:55 PM 6:32:03 PM 9:01:47 PM 9:02:04 PM 9:02:15 PM **B6** 9:32:43 PM **B6** 9:32:57 PM 9:33:11 PM 9:33:12 PM 9:45:07 PM 11:17:03 PM 11:18:05 PM 11:18:06 PM 11:58:17 PM 11:58:18 PM 11:59:06 PM 12:45:06 AM 12:45:29 AM 12:45:30 AM 1:53:36 AM 1:53:49 AM 1:54:14 AM 1:54:15 AM 2:49:27 AM 2:49:28 AM 2:50:03 AM 3:26:42 AM Page 15/49

**B6** Vitals Results 4:00:38 AM 4:00:39 AM 4:01:06 AM 5:12:19 AM 5:12:20 AM 5:12:33 AM 5:19:34 AM 5:21:05 AM 5:34:53 AM 5:35:01 AM 5:54:55 AM 5:55:09 AM 5:55:10 AM 6:27:18 AM 6:27:19 AM 6:27:52 AM 7:18:19 AM 7:18:32 AM 7:18:33 AM **B6** 7:19:29 AM **B6** 7:19:30 AM 7:19:31 AM 7:19:32 AM 7:42:35 AM 8:47:36 AM 8:47:37 AM 8:47:47 AM 8:50:11 AM 9:09:21 AM 11:08:26 AM 11:08:27 AM 11:20:51 AM 11:21:02 AM 12:06:15 PM 12:06:16 PM 12:06:28 PM 12:39:17 PM 1:03:57 PM 1:03:58 PM 1:04:22 PM 1:20:21 PM

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**B6** 

11:06:07 AM

Tufts University
Tufts Cummings School of Vet Med
Cardiology

В6

B6

11:06:48 AM

Page 1 of 2

Tufts University Tufts Cummings School of Vet Med Cardiology

12 Lead: Standard Placement

B6 11:06:48 AM

Page 2 of 2

Tufts University
Tufts Cummings School of Vet Med Cardiology

12 Lead; Standard Placement

**ECG** from Cardio

**B6** 

**B6** 

11:07:04 AM

Tufts University
Tufts Cummings School of Vet Med
Cardiology

B6

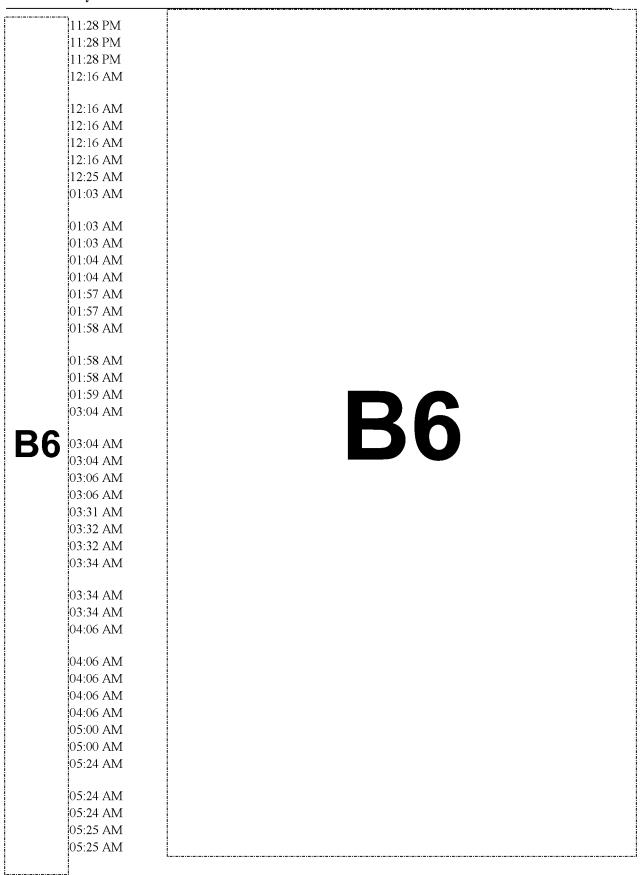
11:07:15 AM
Tufts University
Tufts Cummings School of Vet Med
Cardiology

#### **Patient History**

09:42 PM 09:42 PM 11:05 PM 11:05 PM 11:05 PM 11:05 PM 11:27 PM 11:27 PM 11:28 PM	07:05 PM 07:07 PM 07:10 PM 07:15 PM 07:15 PM 07:15 PM 07:15 PM 07:15 PM 07:23 PM 07:23 PM 07:23 PM 08:12 PM 08:12 PM 08:38 PM 08:38 PM 08:38 PM 08:50 PM 08:50 PM 08:50 PM 08:59 PM 09:00 PM 09:00 PM 09:00 PM 09:00 PM 09:04 PM 09:09 PM	<b>B</b> 6
09:42 PM 09:42 PM 09:42 PM 11:05 PM 11:05 PM 11:05 PM 11:05 PM 11:05 PM 11:27 PM 11:27 PM	09:41 PM	
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**Patient History** 



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**Patient History** 

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**Patient History** 

109:58 AM 09:58 AM 09:58 AM 10:06 AM 10:07 AM 10:07 AM 10:07 AM 10:15 AM 10:15 AM 10:16 AM 10:16 AM 10:19 AM 10:19 AM 10:19 AM 10:19 AM 10:43 AM **B6** 11:03 AM 11:25 AM 11:31 AM **B6** 11:31 AM 11:31 AM 11:33 AM 11:33 AM 11:37 AM 11:37 AM 12:02 PM 12:02 PM 12:02 PM 12:03 PM 12:03 PM 12:55 PM 12:57 PM 12:58 PM 01:10 PM 01:11 PM 01:11 PM **B6** 01:13 PM 01:13 PM 01:13 PM 01:16 PM 01:16 PM

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**Patient History** 

01:30 PM 01:30 PM 01:38 PM 01:38 PM 01:43 PM 01:51 PM 01:51 PM 01:51 PM 03:03 PM 03:03 PM 03:10 PM 03:10 PM 03:10 PM 03:36 PM 03:37 PM 03:37 PM 03:37 PM 04:33 PM 04:33 PM **B6** 04:33 PM **B6** 04:33 PM 04:33 PM 05:08 PM 05:08 PM 05:08 PM 05:18 PM 05:18 PM 06:29 PM 06:31 PM 06:32 PM 06:32 PM 09:01 PM

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**Patient History** 

09:01 PM 09:01 PM 09:02 PM 09:02 PM 09:32 PM 09:32 PM 09:32 PM 09:32 PM 09:32 PM 09:32 PM 09:33 PM 09:33 PM 09:33 PM 09:44 PM 09:45 PM 09:45 PM 11:17 PM 11:17 PM 11:18 PM **B6** 11:18 PM **B6** 11:18 PM 11:58 PM 11:58 PM 11:58 PM 11:59 PM 11:59 PM 12:45 AM 12:45 AM 12:45 AM 12:45 AM 12:45 AM 01:11 AM 01:53 AM 01:53 AM 01:53 AM 01:53 AM 01:54 AM 01:54 AM 01:54 AM 02:49 AM 02:49 AM

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**Patient History** 

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**Patient History** 

07:19 AM 07:19 AM 07:19 AM 07:42 AM 07:42 AM 08:47 AM 08:47 AM 08:47 AM 08:47 AM 108:47 AM 08:48 AM 08:50 AM 08:50 AM 08:56 AM 09:09 AM 09:09 AM 11:08 AM 11:08 AM 11:08 AM 11:20 AM **B6** 11:20 AM **B6** 11:21 AM 11:21 AM 12:06 PM 12:06 PM 12:06 PM 12:06 PM 12:06 PM 12:39 PM 101:03 PM 01:03 PM 01:03 PM 01:04 PM 01:04 PM 01:04 PM 01:20 PM 01:20 PM 01:20 PM 01:20 PM 01:20 PM 01:21 PM 01:21 PM 02:53 PM 03:15 PM

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#### **Patient History**

D3:15 PM 03:15 PM )3:16 PM D3:16 PM 03:40 PM )3:48 PM 03:48 PM 03:48 PM D3:48 PM 03:48 PM **B6** 03:48 PM 53:48 PM 04:45 PM D4:45 PM 04:47 PM 04:47 PM 04:48 PM 05:47 PM 55:47 PM D5:47 PM 05:47 PM

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improsed rechest of refront				
B6 Species: Canine Black/Tan Male (Neutered) Doberman Pinscher Birthdate: B6	<b>B6</b>	B6  Date of request: B6		
B6		Student:		
Date of exam: B6 Patient Location: Ward/Cage:		Weight (kg) 45.20		
Sedation Inpatient BAG Outpatient Time: OBAG Waiting Inpatient Time: Anesthesia to sedate/anesthetize				
Examination Desired: 1 view thoracic radiograph (lateral) - to be done standing in large animal, please.  Presenting Complaint and Clinical Questions you wish to answer:  Emergency				
Pertinent History: B6 is an 8yo MN Dobie presented as referral yesterday for CHF and suspected DCM. Evaluated by rDVM B6 at that time radiographs showed cardiomegaly, pulmonary edema and ECG indicated atrial fibrillation. Patient was given 2 doses of furosemide (4mg/kg total) and referred here. 1 dose of Furosemide overnight.				
	<b>B</b> 6			

#### Condusions:

- Resolving pulmonary edema and unchanged cardiomegaly consistent with diagnosed DCM. A complete thoracic series may be considered for full evaluation.

**B6** 

Dates

Reported: B6

**B6** 

#### Discharge Instructions

B6 Species: Canine Black/Tan Male (Neutered) Doberman Pinscher Birthdate: B6	<b>B6</b>	B6
В	6	

Admit Date:	В6	6:1	957	PM
Discharge Date:		<b>B6</b>		

#### 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 Tults! He is a lovely boy!

On presentation, Bode 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 KCU and was started on cardiac medications in order to help decrease his heart rate and pump better.

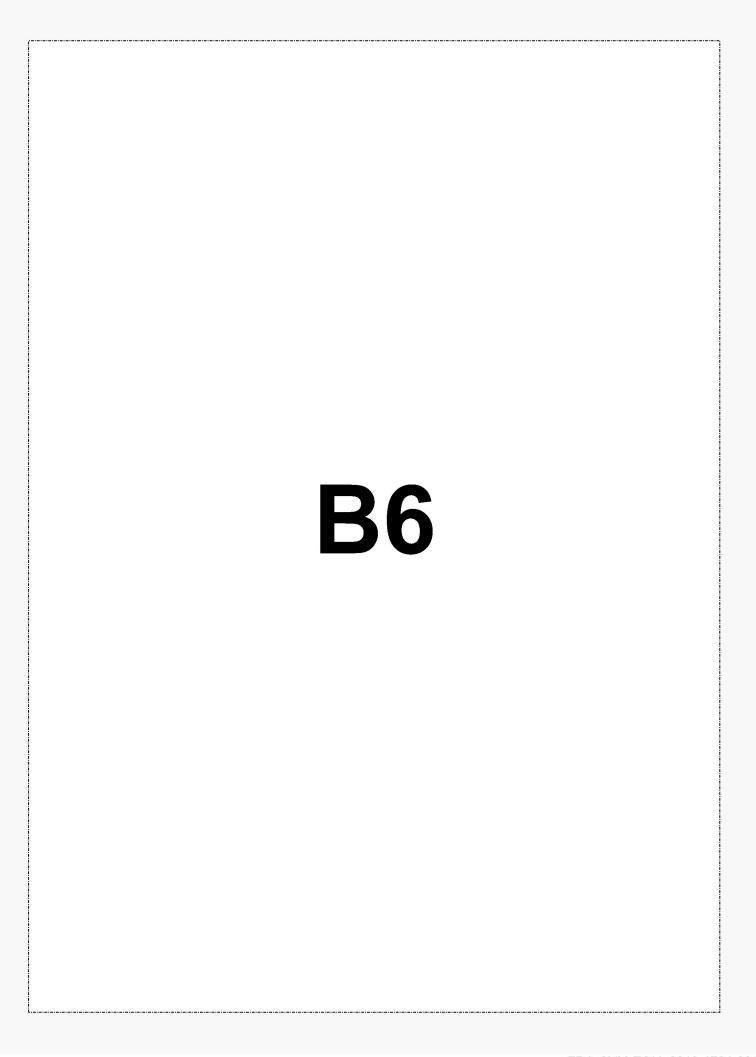
**B6** 

B6 as been diagnosed with a primary heart muscle disease called dilated cardiomyopathy (DCM). This disease is

more common in large and giant breed dogs and is characterized by 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 Discharge Instructions

**B6** 

Alivecor/Kardia Handout

B4, B6

## B4, B6

AT TUFTS UNIVERSITY Cardiology Liaison: 508-887-4696 B6 Canine

B6 Years Old Male (Neutered)

Doberman Pinscher

Black/Tan BW: Weight (kg) 45.20

#### **Cardiology Inpatient**

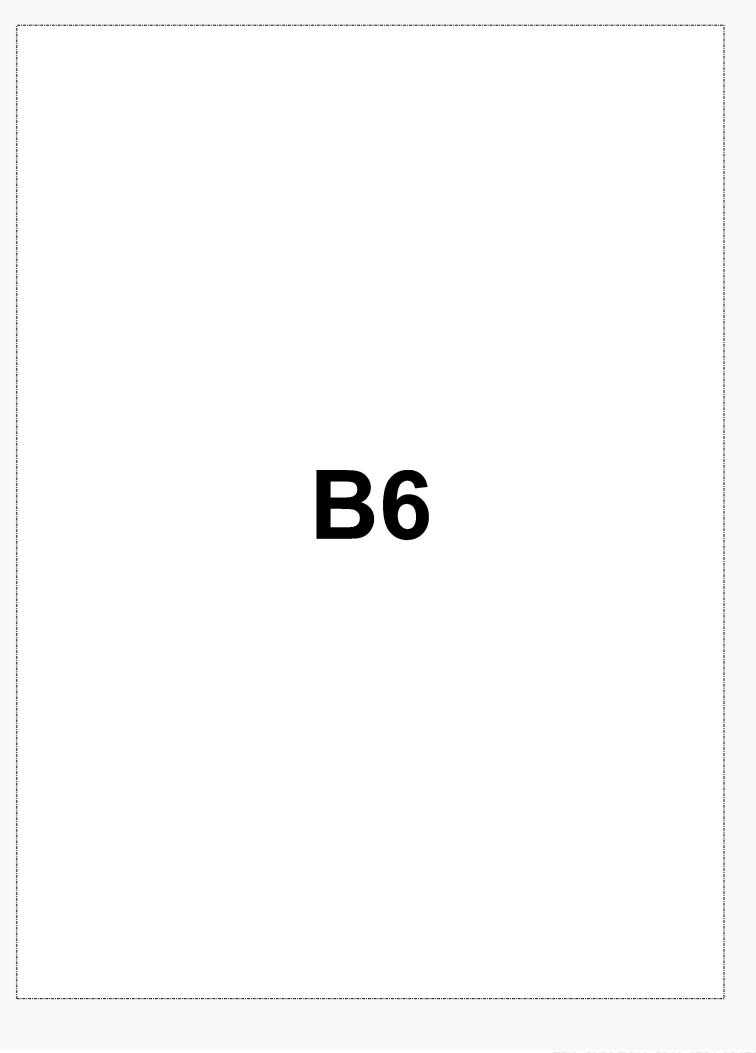
Date: Weight	B6 : Weight (I	g} 45.20	
		<b>B6</b>	

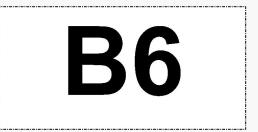
\*STOP - remainder of form to be filled out by Cardiology\*

Physical Examination	
В	6
Muscle condition:	_
<ul><li>Normal</li><li>Mild muscle loss</li></ul>	☐ Moderate cachexia ☐ Marked cachexia
Cardiovascular Physical Exam	
Murmur Grade:	<b>□</b> IV/VI
i None ☑ I/VI	■ 10/VI ■ V/VI
□ ii <b>/v</b> i	□ vi⁄vi
<b>□</b> III <b>/</b> VI	

Murmur location/description: left apical systolic

Jugular vein:	_
Bottom 1/3 of the neck	■ Top 2/3 of the neck
Middle 1/3 of the neck	■ 1/2 way up the neck
Arterial pulses:	
Weak	Bounding
Fair	☑ Pulse deficits
Good	Pulsus paradoxus
■ Strong	Other (describe):
	— ( <i>)</i> -
Arrhythmia:	
None	☐ Bradycardia
Sinusamhythmia	□ Tachycardia - atrial fibrillation
Premature beats	= radificatula - actiai ilmi illacturi
□ Fielladie beas	
Callan	
Gallop:	Pronounced
No No	Other:
Intermittent	
Pulmonary assessments:	
Eupneic Eupneic	Pulmonary Crackles
Mild dyspnea	Wheezes
Marked dyspnea	Upper airway stridor
Normal BV sounds	Other auscultatory findings:
Abdominal exam:	
✓ Normal	Abdominal distension
Hepatomegaly	Mild ascites
Echocardiogram Findings:	
	RA
	DU
Doppler findings:	
Mittal inflow:	
Summated	Pseudonomal Pseudonomal
🖳 Normal	Restrictive
Delayed relaxation	
Blood Pressure (mmHg):	
Cuff size:	
Limb:	
ECG findings:	
Heartrate: B6	





#### **Notice of Patient Admit**

Date: B6 6:19:57 PM	
<b>B6</b>	
B6	
communication with our team.	cy service. Please make note of the following information to facilitate
B6	
The reason for admission to the FH	SA is: DCM, Afib
If you have any questions regarding this Information is updated daily, by noon.	s particular case, please call B6 to reach the Cardiology Service.
Thank you for your referral to our Emer	gency Service.



B6 Male (Neutered) Canine Doberman Pinscher Black/Tan 329174

**B6** 

#### Daily Update From the Cardiology Service

Today's date:	<b>B</b> 6		
Dear	B4, B6		
Thank you for University.	referring patients to	В6	at the Cummings School of Tufts
Your patient	B6 wasadmitted a	nd is being cared for	by the Cardiology Service.
Today B6			
	table condition		
Property Co.	in the oxygen cage		
	ically ill		
<b>™</b> discha	arged from the hospital B	6	
Today's treatr	nents include:		
	work planned/pending		
	ardiography		
_	c catheter procedure planned		
	nent for CHF secondary to DC		
	ng treatment for thrombosis		
	ng treatment for arrhythmia (	atrial fibrillation)	
Additional pla			
Please allow 3	3-5 business days for reports t	o be finalized upon p	atient discharge.
ni!! (co	10\ 007 #CNC L_f F		
Thank you!	16) 867-4696 before 5pm or e	maii us at <b>earciiov</b> eng	Ptufts.edu if you have any questions.
Attending Clin	icia D <i>i</i>	2	
Faculty Clinicia	an: B	<b>O</b>	
Conjurcturdant	t		

# Appears this way on original

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

**Sent:** 11/9/2018 10:28:41 PM

Subject: Nutro Ultra adult dry dog food the superfood plate (chicken: Lisa Freeman -

EON-370712

Attachments: 2058680-report.pdf; 2058680-attachments.zip

A PFR Report has been received and PFR Event [EON-370712] has been created in the EON System.

A "PDF" report by name "2058680-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 "2058680-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

**EON Key:** EON-370712

ICSR #: 2058680

**EON Title:** PFR Event created for Nutro Ultra adult dry dog food the superfood plate (chicken lamb salmon);

2058680

AE Date	09/17/2018 <b>Number Fed/Exp</b>		1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Stable
Breed	Setter - Irish Red		
Age	11 Years		
District Involved	PFR <b>B6</b> DO		

#### **Product information**

**Individual Case Safety Report Number: 2058680** 

Product Group: Pet Food

**Product Name:** Nutro Ultra adult dry dog food the superfood plate (chicken, lamb, salmon)

**Description:** DCM and CHF diagnosed 9/17/18. Unclear if this is a diet-associated DCM because this is not boutique company or grain free but some properties of diet could be suspicious (lamb, rice bran, etc). Owner has fed this same food since dog was a puppy. Has since changed to Pro plan adult sensitive skin and stomach dry plus Science beef/barley canned. Plasma taurine **B6** WB= **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: 1 Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Nutro Ultra adult dry dog food the superfood plate (chicken, lamb, salmon)		

# Sender information

Lisa Freeman 200 Westboro Rd North Grafton, MA 01536 USA

A	· . c .	4 •
Owner	intoi	mation

**B6** 

To view this PFR Event please click the link below:

**B6** 

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

В6

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.



Report Details - EON-	370712		
ICSR:	2058680		
Type Of Submission:	Initial		
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:	2018-11-09 17:18:34 EST		
Reported Problem:	Problem Description:	because this is not b could be suspicious dog was a puppy. Ha	osed 9/17/18. Unclear if this is a diet-associated DCM outique company or grain free but some properties of diet (lamb, rice bran, etc). Owner has fed this same food since as since changed to Pro plan adult sensitive skin and ence beef/barley canned. Plasma taurine B6 WB=B6
	Date Problem Started:	09/17/2018	
	Concurrent Medical Problem:	No	
	Outcome to Date:	Stable	
Product Information:	Product Name:	Nutro Ultra adult dry	dog food the superfood plate (chicken, lamb, salmon)
	Product Type:		
	Lot Number:		
	Package Type:	BAG	
	Product Use Information:	Description:	2 scoops twice daily (scoop is ~1.5 cups)
	Manufacturer /Distributor Information: Purchase Location Information:		
Animal Information:	Name: Type Of Species:	B6	
	5	Setter - Irish Red	
	Gender:	(	
	Reproductive Status:	<u> </u>	
	2 2	28.8 Kilogram	
	5 [	11 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>
			Email:
		Address:	
			<b>B6</b>
	Healthcare Professional Information:	Practice Name: Contact:	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
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:			
	Attachment:	taurine.pdf	
	Description:		
	Туре:	Laboratory Report	
	Attachment:	compiled records	B6 pdf
	Description:		
	Туре:	Medical Records	



**B6** 

#### **All Medical Records**

B6
Breed: Irish Setter
B6

Species: Canine
Sex: Male
(Neutered)

#### **Referring Information**

**B6** 

### **Initial Complaint:**

Emergency

SOAP Text E

**B6** 

9:46AM - Clinician, Unassigned FHSA

#### **Subjective**

**NEW VISIT (ER)** 

**B6** 

Presenting complaint: Bicavitary effusion, respiratory distress

Referral visit? Yes

Diagnostics completed prior to visit

TFAST - Pleural fluid seen

AFAST - Abdominal fluid seen, sample taken

CXR - markedly enlarged R heart

**HISTORY:** 

Signalment: **B6** yo MC Irish Setter

Current history: 1 month ago started to have decreased appetite. Increased respiratory rate and effort, possibly positional. Intermittent liquidy brown diarrhea. Decreased energy level/exercise intolerance, increased thirst, collapsed after claimbing a staircase this morning and that is when O went to rDVM. Normal urination, no c/s/v.

Ate a chipumunk recently.

Prior medical history: Recurrent facial cyst, removed surigically. Hx of Lyme.

Current medications: None

Diet: Ate Nutra-Ultra whole life, waning appetite past month

Vaccination status/flea & tick preventative use: UTD, monthly flea/tick/hw

Travel history: No

EXAM:

**B6** 

BCS(1-9): 3

MCS(normal, mild, moderate, severe): mild

**B6** 

ASSESSMENT:

**B6** 

PLAN:

**B6** 

B6	
<b>B</b> 6	
Diagnostics/procedur	es:
	<b>B6</b>
Cardiology Consult: A	ctive biventricular heart failure likely 2o to severe DCM. B6
	<b>B6</b>
long term prognosis.	n: Discussed with o that B6 was in active biventricular heart failure and that this carried a poor O was very upset but want to do all necessary to get 50 out of heart failure now to e. Outlined treatment with lasix and pimo. O called for update and told him that P is still doing easily after removing some of the fluid.
Deposit & estimate st  B6  Resuscitation code (if	admitting to ICU): yellow
В6	
ADDENDUM:	
- Due to error prescri	bed out pimobendan 5 mg tablets #12 rather then 10 mg #6. Changed orders to reflect this.
SOAP Text B6	8:44AM - Clinician, Unassigned FHSA
<b>B6</b> Daily SOAP	
Subjective	\
***************************************	Irish Setter who presented <b>B6</b> to Tufts ER for dyspnea and was diagnosed with bicavitary tricular CHF. 3L abdominal effusion removed. Started on lasix and pimobendan yesterday. Hx of
	: liquidy brown diarrhea and increased thirst (normal urination).
Did well O/N with RR	between 16 and 32; low appetite.
Exam, cardiology	
	<b>B6</b>
	207

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	u

Overall impression since arrival or since last exam: Improved since admittance, no respiratory effort noted

Appetite: Eating 50% of food offered

**B6** 

Diagnostics completed:

**B6** 

Cardio consult: Active biventricular heart failure likely 20 to severe DCM.

**B6** 

В6

Assessments

**B6** 

Plan

В6

**B6** 

**Initial Complaint:** 

Recheck - **B6** 

**SOAP Text** 

**B6** 

12:05PM -

B6

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	I	3	6
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<u>Initial</u>	Com	plaint:

Emergency

SOAP Text	В6	10:22AM -	В6	7			
Subjective NEW VISIT (E	i		·				
		·					
В	6						
Presenting co	omplaint: o	<u>.</u> dyspnea					
Referral visit							
Diagnostics of	ompleted	prior to visit				1	
		E	36				
Cardiology C	onsult: Act	tive biventricula	ır heart failu	re likely 2o to	severe DCM.	j	
				36			
L							 
HISTORY:							
Signalment:	11YO MN 1	red Irish Setter					
Current histo							 
		een coughing n Iomen has got k					
He was recer	ntly diagno	sed here with I	DCM + CHF.				 ï
			B	6			
EXAM:							 j
Jerne W. F. Li	В	6					
			ŀ	36			

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**B6** 

Client communication:

В6

Deposit & estimate status **B6** 

Resuscitation code (if admitting to ICU): yellow

SOAP approved (DVM to sign): **B6** BVSc

SOAP Text 0 B6 :03AM - Clinician, Unassigned FHSA

**History:** 

B6 is an 11yo CM Irish Setter who presented B6 to Tufts ER then again B6 for dyspnea. Previously diagnosed with DCM and biventricular failure.

## **Subjective:**

T: Not taken

**B6 B6 Objective: B6 ER Diagnostics: B6 Assessments B6** Plan **B6 Initial Complaint:** PAGE ANTOON -**B6** SOAP Text Oct 5 2018 4:07PM -

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<b>B6</b>		 
Initial Complaint:  Recheck B6		
SOAP Text Oct 12 2018 2:16PM	В6	
Initial Complaint:  Recheck - B6		
SOAP Text Oct 19 2018 3:10PM -	В6	
Initial Complaint:  B6 tech - chem 21		
SOAP Text Oct 31 2018 4:12PM	B6	

**Disposition/Recommendations** 



B6
Veterinarian:
В6
Visit ID:

Е	36
Species:	Canine
Breed:	Irish Setter
Sex:	Male (Neutered)
Age:	B6 Years Old

# Lab Results Report

Nova Full Panel-ICU	B6 9:58:25 AM	В6	
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)	<b>D</b> 0	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
A		0 - 0	mmHg
NOVA SAMPLE		0 - 0	
	10/97	B6	

**B4** 

Printed Friday, November 09, 2018

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FiO2			0 - 0	%
CO2			36 - 44	mmHg
O2			80 - 100	mmHg
Н	B		7.337 - 7.467	C
CO2		<b>O</b>	36 - 44	mmHg
O2			80 - 100	mmHg
ICO3			18 - 24	mmol/L
Nova Full Panel-ICU	В6	10:45:25 AM	В6	
est	Results		Reference Range	Units
S (FHSA)			0 - 0	g/dl
CV **	B6		0 - 0	%
S (FHSA)			0 - 0	g/dl
ova Full Panel-ICU	В6	:00:12 PM	B6	
est	Results		Reference Range	Units
BC (ADVIA)			4.4 - 15.1	K/uL
BC(ADVIA)			5.8 - 8.5	M/uL
(GB(ADVIA)			13.3 - 20.5	g/dL
CT(ADVIA)			39 - 55	%
ICV(ADVIA)			64.5 - 77.5	fL
ICH(ADVIA)	<b>D</b> 0		21.3 - 25.9	pg
ICHC(ADVIA)	<b>B6</b>		31.9 - 34.3	g/dL
DW (ADVIA)			11.9 - 15.2	
LT(ADVIA)			173 - 486	K/uL
IPV (ADVIA)			8.29 - 13.2	fl
LTCRT			0.129 - 0.403	%
ETIC(ADVIA)			0.2 - 1.6	%
ETICS (ABS) ADVIA		j	14.7 - 113.7	K/uL
ova Full Panel-ICU	B6	3:00:27 PM	B6	
est	Results		Reference Range	Units
LUCOSE			67 - 135	mg/dL
REA			8 - 30	mg/dL
REATININE			0.6 - 2	mg/dL
HOSPHORUS			2.6 - 7.2	mg/dL
ALCIUM2			9.4 - 11.3	mg/dL
IAGNESIUM 2+	<b>B6</b>		1.8 - 3	mEq/L
. PROTEIN			5.5 - 7.8	g/dL
LBUMIN			2.8 - 4	g/dL
LOBULINS			2.3 - 4.2	g/dL
/G RATIO			0.7 - 1.6	
ODIUM			140 - 150	mEq/L

Printed Friday, November 09, 2018

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CHLORIDE		106 - 116	mEq/L
POTASSIUM		3.7 - 5.4	mEq/L
tCO2 (BICARB)		14 - 28	mEq/L
AGAP		8 - 19	
NA/K		29 - 40	
T BILIRUBIN		0.1 - 0.3	mg/dL
D.BILIRUBIN		O - O.1	mg/dL
I BILIRUBIN		0 - 0.2	mg/dL
ALK PHOS	<b>B6</b>	12 - 127	U/L
GGT		0 - 10	U/L
ALT		14 - 86	U/L
AST		9 - 54	U/L
CK		22 - 422	U/L
CHOLESTEROL		82 - 355	mg/dL
TRIGLYCERIDES		30 - 338	mg/dl
AMYLASE		409 - 1250	U/L
OSMOLALITY (CALCULATED)		291 - 315	mmol/L
Nova Full Panel-ICU	B6 3:00:09 P	м В6	
Test	Results	Reference Range	Units
CEC CO/	<u> </u>	12 06	0/

Nova Full Panel-ICU	B6 3:00:09 PM	В6	
Test	Results	Reference Range	Units
SEGS%		43 - 86	%
LYMPHS%		7 - 47	%
MONOS%		1 - 15	%
EOS%	DO	0 - 16	%
SEGS (AB)ADVIA	<b>B6</b>	2.8 - 11.5	K/ul
LYMPHS (ABS)ADVIA		1 - 4.8	K/uL
MONOS (ABS)ADVIA		0.1 - 1.5	K/uL
EOS (ABS)ADVIA		0 - 1.4	K/uL
WBC MORPHOLOGY	<u> </u>	0 - 0	
No Morphologic Abnormalities			
RBC MORPHOLOGY		0 - 0	
No morphologic abnormalities			

Nova Full Panel-ICU	B6 0:48:21 AM	В6	
Test	Results	Reference Range	Units
GLUCOSE		67 - 135	mg/dL
UREA		8 - 30	mg/dL
CREATININE		0.6 - 2	mg/dL
PHOSPHORUS	B6	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
	i		

**B4** 

12/97 **B6** 

GLOBULINS A/G RATIO SODIUM				
A/G RATIO SODIUM			2.3 - 4.2	g/dL
			0.7 - 1.6	C)
			140 - 150	mEq/L
CHLORIDE			106 - 116	mEq/L
POTASSIUM			3.7 - 5.4	mEq/L
NA/K			29 - 40	-
T BILIRUBIN			0.1 - 0.3	mg/dL
D.BILIRUBIN	B		0 - 0.1	mg/dL
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)		<u></u>	0 - 0	
Nova Full Panel-ICU	В6	11:10:56 AM	B6	
Test	Results		Reference Range	Units
rs (FHSA)	8		0 - 0	g/dl
PCV **	48		0 - 0	%
ΓS (FHSA)	8		0 - 0	g/dl
Nova Full Panel-ICU	B6	3:44:13 PM	B6	
Test	Results		Reference Range	Units
U COLLECT			0 - 0	
	i			
			0 - 0	
J TURBIDITY				
U TURBIDITY U SG	D	6	0 - 0	
J TURBIDITY J SG J PH	В	6	0 - 0 0 - 0 0 - 0 0 - 0	
J TURBIDITY J SG J PH J PROTEIN	В	6	0 - 0 0 - 0 0 - 0	
J TURBIDITY J SG J PH J PROTEIN J GLUCOSE	В	6	0 - 0 0 - 0 0 - 0 0 - 0 0 - 0	
U TURBIDITY U SG U PH U PROTEIN U GLUCOSE U KETONES	В	6	0 - 0 0 - 0 0 - 0 0 - 0 0 - 0 0 - 0	
U TURBIDITY U SG U PH U PROTEIN U GLUCOSE U KETONES	В	6	0 - 0 0 - 0 0 - 0 0 - 0 0 - 0	
U TURBIDITY U SG U PH U PROTEIN U GLUCOSE U KETONES	В	6	0 - 0 0 - 0 0 - 0 0 - 0 0 - 0 0 - 0	
U TURBIDITY U SG U PH U PROTEIN U GLUCOSE U KETONES U BILIRUBIN   B6 U HEME PROTEIN	В	6	0 - 0 0 - 0 0 - 0 0 - 0 0 - 0 0 - 0	
U TURBIDITY U SG U PH U PROTEIN U GLUCOSE U KETONES U BILIRUBIN   B6 U HEME PROTEIN	В	6	0 - 0 0 - 0 0 - 0 0 - 0 0 - 0 0 - 0 0 - 0	/hpf
U TURBIDITY U SG U PH U PROTEIN U GLUCOSE U KETONES U BILIRUBIN  B6 U HEME PROTEIN U WBC U RBC	B6	6	0 - 0 0 - 0 0 - 0 0 - 0 0 - 0 0 - 0 0 - 0	/hpf
U TURBIDITY U SG U PH U PROTEIN U GLUCOSE U KETONES U BILIRUBIN  B6 U HEME PROTEIN U WBC U RBC U BACTERIA	B B6	6	0 - 0 0 - 0	
U TURBIDITY U SG U PH U PROTEIN U GLUCOSE U KETONES U BILIRUBIN  B6 U HEME PROTEIN U WBC U RBC U BACTERIA	B6	6	0 - 0 0 - 0	/hpf
U COLOR U TURBIDITY U SG U PH U PROTEIN U GLUCOSE U KETONES U BILIRUBIN  B6 U HEME PROTEIN U WBC U RBC U BACTERIA U CRYSTALS  Nova Full Panel-ICU  Test		6 3 12:44:20 PM	0 - 0 0 - 0	/hpf /hpf

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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
Г. 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	DC	140 - 150	mEq/L
CHLORIDE	<b>B6</b>	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)	<u>j</u>	291 - 315	mmol/L
Nova Full Panel-ICU	9/21/2018 12:47:01 PM	B6	
Test	Results	Reference Range	Units
TAURINE P	D6	60 - 120	nmol/mL
TAURINE WB	B6	200 - 350	nmol/mL
Nova Full Panel-ICU	9/21/2018 12:48:52 PM	B6	
Гest	Results	Reference Range	Units
ΓS (FHSA)		0 - 0	g/dl
PCV **	B6	0 - 0	%
ΓS (FHSA)		0 - 0	g/dl
Nova Full Panel-ICU	9/30/2018 12:27:25 PM	B6	
Test	Results	Reference Range	Units
SO2%		94 - 100	%
HCT (POC)		38 - 48	%
HB (POC)		12.6 - 16	g/dL
NA (POC)	B6	140 - 154	mmol/L
	טם	3.6 - 4.8	mmol/L
K (POC)	:	109 - 120	mmol/L
CL(POC)		A DESCRIPTION OF THE PROPERTY	
CL(POC) CA (ionized)		1.17 - 1.38	mmol/L
CL(POC)		1.17 - 1.38 0.1 - 0.4	mmol/L mmol/L

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B6				
GLUCOSE (POC)	[		80 - 120	mg/dL
LACTATE			0 - 2	mmol/L
BUN (POC)			12 - 28	mg/dL
CREAT (POC)			0.2 - 2.1	mg/dL
TCO2 (POC)			0 - 0	mmol/L
nCA			0 - 0	mmol/L
nMG			0 - 0	mmol/L
GAP			0 - 0	mmol/L
CA/MG			0 - 0	mol/mol
BEecf	В	6	0 - 0	mmol/L
BEb	D	U	0 - 0	mmol/L
A			0 - 0	mmHg
NOVA SAMPLE			0 - 0	
FiO2			0 - 0	%
PCO2			36 - 44	mmHg
PO2			80 - 100	mmHg
PH			7.337 - 7.467	
PCO2			36 - 44	mmHg
PO2			80 - 100	mmHg
HCO3			18 - 24	mmol/L
Nova Full Panel-ICU	В6	12:47:03 PM	В6	
Test	Results		Reference Range	Units
TS (FHSA)			0 - 0	g/dl
PCV **	B6		0 - 0	%
TS (FHSA)	<u></u>	·-·	0 - 0	g/dl
Nova Full Panel-ICU	B6	12:03:20 PM	В6	
Test	Results		Reference Range	Units
GLUCOSE			67 - 135	mg/dL
UREA			8 - 30	mg/dL
CREATININE			0.6 - 2	mg/dL
PHOSPHORUS			2.6 - 7.2	mg/dL
CALCIUM2			9.4 - 11.3	mg/dL
Γ. PROTEIN			5.5 - 7.8	g/dL
ALBUMIN	B6		2.8 - 4	g/dL
GLOBULINS			2.3 - 4.2	g/dL
A/G RATIO			0.7 - 1.6	
SODIUM			140 - 150	mEq/L
			106 - 116	mEq/L
			3.7 - 5.4	mEq/L
CHLORIDE POTASSIUM NA/K			3.7 - 5.4 29 - 40	mEq/L
POTASSIUM				mEq/L

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T BILIRUBIN		0.1 - 0.3	mg/dL
D.BILIRUBIN		0 - 0.1	mg/dL
I BILIRUBIN		0 - 0.2	mg/dL
ALK PHOS	B6	12 - 127	U/L
ALT	БО	14 - 86	U/L
AST		9 - 54	U/L
CHOLESTEROL		82 - 355	mg/dL
OSMOLALITY (CALCULATED)		291 - 315	mmol/L

Nova Full Panel-ICU	10/5/2018 4:08:20 PM	В6	
Test	Results	Reference Range	Units
GLUCOSE		67 - 135	mg/dL
UREA		8 - 30	mg/dL
CREATININE		0.6 - 2	mg/dL
PHOSPHORUS		2.6 - 7.2	mg/dL
CALCIUM2		9.4 - 11.3	mg/dL
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	<b>B6</b>	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

Nova Full Panel-ICU	10/12/2018 2:16:21 PM	В6	
Test	Results	Reference Range	Units
GLUCOSE		67 - 135	mg/dL
UREA		8 - 30	mg/dL
CREATININE		0.6 - 2	mg/dL
PHOSPHORUS	B6	2.6 - 7.2	mg/dL
CALCIUM2	В	9.4 - 11.3	mg/dL
T. PROTEIN		5.5 - 7.8	g/dL
ALBUMIN		2.8 - 4	g/dL
	<u> </u>		

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<b>B6</b>			
GLOBULINS		2.3 - 4.2	g/dL
A/G RATIO		0.7 - 1.6	
SODIUM		140 - 150	mEq/L
CHLORIDE		106 - 116	mEq/L
POTASSIUM		3.7 - 5.4	mEq/L
NA/K		29 - 40	
T BILIRUBIN	<b>B6</b>	0.1 - 0.3	mg/dL
D.BILIRUBIN	DU	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			

Nova Full Panel-ICU	10/19/2018 4:04:21 PM	B6	
Test	Results	Reference Range	Units
GLUCOSE		67 - 135	mg/dL
UREA		8 - 30	mg/dL
CREATININE		0.6 - 2	mg/dL
PHOSPHORUS		2.6 - 7.2	mg/dL
CALCIUM2		9.4 - 11.3	mg/dL
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
COMMENTS (CHEMISTRY)		0 - 0	
<u></u>	i	DC	
D/	17/97	B6	
D4		Printed Friday, Nov	rember 09, 2018

Printed Friday, November 09, 2018

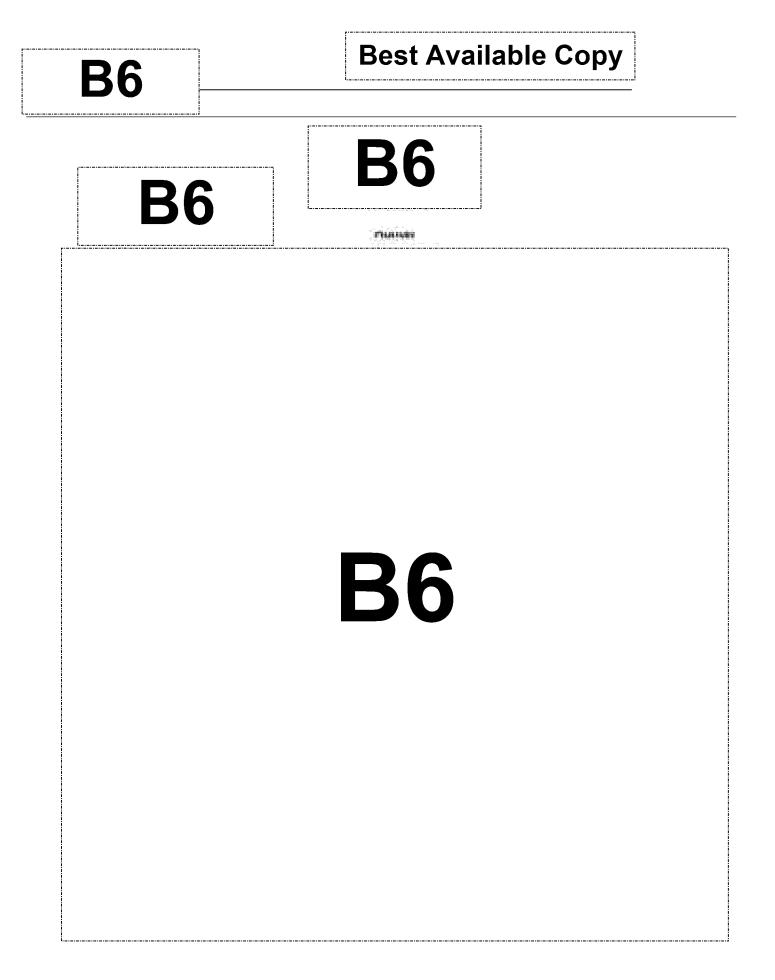
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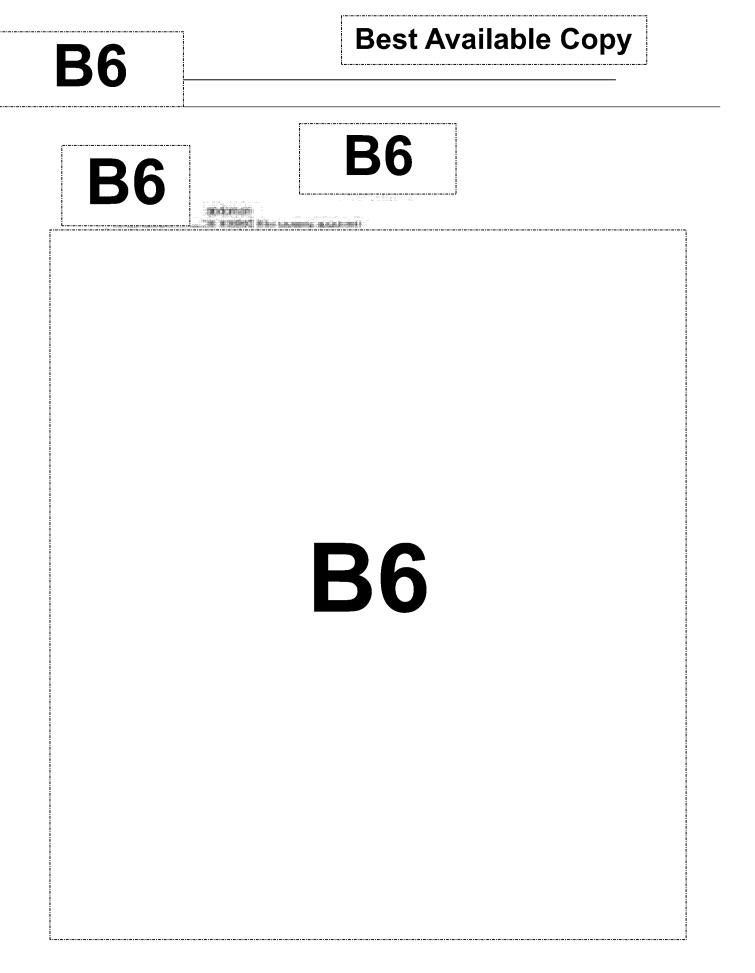
Nova Full Panel-ICU	10/31/2018 4:12:21 PM	В6	
Test	Results	Reference Range	Units
GLUCOSE		67 - 135	mg/dL
UREA		8 - 30	mg/dL
CREATININE		0.6 - 2	mg/dL
PHOSPHORUS		2.6 - 7.2	mg/dL
CALCIUM2		9.4 - 11.3	mg/dL
T. PROTEIN		5.5 - 7.8	g/dL
ALBUMIN		2.8 - 4	g/dL
GLOBULINS		2.3 - 4.2	g/dL
A/G RATIO		0.7 - 1.6	
SODIUM		140 - 150	mEq/L
CHLORIDE	<b>B6</b>	106 - 116	mEq/L
POTASSIUM	DU	3.7 - 5.4	mEq/L
NA/K		29 - 40	
T BILIRUBIN		0.1 - 0.3	mg/dL
D.BILIRUBIN		0 - 0.1	mg/dL
I BILIRUBIN		0 - 0.2	mg/dL
ALK PHOS		12 - 127	U/L
ALT		14 - 86	U/L
AST		9 - 54	U/L
CHOLESTEROL		82 - 355	mg/dL
OSMOLALITY (CALCULATED)		291 - 315	mmol/L
COMMENTS (CHEMISTRY)		0 - 0	

**B4** 

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В6





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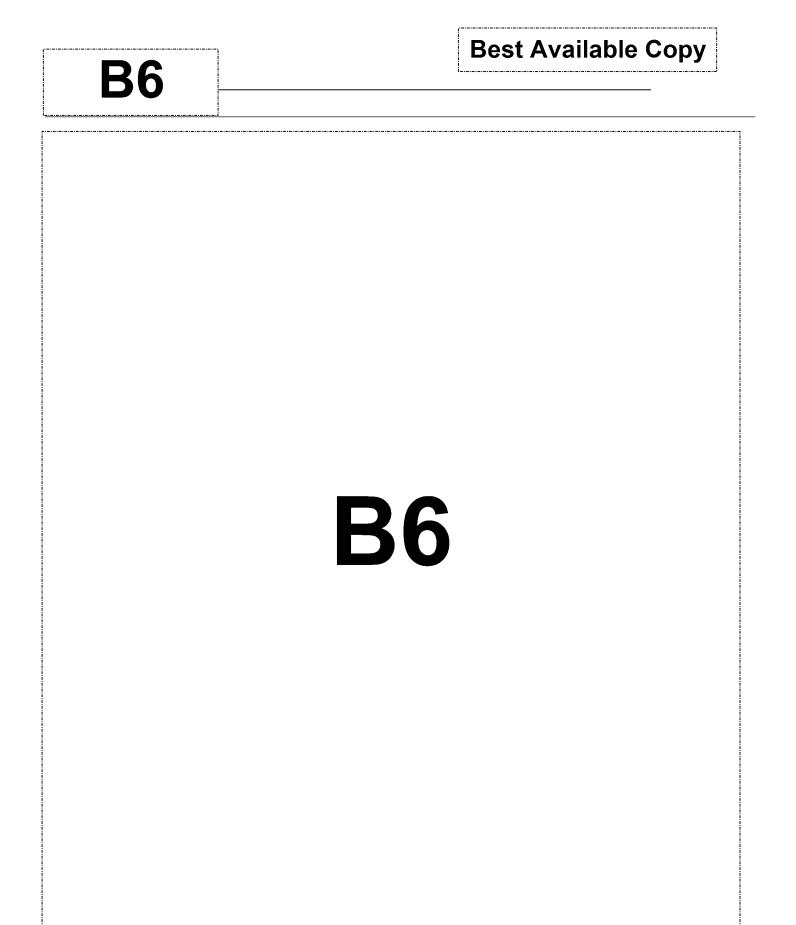
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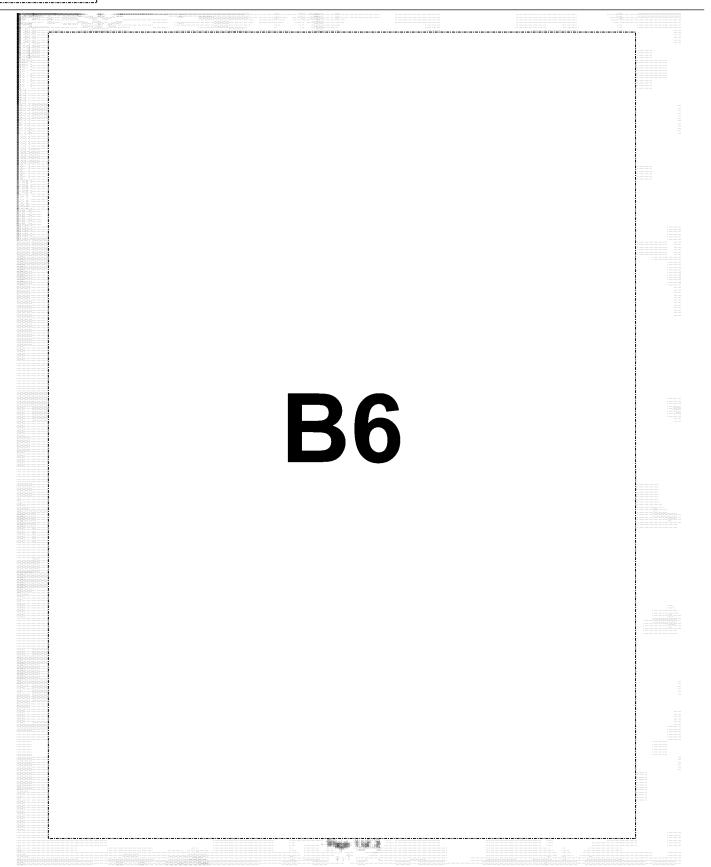


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**B6** 

В6

med hx 8/31/18 - 9/17/18



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**B6** 

B6 med hx 8/31/18 - 9/17/18

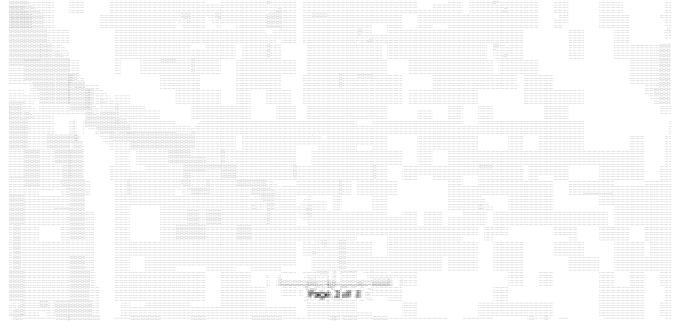
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**B6** 

B6 med hx 8/31/18 - 9/17/18



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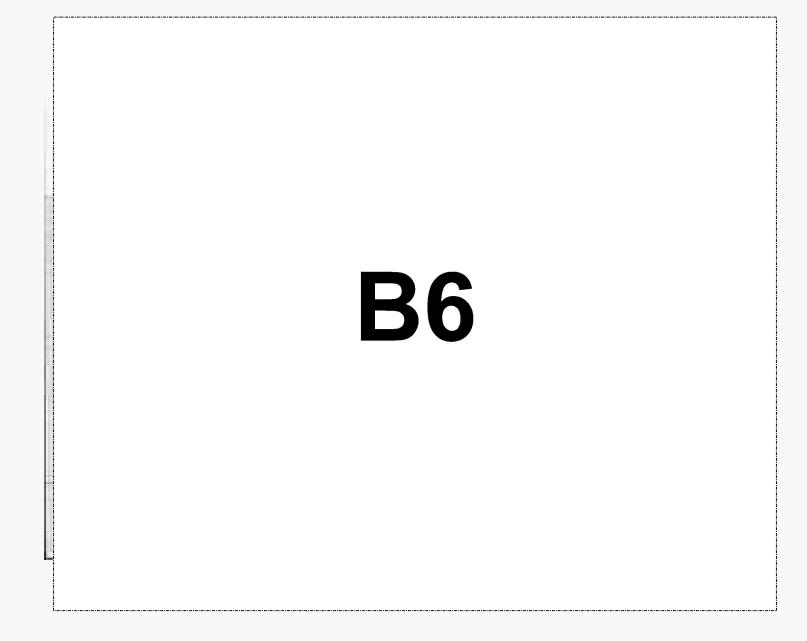
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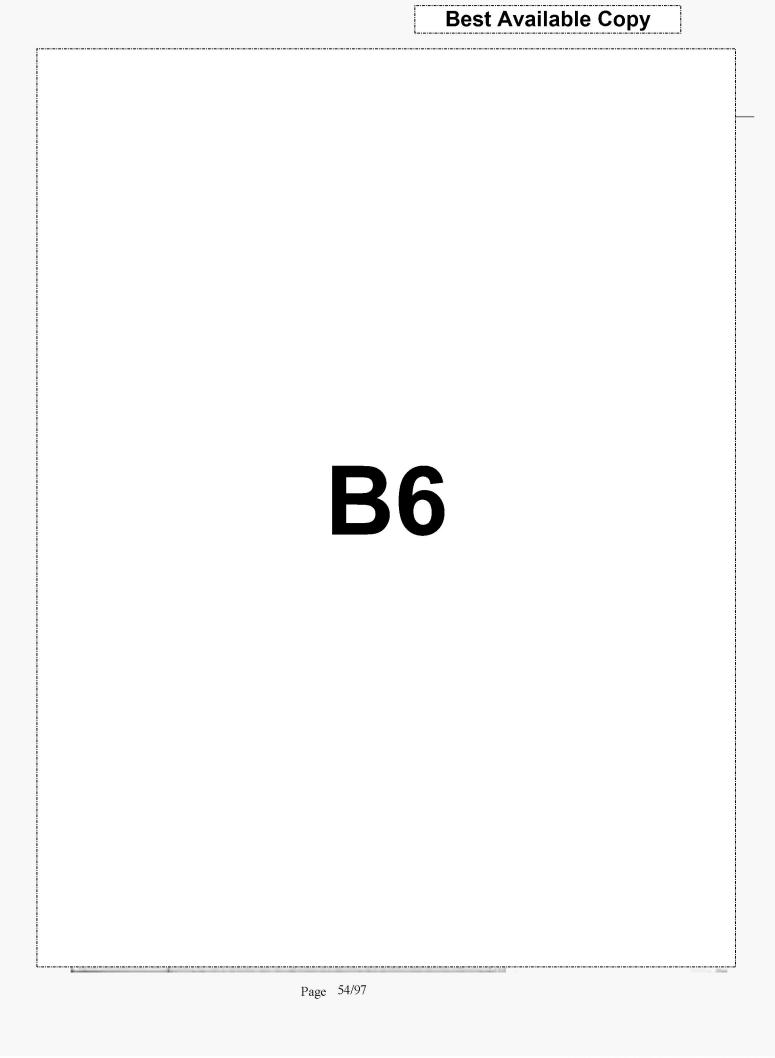
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**B6** 

Multi lead EKG 9/30/18





Lab Image Taurine Panel 9/21/18

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Taurine Panel 9/21/18

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#### Vitals Results

9/17/2018 1:03:12 PM 9/17/2018 5:00:05 PM 9/17/2018 5:02:59 PM 9/17/2018 6:05:47 PM 9/17/2018 6:07:09 PM 9/17/2018 6:40:49 PM 9/17/2018 6:56:57 PM 9/17/2018 7:15:44 PM 9/17/2018 7:15:54 PM 9/17/2018 7:16:05 PM 9/17/2018 7:16:28 PM 9/17/2018 8:22:31 PM 9/17/2018 8:26:28 PM 9/17/2018 8:43:22 PM 9/17/2018 9:59:02 PM 9/17/2018 11:19:15 PM 9/18/2018 12:03:53 AM 9/18/2018 12:16:47 AM 9/18/2018 12:17:26 AM 9/18/2018 12:21:36 AM 9/18/2018 12:39:28 AM 9/18/2018 12:42:19 AM 9/18/2018 12:58:12 AM 9/18/2018 1:53:56 AM 9/18/2018 2:36:04 AM 9/18/2018 4:18:53 AM 9/18/2018 4:19:05 AM 9/18/2018 4:19:28 AM 9/18/2018 4:19:42 AM 9/18/2018 4:41:19 AM 9/18/2018 5:22:13 AM 9/18/2018 5:22:38 AM 9/18/2018 5:35:05 AM 9/18/2018 5:37:04 AM 9/18/2018 8:04:28 AM 9/18/2018 8:04:39 AM 9/18/2018 8:04:57 AM 9/18/2018 8:05:03 AM 9/18/2018 8:05:14 AM

**B6** 

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### Vitals Results

9/18/2018 8:05:29 AM 9/18/2018 8:06:21 AM 9/18/2018 8:06:40 AM 9/18/2018 9:14:59 AM 9/18/2018 9:16:02 AM 9/18/2018 9:36:13 AM 9/18/2018 10:45:55 AM 9/18/2018 11:19:24 AM 9/18/2018 11:19:30 AM 9/18/2018 11:41:02 AM 9/18/2018 1:21:23 PM 9/18/2018 1:34:19 PM 9/18/2018 1:34:33 PM 9/18/2018 4:12:54 PM 9/18/2018 4:13:10 PM 9/18/2018 5:08:43 PM 9/18/2018 6:00:51 PM 9/21/2018 12:54:11 PM 9/30/2018 1:38:08 PM 9/30/2018 1:38:28 PM 9/30/2018 2:40:28 PM 9/30/2018 3:09:45 PM 9/30/2018 3:17:27 PM 9/30/2018 3:17:42 PM 9/30/2018 3:27:07 PM 9/30/2018 3:27:08 PM 9/30/2018 4:12:59 PM 9/30/2018 4:13:00 PM 9/30/2018 4:13:14 PM 9/30/2018 4:13:23 PM 9/30/2018 4:18:00 PM 9/30/2018 5:01:41 PM 9/30/2018 5:01:42 PM 9/30/2018 5:02:02 PM 9/30/2018 5:07:29 PM 9/30/2018 5:07:51 PM 9/30/2018 5:07:52 PM 9/30/2018 5:07:53 PM 9/30/2018 5:35:07 PM 9/30/2018 5:35:24 PM

**B6** 

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# Vitals Results

9/30/2018 5:43:02 PM 9/30/2018 5:58:05 PM 9/30/2018 5:58:12 PM 9/30/2018 5:58:39 PM 9/30/2018 5:58:40 PM 9/30/2018 6:57:23 PM 9/30/2018 6:57:24 PM 9/30/2018 7:08:46 PM 9/30/2018 7:09:01 PM 9/30/2018 7:23:22 PM 9/30/2018 7:49:52 PM 9/30/2018 7:50:51 PM 9/30/2018 7:51:05 PM 9/30/2018 7:51:06 PM 9/30/2018 7:59:51 PM 9/30/2018 8:02:31 PM 9/30/2018 9:15:56 PM 9/30/2018 9:16:06 PM 9/30/2018 9:16:07 PM 9/30/2018 9:18:39 PM 9/30/2018 9:55:59 PM 9/30/2018 9:56:13 PM 9/30/2018 9:56:14 PM 9/30/2018 9:56:45 PM 9/30/2018 9:56:59 PM 9/30/2018 10:57:00 PM 9/30/2018 10:57:30 PM 9/30/2018 11:08:05 PM 9/30/2018 11:08:06 PM 9/30/2018 11:52:45 PM 9/30/2018 11:52:46 PM 9/30/2018 11:53:01 PM 9/30/2018 11:53:13 PM 10/1/2018 12:32:18 AM 10/1/2018 12:46:37 AM 10/1/2018 1:10:40 AM 10/1/2018 1:10:41 AM 10/1/2018 1:10:52 AM 10/1/2018 1:11:02 AM

**B6** 

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## Vitals Results

10/1/2018 1:51:15 AM 10/1/2018 1:51:26 AM 10/1/2018 1:51:40 AM 10/1/2018 1:52:22 AM 10/1/2018 1:52:23 AM 10/1/2018 1:52:41 AM 10/1/2018 1:54:08 AM 10/1/2018 1:54:29 AM 10/1/2018 2:50:29 AM 10/1/2018 2:50:30 AM 10/1/2018 2:50:55 AM 10/1/2018 2:52:53 AM 10/1/2018 4:06:37 AM 10/1/2018 4:06:38 AM 10/1/2018 4:06:51 AM 10/1/2018 4:07:01 AM 10/1/2018 4:08:40 AM 10/1/2018 4:54:42 AM 10/1/2018 4:54:57 AM 10/1/2018 4:55:13 AM 10/1/2018 4:55:14 AM 10/1/2018 5:36:51 AM 10/1/2018 5:57:45 AM 10/1/2018 5:58:02 AM 10/1/2018 6:00:04 AM 10/1/2018 6:00:05 AM 10/1/2018 6:48:28 AM 10/1/2018 6:48:29 AM 10/1/2018 6:48:41 AM 10/1/2018 6:51:15 AM 10/1/2018 8:23:52 AM 10/1/2018 8:24:12 AM 10/1/2018 8:24:13 AM 10/1/2018 8:24:35 AM 10/1/2018 8:36:21 AM 10/1/2018 8:36:34 AM 10/1/2018 9:13:05 AM 10/1/2018 9:13:06 AM 10/1/2018 9:13:23 AM 10/1/2018 9:13:33 AM

10/1/2018 9:17:38 AM

**B6** 

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# Vitals Results

10/1/2018 9:21:44 AM 10/1/2018 9:22:17 AM 10/1/2018 10:20:18 AM 10/1/2018 10:20:19 AM 10/1/2018 10:20:34 AM 10/1/2018 10:22:08 AM 10/1/2018 11:07:38 AM 10/1/2018 11:07:39 AM 10/1/2018 11:13:05 AM 10/1/2018 12:04:43 PM 10/1/2018 12:06:57 PM 10/1/2018 12:53:17 PM 10/1/2018 12:53:38 PM 10/1/2018 1:24:48 PM 10/1/2018 1:24:49 PM 10/1/2018 1:25:00 PM 10/1/2018 1:25:17 PM 10/1/2018 1:26:44 PM 10/1/2018 2:00:20 PM 10/1/2018 2:02:32 PM 10/1/2018 2:02:33 PM 10/1/2018 2:03:03 PM 10/1/2018 2:06:03 PM 10/1/2018 3:46:00 PM 10/1/2018 3:54:51 PM 10/1/2018 3:54:52 PM 10/1/2018 4:12:28 PM 10/1/2018 4:12:45 PM 10/1/2018 4:48:46 PM 10/1/2018 4:53:24 PM 10/1/2018 4:53:25 PM 10/1/2018 5:10:05 PM 10/1/2018 5:10:55 PM 10/1/2018 5:28:46 PM 10/1/2018 6:02:40 PM 10/1/2018 6:21:56 PM 10/1/2018 6:21:57 PM 10/1/2018 6:50:24 PM

**B6** 

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# Vitals Results

10/12/2018 1:49:20 PM 10/19/2018 3:24:04 PM 10/31/2018 4:13:56 PM

ECG from cardio

**B6** 

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ECG from cardio

**B6** 

Rads 9/17/18



**B6** 

Rads 9/17/18



09/17/2018 09:33 AM

### **Patient History**

03,17,2010 03.551111
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**B6** 

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### Patient History

09/17/2018 07:16 PM 09/17/2018 07:16 PM 09/17/2018 08:22 PM 09/17/2018 08:22 PM 09/17/2018 08:26 PM 09/17/2018 08:26 PM 09/17/2018 08:43 PM 09/17/2018 08:43 PM 09/17/2018 09:59 PM 09/17/2018 09:59 PM 09/17/2018 11:19 PM 09/17/2018 11:19 PM 09/18/2018 12:03 AM 09/18/2018 12:03 AM 09/18/2018 12:16 AM 09/18/2018 12:16 AM 09/18/2018 12:16 AM 09/18/2018 12:17 AM 09/18/2018 12:21 AM 09/18/2018 12:21 AM 09/18/2018 12:39 AM 09/18/2018 12:39 AM 09/18/2018 12:42 AM 09/18/2018 12:42 AM 09/18/2018 12:58 AM 09/18/2018 12:58 AM 09/18/2018 01:15 AM 09/18/2018 01:44 AM 09/18/2018 01:53 AM 09/18/2018 01:53 AM 09/18/2018 02:13 AM 09/18/2018 02:20 AM 09/18/2018 02:36 AM 09/18/2018 02:36 AM 09/18/2018 04:18 AM 09/18/2018 04:18 AM 09/18/2018 04:19 AM 09/18/2018 04:41 AM 09/18/2018 04:41 AM 09/18/2018 05:22 AM

**B6** 

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#### **Patient History**

09/18/2018 05:22 AM 09/18/2018 05:22 AM 09/18/2018 05:22 AM 09/18/2018 05:35 AM 09/18/2018 05:35 AM 09/18/2018 05:37 AM 09/18/2018 05:37 AM 09/18/2018 08:04 AM 09/18/2018 08:05 AM 09/18/2018 08:06 AM 09/18/2018 08:06 AM 09/18/2018 08:06 AM 09/18/2018 08:06 AM 09/18/2018 09:14 AM 09/18/2018 09:14 AM 09/18/2018 09:16 AM 09/18/2018 09:16 AM 09/18/2018 09:36 AM 09/18/2018 09:36 AM 09/18/2018 09:38 AM 09/18/2018 10:18 AM 09/18/2018 10:45 AM 09/18/2018 10:45 AM 09/18/2018 10:48 AM 09/18/2018 10:48 AM 09/18/2018 10:48 AM 09/18/2018 10:50 AM 09/18/2018 11:19 AM 09/18/2018 11:19 AM 09/18/2018 11:19 AM 09/18/2018 11:19 AM

**B6** 

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### Patient History

09/18/2018 11:41 AM 09/18/2018 11:41 AM 09/18/2018 12:51 PM 09/18/2018 12:51 PM 09/18/2018 01:21 PM 09/18/2018 01:21 PM 09/18/2018 01:22 PM 09/18/2018 01:32 PM 09/18/2018 01:34 PM 09/18/2018 02:15 PM 09/18/2018 02:15 PM 09/18/2018 03:44 PM 09/18/2018 04:12 PM 09/18/2018 04:12 PM 09/18/2018 04:13 PM 09/18/2018 04:13 PM 09/18/2018 05:08 PM 09/18/2018 05:08 PM 09/18/2018 05:58 PM 09/18/2018 05:59 PM 09/18/2018 06:00 PM 09/18/2018 06:00 PM 09/18/2018 06:01 PM 09/18/2018 06:01 PM 09/18/2018 06:09 PM 09/18/2018 06:10 PM 09/18/2018 06:11 PM 09/21/2018 11:35 AM 09/21/2018 12:14 PM 09/21/2018 12:15 PM 09/21/2018 12:16 PM 09/21/2018 12:43 PM 09/21/2018 12:44 PM 09/21/2018 12:45 PM 09/21/2018 12:45 PM 09/21/2018 12:48 PM 09/21/2018 12:54 PM 09/22/2018 03:53 PM 09/25/2018 11:19 AM

**B6** 

FDA-CVM-FOIA-2019-1704-001849

**Patient History** 

09/26/2018 12:52 PM

09/30/2018 10:46 AM

09/30/2018 10:47 AM

09/30/2018 12:13 PM

09/30/2018 12:27 PM

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#### **Patient History**

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### **Patient History** 09/30/2018 09:15 PM 09/30/2018 09:16 PM 09/30/2018 09:16 PM 09/30/2018 09:16 PM 09/30/2018 09:18 PM 09/30/2018 09:18 PM 09/30/2018 09:55 PM 09/30/2018 09:55 PM 09/30/2018 09:56 PM 09/30/2018 10:57 PM 09/30/2018 10:57 PM 09/30/2018 10:57 PM 09/30/2018 10:57 PM 09/30/2018 11:08 PM **B6** 09/30/2018 11:08 PM 09/30/2018 11:08 PM 09/30/2018 11:51 PM 09/30/2018 11:52 PM 09/30/2018 11:52 PM 09/30/2018 11:52 PM 09/30/2018 11:53 PM 10/01/2018 12:32 AM 10/01/2018 12:46 AM 10/01/2018 12:46 AM 10/01/2018 01:10 AM 10/01/2018 01:11 AM

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#### **Patient History**

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### **Patient History** 10/01/2018 05:36 AM 10/01/2018 05:57 AM 10/01/2018 05:57 AM 10/01/2018 05:58 AM 10/01/2018 05:58 AM 10/01/2018 06:00 AM 10/01/2018 06:00 AM 10/01/2018 06:00 AM 10/01/2018 06:48 AM 10/01/2018 06:51 AM 10/01/2018 06:51 AM 10/01/2018 07:50 AM 10/01/2018 07:52 AM 10/01/2018 07:52 AM 10/01/2018 07:55 AM **B6** 10/01/2018 07:55 AM 10/01/2018 08:12 AM 10/01/2018 08:23 AM 10/01/2018 08:23 AM 10/01/2018 08:24 AM 10/01/2018 08:36 AM 10/01/2018 09:13 AM 10/01/2018 09:17 AM

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Patient	History
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### **Patient History** 10/01/2018 06:35 PM 10/01/2018 06:50 PM 10/04/2018 10:27 AM 10/05/2018 04:07 PM 10/05/2018 04:07 PM 10/05/2018 04:07 PM 10/05/2018 04:34 PM 10/05/2018 04:34 PM 10/05/2018 04:35 PM 10/05/2018 04:36 PM 10/05/2018 04:38 PM 10/05/2018 04:38 PM 10/05/2018 04:42 PM 10/05/2018 05:22 PM 10/11/2018 01:31 PM 10/11/2018 04:02 PM 10/12/2018 01:25 PM 10/12/2018 01:42 PM **B6** 10/12/2018 01:44 PM 10/12/2018 01:49 PM 10/12/2018 01:58 PM 10/12/2018 02:16 PM 10/16/2018 09:58 AM 10/19/2018 03:12 PM 10/19/2018 03:23 PM 10/19/2018 03:24 PM 10/19/2018 03:46 PM 10/19/2018 04:03 PM 10/19/2018 04:06 PM 10/26/2018 12:48 PM 10/26/2018 12:51 PM 10/26/2018 12:52 PM 10/26/2018 12:55 PM 10/26/2018 12:55 PM

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### **Patient History**

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# **Best Available Copy**



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### Dully Update From the Cardiology Service

Today's date:	В6		
	В6		
Thank you for r University.	eferring putients to t	B6	at the Cummings School of Tult:
Your patient	B6 Conti was admi	tted and is being cared for	by the Cardiology Service.
Today, B6			
is still in is critica in might b	e discharged from the	hospital today	
echoca cordiac de ongoing ongoing	ents include; ork planned/pending rdiography catheter procedure pla g treatment for OIF g treatment for thromb g treatment for ambyth	osls	
Additional plan		<b>B6</b>	
Senior student:	H		i

FDA-CVM-FOIA-2019-1704-001867

## Best Available Copy



**B6** 

Ľ	B6		
	Thank you for referring B6 with their pet B6		
	If you have any questions, or concerns, please contact us at Thank you,	В6	
-	B6		



**B6** 

**B6** 

Thank you for referring B6 with their pet B6

If you have any questions, or concerns, please contact us at \_\_\_\_\_\_B6

Thank you,



**B6** 

**B6** 

B6			
Thank you for referring	В6	with their	pet B6
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Thank you.
B6





B6	
Thank you for referring B6 with their pet B6	
If you have any questions, or concerns, please contact us of	В6
Thank you,	
B6	



Thank you for referring B6 with their pert B6

If you have any questions, or concurre, please contact us at B6

Thank you.

B6

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Species: C	anine			
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Sample Typ	e: 🗸 Plasma	✓ Whole Blood Uri	ne Food Otl	ner:
Test Items:		Complete Amino Acid		
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Taurine Re	sults (nmol/ml)	·		
` [		DC		
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1				
Reference	Ranges (nmol/ml	)		
		Plasma	Wh	ole Blood
	Normal Range	No Known Risk for	Normal Range	No Known Risk fo

	F	Plasma	Who	ole 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

22207 PL 22208 WB

B6	UC CUSTOMERS ONLY: Non-federal funds ID/Account Number to bill:
Email: clinpath@tufts.edu; cardiovet@tufts.edu	
Tel: 508-887-4669 Fa	508-839-7936
Species: canine  B6  Sample Type: Plasma Whole Blood  Test Items: Taurine Complete Amino	
Taurine Results (nmol/ml) Plasma:B6 Whole Blood:B6	Urine: Food:
Reference Ranges (nmol/ml)  Plasma	Whole Blood

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

2210 WB Sample Submission Form B6	UC CUSTOMERS ONLY:  Non-federal funds ID/Account Number  to bill:
	B6
Email: clinpath@tufts.edu; cardiovet@tufts.e Tel: 508-887-4669	Fax: 508-839-7936
Species: Canine B6	
Sample Type: Plasma Whole Blo	od Urine Food Other:

	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

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

**Sent:** 11/10/2018 8:40:39 PM

Subject: Pure Balance Salmon and Pea dry: Lisa Freeman - EON-370760

Attachments: 2058697-report.pdf; 2058697-attachments.zip

A PFR Report has been received and PFR Event [EON-370760] has been created in the EON System.

A "PDF" report by name "2058697-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 "2058697-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

**EON Key:** EON-370760

ICSR #: 2058697

**EON Title:** PFR Event created for Pure Balance Salmon and Pea dry, Taste of the Wild High Prairie dry;

2058697

AE Date	10/31/2018	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Stable
Breed	Retriever - Golden		
Age	6.8 Years		
District Involved	PFR- <b>B6</b> DO		

### **Product information**

**Individual Case Safety Report Number: 2058697** 

Product Group: Pet Food

**Product Name:** Pure Balance Salmon and Pea dry, Taste of the Wild High Prairie dry **Description:** DCM and CHF diagnosed 10/31/18. On BEG diet. Taurine pending

**Submission Type:** Initial

**Report Type:** Adverse Event (a symptom, reaction or disease associated with the product)

Outcome of reaction/event at the time of last observation: Stable

Number of Animals Treated With Product: 1

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

Product Name	Lot Number or ID	Best By Date
Taste of the Wild High Prairie dry		
Pure Balance Salmon and Pea dry		

### Sender information

Lisa Freeman 200 Westboro Rd North Grafton, MA 01536 USA

Owner information
<b>B6</b>

To view this PFR Event, please click the link be	elow:
В6	

To view the PFR Event Report, please crick the link below.	
B6	

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.

	370760				
ICSR:	2058697				
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 15:28:40 EST				
Reported Problem:	Problem Description:	<u> </u>	nosed 10/31/18. On BEG diet	t. Taurine pending	
	Date Problem Started:	10/31/2018			
	Concurrent Medical Problem:	Yes			
	Pre Existing Conditions:	Dermatitis			
	Outcome to Date:	Stable			
Product Information:	Product Name:	Taste of the Wild Hig	jh Prairie dry		
	Product Type:	7			
	Lot Number:	# ************************************			
	Package Type:	BAG			
	Product Use Information:	Description:	Fed for last 3 months until 2 Beneful Salmon dry	weeks ago when changed to	
	Manufacturer /Distributor Information:				
	Purchase Location Information:				
	Product Name:	Pure Balance Salmon and Pea dry			
	Product Type:	: Pet Food			
	Lot Number:				
	Package Type:	BAG			
	Product Use Information:	Description:	Fed for past 6 years until ab	out 3 months ago	
	Manufacturer /Distributor Information:				
	Purchase Location Information:				
Animal Information:	Name:	B6			
	Type Of Species:	(L			
		Retriever - Golden			
	Gender:	<u>.</u> 	114 A D 1 14 A D 114 A		
	Reproductive Status:				
	<u> </u>	25.5 Kilogram			
	Age	B6	a nta a a bina a bra a di nota a bra a a nota a bra da nota a brita a bra a bra a bina a bra a bra a bra a br	nista nortalia nortalia norta a nota a nota a norta a norta a nota a nota nota dia nota a notalita a nota a	
	Assessment of Prior Health:	Good			
	Number of Animals Given the Product:	1			
	Number of Animals Reacted:	1			
	Owner Information:	Owner Information provided:	Yes		
		Contact:	Name: Phone	6	
			Email		

Address:  200 Westboro Rd North Grafton Massachusetts
Contact: Name: Lisa Freeman Phone: (508) 887-4523 Email: lisa.freeman@tufts.edu  Address: 200 Westboro Rd North Grafton Massachusetts 01536 United States  Sender Information: Lisa Freeman  Address: 200 Westboro Rd North Grafton Massachusetts  Address: 200 Westboro Rd North Grafton Massachusetts
Address:   Lisa Freeman   Lisa Freem
Address: 200 Westboro Rd North Grafton Massachusetts 01536 United States  Sender Information: Lisa Freeman  Address: 200 Westboro Rd North Grafton Massachusetts
Sender Information:  Name:  Lisa Freeman  Address:  Address:  North Grafton Massachusetts  United States  Lisa Freeman  200 Westboro Rd North Grafton Massachusetts
Address: 200 Westboro Rd North Grafton Massachusetts
North Grafton  Massachusetts
01536 United States
<b>Contact</b> : <b>Phone</b> : 5088874523
Email: lisa.freeman@tufts.edu
Permission To Contact Yes Sender:
Preferred Method Of Contact:
Additional Documents:
Attachment: compiled medical record <b>B6</b> pdf
Description: Records
Type: Medical Records



**B6** 

All Medical Records

B6

Breed: Golden Retriever

B6

Species: Canine Sex: Female (Spayed)

# Referring Information

**B6** 

# **Initial Complaint:**

Emergency

SOAP Text

8:41AM - Clinician, Unassigned FHSA

# **Subjective**

**NEW VISIT (ER)** 

**B6** 

Presenting complaint: Hot spots

Referral visit? No

Diagnostics completed prior to visit: None

**B6** 

### HISTORY:

Signalment: 6 yo FS Golden retriever

Current history: Over the last week or so (starting caudal ventral abdomen) she has been getting worse areas of alopecia and erythema. No V/D/S, her appetite has been lowered for the last couple of days, no lethargy. The last few days the hot spots have been spreading to her hind limbs. Over the last few days she has developed a cough over the last week or so, sporadic. O has been treating the hot spots with a topical spray (antiseptic, antiitch) and has been shaving the areas. She licked at it a lot last night and it was significantly worse this morning. No other pets in the house.

Prior medical history: None except for a history of hot spots, usually treated with a topical spray, owner generally can stay on top of it without medical intervention.

Current medications: This morning she got 25mg of benadryl, none other

B6			
Diet: Call of the wild dry food Vaccination status/flea & tick prev Travel history: None	/entative use: Up to d	ate	
EXAM:			 
	_		
		36	
	•		
ASSESSMENT:			 
ASSESSIMENT.			
	R		
	D		
Diagnostics completed: None			
Diagnostics pending:			

Client communication:

**B6** 

SOAP approved (DVM to sign) **B6** DVM

**Initial Complaint:** 

Emergency

None

ı		C
	D	O

**SOAP Text B6** 4:27PM -**B6** SubjectiveNEW VISIT (ER) **B6** Presenting complaint: Coughing, weight loss Referral visit? Y Diagnostics completed prior to visit: **B6** HISTORY: Signalment: 6yo FS Golden retriever Current history: Presented to Tufts for a hot spot 5-6 weeks ago, cough started back then, has continued to get worse, saw RDVM in spencer and was treated for kennel cough, seemed to improve but never resolved, followed up with rDVM and had radiographs, started on furosemide which helped but did nto resolve, radiographs repeated and tracheal compression suspected. Was the runt of the litter. Has been drinking normally, eating on and off, u/d normal, no c/v/d, eating around 2/3 of her normal diet. Decreased activity level. Prior medical history: Chronic hot spots, otherwise healthy Current medications: EXAM:

<b>B6</b>			 
	E	36	
ESSMENT:			
		36	
AN:			
	<b>B6</b>		
agnostics completed:			
agnostics completed:	B6		 
agnostics completed: ardio consult: - DCM with marked	B6  LA enlargement and suspec	cted active CHF	

Discussed finding of DCM on cardiology consult, recommended hospitalization overnight to titrate medications and provide supplemental oxygen if necessary versus discharge tonight and starting medications and monitoring at home; O elected to take P home tonight. Discussed enrollment in cardiology's grain-free diet/DCM study - the study covers the cost of blood work and echo today and potentially will cover echo and bloodwork at 3-month and 6-month recheck appointments; ER fee and hospitalization would still be paid for by O, as well as recheck appointment fees (including echo and bloodwork if indicated) in 10-14 days. O understood and agreed to enroll P in the study. Recheck scheduled with cardio on B6

Deposit & estimate status: none

Resuscitation code (if admitting to ICU): n/a

SOAP approved (DVM to sign): B6

**Initial Complaint:** 

Recheck - **B6** - DCM study - ECC consult

SOAP Text B6 3:45PM B6

**Disposition/Recommendations** 

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# Cummings Veterinary Medical Center

B6	
Veterinarian:	
B6	
Visit ID:	

# **B6**

В	<b>S</b>
Species:	Canine
Breed:	Golden Retriever
Sex:	Female (Spayed)
Age:	B6 Years Old

# Lab Results Report

	10/31/2018 7:11:55 PM	B6	
Test	Results	Reference Range	Units
Troponin I Research - FHSA	В6	0 - 0.08	mg/dl
	11/9/2018 3:46:15 PM	В6	
Test	Results	Reference Range	Units
U COLLECT		0 - 0	
Urine - Cystocentesis			
U COLOR		0 - 0	
U TURBIDITY		0 - 0	
U SG	DC	0 - 0	
U PH	<b>B6</b>	0 - 0	
U PROTEIN		0 - 0	
U GLUCOSE		0 - 0	
U KETONES		0 - 0	
U BILIRUBIN		0 - 0	
Negative			
B6		0.0	
U HEME PROTEIN		0 - 0	п. С
U WBC		0 - 0	/hpf
URBC	<b>B6</b>	0 - 0	/hpf
U BACTERIA	DU	0 - 0	/hpf
U CRYSTALS		0 - 0	/hpf
UFAT		0 - 0	/hpf
R4	7/32	В6	
UT .		Printed Saturday	В6

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B6		
COMMENTS (URINALYSIS)	0 - 0	
Less than 1 ml urine submitted		
B4	8/32 <b>B6</b>	
D4	Printed Saturday, <b>E</b>	36

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**B4**, **B6** 

10/29/18

B4, B6

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**B6** 

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DUPLICATE.

**B6** 

**B6** 

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Research CBC/Chem

**MALICAL** 

**B6** 

**B6** 

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B4 CARDIOPET 11/1/18

Diet history 10/31/18

**B6** CARDIOLOGY SET HISTORY FORM Phone consent the following quantities discribycia pet **B6** 

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# Vitals Results

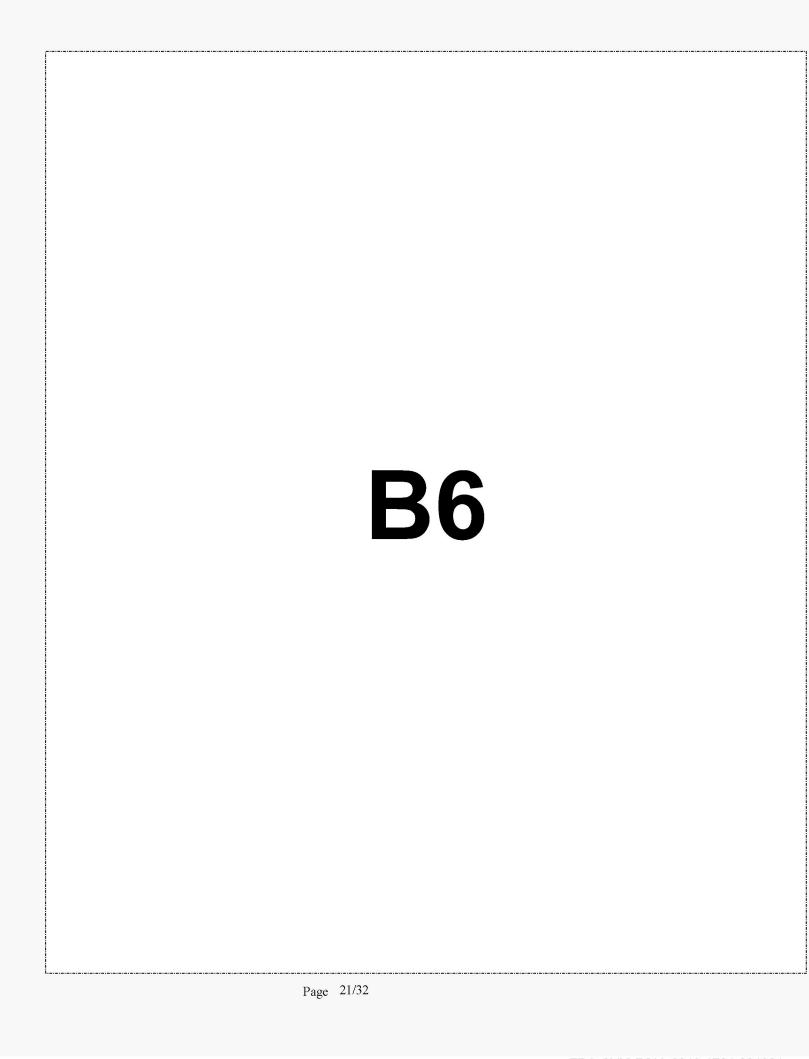
9/2/2018 10:08:25 AM 10/31/2018 5:41:28 PM

10/31/2018 7:52:51 PM 10/31/2018 7:52:52 PM 10/31/2018 7:52:53 PM 10/31/2018 7:52:54 PM 11/9/2018 2:52:06 PM

B6 rad

rad 10/29/18







**ECG** from Cardio

10/29/18

**B6** 

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# **Patient History**

09/02/2018 08:04 AM 09/02/2018 08:05 AM 09/02/2018 10:00 AM 09/02/2018 10:08 AM 09/02/2018 10:11 AM 09/02/2018 10:11 AM 09/02/2018 10:15 AM 09/02/2018 10:17 AM 09/02/2018 10:18 AM 09/02/2018 10:19 AM 10/31/2018 05:24 PM 10/31/2018 05:25 PM 10/31/2018 05:41 PM 10/31/2018 05:59 PM 10/31/2018 06:03 PM 10/31/2018 06:12 PM 10/31/2018 07:04 PM **B6** 10/31/2018 07:04 PM 10/31/2018 07:06 PM 10/31/2018 07:08 PM 10/31/2018 07:09 PM 10/31/2018 07:09 PM 10/31/2018 07:09 PM 10/31/2018 07:17 PM 10/31/2018 07:52 PM 10/31/2018 07:52 PM 10/31/2018 07:52 PM 10/31/2018 07:52 PM 11/01/2018 11:57 AM 11/09/2018 02:35 PM 11/09/2018 02:52 PM 11/09/2018 03:11 PM 11/09/2018 03:45 PM 11/09/2018 03:46 PM 11/09/2018 03:46 PM 11/09/2018 04:07 PM 11/09/2018 04:30 PM 11/09/2018 04:33 PM 11/10/2018 12:09 PM

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**B6** 

**B6** 

Thonk you.

R.



Toes Robert 460 Stafford St Charlton, MA 01507 (508) 344 4495 **B6** 

**B6** 

**B6** 

Blank you.

**B6** 

- Emergency & Official Care)

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

**B6** 

**Sent:** 11/9/2018 11:12:45 PM

Subject: Rachel Ray peak open range recipe (beef: Lisa Freeman - EON-370720

Attachments: 2058685-report.pdf; 2058685-attachments.zip

A PFR Report has been received and PFR Event [EON-370720] has been created in the EON System.

A "PDF" report by name "2058685-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 "2058685-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

**EON Key:** EON-370720

ICSR #: 2058685

EON Title: PFR Event created for Rachel Ray peak open range recipe (beef venison lamb); 2058685

AE Date	10/06/2018	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Stable
Breed	Boxer (German Boxer)		
Age	<b>B6</b> Years		
District Involved	PFR <b>B6</b> DO		

# **Product information**

**Individual Case Safety Report Number: 2058685** 

**Product Group:** Pet Food

**Product Name:** Rachel Ray peak open range recipe (beef, venison, lamb)

**Description:** DCM and arrhythmias diagnosed at time of GDV surgery so unclear if sepsis/post-op or true DCM. Had recheck echo 10/31/18 and still has DCM. Taurine pending. Owner has changed diet to Royal Canin Boxer

**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
Rachel Ray peak open range recipe (beef, venison, lamb)		

# Sender information

Lisa Freeman 200 Westboro Rd North Grafton, MA 01536 USA



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

**B6** 

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

**B6** 

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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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-	370720					
ICSR:	2058685					
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 18:09:56 EST					
Reported Problem:	Problem Description:	op or true DCM. Had	as diagnosed at time of GDV surgery so unclear if sepsis/post- d recheck echo 10/31/18 and still has DCM. Taurine pending. diet to Royal Canin Boxer			
	Date Problem Started:	10/06/2018				
	Concurrent Medical Problem:	Yes				
	Pre Existing Conditions:	GDV 10/6/18				
	Outcome to Date:	73. 				
Product Information:	Product Name:	Rachel Ray peak op	en range recipe (beef, venison, lamb)			
	Product Type:	<u> </u>				
	Lot Number:					
	Package Type:	BAG				
	Product Use Information:	Description:	Rachael Ray's since about 2017- prior to that it has been Purina One chicken and rice. The Rachael Ray that I fed him was "PEAK- open range receipt some with chicken			
			some with lamb or beef. The dry was served with one half a can of newman's organic chicken and brown rice. I also cooked chicken breasts and rice as well as hamburger and rice every other week and used cup of this instead of the canned food. Mixed it in with the dry food. I have as of last Thursday switched him to Royal Canin dry food for Boxers with 1/2 can of science diet healthy cusine-roasted chicken, carrots and spinach stew mixed with about two cups of this dry food			
Animal Information:	Manufacturer /Distributor Information:					
	Purchase Location Information:					
	Name:	В6				
	Type Of Species:	Dog				
	3)	Boxer (German Box	er)			
	Gender:	<u> </u>				
	Reproductive Status:	Intact				
	1	34.8 Kilogram				
		B6 /ears				
	Assessment of Prior Health:					
	Number of Animals Given the Product:	1				
	Number of Animals Reacted:	1				
	Owner Information:	Owner Information provided:				
		Contact:	Name: Phone: Email:  B6			
	3		7.4 kg			

Healthcare Professional Information:   Practice Name: Tufts Cummings School of Veterinary Medicine   Contact: Name: Lisa Freeman   Phone: (508) 887-4523   Email:   sa.freeman@tufts.edu	Information:  Contact: Name: Lisa Freeman Phone: (508) 887-4523 Email: lisa.freeman@tufts.edu  Address: 200 Westboro Rd North Grafton Massachusetts 01536 United States  Sender Information:  Address: 200 Westboro Rd North Grafton Massachusetts 01536 United States  Contact: Permission To Contact Sender: Preferred Method Of Contact:  Additional Documents:  Attachment: compiled medical record.pdf Records	Information:  Contact: Name: Lisa Freeman Phone: (508) 887-4523 Email: lisa.freeman@tufts.edu  Address: 200 Westboro Rd North Grafton Massachusetts 01536 United States  Sender Information:  Address: 200 Westboro Rd North Grafton Massachusetts 01536 United States  Contact: Permission To Contact Sender: Preferred Method Of Contact: Preferred Method Of Contact: On the Contact Contact: Description: Compiled medical record.pdf  Attachment: compiled medical record.pdf	Information:  Contact:  Name: Lisa Freeman Phone: (508) 887-4523 Email: lisa.freeman@tufts.edu  Address: 200 Westboro Rd North Grafton Massachusetts 01536 United States  Contact:  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: Records  Additional Documents:  Attachment: compiled medical record.pdf	Information:   Contact:   Name:   Lisa Freeman   Phone: (508) 887-4523   Email:   lisa.freeman@tufts.edu			Address:	В	6
Sender Information:  Name: Lisa Freeman Phone: (508) 887-4523  Email: lisa.freeman@tufts.edu  Address: 200 Westboro Rd North Grafton Massachusetts 01536 United States  Sender Information:  Name: Lisa Freeman Phone: (508) 887-4523  Email: lisa.freeman@tufts.edu  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: Records	Contact:   Name:   Lisa Freeman   Phone:   (508) 887-4523   Email:   lisa.freeman@tufts.edu	Contact:   Name:   Lisa Freeman   Phone:   (508) 887-4523   Email:   lisa.freeman@tufts.edu	Contact:   Name:   Lisa Freeman   Phone:   (508) 887-4523   Email:   lisa.freeman@tufts.edu	Sender Information:  Name: Lisa Freeman Phone: (508) 887-4523  Email: lisa.freeman@tufts.edu  Address: 200 Westboro Rd North Grafton Massachusetts 01536 United States  Sender Information:  Name: Lisa Freeman Phone: (508) 887-4523  Email: lisa.freeman@tufts.edu  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: Records		Healthcare Professional	Practice Name:	Tufts Cumming	 s School of Veterinary Medicine
Phone: (508) 887-4523   Email:   lisa.freeman@tufts.edu	Phone: (508) 887-4523 Email: lisa freeman@tufts.edu  Address: 200 Westboro Rd North Grafton Massachusetts 01536 United States  Sender Information: Lisa Freeman  Address: 200 Westboro Rd North Grafton Massachusetts 01536 United States  Contact: 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: Compiled medical record.pdf Description: Records	Phone: (508) 887-4523 Email: lisa.freeman@tufts.edu  Address: 200 Westboro Rd North Grafton Massachusetts 01536 United States  Name: Lisa Freeman  Address: 200 Westboro Rd North Grafton Massachusetts 01536 United States  Contact: 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: Compiled medical record.pdf Description: Records	Phone: (508) 887-4523 Email: lisa freeman@tufts.edu  Address: 200 Westboro Rd North Grafton Massachusetts 01536 United States  Name: Lisa Freeman  Address: 200 Westboro Rd North Grafton Massachusetts 01536 United States  Contact: 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: Compiled medical record.pdf Description: Records	Phone: (508) 887-4523   Email:   lisa.freeman@tufts.edu		Information:	Contact:	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    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    Name: Lisa Freeman	Address: 200 Westboro Rd North Grafton Massachusetts 01536 United States    Name: Lisa Freeman				Phone:	(508) 887-4523
Sender Information:  Name:  Lisa Freeman  Address:  Address:  Contact:  Permission To Contact Sender:  Preferred Method Of Contact:  Preferred Method Of Contact:  Records  Additional Documents:  Attachment:  Compiled medical record pdf  Records	Sender Information:  Name:  Lisa Freeman  Address:  200 Westboro Rd North Grafton Massachusetts 01536 United States  Contact: Phone: 5088874523 Email: lisa.freeman@tufts.edu  Permission To Contact Sender: Preferred Method Of Contact:  Preferred Method Of Contact: Records  Attachment: Compiled medical record.pdf Description: Records	Sender Information:  Name:  Lisa Freeman  Address:  200 Westboro Rd North Grafton Massachusetts 01536 United States  Contact: Phone:  5088874523 Email: lisa.freeman@tufts.edu  Permission To Contact Sender: Preferred Method Of Contact:  Phone:  Email: Records	Sender Information:  Name:  Lisa Freeman  Address:  200 Westboro Rd North Grafton Massachusetts 01536 United States  Contact: Phone: 5088874523 Email: lisa.freeman@tufts.edu  Permission To Contact Sender: Preferred Method Of Contact:  Preferred Method Of Contact: Records  Attachment: Compiled medical record.pdf Description: Records	Sender Information:  Name:  Lisa Freeman  Address:  Address:  Contact:  Permission To Contact Sender:  Preferred Method Of Contact:  Preferred Method Of Contact:  Records  Additional Documents:  Attachment:  Compiled medical record pdf  Records				Email:	lisa.freeman@tufts.edu
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						Type:	Medical Records		



**B6** 

All Medical Records

**B6**Breed: Golden Retriever

В6

Species: Canine Sex: Male

(Neutered)

Referring Information

**B6** 

**Initial Complaint:** 

Scanned Record

**Initial Complaint:** 

New **B6** DCM study

SOAP Text

**B6** 

12:08PM -

**B6** 

**Disposition/Recommendations** 

# CUMMINGS Veterinary Medical Center

Veterinarian:

B6

Visit ID:

# **B6**

В	6
Species:	Canine
Breed:	Golden Retriever
Sex:	Male (Neutered)
Age:	B6 Years Old

### Lab Results Report

	В6	1:29:30 PM	В6	
Test	Results		Reference Range	Units
Troponin I Research - FHSA	B6		0 - 0.08	mg/dl

B4, B6

| 3/22 | B6 |
| Printed Friday | B6 |

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records



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#### FECAL ANALYSIS: On House)

### FECAL ANALYSIS: On Hoose)



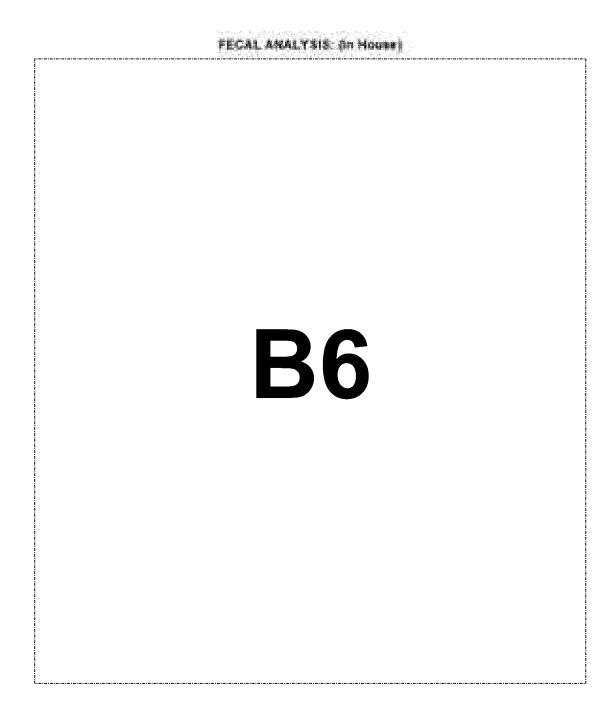
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B4, B6 11/8/2018

**B6** 

Section.

**B6** 

DEPLICATE

CBC/Chem

**B6** 





300 Westvers Read Worth Gradien, SGA (FEEE)

**B6** 

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DEPLICATE

### Tefts Cummings School Of Veterinary Medicine

300 Westberr Road Wants Gradien, 365, 81238



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| B6 | 11:32:13 AM | B6 |

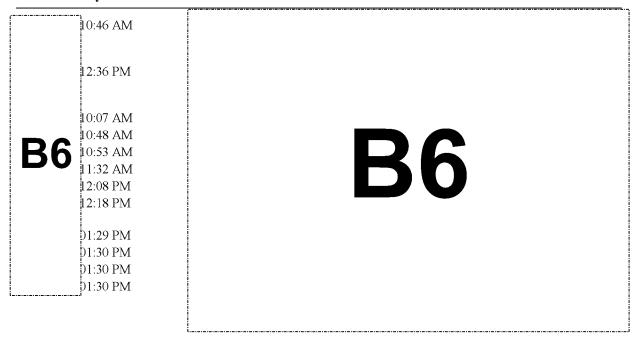


ECG from cardio



ECG from cardio

#### **Patient History**



Address:    200 Westboro Rd   North Grafton   Massachusetts   01536   United States	Information:   Contact:   Name:   Lisa Freeman   Phone: (508) 887-4523   Email:   lisa freeman@tufts.edu				B6	
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		Healthcare Professional	Practice Name:	Tufts Cumming	s School of Veterinary Medicine
Phone: (508) 887-4523   Email:   sa.freeman@tufts.edu	Phone: (508) 887-4523   Email:    isa.freeman@tufts.edu		Information:		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: Contact: 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: 200 Westboro Rd North Grafton Massachusetts 01536 United States  Contact: 200 Westboro Rd North Grafton Massachusetts 01536 United States  Email: lisa.freeman@tufts.edu  Permission To Contact Sender: 27es  Preferred Method Of Contact: 32email Contact: 32email  Additional Documents: 32email Additional Pocuments: 32email Additional Pocumen					(508) 887-4523
North Grafton   Massachusetts   Ol 1536   United States	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:  Pmail  Additional Documents:  Attachment: compiled medical record.pdf 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: Pmail  Additional Documents:  Attachment: compiled medical record.pdf  Records			Address:	North Grafton Massachusetts 01536	
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Permission To Contact Sender: Preferred Method Of Contact:  Additional Documents:  Attachment: Description:    Email:   lisa.freeman@tufts.edu	Permission To Contact Sender: Preferred Method Of Contact:  Additional Documents:  Attachment: Description:    Email:   lisa.freeman@tufts.edu     Yes		Address:	North Grafton Massachusetts 01536		
Permission To Contact Sender: Preferred Method Of Contact:  Additional Documents:  Attachment: Description:    Email:   lisa.freeman@tufts.edu	Permission To Contact Sender: Preferred Method Of Contact:  Additional Documents:  Attachment: Description:    Email:   lisa.freeman@tufts.edu     Yes		Contact:	Phone:	5088874523	
Sender: Preferred Method Of Contact:  Additional Documents:  Attachment: compiled medical record.pdf Description: Records	Sender: Preferred Method Of Contact:  Additional Documents:  Attachment: compiled medical record.pdf Description: Records				lisa.freeman@	tufts.edu
Contact:  Additional Documents:  Attachment: compiled medical record.pdf  Description: Records	Contact:  Additional Documents:  Attachment: compiled medical record.pdf  Description: Records			Yes		
Attachment: compiled medical record.pdf  Description: Records	Attachment: compiled medical record.pdf  Description: Records			Email		
Description: Records	Description: Records	Additional Documents:				
			Attachment:	compiled medical re-	cord.pdf	
Type: Medical Records	Type: Medical Records		Description:	Pecords		
			Description.	records		



Client: Address:

**B6** 

**All Medical Records** 

Patient: **B6**Breed: Golden

DOB:

d: Golden Retriever
3: **B6** 

Species: Canine Sex: Male

(Neutered)

Referring Information

**B6** 

**Initial Complaint:** 

Scanned Record

**Initial Complaint:** 

New - B6 DCM study

SOAP Text

**B6** 

12:08PM -

**B6** 

**Disposition/Recommendations** 



Client:	
Veterinariar	<b>R6</b>
Patient ID:	DU
Visit ID:	l

Patient:	B6
Species:	Canine
Breed:	Golden Retriever
Sex:	Male (Neutered)
Age:	B6 Years Old

### Lab Results Report

stringsoft.

	B6	1:29:30 PM	Accession ID: B6	
Test	Results		Reference Range	Units
Troponin I Research - FHSA	B6		0 - 0.08	mg/dl
-		3/22	B6	

Printed Friday, November 09, 2018

Client: **B6**Patient

**Best Available Copy** 

B4, B6 H records

B4, B6

**B4**, **B6** 

records

B4, B6

Client: Patient B6

B4, B6 ecords

B4, B6

B4, B6

records

B4, B6

B4, B6

**B6** 

Populit at 8

Client: Patient: **B6** 

B4, B6

**B6** 

Page 1 at 8

B4, B6

Client: **B6** 

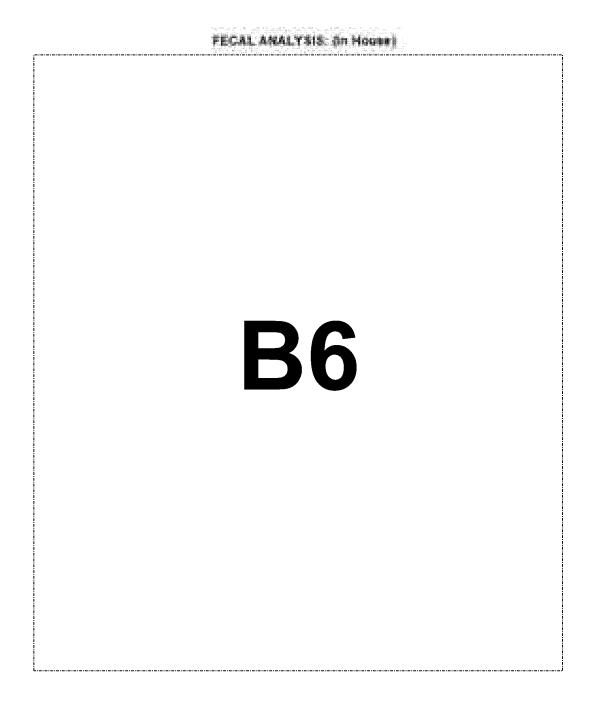
B4, B6

FECAL ANALYSIS: On House)

Client: Patient: B6

Best Available Copy

B4, B6 records



Client: Patient:

**B6** 

**Best Available Copy** 

B4, B6

**B6** 

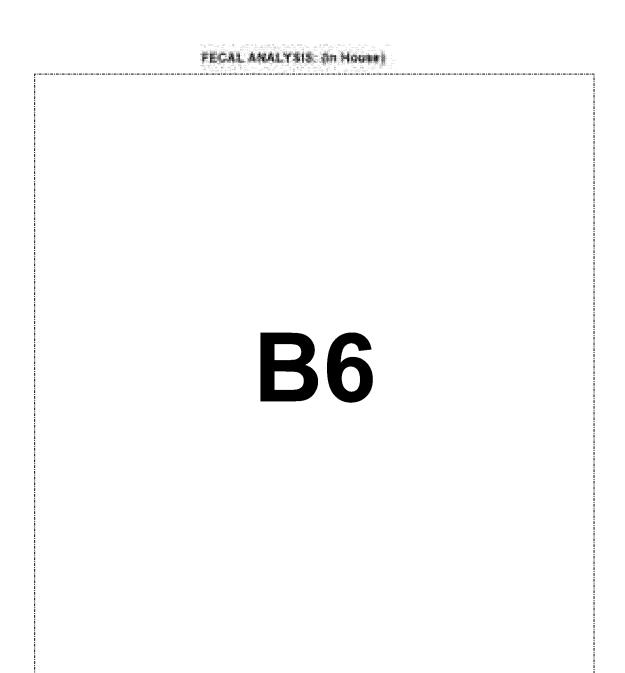
Populit at 8

Best Available Copy

Client: B6

B4, B6

records



Client: Patient B6
B4, B6

**B6** 

Best Available Copy

Client: Patient:

**B6** 

CBC/Chen

DUPLICATE.

**B6** 

Teffs	Communities	School	Of Vetermary	v Modicinie
THE PERSON NAMED IN	TO THE REAL PROPERTY AND ADDRESS.	ALC: HE WORKS	THE R. P. LEWIS CO., LANSING, LAST,	A CAMP PARTY OF PERSONS ASS.

300 Westberr Road Wants Gradien, NA 91218

**B6** 

Page 16/22

Client: B6

CBC/Chem B6

Teffs Cammings School Of Veterinary Medicine

Many Confine Model

Many Confine Mo

**B6** 

ECG from cardio



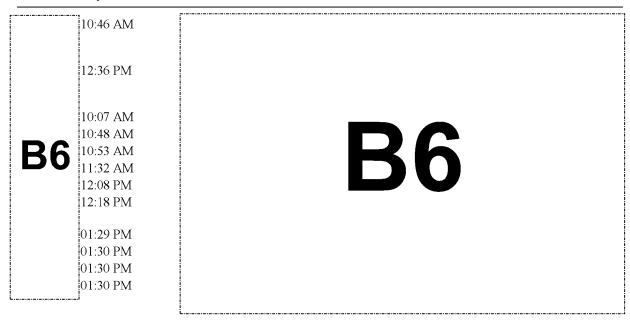
ECG from cardio

**B6** 

ECG from cardio

**B6** 

### **Patient History**



From:	PFR Event <pfreventcreation@fda.hhs.gov></pfreventcreation@fda.hhs.gov>	
То:	Cleary, Michael *; HQ Pet Food Report Notification <b>B6</b>	
Sent:	11/10/2018 10:52:28 PM	
Subject:	Zignature Trout & Salmon Meal Limited Ingredient Formula Grain-Free Dry Dog Food <b>B6</b> EON-370762	
Attachments:	2058699-report.pdf; 2058699-attachments.zip	

A PFR Report has been received and PFR Event [EON-370762] has been created in the EON System.

A "PDF" report by name "2058699-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 "2058699-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

**EON Key:** EON-370762

ICSR #: 2058699

EON Title: PFR Event created for Zignature Trout & Salmon Meal Limited Ingredient Formula Grain-Free Dry

Dog Food; 2058699

AE Date	04/24/2017	Number Fed/Exposed	2
Best By Date		Number Reacted	2
Animal Species	Dog	Outcome to Date	Better/Improved/Recovering
Breed	Retriever - Golden		
Age	8 Years		
District Involved	pfr <b>B6</b> do		

### **Product information**

**Individual Case Safety Report Number: 2058699** 

Product Group: Pet Food

**Product Name:** Zignature Trout & Salmon Meal Limited Ingredient Formula Grain-Free Dry Dog Food **Description: B6** has been eating Zignature Trout & Salmon kibble (1c. 2x/day) for over three years, since approximately August 2014. **B6** was diagnosed with a heart murmur in April 2017. Our regular vet said that it was not of concern it **B6** was not experiencing concerning symptoms, like being short of breath. In September 2018, **B6** started refusing to eat. She was also coughing and vomiting. On **B6** she collapsed and was

ting at University of opathy. She has since <b>B6</b> Our arate report regarding th the product)	California- e been enrolled younger dog,
Lot Number or ID	Best By Date
1	arate report regarding th the product) ed/Recovering  Lot Number or

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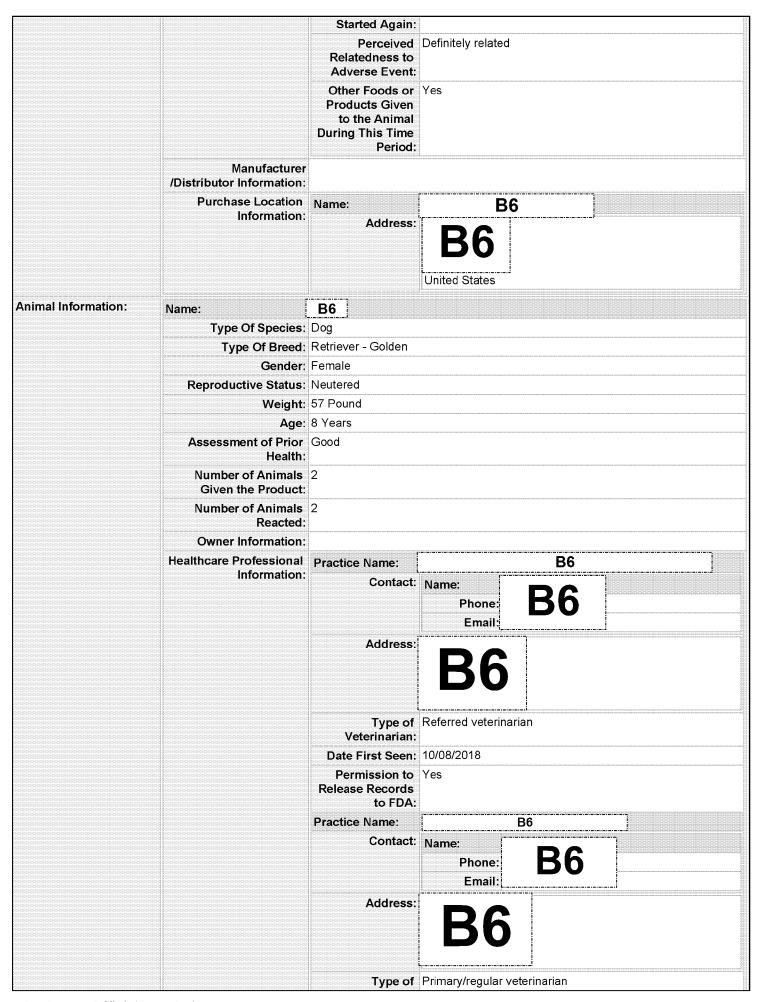
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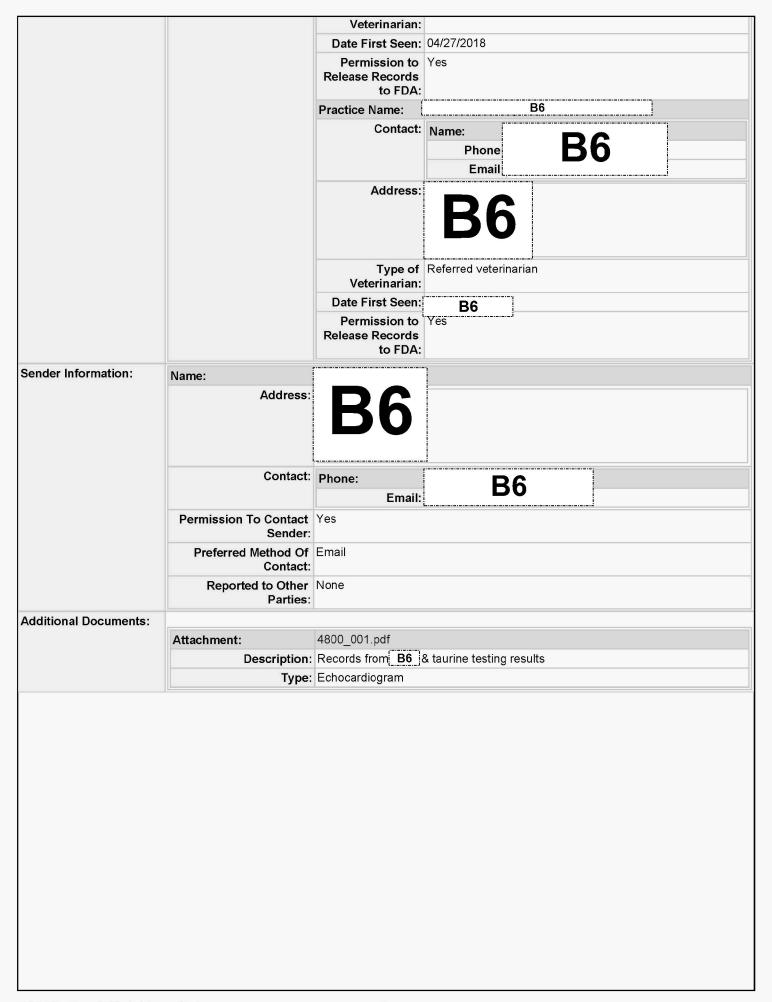
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through your local district FDA office.

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	-370762				
ICSR:	2058699				
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				
	: 2018-11-10 17:44:49 EST				
Reporter is the Animal	Yes				
Owner:					
Reported Problem:	Problem Description:	three years, since as murmur in April 201 not experiencing cor B6, B6 she collapse minutes. She was reemergency hospital, University of Californ of Dilated Cardiomydiet-related Dilated C	ng Zignature Trout & Salmon kibble (1c. 2x/day) for over oppoximately August 2014. B6 was diagnosed with a heart 7. Our regular vet said that it was not of concern if B6 was necerning symptoms, like being short of breath. In B6 refusing to eat. She was also coughing and vomiting. On B6 d and was unconscious and not breathing for several suscitated with CPR. She was brought to a veterinary where her blood was collected for taurine testing at hia-Davis, and an echocardiogram diagnosed a severe case opathy. She has since been enrolled in a study program for Cardiomyopathy in dogs at B6 Our younger ignosed with DCM on B6 and I will be making a urding him.		
	Date Problem Started:	04/24/2017			
	Concurrent Medical Problem:				
	Outcome to Date:	Better/Improved/Recovering			
Product Information:	Product Name:	Zignature Trout & Salmon Meal Limited Ingredient Formula Grain-Free Dry Dog Food			
	Product Type:	Pet Food			
	Lot Number:				
	Package Type:	BAG			
	Package Size:	7			
	Purchase Date:	: 08/01/2014			
	Number Purchased:	<u>-</u>			
	Possess Unopened Product:				
	Possess Opened Product:				
	Storage Conditions:	The food was stored	in an airtight plastic container after the bag was opened.		
	Product Use Information:	Description:	I fed my two dogs exactly 1 cup each of this food twice per day.		
		First Exposure Date:			
		Last Exposure Date:	B6		
		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		





## Cummings Veterinary Medical Center

AT TUFTS UNIVERSIT

**B6** 

**Discharge Instructions** 

**B6** 

Species: Canine

Blonde Female (Spayed) Golden

Retriever

Birthdate:

**B6** 

R6

**B6** 

**B6** 

Admit Date 8:30:52 PM Discharge Date: B6

Diagnoses: Dilated cardiomyopathy (DCM) with congestive heart failure

Case summary:

Thank you for bringing Jesse in to B6 for evaluation of her inappetence, lethargy and vomiting. B6 was diagnosed with dilated cardiomyopathy by your family veterinarian who started several cardiac medications (Furosemide, Enalapril, Pimobendan). She had been stable until two days ago when her appetite decreased, she appeared lethargic and she vomited.

On echocardiogram (ultrasound of the heart), we confirmed a diagnosis of dilated cardiomyopathy (DCM). This disease is more common in large and giant breed dogs and is characterized by thinning of the walls of the heart, reduced cardiac pump function, and enlargement of the upper chambers of the heart. Many dogs with DCM will also have significant arrhythmias which can be life-threatening and also require medical management. At this time B6 has very infrequent, isolated arrhythmic heart beats. It is unclear whether arrhythmia was the cause of her collapse. 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.

It is difficult to determine if **B6** more recent signs are related to her heart disease, a medication side effect or to changing her diet. We also recommend starting a daily taurine supplement, as we wait the results of B6 Taurine level bloodwork. Some dogs with DCM respond well to taurine supplementation and can have a decrease in heart size.

Monitoring at home:



**Recommended Medications:** 

**B6** 

Diet suggestions:

At this time, we would like you to start **B6** on a heart healthy diet such as <u>Royal Canin Early Cardiac diet</u>, <u>Royal Canin Boxer</u>, <u>or ProPlan Adult Weight Management</u>. If she preferes wet food you can try an option like Hill's Science Diet Adult Beef & Barely entree. Please contact us if you need more options.

Dogs with heart failure accumulate more fluid in their body if they eat large amounts of sodium (salt). Sodium can be found in all foods, but some foods are lower in sodium than others. Many pet treats, people foods, and supplements used to give pills often have more sodium than is desirable - a sheet that has suggestions for low sodium treats can be found on the HeartSmart web site (http://vet.tufts.edu/heartsmart/diet/)

### **Exercise Recommendations:**

Repetitive or strenuous high energy activities (repetitive ball chasing, running fast off-leash, etc.) are generally not advised at this stage of heart failure.

### **Recheck Visits:**

B6 |

We would like you schedule a **recheck appointment in 1 week** so that we can recheck **B6** bloodwork values and assess whether or not we should start a different ACEi. We also would like to schedule a **recheck echocardiogram in 4 months** for

	us with <b>B6</b> care. Please cor scheduling and non-emergent	ntact our Cardiology liaison at (508)-887-4696 or email us at questions or concerns.
Please visit our HeartSm http://vet.tufts.edu/hea	art website for more information	on Control of the Con
<b>Prescription Refill Disclain</b> For the safety and well-be year in order to obtain pre	ing of our patients, your pet mus	st have had an examination by one of our veterinarians within the past
please call 7-10 days in ac		e recommended diet(s). If you wish to purchase your food from us, the food is in stock. Alternatively, veterinary diets can be ordered from
	n which our veterinary doctors wo tment. Please see our website: <u>ve</u>	rk with you and your pet to investigate a specific disease process or a <a href="https://example.com/c/clinical-studies">https://example.com/c/clinical-studies</a>
-	В6	Discharge Instructions

# CUMMINUS Veterinary Medical Center

AT TUFTS UNIVERSITY Cardiology Liaison: 508-887-4696

Mild muscle loss

**B6** 

B6

**B6** Canine

**B6** Years Old Female (Spayed) Golden

Retriever

Blonde BW: Weight (kg) 27.70

Date: B6	Cardiology Inpatient
Weight: Weight (kg) <b>B6</b>	
B	
	ts.
Thoracic radiographs available for Yes - in SS	review?
Yes - in PACS	
No	
collapsing episode. She was started Furosemide 60mg PO q12. She was until <b>B6</b> when she began to lot her sudden change so they brough once (liquid/brown/grass) and was	nt concurrent diseases: who was diagnosed through the ER or B6 with DCM after a I on Enalapril 15mg PO q12, Pimobendan 7.5mg PO q12, and scheduled for a cardiology appointment on 10/17/18. She was stable see her appetite and became lethargic, owners were concerned about ther into Tufts ER on B6 Prior to arriving at the ER she vomited retching. She has a test pending for taurine levels. She had previously witched to Nature's variety instinct raw beef and barely.
BUN 48 [H], Crea 1.3), CBC/Chem/Uinterstitial pattern, report pending	Jinitial diagnostics included NOVA (PCV 40, TS 6.5, Lactate 2.3 [H] JA-pending, chest radiographs (Cardiomegaly, possible perihilar and AFAST/TFAST (no FF, LV dilation w/ poor contractility). She was
	try and scheduled for a cardio consult today <b>B6</b> ainder of form to be filled out by Cardiology*
Physical Examination	
<b>B6</b>	
Muscle condition:  Normal	■ Moderate cachexia

Marked cachexia

Cardiovascular Physical Exam	
Murmur Grade:	*
None	
I/VI	□ v/vi
<u> </u>	□ vi/vi
	W.L. VI
□ III/VI	
Murmur location/description: systol	iv left anical
Warmar location, acsemption. Syston	in left apieur
Jugular vein:	
Bottom 1/3 of the	☐ Top 2/3 of the neck
	Top 2/3 of the fleck
neck	
Middle 1/3 of the	1/2 way up the neck
neck	
Arterial pulses:	Statement'
■Weak	■ Bounding
☑ Fair	Pulse deficits
Good	Pulsus paradoxus
Strong	Other (describe):
<u> </u>	e outer (describe).
Arrhythmia:	
□ None	☐ Bradycardia
	Garage Control of the
Sinus arrhythmia	Tachycardia
Premature beats - isolated Vi	PCs
ai.	
Gallop:	(BARCON)
Yes ***	Pronounced
₩ No	Other:
Intermittent	
Pulmonary assessments:	
Eupneic	Pulmonary Crackles
Mild dyspnea	Wheezes
Marked dyspnea	Upper airway stridor
Normal BV sounds	Other auscultatory findings:
Mormal By sounds	Other auscultatory lindings:
<u>*</u> .	
Abdominal exam:	
■ Normal	Abdominal distension
Hepatomegaly	Mild ascites
Echocardiogram Findings:	
	<b>B6</b>
Doppler findings:	3.
B6	
<b>D</b> 0	

<b>B</b> 6			
Mitral inflow:  Summated  Normal  Delayed relaxation	Pseudonormal Restrictive		
Blood Pressure (mmHg)	; 100mmHg		
B6	â		
ECG findings:		W.	
· · ·	<b>B6</b>		
Radiographic findings:			
	<b>B6</b>		<sup>©</sup> th
Assessment and recommodister and recommodister and recommodistance and recommodistance are also assessment	nendations: Findings revealed ac	dvanced LV dilation and <b>B6</b>	systolic dysfunction
	Be	3	
Treatment plan:			
	B6	3	
Final Diagnosis: - Advanced dilated cardi	omyopathy with suspected mild	LCHF (r/o primary vs. die	t induced)

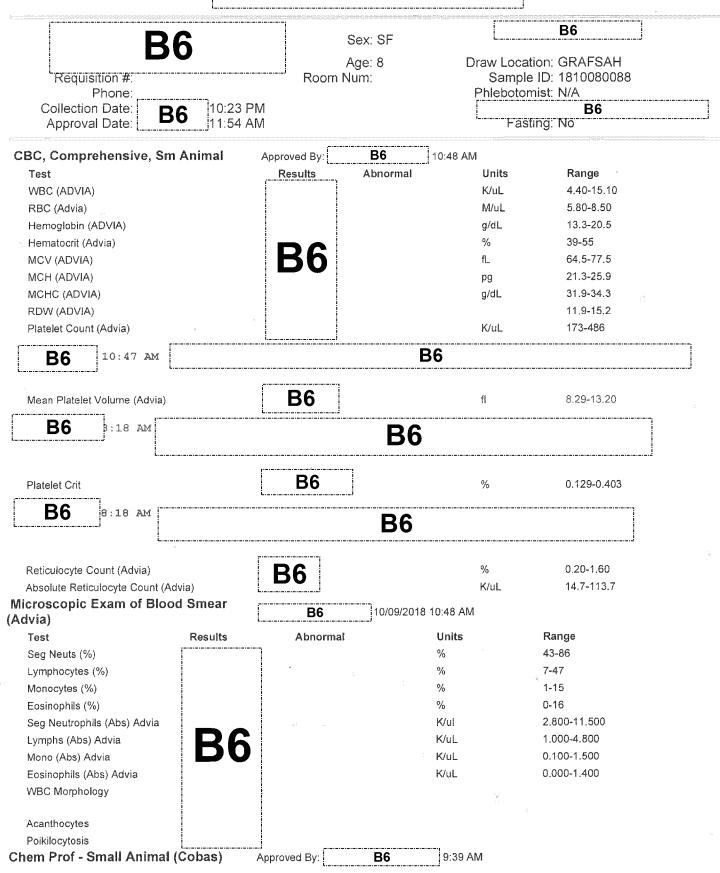
**Heart Failure Classification Score**:

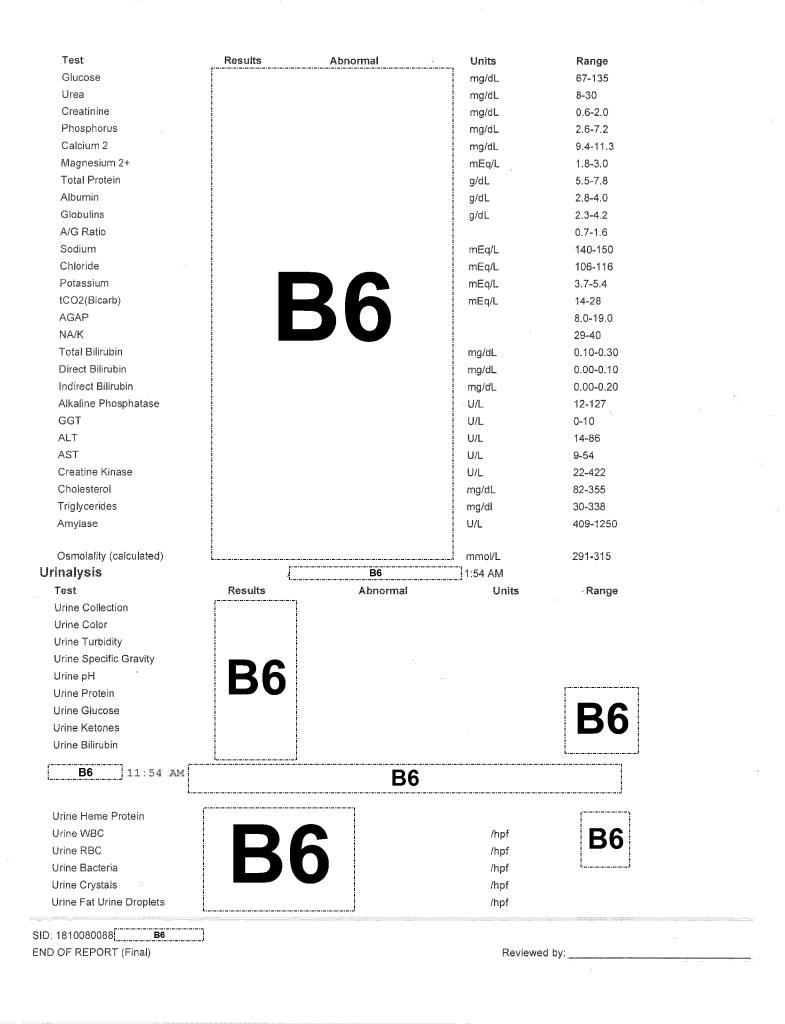
ISACHC Classification: ☐ IIIa ☐ la □lb ■ IIIb **2** 11 **ACVIM CHF Classification**: M C ■ B1 ΠD ■ B2 M-Mode IVSd cm cm LVIDd LVPWd cm **IVSs** cm **LVIDs** cm **LVPWs** cm % %FS Max LA cm Time ms BPM HR I/min CO(Teich) I/minm CI(Teich) **EPSS** cm M-Mode Normalized (0.29 - 0.52)**IVSdN** LVIDdN (1.35 - 1.73)!(0.33 - 0.53)LVPWdN **B6** (0.43 - 0.71)!**IVSsN** (0.79 - 1.14)!LVIDsN (0.53 - 0.78)**LVPWsN** 2D SA LA cm Ao Diam cm SA LA / Ao Diam IVSd cm cm LVIDd **LVP.Wd** cm ml EDV(Teich) cm IVSs cm LVIDs **LVPWs** cm ml ESV(Teich) EF(Teich) % % %FS SV(Teich) ml LVLd LAX cm

		,		
LVAd LAX				cm
LVEDV A-L LAX				ml
LVEDV MOD LAX				ml
LVLs LAX				cm
LVAs LAX			73	cm
LVESV A-L LAX				ml
LVESV MOD LAX			.W	ml
HR .				BPM
EF A-L LAX	**			%
LVEF MOD LAX				%
SV A-L LAX				ml
SV MOD LAX				ml
CO A-L LAX				I/min
CO MOD LAX				l/min
Doppler				
MV E Vel ·				m/s
MV DecT		DC		ms
MV A Vel		<b>B6</b>		m/s
MV E/A Ratio				
E'				m/s
A'				m/s
E/E'				
S'				m/s
MR Vmax				m/s
MR Vmean				m/s
MR maxPG				mmHg
MR meanPG			C.	mmHg
MR VTI				cm
PV Vmax				m/s
PV maxPG				mmHg
AV Vmax	1.30			m/s
AV maxPG				mmHg
IVRT				ms
TR Vmax				m/s
TO DO		:		

TR Vmax TR maxPG

mmHg





**B6** Sex: SF Age: 8 Draw Location: GRAFSAH Requisition #: Room Num: Sample ID: 1810080089 Phone: Phlebotomist: N/A Collection Date: 10:28 PM В6 В6 Approval Date: 1:33 AM Fasting: No B6 Nova Full Panel-ICU 1:33 AM Test Results Abnormal Units Range рΗ 7.337-7.467 pCO2 mmHg 36.0-44.0 pQ2 mmHg 80.0-100.0 SQ2% % 94.0-100.0 Hct (POC) % 38-48 Hb (POC) g/dL 12.6-16.0 Sodium (POC) mmol/L 140.0-154.0 K (POC) mmol/L 3.6-4.8 CI (POC) 109-120 mmol/L Ca (ionized) mmol/L 1.17-1.38 Mg, (ionized) (POC) 0.1-0.4 mmol/L **B6** Glucose (POC) 80-120 mg/dL Lactate mmol/L 0.0-2.0 BUN (POC) 12.0-28.0 mg/dL Creat (POC) mg/dL 0.2 - 2.1TCO2 (POC) mmol/L mmol/L nCa nMg mmol/L mmol/L Gap Ca/Mg mol/mol **BEecf** mmol/L BEb mmol/L HCO<sub>3</sub> 18.0-24.0 mmol/L mmHg NOVA Sample Source FiO2 %

SID: 1810080089 END OF REPORT (Final)

**B6** 

Reviewed by:

**B6 B6** Sex: SF Age: 8 Draw Location: GRAFSAH Requisition #: Room Num: Sample ID: 1810090060 Phone: Phlebotomist: N/A Collection Date: 10:19 AM **B6 B6** Approval Date: 1:06 PM Fasting: No Chemistry 21 (Cobas) В6 1:06 PM Test Results Abnormal Units Range Glucose mg/dL 67-135 Urea mg/dL 8-30 Creatinine mg/dL 0.6-2.0 Phosphorus mg/dL 2.6-7.2 Calcium 2 mg/dL 9.4-11.3 Total Protein g/dL 5.5-7.8 Albumin g/dL 2.8-4.0 Globulins g/dL 2.3-4.2 A/G Ratio 0.7-1.6 Sodium **B6** mEq/L 140-150 Chloride mEq/L 106-116 Potassium 3,7-5,4 mEq/L NA/K 29-40 Total Bilirubin 0.10-0.30 mg/dL Direct Bilirubin mg/dL 0.00-0.10 Indirect Bilirubin mg/dL 0.00-0.20 Alkaline Phosphatase U/L 12-127 ALT U/L 14-86 AST U/L 9-54 Cholesterol mg/dL 82-355 Osmolality (calculated) 291-315 mmol/L Comments (Chemistry) SID: 1810090060 В6

END OF REPORT (Final)

Reviewed by:

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

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

From:	PFR Event <pfreventcreation@fda.hhs.gov></pfreventcreation@fda.hhs.gov>	
То:	B6	
Sent:	11/9/2018 10:36:55 PM	
Subject:	Zignature trout and salmon dry: Lisa Freeman - EON-370713	
Attachments:	2058681-report.pdf; 2058681-attachments.zip	

A PFR Report has been received and PFR Event [EON-370713] has been created in the EON System.

A "PDF" report by name "2058681-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 "2058681-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

**EON Key:** EON-370713

ICSR #: 2058681

**EON Title:** PFR Event created for Zignature trout and salmon dry; 2058681

AE Date	10/08/2018	Number Fed/Exposed	3
Best By Date		Number Reacted	2
Animal Species	Dog	Outcome to Date	Stable
Breed	Retriever - Golden		
Age	8 Years		
District Involved	PFR <b>B6</b> DO		

### **Product information**

**Individual Case Safety Report Number: 2058681** 

**Product Group:** Pet Food

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

**Description:** DCM and CHF. From late-2014 through 09/30/18, **B6** at about 1 cup of Zignature trout & salmon dry food twice per day. Then, from 10/01-10/14/18, she ate Nature?s Variety Instinct Raw beef & barley dryg food (1.5c. 2x/day). The primary cookies she ate was Earthborn Holistic Grain-Free, all varieties, and she might have had 3-4 cookies per day. The only other cookies she would have eaten were misc. varieties brought by misc. delivery people (propane, UPS, etc.) and not regularly. If we ever had to give her medication, we always used the Greenies Pill Pockets. Taurine for **B6** - 327 whole blood Owners' other Golden, **B6**, is four and

<del>-</del>	F		0/01/18 (see separate report). We also
have a Golden puppy <b>B6</b> who	was born on <b>B6</b>	and ate the same	e Zignature from 07/23-10/01/18.
Submission Type: Initial	\ <b>\</b>		
<b>Report Type:</b> Adverse Event (a sy	_		with the product)
Outcome of reaction/event at the		ion: Stable	
Number of Animals Treated Wit			
Number of Animals Reacted Wi	th Product: 2		
	Г	T	
Product Name	Lot Number or ID	Best By Date	
Zignature trout and salmon dry			
			_
Sender information			
Lisa Freeman			
200 Westboro Rd			
North Grafton, MA 01536			
USA			
Owner information			
<b>B</b> 6			
DU	•		
		j	
To view this PFR Event, please cli	ck the link below:		
B6			
To view the PFR Event Report, plo	ease click the link below	<u>W:</u>	
		36	
		,0	
L			

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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-3	370713				
ICSR:	2058681				
Type Of Submission:	Initial				
	FPSR.FDA.PETF.V.V1				
Type Of Report:	Adverse Event (a symptom,	reaction or disease a	associated with the product)		
	Voluntary				
Report Submission Date:					
Reported Problem:	Problem Description:	DCM and CHF. From late-2014 through 09/30/18, B6 ate about 1 cup of Zignature trout & salmon dry food twice per day. Then, from 10/01-10/14/18, she ate Natures Variety Instinct Raw beef & barley dryg food (1.5c. 2x/day). The primary cookies she ate was Earthborn Holistic Grain-Free, all varieties, and she might have had 3-4 cookies per day. The only other cookies she would have eaten were misc. varieties brought by misc. delivery people (propane, UPS, etc.) and not regularly. If we ever had to give her medication, we always used the Greenies Pill Pockets. Taurine for B6 - 327 whole blood Owners' other Golden, B6 is four and was born on B6 He ate Zignature trout & salmon from 09 730/15-10/01/18 (see separate report). We also have a Golden puppy B6 who was born or B6 and ate the same Zignature from 07/23-10/01/18.			
	Date Problem Started:	7			
	Concurrent Medical Problem:	No			
	Outcome to Date:	Stable			
Product Information:	Product Name:	Zignature trout and	salmon dry		
	Product Type:	Pet Food			
	Lot Number:	<b>7</b>			
	Package Type:	BAG	p=1-1-1-1-1-1		
	Product Use Information:	Description:	From late-2014 through 09/30/18, <b>B6</b> ate about 1 cup of Zignature trout & salmon dry food twice per day. Then, from 10/01-10/14/18, she ate Natures Variety Instinct Raw beef & barley dryg food (1.5c. 2x/day). The primary cookies she ate was Earthborn Holistic Grain-Free, all varieties, and she might have had 3-4 cookies per day. The only other cookies she would have eaten were misc. varieties brought by misc. delivery people (propane, UPS, etc.) and not regularly. If we ever had to give her medication, we always used the Greenies Pill Pockets.		
	Manufacturer /Distributor Information:				
	Purchase Location Information:				
Animal Information:	Name:	B6 (will report other dog separately)			
	Type Of Species:	Dog			
	Type Of Breed:	Retriever - Golden			
	Gender:	Female			
	Reproductive Status:	Neutered			
	Weight:	27.7 Kilogram			
		8 Years			
	Assessment of Prior Health:				
	Number of Animals Given the Product:				
	Number of Animals Reacted:	***************************************			
	Owner Information:	Owner Information provided:	Yes		

	Contact:	Name:	DC	
		Phone:	B6	
	Address:		<b>B6</b>	
Healthcare Professional Information:		United States		
	Practice Name:	Tufts Cumming	s School of Veterinary Medicine	
	Contact:	Name:	Lisa Freeman	
		Phone:	(508) 887-4523	
		Email:	lisa.freeman@tufts.edu	
	Address:	200 Westboro 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@t	ufts.edu	
Permission To Contact Sender:	Yes			
Preferred Method Of Contact:	Email			
Attachment:	compiled records ad	f		
	Name:  Address:  Contact:  Permission To Contact Sender: Preferred Method Of Contact:  Attachment: Description:	Healthcare Professional Information:  Name:  Lisa Freeman  Address:  Address:  Address:  Contact:  Address:  Preferred Method Of Contact:  Email:  Address:	Healthcare Professional Information:  Practice Name: Contact: Phone: Email:  Address: 200 Westboro North Grafton Massachusetts 01536 United States  Name:  Lisa Freeman 200 Westboro Rd North Grafton Massachusetts 01536 United States  Contact: Phone: Femail: Isa Freeman 200 Westboro Rd North Grafton Massachusetts 01536 United States  Contact: Phone: Femail: Isa freeman@t Permission To Contact Sender: Preferred Method Of Contact: Compiled records.pdf Medical records	





All Medical Records

**B6**Breed: Golden Retriever

В6

Species: Canine Sex: Female

Female (Spayed)

**Referring Information** 

**B6** 

**Initial Complaint:** 

**DCM** 

**SOAP Text** 

**B6** 

9:04PM

**B6** 

**Subjective** 

**NEW VISIT (ER)** 

**B6** 

Presenting complaint: anorexia, vomiting, lethargy

Referral visit? no

Diagnostics completed prior to visit: none

**HISTORY:** 

Signalment: 8 YO, FS, golden

Current history: Presenting to ER for history of collapse last Sunday. She was taken to an ER clinic at that time and diagnosed with DCM. She was put on pimobendan, furosemide and enalapril. She had been doing well up until yesterday. She lost her appetite (didnt eat any dinner or treats) and became lethargic and spacey. Has been drinking more since starting the new medications. Has an appointment with a cardiologist on the 17th, but worried about her sudden change today. Has a test pending for taurine levels. She vomited today before arriving, observed retching and the vomitus was brown and liquid with grass. No diarrhea. No C/S. O would like to see if we can fit her into cardio apt tomorrow rather than waiting for their planned appt.

Prior medical history: DCM diagnosed **B6** chronic ear infections



Current medications:

**B6** 

EXAM:

**B6** 

ASSESSMENT:

**B6** 

PLAN:

**B6** 

Diagnostics completed:

<b>B6</b>	
	<b>B6</b>
Diagnostics pending:	
Client communication	B6
<u> </u>	B6
Deposit & estimate statu	usį <b>B6</b>
Resuscitation code (if ad	mitting to ICU): YELLOW
SOAP approved (DVM to	sign). <b>B6</b> DVM
SOAP Text B6	6:47AM - Clinician, Unassigned FHSA
Daily Exam, Cardiology	B6
was started on Enalapril for a cardiology appoint became lethargic, owne Prior to arriving at the E	Retriever who was diagnosed through the ER or B6 with DCM after a collapsing episode. She 15mg PO q12, Pimobendan 7.5mg PO q12, and Furosemide 60mg PO q12. She was scheduled ment on B6 She was stable until B6 when she began to lose her appetite and rs were concerned about her sudden change so they brought her into Tufts ER or B6 R she vomited once (liquid/brown/grass) and was retching. She has a test pending for taurine y been on a grain free diet, but was switched to Nature's variety instinct raw beef and barely.
Crea 1.3), CBC/Chem/UA	R or <b>B6</b> initial diagnostics included NOVA (PCV 40, TS 6.5, Lactate 2.3 [H], BUN 48 [H], A-pending, chest radiographs (Cardiomegaly, possible perihilar interstitial pattern, report ST (no FF, LV dilation w/ poor contractility). She was hospitilized overnight with telemetry and onsult today <b>B6</b>
<u>Subjective</u>	
E	36
remained between 65 to	picked at her food overnight and ate well this morning, she did not have any eliminations. HR of 119bpm. Cardiac rhythm was normal majority of the time (SA or NSR) with occasional isolated were in normal parameters (high 20s-low 30s).
<u>Objective</u>	
	B6
<u> </u>	Page 3/38



Assessments

**B6** 

<u>Plan</u>

**B6** 

SOAP completed by: B6
SOAP reviewed by:

**Disposition/Recommendations** 

# Cummings Veterinary Medical Center



## **B6**

В	6
Species:	Canine
Breed:	Golden Retriever
Sex:	Female (Spayed)
Age:	<b>B6</b> Years Old

### Lab Results Report

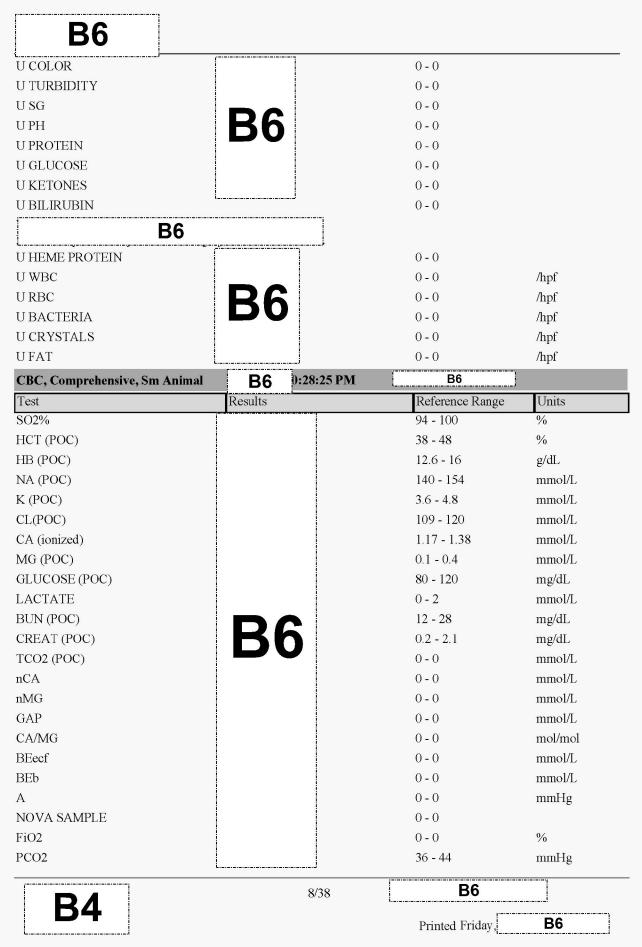
CBC, Comprehensive, Sm Animal	В6	12 PM	B6	
Test	Results		Reference Range	Units
WBC (ADVIA)			4.4 - 15.1	K/uL
RBC(ADVIA)			5.8 - 8.5	M/uL
HGB(ADVIA)			13.3 - 20.5	g/dL
HCT(ADVIA)			39 - 55	%
MCV(ADVIA)			64.5 - 77.5	fL
MCH(ADVIA)			21.3 - 25.9	pg
MCHC(ADVIA)	<b>B6</b>		31.9 - 34.3	g/dL
RDW (ADVIA)			11.9 - 15.2	
PLT(ADVIA)			173 - 486	K/uL
MPV (ADVIA)			8.29 - 13.2	fl
PLTCRT			0.129 - 0.403	%
RETIC(ADVIA)			0.2 - 1.6	%
RETICS (ABS) ADVIA			14.7 - 113.7	K/uI.
CBC, Comprehensive, Sm Animal	В6	):23:27 PM	B6	
Test	Results	····	Reference Range	Units
GLUCOSE			67 - 135	mg/dL
UREA			8 - 30	mg/dL
CREATININE			0.6 - 2	mg/dL
PHOSPHORUS	<b>B6</b>		2.6 - 7.2	mg/dL
CALCIUM2			9.4 - 11.3	mg/dL
MAGNESIUM 2+			1.8 - 3	mEq/L
D4	—زــــــــــــــــــــــــــــــــــــ	6/38	В6	

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**B6** 

Printed Friday,

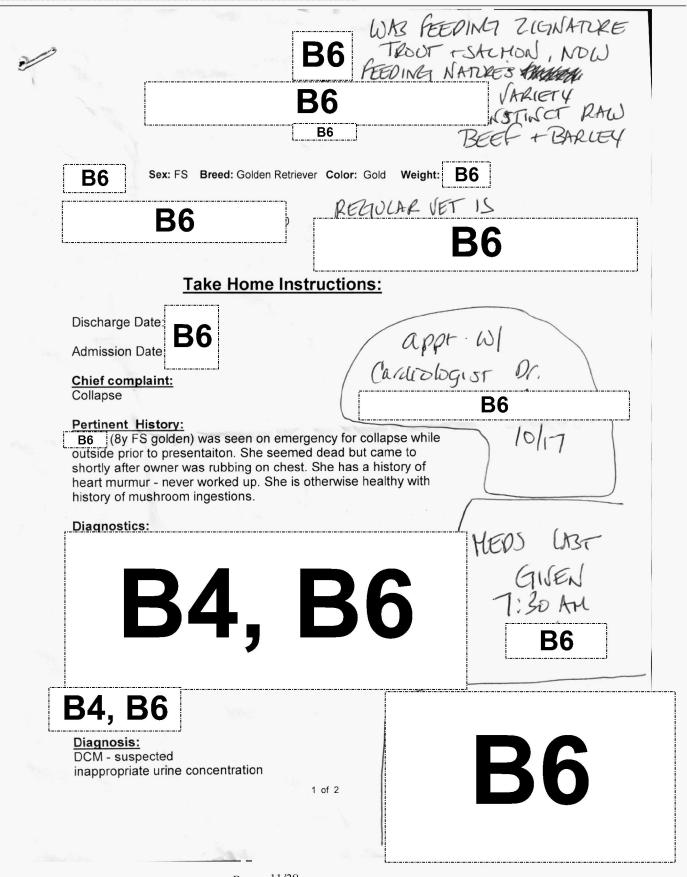
B6				
T. PROTEIN			5.5 - 7.8	g/dL
ALBUMIN			2.8 - 4	g/dL
GLOBULINS			2.3 - 4.2	g/dL
A/G RATIO			0.7 - 1.6	
SODIUM			140 - 150	mEq/L
CHLORIDE			106 - 116	mEq/L
POTASSIUM			3.7 - 5.4	mEq/L
CO2 (BICARB)			14 - 28	mEq/L
AGAP			8 - 19	1
NA/K			29 - 40	
BILIRUBIN			0.1 - 0.3	mg/dL
D.BILIRUBIN	<b>B6</b>		0 - 0.1	mg/dL
BILIRUBIN			0 - 0.2	mg/dL
ALK PHOS			12 - 127	U/L
GGT			0 - 10	U/L
ALT			14 - 86	U/L
AST			9 - 54	U/L
CK			22 - 422	U/L
CHOLESTEROL			82 - 355	mg/dL
TRIGLYCERIDES			30 - 338	mg/dl mg/dl
AMYLASE			409 - 1250	U/L
1816 Result(s) venified			407 - 1230	O/L
OSMOLALITY (CALCULATED)			291 - 315	mmol/L
CBC, Comprehensive, Sm Animal	B6	10:23:10 PM	B6	
rest -	Results	! <u>-</u>	Reference Range	Units
SEGS%			43 - 86	%
LYMPHS%			7 - 47	0/0
MONOS%			1 - 15	%
EOS%			0 - 16	%
SEGS (AB)ADVIA			2.8 - 11.5	K/ul
LYMPHS (ABS)ADVIA	D	2	1 - 4.8	K/uL
MONOS (ABS)ADVIA	B	)	0.1 - 1.5	K/uL
EOS (ABS)ADVIA			0 - 1.4	K/uL
WBC MORPHOLOGY			0 - 0	
No Morphologic Abnormalities				
	rus		0 - 0	
POIKILOCYTOSIS	<u> </u>		0 - 0	
CBC, Comprehensive, Sm Animal	В6	23:14 PM	B6	
Гest	Results		Reference Range	Units
U COLLECT	Not Indic	ated	0 - 0	
R/		7/38	B4	
D4			Printed Friday	!



Page 8/38

PO2			80 - 100	mmHg
РН			7.337 - 7.467	
PCO2	<b>B6</b>		36 - 44	mmHg
202			80 - 100	mmHg
ICO3			18 - 24	mmol/L
CBC, Comprehensive, Sm Animal	B6	0:37:16 PM	B6	
est	Results		Reference Range	Units
S (FHSA)			0 - 0	g/dl
CV **	<b>B6</b>		0 - 0	%
S (FHSA)			0 - 0	g/dl
BC, Comprehensive, Sm Animal	B6	0:19:21 AM	B6	
est	Results		Reference Range	Units
JLUCOSE			67 - 135	mg/dL
JREA			8 - 30	mg/dL
REATININE			0.6 - 2	mg/dL
PHOSPHORUS			2.6 - 7.2	mg/dL
CALCIUM2			9.4 - 11.3	mg/dL
'. PROTEIN			5.5 - 7.8	g/dL
LBUMIN			2.8 - 4	g/dL
GLOBULINS			2.3 - 4.2	g/dL
/G RATIO			0.7 - 1.6	
ODIUM			140 - 150	mEq/L
HLORIDE	H	6	106 - 116	mEq/L
OTASSIUM		U	3.7 - 5.4	mEq/L
JA/K			29 - 40	
BILIRUBIN			0.1 - 0.3	mg/dL
D.BILIRUBIN			0 - 0.1	mg/dL
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)		<u></u> j	0 - 0	
CBC, Comprehensive, Sm Animal	B6	0:48:18 AM	В6	
l'est	Results		Reference Range	Units
S (FHSA)			0 - 0	g/dl
CV **	B6		0 - 0	%
TS (FHSA)			0 - 0	g/dl
			<u> </u>	
D/		9/38	B6	

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**B6** 

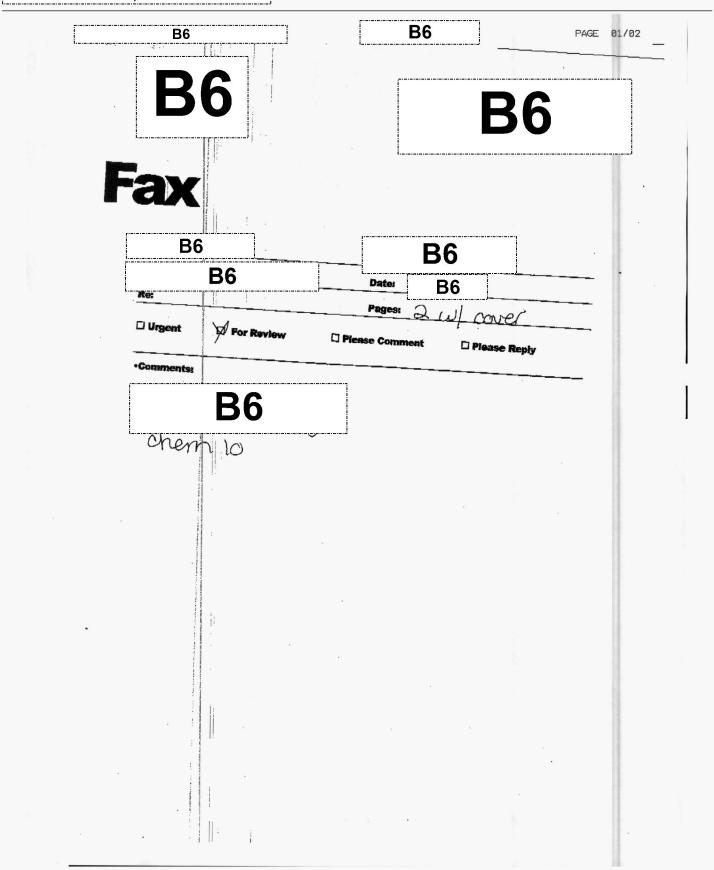
**Take Home Instructions:** 

**B6** 

Medications:

**B6** 

2 of 2



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В6		[	B4, B6		PAGE 02/02
Tr Line Control of the Control of th		· I		i	Page Lof I
A Marie Carlos de Carlos d	Date	Catalyst e Performed:	Dx B6 03:50 PM		And the second s
<b>B6</b>	Sp	pecies: Canine	[	) / I	D6
Provider: 0	Bir	reed: Golden Retrie rthdate: B6 ox: FS	ever	34, I	DU
GLU	1				
CREA					and the state of t
BUN					
BUN/QREA Name /- Qune \ Alovid				^	Sec. 1808
ALD ALD	1		B	n n	
GKGB					
ALE/GLOB					Service of the servic
ALTE CIRE					and Transcally
Arke.					
GEG	i.				maticketiment
BLOG	WAY COMPANY OF THE PARTY OF THE				
AUP/ANA	Grant Control of the				riobit; i
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	NAME AND POST OF THE PARTY OF T				
file:///C:/Program%	520Files%20(x86)/J	nfinity/def.htm			B6

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<b>B6</b>	Species: Canine
Breed: Golden re-trievec	В6
Current Diet: Zignatuse trou	t a salmon
Sample type: Plasma Whole Blood Urine Test: (Taurine) Complete Amino Acids Other	Food Otherer:
Taurine Results (lab use only) Plasma: Whole Blood: B6	Food:
Discove (nWeilm)	Whole Blood (nMol/ml)

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

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

### **UCDavis Taurine Level**

### UNIVERSITY OF CALIFORNIA, DAVIS

BENEFICIAL . DEGLE . EKUNU . FUR VUCETUR . MENCER . MARKENDE . RYK PLEND . DVM LKYNGEND.



SANTARARHARA - SANTACRUZ

STERN CARDIAC GENETICS LABORATORY
JOSHUA A. STERN, DVM, PHD, DACVIM (CARDIOLOGY)
stemgenetics@ucdavis.edu; August 9, 2018

### 

Taurine reference ranges for Golden Retrievers: The Stern Lab suggests that the following clinical reference ranges be used for Golden Retrievers and be considered for other known taurine-sensitive breeds such as Newfoundlands or American Cocker Spaniels. This is primarily based on 3 observations:

- Golden Retrievers with marginal taurine levels (defined below) have been diagnosed with dilated cardiomyopathy and have documented disease reversal after taurine supplementation and diet chance.
- 2. Previously published work documents taurine sensitivity in Golden Retrievers.
- 3. The most recently published reference on normal blood taurine values shows higher levels than previously reported.
  - a Normal whole blood taurine: >250emol/ml.
  - Normal plasma taurine: >70nmol/ml.
  - o Marginal whole blood taurine: 200-250nmol/ml.
  - Marginal plasma taurine: 60-70nmol/ml.
  - Low whole Blood taurine: <200nmol/ml.</li>
  - e Low plasma taurine: <60nmol/mL

### References:

Kramer GA, Kutteren MD. Fox PR, Lewis J. Fron PD. Plasma faurine concentrations with normal dogs and in dogs with heart disease. I Vet Intern Med 1995;9:253-258.

Helanger MC, Quellet M, Queney G, Morsau M. Taurine-deficient dilated cardiomyopathy in a family of golden zetrievers. J Am Anim Hosp Asiac 2005;41:284-291.

Kittlesse MD, Keene E, Pion PD, Loyer CG, MUST Stody tovestigators. Results of the multicenter spaniel trial (MUST): tracine; and comming-responsive dilated cardiocaycopathy in American Cocker Spaniels with decreased plasma tauring concentration. J Vet Intern Red 1197:12:204-211.

Barkus RC, Choen G, Pion PD, Good KL, Rogers QR, Pascetti AJ. Taurine deficiency in Newfoundlands fed commercially assistable complete and balanced diets. J Am Vet Med Assoc 2002;223:1130-1136. Fascetti AJ. Reed JR, Rogers QR, Barkos RC. Taurine deficiency in dogs with diluted cardiomyopathy: 12 cases (1997-2001). J Am Vet Med

Assoc 2003;223:1137-1141.
Freeman LM, Michel KE, Breum DJ, Kaplan FM, Stamoulis MF, Resenthal SL, Roene SW, Bush JE. Idiopathic dilated cardiomycpathy in

Bairastians: nine cases (1990-1995). J Am Vet Med Azios: 1996;205:1592-1596.

Delinny SI, Kiris PH, Rogers QR. Fascetsi Al. Plasma and whole blood taurine in normal dogs of varying size fed commercially prepared food; J Anim Pour Anim Note: 2003;67:236-246.

Plasma vs. whole blood taurine testing:

If at all possible, we recommend that paired (plasma and whole blood) taurine samples be submitted for analysis. A low value on either or both tests is clinically relevant. If your dog is diagnosed with DCM, submitting paired taurine samples (plasma and whole blood) is imperative. We recommend that the UC Davis Amino Acid Laboratory be used for taurine testing, as this is where the literature utilized for our reference ranges was generated. https://www.vetmed.ucdavis.edu/labs/amino-acid-laboratory. If a single test is submitted the Stern Lab recommends that whole blood be submitted preferentially. This is due to the false elevation of taurine levels that is possible in plasma samples due to sample handling issues. This is an area of some debate between clinicians and conflicting information on preference for plasma vs. whole blood exists. This underscores the value of paired sampling.

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### Clinical Recommendations for Golden Retrievers based on taurine levels:

### If taurine levels test <200nmol/mL in whole blood or <60nmol/mL in plasma

- An echocardiogram by a board-certified veterinary cardiologist is indicated
- · After echocardiogram has been completed, a diet change is recommended.
  - If DCM is diagnosed, this patient may need a variety of cardiac medications that would be prescribed by the attending cardiologist.
  - If DCM is diagnosed, prescribed supplementation with oral taurine and I-carnitine is recommended.
  - Reevaluation of taurine levels is warranted after three months of diet change and supplementation.
  - Cardiology reevaluation schedules will be recommended by the attending clinician pending echocardiographic findings.
  - Many Golden Retrievers with taurine-deficient DCM in our study showed slow and steady improvement over a period of 6-12 months.

### If tourine levels test 200 - 250nmol/mL in whole blood or 60-70nmol/mL in plasma

- An echocardiogram by a board-certified cardiologist is recommended.
- · After echocardiogram has been completed, a diet change is recommended.
- We recognize that many dogs in this category may have normal echocardiograms and thus
  the value of screening should be carefully considered. If the dog is eating a diet that falls
  within the FDA warning or shares features with the diets identified in our study (see diets of
  concern section below), we encourage echocardiographic screening with greater enthusiasm.
- If an echocardiogram is not performed, a diet change is still recommended and a taurine level reevaluation after three months on the new diet should be considered.
- If DCM is diagnosed, this patient may need a variety of cardiac medications that would be prescribed by the attending cardiologist.
  - If DCM is diagnosed, prescribed supplementation with oral taurine and l-carnitine is recommended.
  - Reevaluation of taurine levels is warranted after three months of diet change and supplementation.
  - Cardiology reevaluation schedules will be recommended by the attending clinician pending echocardiographic findings.
  - Many Golden Retrievers with taurine-deficient DCM in our study showed slow and steady improvement over a period of 6-12 months.

### If tauring levels test >250nmol/mL in whole blood or >70nmol/mL in plasma

- Diet change is recommended if you are feeding a diet that falls within the FDA warning or shares features with the diets identified in our study (see diets of concern section below)
- If your pet shows any signs of cardiac disease (trouble breathing, exercise intolerance, fainting/collapse, coughing) we recommend your veterinarian evaluate your pet.

### **UCDavis Taurine Level**

Diets of Concern & Choosing a diet

The FDA alert called attention to several dietary ingredients that should be considered when evaluating whether your pet is at risk (for example legumes like peas and lentils, white or sweet potatoes). These findings were largely recapitulated in our current study of Golden Retrievers with low taurine levels and DCM. Our lab considers these ingredients to be of greatest concern when present within the first 5 listed ingredients on the dog food bag. Additionally, we noted a high percent of diets in our study were using protein sources other than chicken or beef and labeled as grain-free.

Points to consider when making a diet change:

- Choose a diet that does not contain the concerning components listed above
- Choose a diet that meets the WSAVA Global Nutrition Assessment Guidelines published as consensus by veterinary nutritionists from around the world:
  - https://www.wsava.org/WSAVA/media/Arpita-and-Emma-editorial/Selecting-the-Best-Food-for-your-Pet.pdf
- · FDA alert found here:
  - o https://www.fda.gov/AnimalVeterinary/NewsEvents/CVMUpdates/ucm613305.htm

Choosing a taurine or 1-carnitine supplement:

Selecting supplements should be performed based upon those that match their stated contents and are readily available for absorption. Luckily a previous publication tested multiple taurine and l-carnitine supplements. Based upon this publication our laboratory recommends the following supplements as those meeting our quality criteria. (Bragg et al. 2009 J Am Vet Med Assoc; 234(2))

Tested taurine supplements that test within 5% of stated contents and if applicable disintegrated within 30 minutes

- Mega taurine caps by Twinlab (1000 capsule)
- Taurine by Swanson Health Products (500mg capsule)
- · Taurine by NOW foods (500mg capsule)
- Taurine 500 by GNC (\$00mg tablet)

Tested L-carnitine supplements that test within 5% of stated contents and if applicable disintegrated within 30 minutes

- 1-carnitine 500 by Jarrow Formulas (500mg capsule)
- L-carnitine caps by Country Life (500mg capsule)
- Maxi L-carnitine by Solgar Vitamin and Herb (500mg tablet)
- L-carnitine by Puritan's Pride (500mg tablet)

The Stern lab does not recommend the empirical supplementation of taurine or 1-carnitine to dogs without evidence of DCM and/or significant deficiency. If DCM is diagnosed we typically recommend dogs over 50lbs receive 1000mg of taurine every 12hrs and dogs under 50lbs receive 500mg of taurine every 12hours. We recommend 1-carnitine at a dose of ~50mg/kg orally with food every 8hrs. Your veterinary cardiologist or family veterinarian should be consulted for prescribing the best dose for your dog.

Reporting to the FDA:

Understanding the basis of this condition requires a great deal of research and investigation. Clients with affected dogs can contribute their data to help propel this research forward. You can report cases of taurine deficiency, dilated cardiomyopathy, sudden cardiac death, or any combination of these events to the FDA by following the information found here: https://www.fda.gov/animalveterinary/safetyhealth/reportaproblem/ucm182403.htm

Additional questions or comments: sterngenetics@ucdavis.edu This document last updated: Aug. 20, 2018

Page 3 of 3

	Please answer the follo	DIET HISTORY  owing questions	about your p	et	
	В6	7.6		Today's date:	10/26/18
1.	How would you assess your pet's appetite? On a scale	of 1-10 with 1 beir	ng poor and 10 b	eing excellent:	10 (currently
2.	Have you noticed a change in your pet's appetite over t  Eats about the same amount as usual  Eats  Seems to prefer different foods than usual	less than usual	Eats more the	han usual	
3.	Over the last few weeks, has your pet (check one)  Lost weight Gained weight Stayed a	about the same wei	ight 🜘 Don't	know	
4.	Please list below <u>ALL</u> pet foods, people food, treats, sn currently eats. Please include the brand, specific productions are the production of the producti	ack, dental chews, ct, and flavor so w	, rawhides, and a e know exactly v	any other food it what you pet is e	em that your po ating.
	Food (include specific product and flavor) For Examples are shown in the table – please provide enough	orm Amo		v often?	Fed since
	Examples are shown in the table – please provide enou	ugn detail triat we c	oula go ao ine s	store and buy un	e exact same n
	Food (include specific product and flavor)	Form	Amount	How often?	Fed since
	Nutro Grain Free Chicken, Lentil, & Sweet Potato Adult	dry	1 ½ cup	2x/day	Jan 2018
	85% lean hamburger	microwaved	3 oz	1x/week	Jan 2015
	Pupperoni original beef flavor	treat	1/2	1x/day	Aug 2015
	Rawhide	treat	6 inch twist	1x/week	Dec 2015
	Royal Canin Early Cardiac	dry	1.5c	2x/day	10/14/18
	Greenies Pill Pockets che ese flavor	treat w/ meds	1	2x/day	10/01/18
					\$ \$
	*Any additional diet information can be listed at the				ari
)	Do you give any dietary supplements to your pet (for ex supplements)?    Yes No If yes, please list which Brand.			nts:	other ount per day
	Taurine  Camitine  O Yes O No  Antioxidants  O Yes O No  O Yes O No  O Yes O No		<del></del>	1000 mg 2x/day	
	Multivitamin				
	Other (please list): Example: Vitamin C Nature	e's Bounty		500 mg tabl	ets – 1 per da

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):
Additional diet or supplement information:  B6 has a couple cookies every day, but the brands really depend on what's on hand or what the UPS driver has in his pocket. We are going to stop or the provided and narrowher treats down to a brand/variety that is in compliance with medical recommendations.
Information below to be completed by the veterinarian:  Current body weight:kg Current body condition score (1-9):/9
Muscle Condition Score: normal muscle mild muscle loss moderate muscle loss severe muscle loss



Fax to: 1-800-600-8285 Or Call: 1-888-738-6331

### **Prescription Authorization Request**

- 1. Please Approve by signing this form or Deny by checking "Denied"
- 2. Make any necessary changes to script below.
- 3. Fax this form back or call (both toll-free).
- Or visit www.1800petmeds.com/vetlogin to electronically approve or deny.

Dear Doctor,

Thank you for taking the time today to help process this client's order! Please authorize within 24 hours.

**B6** 

Your client placed an order on: OCTOBER 29 2018

**B6** 

By signing this prescription authorization request. I confirm that I have conducted a physical examination of this pet and have a valid veterinarian-client-patient relationship as defined by federal law.

We're .Pharmacy accredited by the NABP. All products are FDA/EPA approved for sale in the U.S.

**Our Pharmacists:** 

Ensure the accuracy of prescriptions

Ensure products have ample expiration dates

Ensure proper storage of all medications

✓ Offer generics

PetMed Express, Inc.



Fax to: 1-800-600-8285 Or Call: 1-888-738-6331

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- 1. Please Approve by signing this form or Deny by checking "Denied"
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Dear Doctor,

Thank you for taking the time today to help process this client's order! Please authorize within 24 hours.

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We're .Pharmacy accredited by the NABP. All products are FDA/EPA approved for sale in the U.S.

Our Pharmacists:

Ensure the accuracy of prescriptions

☑ Ensure products have ample expiration dates

Ensure proper storage of all medications

Offer generics PetMed Express, Inc.

Page 21/38

### Vitals Results

9:38:50 PM 9:38:51 PM 9:38:53 PM 9:38:53 PM 10:37:46 PM 11:20:22 PM 11:20:21 PM 11:20:38 PM 11:31:50 PM 11:32:19 PM 11:32:19 PM 11:32:27 PM 11:32:27 PM 11:32:28 PM 11:32:27 PM 11:32:28 PM 12:32:17 AM 10:133 AM 1:37:51 AM 10:133 AM 1:37:51 AM 2:26:32 AM 3:23:02 AM 3:25:54 AM 3:26:06 AM 3:26:07 AM 4:33:21 AM 4:33:37 AM 4:53:56 AM 5:23:33 AM 6:35:59 AM 6:36:50 AM 7:36:54 AM 7:37:11 AM 7:37:39 AM	vitais itesuits	
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Page 22/38

Vitals Results 7:55:45 AM 7:55:46 AM 8:56:24 AM 8:56:35 AM 9:56:19 AM 9:56:20 AM 10:11:00 AM 10:17:43 AM 10:48:49 AM 11:01:04 AM 11:18:13 AM 11:18:14 AM 11:19:09 AM 11:30:31 AM 11:48:52 AM 11:49:05 AM 11:49:06 AM 1:09:11 PM **B6** 1:09:12 PM **B6** 1:11:03 PM 1:31:12 PM 1:31:23 PM 1:56:24 PM 1:56:25 PM 1:56:35 PM 2:11:54 PM 2:12:20 PM 2:51:14 PM 2:51:15 PM 2:51:25 PM 4:01:27 PM 4:01:28 PM 4:02:21 PM 4:54:43 PM 4:54:44 PM 4:54:54 PM 5:31:51 PM 5:37:43 PM 5:58:52 PM 5:59:01 PM

Vitals Results

5:59:18 PM 5:59:19 PM 5:55:15 PM 7:48:07 PM



**ECG** from Cardio



**ECG** from Cardio

B6 B6 B6 B6

**ECG** from Cardio

В6

**B6** 10:39:03 AM Page 2 of 2

### **Patient History**

11:32 PM	D9:46 PM  10:03 PM 10:03 PM 10:23 PM 10:28 PM 10:34 PM 10:34 PM 10:37 PM 10:37 PM 10:40 PM 11:20 PM 11:23 PM 11:23 PM 11:23 PM 11:31 PM 11:31 PM 11:31 PM 11:32 PM	<b>B</b> 6
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**Patient History** 

2:32 AM 2:32 AM 2:32 AM 1:01 AM 1:01 AM 1:37 AM 1:37 AM 1:37 AM 2:26 AM 2:26 AM 2:26 AM 3:23 AM 3:23 AM 3:23 AM 3:25 AM 3:25 AM 3:26 AM 3:26 AM 3:26 AM **B6** 4:33 AM 4:33 AM 4:33 AM 4:33 AM )4:33 AM )4:54 AM 4:54 AM \$4:55 AM 4:55 AM 5:23 AM 5:23 AM 5:23 AM 6:35 AM 6:35 AM 6:35 AM 7:31 AM 7:36 AM 7:36 AM 7:36 AM 7:36 AM 7:37 AM 7:37 AM

Page 29/38

**Patient History** 

07:37 AM 07:44 AM 07:55 AM 07:55 AM 07:55 AM 08:19 AM 08:20 AM 08:22 AM 08:56 AM 08:56 AM 08:56 AM 09:20 AM 09:21 AM 09:56 AM 09:56 AM 09:56 AM 10:01 AM 10:08 AM 10:10 AM **B6 B6** 10:11 AM 10:11 AM 10:17 AM 10:19 AM 10:21 AM 10:48 AM 10:48 AM 10:51 AM 11:01 AM 11:01 AM 11:18 AM 11:18 AM 11:18 AM 11:19 AM 11:19 AM 11:20 AM 11:28 AM 11:30 AM 11:30 AM 11:48 AM 11:48 AM 11:49 AM

Page 30/38

**Patient History** 

11:49 AM 11:49 AM 01:09 PM 01:09 PM 01:09 PM 01:11 PM 01:11 PM 01:31 PM 01:31 PM 01:31 PM 01:31 PM 01:31 PM 01:56 PM 01:56 PM 101:56 PM 101:56 PM 01:56 PM 02:11 PM 02:12 PM 102:51 PM **B6** 02:51 PM **B6** 02:51 PM 02:51 PM 02:51 PM 04:01 PM 04:01 PM 04:01 PM 04:02 PM 04:02 PM 04:54 PM 04:54 PM 04:54 PM 04:54 PM 04:54 PM 05:31 PM 05:31 PM 05:31 PM 05:37 PM 05:37 PM 05:58 PM 05:58 PM 05:59 PM 05:59 PM 05:59 PM 

Page 31/38

B6
Patient History

05:59 PM
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06:55 PM
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07:35 PM

07:48 PM
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01:12 PM
10:46 AM

Appears this way on Original

Appears this way on Original

# Cummings Veterinary Medical Center

**B6** 

### **Notice of Patient Admit**

Date:	<b>B6</b>	8:30:52 PM	Case ■ o: 429859				
		<b>B6</b>					
	В6						
Your patient presented to our Emergency service. Please make note of the following information to facilitate communication with our team.							
		B6					

If you have any questions regarding this particular case, please call 508-887-4988 to reach the Cardiology Service. Information is updated daily, by noon.

Thank you for your referral to our Emergency Service.

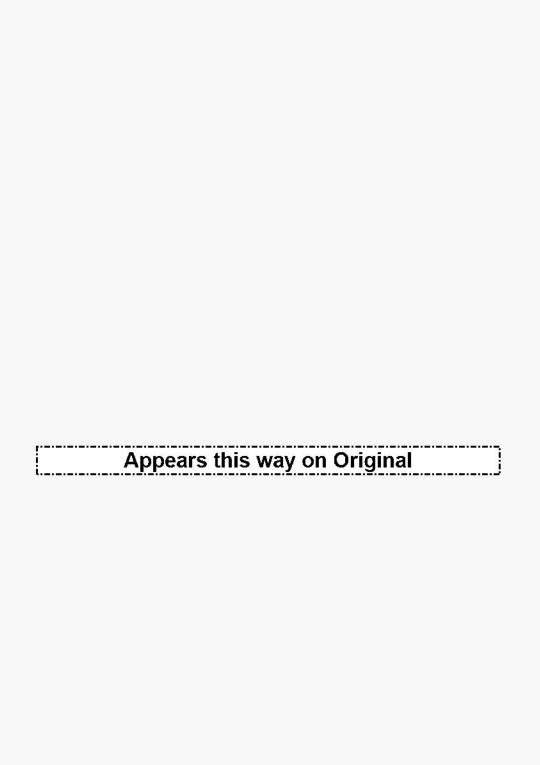
### Cummings Veterinary Medical Center



**B6** 

Daily Update From the Cardiology Service

		7				
Today's date:	·-·i					
B6						
Thank you for referring patients to the Foster Hospital for Small Animals at the Cummings School of Tufts University.						
Your patient	В6	was admitted and is being cared for	by the Cardiology Service.			
B6	]					
<ul> <li>is in stable condition</li> <li>is still in the oxygen cage</li> <li>is critically ill</li> <li>idischarged from the hospital today</li> <li>Today's treatments include:</li> <li>bloodwork planned/pending</li> <li>echocardiography</li> <li>cardiac catheter procedure planned</li> <li>treatment for CHF from DCM</li> <li>ongoing treatment for thrombosis</li> <li>ongoing treatment for arrhythmia</li> </ul>						
Additional plans:						
Please allow 3-5 business days for reports to be finalized upon patient discharge.						
Please call (508) 887-4696 before 5pm or email us at <b>eardiovet@tufts.edu</b> if you have any questions. Thank you!						
		B6	<b>6/8/1</b>			
Senior studen	t:					



# Cummings Veterinary Medical Center

**B6** 

10/11/2018

**B6** 

Female (Spayed) Canine Golden Retriever Blonde 429859

B6	]	
Thank you for referring	В6	with their pet B6
<b>.</b>		
If you have any questions,	or concer	ns, please contact us at 508-887-4988
Thank you,		
B6		

From: Palmer, Lee Anne </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CF7C8BD53B6C45A39318A596ACEA7C53-

LPALMER>

Carey, Lauren; Rotstein, David; Jones, Jennifer L; Peloquin, Sarah; Reimschuessel, Renate; To:

Hartogensis, Martine; Norris, Anne; Burkholder, William

Sent: 2/19/2019 2:04:57 PM

Subject: DCM paper - Darcy Adin, 2019 Vet Cardiology

Attachments: Adin 2019.pdf

Hi – please forgive me if we have this already, but I think this just came out.

I haven't read it yet.

Thanks, lee Anne

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

**Center for Veterinary Medicine** OSC, Division of Veterinary Product Safety U.S. Food and Drug Administration Tel: 240-402-5767



Leeanne.palmer@fda.hhs.gov









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:** 3/20/2019 10:26:46 AM **Subject:** DCM reports 3/20/19; 0630

Attachments: Fromm's Four Star Grain Free Salmon and Tunalini: **B6** EON-382722; Natural Balance

LID High Protein Grain-free Lamb or Beef flavors: Lisa Freeman - EON-382772; Redford Limited

Ingredient Grain-Free Lamb and Sweet Potato: **B6** EON-382721

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

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

Sent: 3/19/2019 1:48:37 PM

Subject: Fromm's Four Star Grain Free Salmon and Tunalini: B6 EON-382722

Attachments: 2064246-report.pdf; 2064246-attachments.zip

A PFR Report has been received and PFR Event [EON-382722] has been created in the EON System.

A "PDF" report by name "2064246-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 "2064246-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

**EON Key:** EON-382722

ICSR #: 2064246

**EON Title:** PFR Event created for Fromm's Four Star Grain Free Salmon and Tunalini; 2064246

AE Date	03/06/2019	Number Fed/Exposed	3
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Stable
Breed	Mixed (Dog)		
Age	3 Years		
District Involved	PFR- <b>B6</b> DO		

#### **Product information**

**Individual Case Safety Report Number: 2064246** 

**Product Group:** Pet Food

Product Name: Fromm's Four Star Grain Free Salmon and Tunalini

**Description:** B6 was seemingly healthy and given an echocardiogram to collect "normal" values for training purposes. Echo results were not normal, but revealed he had early stages of Dilated Cardiomyopathy. He was adopted in March 2016 at age 12 weeks and was started on Fromm Gold Puppy Dry kibble until age 1, when he was transitioned to Fromm Four Star Grain Free Salmon and Tunalini kibble diet. He ate that food until July 2018 when FDA warning was released. He was then transitioned to Purina ProPlan Sensitive Skin and Stomach Salmon and Rice.

**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: 1

Product Name	Lot Number or ID	Best By Date
Fromm's Four Star Grain Free Salmon and Tunalini		

Sender information <b>B6</b>				
JSA	<u></u> j			
Owner information				
<b>B6</b>		ts.		

B6

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

1 / 1	
B6	

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

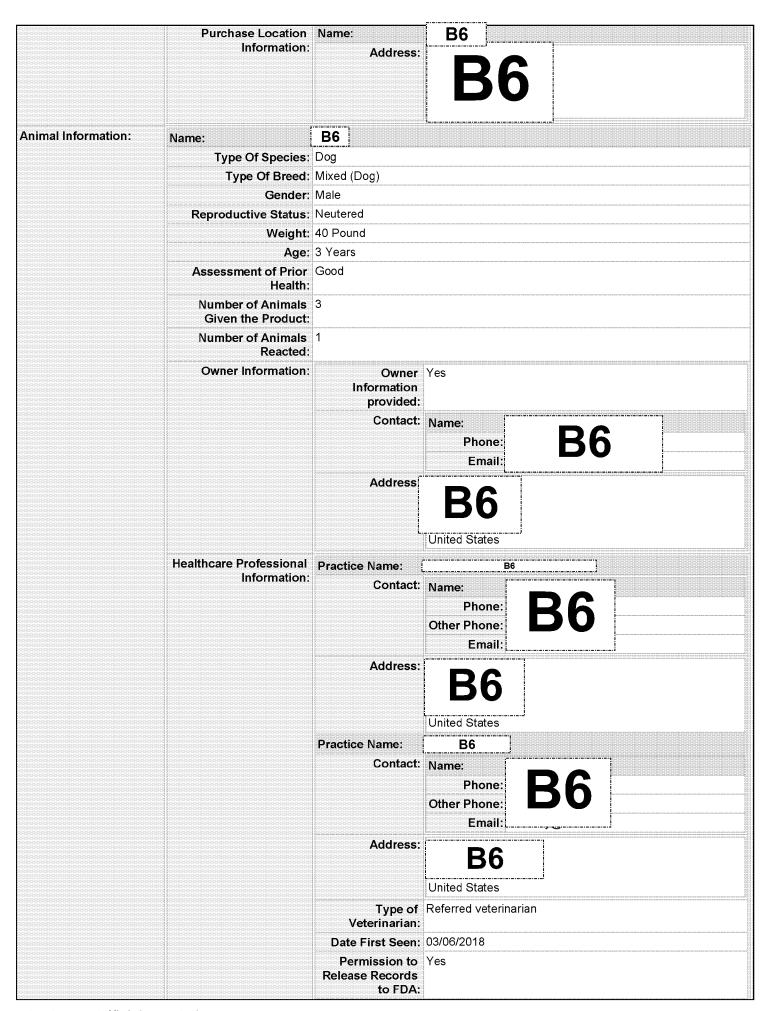
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Report Details - EON-	382722		
ICSR:	2064246		
Type Of Submission:	Initial		
Report Version:	FPSR.FDA.PETF.V.V1		
Type Of Report:	Adverse Event (a symptom,	reaction or disease a	associated with the product)
Reporting Type:	Voluntary		
Report Submission Date:	2019-03-19 09:41:10 EDT		
Reported Problem:		values for training pu early stages of Dilate weeks and was start was transitioned to F He ate that food unti transitioned to Purin	y healthy and given an echocardiogram to collect "normal" urposes. Echo results were not normal, but revealed he had ed Cardiomyopathy. He was adopted in B6 at age 12 ted on Fromm Gold Puppy Dry kibble until age 1, when he Fromm Four Star Grain Free Salmon and Tunalini kibble diet. If July 2018 when FDA warning was released. He was then a ProPlan Sensitive Skin and Stomach Salmon and Rice.
	Date Problem Started:	03/06/2019	
	Concurrent Medical Problem:	No	
	Outcome to Date:	Stable	
Product Information:	Product Name:	Fromm's Four Star C	Grain Free Salmon and Tunalini
	Product Type:	Pet Food	
	Lot Number:		
	Package Type:	BAG	
	Package Size:	26 Pound	
	Purchase Date:	06/01/2018	
	Number Purchased:	1	
	Possess Unopened Product:	No	
	Possess Opened Product:	5 1 1 1	
	Storage Conditions:	Stored in bag	
	Product Use Information:	Description: Last Exposure Date:	Feed in a bowl 07/15/2018
		Time Interval between Product Use and Adverse Event:	
		Product Use Stopped After the Onset of the Adverse Event:	Yes
		Adverse Event Abate After Product Stop:	No
		Product Use Started Again:	
		Perceived Relatedness to Adverse Event:	Possibly related
		Other Foods or Products Given to the Animal During This Time Period:	No
	Manufacturer /Distributor Information:		



Sender Information:	Name:	
	Address:	DC
	Address.	<b>B6</b>
		В
		United States
	Contact:	Phone:
		Other Phone: <b>B6</b>
		Email:
	Permission To Contact Sender:	Yes
	Preferred Method Of Contact:	Email
	Reported to Other Parties:	None
Additional Documents:		
	Attachment:	B6 choreport.pdf
	Description:	
	Туре:	Echocardiogram

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

**Sent:** 3/19/2019 8:56:56 PM

Subject: Natural Balance LID High Protein Grain-free Lamb or Beef flavors: Lisa

Freeman - EON-382772

Attachments: 2064292-report.pdf; 2064292-attachments.zip

A PFR Report has been received and PFR Event [EON-382772] has been created in the EON System.

A "PDF" report by name "2064292-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 "2064292-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

**EON Key:** EON-382772

ICSR #: 2064292

EON Title: PFR Event created for Natural Balance LID High Protein Grain-free Lamb or Beef flavors; 2064292

AE Date	03/17/2019	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Stable
Breed	Mixed (Dog)		
Age	9 Years		
District Involved	PFR- <b>B6</b> DO		

#### **Product information**

**Individual Case Safety Report Number: 2064292** 

**Product Group:** Pet Food

**Product Name:** Natural Balance LID High Protein Grain-free Lamb or Beef flavors

**Description:** DCM and CHF diagnosed 3/17/19 Eating BEG diet Owners have given permission to report and are willing to answer questions Changing to new diet and will recheck in 3 months Taurine and troponin pending

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
Natural Balance LID High Protein Grain-free Lamb or Beef flavors		

#### Sender information

Lisa Freeman 200 Westboro Rd North Grafton, MA 01536 USA

wn			

**B6** 

USA

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

**B6** 

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

**B6** 

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Report Details - EON-	3			
ICSR:	2064292			
Type Of Submission:	Initial			
Report Version:	FPSR.FDA.PETF.V.V1			
Type Of Report:	Adverse Event (a symptom,	reaction or disease	ssociated with the product)	
Reporting Type:	Voluntary			
Report Submission Date:	2019-03-19 16:49:38 EDT			NATA DA MANANTA NA DA MANANTA NA
Reported Problem:	Problem Description:	permission to report	osed 3/17/19 Eating BEG diet Ov and are willing to answer question ths Taurine and troponin pending	ns Changing to new diet and
	Date Problem Started:	03/17/2019		
	Concurrent Medical Problem:	Yes		
	Pre Existing Conditions:		c issues - likely environmental (im	
	Outcome to Date:	Stable	3300130 \$100133 DE1440 0013 DE1610 0013 O E1610 0033 O E610 0033 O E610 0034 O E610 0044 O DE160 DE160 DE160	
Product Information:	Product Name:	Natural Balanca LID	High Protein Grain-free Lamb or l	Reef flavore
i reduce illioringueni	Product Type:		Thigh Frotein Grain-free Carib or	Deel llavois
	Lot Number:	Fet Food		
	1	DAC		
	Package Type:	5		
	Possess Unopened Product:	7 7 7 7 7 7		
	Possess Opened Product:	No		
	Product Use Information:	Description:	This diet (either lamb or beef flav for last 1 year. Before that, feedir chicken, beef, or lamb flavors sin history form for further details Ov product bag but I have sample of	ng Natural Balance LID fish, ice 1 year of age. See diet vner does not have current
	Manufacturer /Distributor Information:			
	Purchase Location Information:			
Animal Information:	Name:	B6		
7	Type Of Species:			
	Type Of Breed:	<u> </u>		
	Gender:	<u> </u>		
		·		
	Reproductive Status:	7 		***************************************
	1	28.5 Kilogram		
	Age: Assessment of Prior Health:	9 Years Excellent		
	Number of Animals Given the Product:	1		
	Number of Animals Reacted:	1		
	Owner Information:	Owner Information	Yes	
		provided: Contact:	N	
		GOIIIaGI,	ivame.	
			Phone: Other Phone:	
			Email:	!

Healthcare Professional Information:  Healthcare Professional Information:  Contact:  Name:  Contact:  Name:  Contact:  Name:  Lisa Freeman Phone: (508) 887-4523 Email: lisa.freeman@tufts.edu  Address: 01536 United States  Contact:  Contact:  Name:  Contact:  Address: 01536 United States  Contact:  Contact:  Phone:  Some States  Contact:  Contact:  Permission To Contact Sender:  Preferred Method Of Contact:  Contact:  Preferred Method Of Contact:  Cont	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: 5088874523  Email: lisa.freeman@tufts.edu  Contact: Phone: 5088874523  Email: lisa.freeman@tufts.edu  Permission To Contact Sender: Preferred Method Of Contact: Sender: Preferred Method Of Contact: Compiled medical records	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   Name: Lisa Freeman Phone: (508) 887-4523 Email: lisa.freeman@tufts.edu  Address: 200 Westboro Rd North Grafton Massachusetts 01536 United States  Contact: 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: Compiled medical record_preview.pdf  Additional Documents: Description: Compiled medical records	Healthcare Professional Information:  Practice Name: Contact: Phone: (508) 887-4523 Email: (lisa Freeman Phone: (508) 887-4523 Email: (lisa Freeman) Phone: (158) 887-4523 Email: (lisa Freeman) Phone: (158) 887-4523 Email: (lisa Freeman) Phone: (lisa Freeman) Phone: (lisa Freeman) Phone			Address:	DC
Healthcare Professional Information:  Practice Name: Contact: Name: Lisa Freeman Phone: (508) 887-4523 Email: lisa.freeman@tufts.edu  Address: O1536 United States  Contact: Phone: 5088874523 Email: lisa.freeman@tufts.edu  Address: O1536 United States  Contact: Phone: 5088874523 Email: lisa.freeman@tufts.edu  Address: O1536 United States  Contact: Permission To Contact Sender: Preferred Method Of Contact:  Preferred Method Of Contact: Contact: Preferred Method Of Contact: Contact: Description: Compiled medical record_preview.pdf Compiled medical records	Healthcare Professional Information:  Practice Name: Contact: Name: Lisa Freeman Phone: (508) 887-4523 Email: lisa.freeman@tufts.edu  Address: O1536 United States  Contact: Phone: 5088874523 Email: lisa.freeman@tufts.edu  Address: O1536 United States  Contact: Phone: 5088874523 Email: lisa.freeman@tufts.edu  Address: O1536 United States  Contact: Phone: 5088874523 Email: lisa.freeman@tufts.edu  Permission To Contact Sender: Preferred Method Of Contact:  Additional Documents:  Additional Documents:  Additional Pocuments:  Additional Documents:  Additional Documents:  B6 pt_medical_ecord_preview.pdf Compiled medical records	Healthcare Professional Information:  Practice Name: Contact:  Name: Lisa Freeman Phone: (508) 887-4523 Email: lisa.freeman@tufts.edu  Address: O1536 United States  Contact: Phone: 5088874523 Email: lisa.freeman@tufts.edu  Address: O1536 United States  Contact: Phone: 5088874523 Email: lisa.freeman@tufts.edu  Address: O1536 United States  Contact: Permission To Contact Sender: Preferred Method Of Contact:  Additional Documents:  Additional Documents: Additional Documents:  Attachment: Description: Contact:  B6 pt_medical_record_preview.pdf Compiled medical records	Healthcare Professional Information:  Practice Name: Contact:  Name: Lisa Freeman Phone: (508) 887-4523 Email: lisa.freeman@tufts.edu  Address: O1536 United States  Contact: Phone: 5088874523 Email: lisa.freeman@tufts.edu  Address: O1536 United States  Contact: Phone: 5088874523 Email: lisa.freeman@tufts.edu  Address: O1536 United States  Contact: Permission To Contact Sender: Preferred Method Of Contact:  Additional Documents:  Additional Documents: Additional Documents:  Attachment: Description: Contact:  B6 pt_medical_record_preview.pdf Compiled medical records				B6 United States
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		Healthcare Professional	Practice Name:	
Address:   Contact   Permission To Contact   Sender Information:   Preferred Method Of Contact:   Preferred Method Of Contact:   Preferred Method Of Contact:   Description:   Other Method Of Compilied medical records   Description:   Other Method of Compilied medical records   Description:   Descri	Address:   200 Westboro Rd North Grafton Massachusetts 01536 United States	Address:   Contact   Permission To Contact   Sender Information:   Preferred Method Of Contact:   Preferred Method Of Contact:   Preferred Method Of Contact:   Description:   Other Method Of Compilied medical records   Description:   Other Method of Compilied medical records   Description:   Descri	Address:   Contact   Permission To Contact   Sender Information:   Preferred Method Of Contact:   Preferred Method Of Contact:   Preferred Method Of Contact:   Description:   Other Method Of Compilied medical records   Description:   Other Method of Compilied medical records   Description:   Descri		Information:		
Address: 200 Westboro Rd North Grafton Massachusetts 01536 United States  Name: Lisa Freeman  Address: 200 Westboro Rd North Grafton Massachusetts 01536 United States  Contact: 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: Semail  Additional Documents:  Attachment: B6 pt_medical_record_preview.pdf Description: Compiled medical 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: 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: Compiled medical record_preview.pdf Description: Compiled medical 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: 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: Compiled medical record_preview.pdf  Description: Compiled medical 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: 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: Compiled medical record_preview.pdf  Description: Compiled medical records				Phone: (508) 887-4523
North Grafton   Massachusetts   O1536   United States	North Grafton   Massachusetts   O1536   United States	Sender Information:  Name:  Lisa Freeman  Address:  200 Westboro Rd North Grafton Massachusetts 01536 United States  Contact: 01536 United States  Phone: 5088874523 Email: lisa.freeman@tufts.edu  Permission To Contact Sender: Preferred Method Of Contact: Sender:  Preferred Method Of Contact: Contact:  Additional Documents:  Attachment: B6 pt_medical_record_preview.pdf Description: Compiled medical records	Sender Information:  Name:  Lisa Freeman  Address:  200 Westboro Rd North Grafton Massachusetts 01536 United States  Contact: 01536 United States  Phone: 5088874523 Email: lisa.freeman@tufts.edu  Permission To Contact Sender: Preferred Method Of Contact: Sender:  Preferred Method Of Contact: Contact:  Additional Documents:  Attachment: B6 pt_medical_record_preview.pdf Description: Compiled medical records				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:  Preferred Method Of Contact:  Additional Documents:  Attachment: B6 pt_medical_record_preview.pdf Description: Compiled medical records	Address:    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:  Preferred Method Of Contact:  Additional Documents:  Attachment: B6 pt_medical_record_preview.pdf Description: Compiled medical 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:  Additional Documents:  Attachment: B6 pt_medical_record_preview.pdf Description: Compiled medical records			Address:	North Grafton Massachusetts 01536
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: B6 pt_medical_record_preview.pdf Description: Compiled medical records	North Grafton   Massachusetts   01536   United States	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: B6 pt_medical_record_preview.pdf Description: Compiled medical 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: B6 pt_medical_record_preview.pdf Description: Compiled medical records	Sender Information:	Name:	Lisa Freeman	
Permission To Contact Sender: Preferred Method Of Contact:  Additional Documents:  Attachment:  Description:    Email:   lisa.freeman@tufts.edu	Permission To Contact Sender: Preferred Method Of Contact:  Additional Documents:  Attachment:  Description:    Email:   lisa.freeman@tufts.edu	Permission To Contact Sender: Preferred Method Of Contact:  Additional Documents:  Attachment:  Description:    Email:   lisa.freeman@tufts.edu	Permission To Contact Sender: Preferred Method Of Contact:  Additional Documents:  Attachment:  Description:    Email:   lisa.freeman@tufts.edu			North Grafton Massachusetts 01536 United States	
Permission To Contact Sender:  Preferred Method Of Contact:  Additional Documents:  Attachment:  Description:  Permission To Contact Yes  Email  Email  Contact:  Description:  Description:  Description:  Description:  Preferred Method Of Contact:  Email  Description:	Permission To Contact Sender:  Preferred Method Of Contact:  Additional Documents:  Attachment:  Description: Compiled medical records  Permission To Contact:  Yes  Email  Description: Compiled medical record_preview.pdf	Permission To Contact Sender:  Preferred Method Of Contact:  Additional Documents:  Attachment:  Description: Compiled medical records  Permission To Contact:  Yes Email  Description: Compiled medical record_preview.pdf	Permission To Contact Sender:  Preferred Method Of Contact:  Additional Documents:  Attachment:  Description: Compiled medical records  Permission To Contact:  Yes Email  Description: Compiled medical record_preview.pdf		Contact:		
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Additional Documents:  Attachment:  Description: Compiled medical records	Additional Documents:  Attachment:  Description: Compiled medical records	Additional Documents:  Attachment:  Description: Compiled medical records  Contact:  Description: Compiled medical records	Additional Documents:  Attachment:  Description: Compiled medical records		Sender:	Yes	
Attachment: pt_medical_record_preview.pdf  Description: Compiled medical records	Attachment: pt_medical_record_preview.pdf  Description: Compiled medical records	Attachment: pt_medical_record_preview.pdf  Description: Compiled medical records	Attachment: pt_medical_record_preview.pdf  Description: Compiled medical records				
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				Additional Documents:	Contact:		
Type. Miculati Necolus	Type: Mcdical records	Type. Incurat records	Type.   Medical records	Additional Documents:	Contact: Attachment:	<b>B6</b> pt_medica	
				Additional Documents:	Contact:  Attachment:  Description:	B6 pt_medical	
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				Additional Documents:	Contact:  Attachment:  Description:	B6 pt_medical	
				Additional Documents:	Contact:  Attachment:  Description:	B6 pt_medical	

Cummings
Veterinary Medical Center

B4, B6

**B6** 

All Medical Records

B6

Breed: Labrador Retriever Cross

B6

Species: Canine
Sex: Female
(Spayed)

**Referring Information** 

**B6** 

**Initial Complaint:** 

Emergency

SOAP Text **B6** 12:28PM - **B6** 

**Subjective** 

**NEW VISIT (ER)** 

**B6** 

Presenting complaint: Cardiac enlargement, dyspnea

Referral visit? Yes

Diagnostics completed prior to visit: CXR, CBC/Chem from 3/14/19

**B6** 

**HISTORY:** 

Signalment: 9yo SF Lab cross

Current history: Presenting today for cardiac enlargement and dyspnea. B6 visited her rDVM earlier this week (3/14) for repeat bloodwork for monitoring of ELE. Additionally, they wanted her to be evaluated because earlier this week, they noticed that B6 breathing pattern did not seem quite right - particularly at night. Also, B6 vomited up bile a few times this week. B6 breathing continued to get worse throughout the week. She visited her regular veterinarian for thoracic radiographs yesterday, which revealed generalized cardiac enlargement - O was instructed to make an appointment/consult with a veterinary cardiologist. The owners were planning to do this, but they report that respiratory rate and effort have increased significantly today, to the point that they became very concerned and

В6	
collapse.	appetite has been waxing and waning over the last week and a half. No reported episodes of
Prior medical history:	
E	36
Current medications:	B6
<del></del>	O High protein, grain free diet Sk tick preventative use: UTD
Travel history: N/A	<u> </u>
EXAM:	
ASSESSMENT:	<b>B6</b>
	<b>B6</b>

<b>B</b> 6	
	B6
Diagnostics completed:	
	<b>B6</b>
failure and help her heart t most likely rapid. There are free diet is definitely the ca respond very well to cardia somewhere around 6mont comfortable, though, it is u Deposit & estimate status:	L
Resuscitation code (if admi	tting to ICU): RED
B6 V19 SOAP approved (DVM to sig	gn) <b>B6</b> DVM
SOAP Text B6	:48AM - Clinician, Unassigned FHSA
History: B6 a 9 yo SF Lab x, preso	ented to the ER yesterday for worsening increased RR and RE.
	Es and had radiographs done at the rDVM that revealed generalized cardiomegaly. A s done yesterday and revealed DCM with active LCHF. The patient is on a grain free diet and budy.
Subjective	
	<b>B6</b>
	rival or since last exam: Improved compared to yesterday. B6 is not longer in the oxygen RR and RE are much improved compared to previously. It has been less than 40 most of the

Page 3/67

Appetite: good appetite, ate at 8am today

Objective:

**B6** 

**Diagnostic Results:** 

**B6** 

**B6** 

**Assessments** 

**B6** 

<u>Plan</u>

SOAP completed by SOAP reviewed by:

B6

DVM

Disposition/Recommendations

## Cummings Veterinary Medical Center

B4, B6

-	B6	
	Veterinarian:	
	В6	
	Visit ID:	

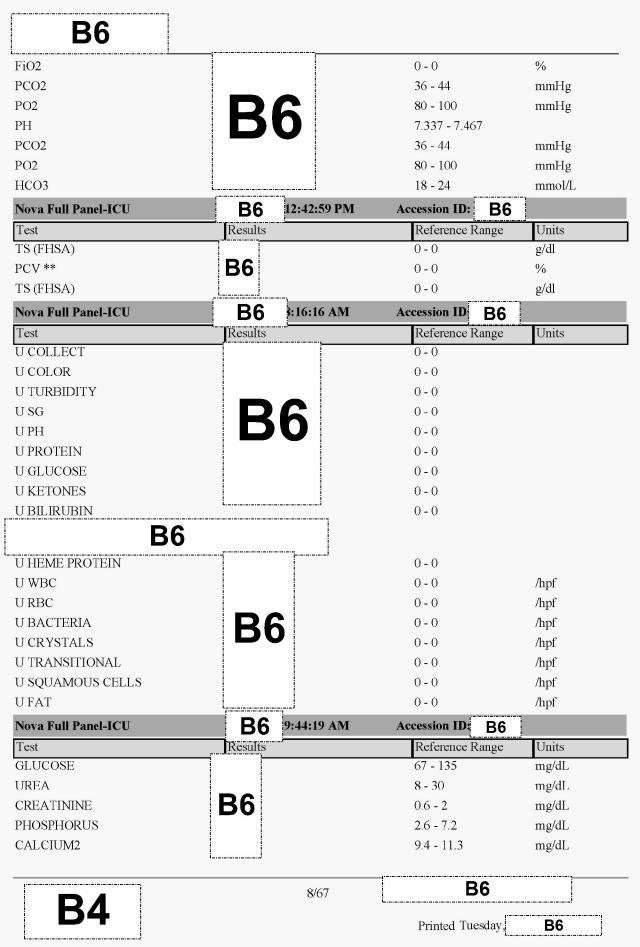
B6			
Species:	Canine		
Breed:	Labrador Retriever Cross		
Sex:	Female (Spayed)		
Age:	<b>B6</b> Years Old		

### Lab Results Report

Nova Full Panel-ICU	B6	12:35:25 PM	Accession ID:	B6
Test	Results		Reference Ran	nge Units
SO2%	<del>-</del>		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
A			0 - 0	mmHg
NOVA SAMPLE			0 - 0	
,		. <u>i</u>		

**B6** 7/67 Printed Tuesday, **B6** 

Page 7/67



Page 8/67

O - O	
291 - 315	mmol/L
82 - 355	mg/dL
9 - 54	U/L
14 - 86	U/L
12 - 127	U/L
0.1 - 0.3	mg/dL
29 - 40	
	mEq/L
	mEq/L
	mEq/L
	B, C.L.
	g/dL g/dL
	g/dL g/dL
	0.1 - 0.3 12 - 127 14 - 86 9 - 54 82 - 355 291 - 315

	answer the follo	wing questic	mo about ye	our pet	f
	B6			Today's	date: B6
How would you assess your pet's app Example: Poor_	petite? (mark the po	oint on the line	below that bes	represents yo Excellent	our pet's appetite)
Poor			ı	Excellent	SKIN ISS
					MUSTEY
Have you noticed a change in your pe DEats about the same amount as us Seems to prefer different foods that	ual lowEats less	than usual	ks? (check all	that apply) e than usual	FROM PENCE LAST 1.50
Oyer the last few weeks, has your pel SLost weight □Gained weight □	t (check one) Stayed about the	same weight	□Don't know		EXERCISE
Please list below <u>ALL</u> pet foods, peop currently eats and that you have fed it	n the last 2 years.				pod itern that your pe
Please provide enough detail that we Food (include specific produc					Andrew Andrews Control of the Control
Nutro Grain Free Chicken, Lentil, & S	weet Potato Adult	Form dry	Amount 1 ½ cup	How often?	Dates fed
85% lean hamburger	Woot / Otato Addit	microwaved	3 oz	2x/day 1x/week	Jan 2016-present
Pupperoni original beef flavor		treat	1/2	1x/day	June -Aug 2016
Rawhide		treat	6 inch twist	1x/week	Sept 2016-present Dec 2018-present
VATURAL BALANCE LID	17161+	DUA		DAY INIA	
PROTEIN BEEF SIZL	MB	531-	2017/	1×10	~192
lana landura III	GU II	5. (			
ADML BALANCE LID	715171	DA			SINGE 14R
CHUMON, BEEF, LA	M 15				DLD_
7	SAVOIZ ADVE	र दांभाव्या	का केपरा	Beer -1	ર્ટા ∈
I HAVED TO PROPUNT	DAY ALOO		19 10 500 1	1.001 11	944
'Any additional diet information can be	listed on the back	of this shoot			
Do you give any dietary supplements supplements)?	es, please list which	mple: vitamins, ch ones and giv concentration	glucosamine, e brands and	fatty acids, or amounts:	any other Amount per day
Antioxidants					
/lultivitamin □Yes □No					
DIES DINO				-	
Delizyille with Lifes Lino			× 1		
Other (please list): Example: Vitamin C	Natu	ire's Bounty		The state of the s	tablets – 1 per day
				=	



#### Tufts Cummings School Of Veterinary Medicine

200 Westboro Road North Grafton, MA 01536

DUPLICATE

B6 Sex: SF Order Location: V320559: Investigation into
Phone number: Age: 9 Sample ID: 1903170047

Collection Date: Approval date: B6 36 AM Species: Canine
Breed: Labrador Retriever Cross

CBC, Comprehensive, Sm Animal (Research)

**B6** 

Microscopic Exam of Blood Smear (Advia)

**B6** 

Page 11/67



#### Tufts Cummings School Of Veterinary Medicine

200 Westboro Road North Grafton, MA 01536

#### DUPLICATE

Provider. Dr. Lisa Freeman **B6** Sex: SF Order Location: V320559: Investigation into Phone number: Age: 9 Sample ID: 1903170047 Collection Date: 6:39 PM Species: Canine **B6** 9:36 AM Approval date: Breed: Labrador Retriever Cross

#### Microscopic Exam of Blood Smear (Advia) (cont'd)

Research Chemistry Profile - Small Animal (Cobas)

ABLASOTTO 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

Cholesterol Triglycerides Amviase

Osmolality (calculated)

**B6** 

Ref. Range/Females 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/L 106-116 mEq/L 3.7-5.4 mEq/L 14-28 mEq/L 8.0-19.0 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: 1903170047/2 REPRINT: Orig. printing on B6 Final) Reviewed by: Page 2

#### Chem 3/18/19



#### Tufts Cummings School Of Veterinary Medicine

200 Westboro Road North Grafton, MA 01536

#### DUPLICATE

B6	Sex: SF	В6
Phone number:	Age: 9	Sample ID: 1903180043
04 5 5 5 6	4 AM Species: Canine	
Approval date: <b>DO</b> 11:	58 AM Breed: Labrador Retri	ever Cross

#### Chemistry 21 (Cobas)

ABLASOTTO Glucose Urea Creatinine Phosphorus Calcium 2 Total Protein Albumin Globulins A/G Ratio Sodium Chloride Potassium NA/K Total Bilirubin Alkaline Phosphatase ALT AST

Cholesterol

Osmolality (calculated) Comments (Chemistry) **B6** 

Ref. Range/Females 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 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/L 106-116 mEq/L 3.7-5.4 mEq/L 29-40 0.10-0.30 mg/dL 12-127 U/L 14-86 U/L 9-54 U/L 82-355 mg/dL 291-315 mmol/L

Sample ID: 1903180043/1
REPRINT: Orig. printing on **B6** Final)

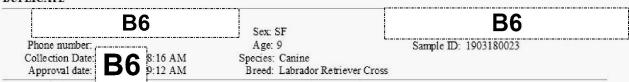
Reviewed by:



#### Tufts Cummings School Of Veterinary Medicine

200 Westboro Road North Grafton, MA 01536

#### DUPLICATE



#### Urinalysis

EUNDERWOOD
Urine Collection
Urine Color
Urine Turbidity
Urine Specific Gravity
Urine pH
Urine Protein
Urine Glucose
Urine Ketones
Urine Bilirubin
B6 9:12 AM

Urine Heme Protein
Urine WBC
Urine RBC
Urine B acteria
Urine Crystals
Urine Transitional Cells
Urine Squamous Cells
Urine Fat Urine Droplets

**B6** 

**B**6

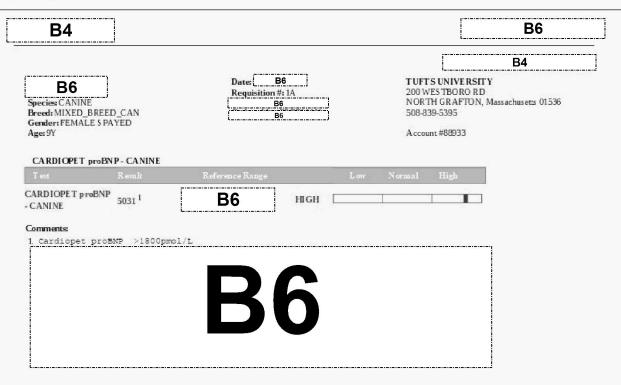
Ref. Range/Females

36

Sample ID: 1903180023/1
REPRINT: Orig. printing on **B6** (Final)

Reviewed by:

#### NT-proBNP 3/17/19



#### Vitals Results

	12:04:05 PM	
	12:04:37 PM	
	12:04:38 PM	
	12:04:39 PM	
	12:17:42 PM	
	12:29:38 PM	
	3:00:04 PM	
	3:07:39 PM	
	3:08:41 PM	
	4:44:14 PM	
	5:16:54 PM	
	5:34:29 PM	
	6:04:49 PM	
	6:04:49 PM 6:04:51 PM	
	7:11:06 PM	
	7:26:12 PM	
	7:45:50 PM	
	7:45:58 PM	
	7.46.04 70.6	
<b>B6</b>	8:02:30 PM	<b>B6</b>
	8:58:07 PM	
	9:21:47 PM	
	9:21:55 PM	
	9:46:12 PM	
	11:06:30 PM	
	11:07:24 PM	
	11:41:43 PM	
	11:42:03 PM	
	11:42:14 PM	
	12:34:47 AM	
	1:09:36 AM	
	2:04:31 AM	
	3:10:04 AM	
	3:10:21 AM	
	3:10:38 AM	
	3:18:36 AM	
	3:18:59 AM	
	3:38:33 AM	
	4:01:33 AM	
L	i	

Page 16/67

1:44:01 PM 1:44:16 PM

1:44:30 PM 3:03:59 PM 3:51:02 PM 3:56:05 PM

Vitals Results 4:51:52 AM 4:53:21 AM 4:59:31 AM 6:00:13 AM 7:59:03 AM 7:59:19 AM 8:08:55 AM 8:09:16 AM 8:09:28 AM 8:09:35 AM 9:16:05 AM **B6 B6** 9:17:02 AM 10:00:15 AM 10:00:15 AM 10:00:51 AM 11:03:49 AM 12:03:01 PM 1:13:43 PM

B6 4:53:55 PM
Tufts University
Tufts Cummings School of Vet Med Cardiology

В6

Page 1 of 2

B6 4:54:24 PM Page 1 of Tufts University Tufts Cummings School of Vet Med Cardiology

В6

**B6** 

Page 2 of 2

4:54:24 PM Page 2 o Tufts University Tufts Cummings School of Vet Med Cardiology

#### **Patient History**

12:04 PM 12:04 PM 12:04 PM 12:04 PM 12:07 PM 12:17 PM 12:17 PM 12:17 PM 12:28 PM 12:28 PM 12:28 PM 12:29 PM 12:29 PM 12:35 PM 12:35 PM 12:35 PM 12:35 PM 12:45 PM 12:53 PM 12:54 PM 12:54 PM 12:57 PM 03:00 PM 03:00 PM 03:00 PM 03:01 PM 03:01 PM 03:07 PM 03:07 PM 03:07 PM 03:08 PM 03:08 PM 03:08 PM 03:08 PM 03:08 PM 03:09 PM 03:09 PM 03:01 PM	<b>B</b> 6
05:16 PM	

Page 21/67

**Patient History** 

06:04 PM 06:04 PM 06:04 PM 06:04 PM 06:43 PM D7:11 PM 07:11 PM 07:25 PM 07:26 PM 07:26 PM 07:35 PM 07:41 PM 07:45 PM 07:45 PM 07:45 PM 07:45 PM 07:46 PM 07:46 PM 08:02 PM 08:02 PM **B6** 08:58 PM **B6** 08:58 PM 08:58 PM 09:21 PM 09:21 PM 09:21 PM 09:21 PM 09:46 PM 09:46 PM 11:06 PM 11:06 PM 11:07 PM 11:07 PM 11:41 PM 11:41 PM 11:42 PM 11:42 PM 11:42 PM 12:34 AM 12:34 AM 01:09 AM 01:09 AM 02:04 AM

Page 22/67

**Patient History** )2:04 AM )3:10 AM )3:10 AM )3:10 AM 03:10 AM 03:10 AM **3:10** AM D3:10 AM **D3:10 AM** D3:18 AM D3:18 AM )3:18 AM D3:21 AM D3:38 AM 03:38 AM 04:01 AM 54:01 AM 54:51 AM 54:51 AM D4:53 AM **B6** D4:53 AM 04:59 AM **B6** 54:59 AM 6:00 AM 06:00 AM 57:20 AM D7:20 AM D7:59 AM )7:59 AM 08:80 AM D8:08 AM D8:08 AM 08:09 AM 08:09 AM 08:09 AM 08:09 AM )8:09 AM 08:09 AM 08:09 AM 58:24 AM b9:16 AM 9:16 AM 9:17 AM 9:17 AM D9:17 AM Page 23/67

Patient History

D9:44 AM
10:00 AM

10:00 AM 10:00 AM 10:00 AM 10:00 AM 10:00 AM 10:41 AM 10:42 AM 10:42 AM 11:03 AM 11:03 AM 11:16 AM 12:03 PM 12:03 PM 91:13 PM D1:13 PM 01:34 PM D1:44 PM **B6** 51:44 PM 01:44 PM D1:44 PM 01:44 PM D1:44 PM D3:01 PM D3:03 PM 03:03 PM 03:12 PM 93:12 PM 03:51 PM )3:51 PM 03:56 PM D3:56 PM D4:55 PM 04:56 PM 04:56 PM 05:23 PM

Patient Account History Description Qty price Extended Disc Pmt

<b>B</b> 6					
Patient Account Histor	y Description	Qty	price	Extended Disc	Pmt
Sunday, <b>B6 B6</b> 12:17	Appointment: Emergency Room	m Visit		B6	

<b>B6</b>					
Patient Account History	Qty	price	Extended	Disc	Pmt
Sunday <b>B6</b> B6 12:17	В	6			

<b>B6</b>						
Patient Account History	Description	Qty	price	Extended	Disc	Pmt
Sunday, <b>B6</b>		В	6			

<b>B6</b>						
Patient Account Histor	y Description	Qty	price	Extended	Disc	Pmt
Sunday, <b>B6</b> 2019 12:45		В	6			

<b>B</b> 6					
Patient Account History	Qty	price	Extended	Disc	Pm
Sunday, <b>B6</b>	 В	6			

Patient Account History Description Qty price Extended Disc

Sunday, B6
B6 5:01

B6

Pmt

<b>B6</b>					
Patient Account History	Description	Qty	price	Extended Disc	Pmt
Sunday, <b>B6 B6</b> 5:01		В	3		

B6						
Patient Account History	Description	Qty	price	Extended	Disc	Pmt
Sunday, <b>B6 B6</b> 6:30		В	6			

<b>B</b> 6					
Patient Account Histo	ory Description	Qty	price	Extended Disc	Pmt
Sunday <b>B6 B6</b> 16:55		В	6		

B6						
Patient Account History	Description	Qty	price	Extended	Disc	Pmt
Sunday <b>B6 B6</b> 19:25		В	6			

Patient Account History Description Qty price Extended Disc Pmt

Sunday, B6
B6 9:34

B6

Patient Account History	Description	Qty	price	Extended	Disc	Pmt
Monday <b>B6</b> B6 3:10		В6	3			

Patient Account History	Description	Qty	price	Extended Disc	Pmt
Monday, <b>B6</b>		В6	<b>)</b>		

<b>B</b> 6					
Patient Account History Description	Qty	price	Extended	Disc	Pmt
Monday, <b>B6</b> 7:20		B6			

<b>B6</b>	j
Patient Account History	Description

Monday <b>B6</b>	B6
<u></u>	

Qty

price

Extended Disc

Pmt

B6						
Patient Account History	Description	Qty	price	Extended	Disc	Pmt
Monday, <b>B6 B6</b> 109:44		В	6			

Patient Account History	Description	Qty	price	Extended	Disc	Pmt
Monday, <b>B6 B6</b> 1:16		В	3			

B6					
Patient Account History	Qty	price	Extended	Disc	Pmt
Monday <b>B6</b>	 В	6			

Patient Account History Description Qty price Extended Disc Pmt

Monday, B6
B6 15:12
B6

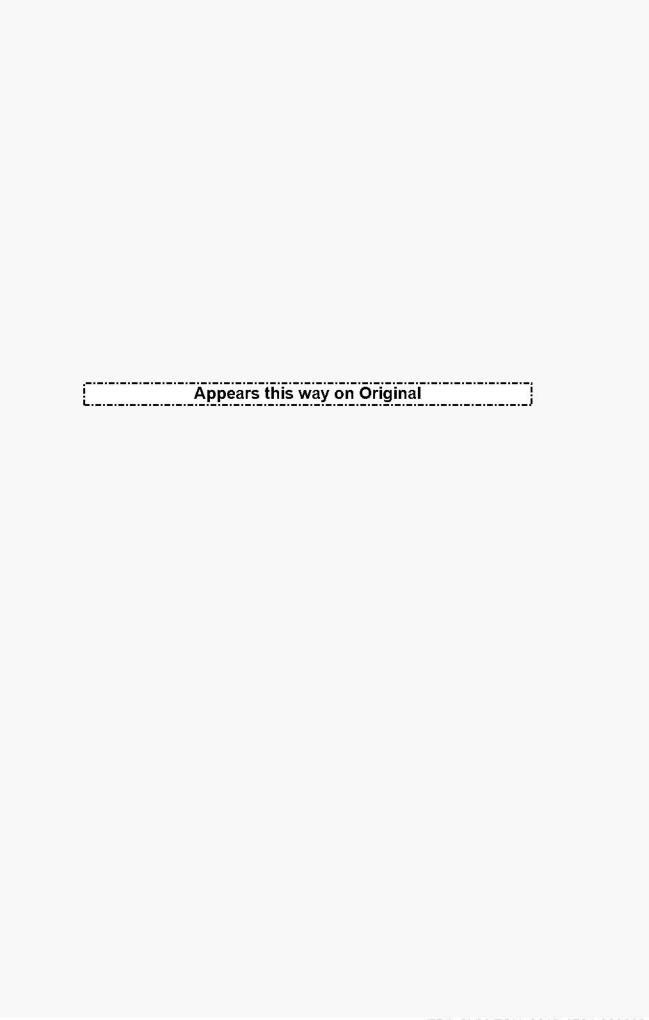
B6				
Patient Account History Description	Qty	price	Extended Disc	Pmt
Monday, <b>B6</b> 6:55	В			

<b>B</b> 6						
Patient Account History	Description	Qty	price	Extended	Disc	Pmt
Monday <b>B6 B6</b> 16:56		Вб	3			

B6					
Patient Account History Description	Qty	price	Extended	Disc	Pmt
Monday <b>B6</b> 56	Е	36			

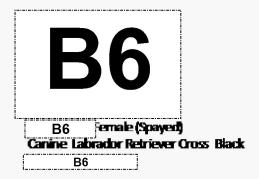
B6				
Patient Account History	Description	Qty	price	Extended Disc
Monday <b>B6</b>		B6		

Pmt





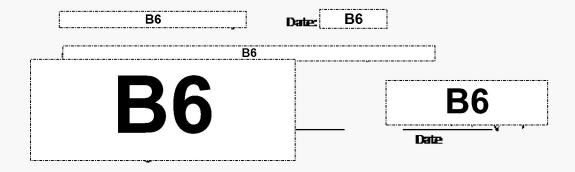
## Cummings Veterinary Medical Center



### STANDARD CONSENT FORM

B4, B6

### B4, B6



B4, B6



### Treatment Plan

**B4**, **B6** 

Estimated Charges

**B6** 

This estimate is based upon our preliminary examination. This is an estimate and is not the final bill. Every effort will be made to keep you informed of the current status of your bill throughout your animal's hospitalization. The final fee may vary considerably from this estimated cost.

B6 Description Low Oty Low Extended High City High Extended B6

**B6** 

**B6** 

I understand that no guarantee of successful treatment is made. I certify that I have read and fully understand the authorization for medical and/or surgical treatment, the reason for why such medical and/or surgical treatment is considered necessary, as well as its advantages and possible complications, if any. I also assume financial responsibility for all charges incurred to this patient(s). I agree to pay 75% of the estimated cost at the time of admission. Additional deposits will be required if additional care or procedures are required. I further agree to pay the balance of the charges when this patient(s) is released.

Procedural billing is inclusive up to and including the estimated duration of hospitalization. There will be additional expenses if hospitalization extends beyond the specified duration. I have read, understand, and agree to accept the conditions of this treatment plan.

Thank you for entrusting us with your pers care.

High Total
Low Total
75% Deposit

B6

Page 1/1

Printed Sunda



B6 Canine

B6 (ears Old Female (Spayed) Labrador

Retriever Cross

Black BW: Weight (kg) 28.40

Cardiology Inpatient ENROLLED IN DOM STUDY

Date	<b>B6</b>		
Weight	t Weight (kg	28.40	
		DC	
		<b>B6</b>	

Thoracic radiographs available for review?

- Yes in SS
- Yes in PACS
- **☑** No.

Patient location: ER

**Presenting complaint and important concurrent diseases:** Presented to ER today on a referral basis for generalized cardiac enlargement and dyspnea. O reports that rDVM radiographs were taken (we do not have access to them at this point) and revealed an enlarged heart.

- -Hx of elevated liver enzymes
- -Hypothyroidism

#### Current medications and doses:

В6

At-home diet: (name, form, amount, frequency)

Grain free Natural balance

Key indication for consultation: (murmur, arrhythmia, needs fluids, etc.)

-suspect DCM

Questions to be answered: DCM? CHF?

**Is your consult time-sensitive?** (e.g., anesthesia today, owner waiting, trying to get biopsy today).

• Yes (explain):

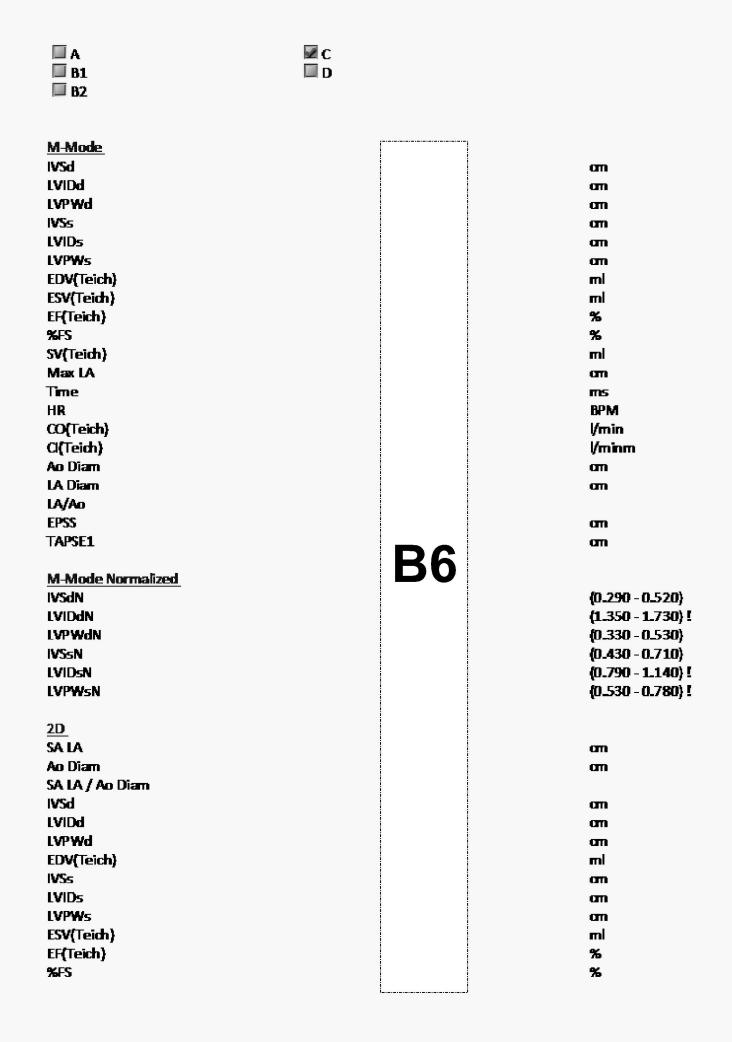
No No

### \*STOP - remainder of form to be filled out by Cardiology\*

Physical Examination	
B6	B6
Muscle condition:	_
Normal Normal	Moderate cachexia
Mild muscle loss	Marked cachexia
Cardiovascular Physical Exam	
Murmur Grade:	
None	□ IV/VI
<u> </u>	□ v/vi
□ II/VI	■ vi/vi
<b>☑</b> III <b>/</b> VI	
Murmur location/description: left apid	cal, systolic
Jugular vein:	_
Bottom 1/3 of the neck	Top 2/3 of the neck
■ Middle 1/3 of the neck	■ 1/2 way up the neck
Arterial pulses:	
■ Weak	■ Bounding
🗹 Fair	Pulse deficits
Good	Pulsus paradoxus
Strong	Other (describe):
Arrhythmia:	
✓ None	☐ Bradycardia
Sinus arrhythmia	☐ Tachycardia
Premature beats	•
Gallop:	
i Yes	Pronounced
<b>☑</b> No	Other:
Intermittent	
Pulmonary assessments:	
Eupneic	☑ Pulmonary Crackles
☑ Mild dyspnea	Wheezes
Marked dyspnea	Upper airway stridor
Normal BV sounds	Other auscultatory findings:
Abdominal exam:	
Normal	Abdominal distension
Hepatomegalv	☐ Mild ascites

Echocardiogram Findings:		
	<b>B6</b>	
Doppler findings:		
B6		
	Pseudonormal Restrictive	
ECG findings: Normal sinus rhythm during echocardiog	gram.	
Radiographic findings:		
	<b>B6</b>	
Assessment and recommendations:		
The decreased contractile function with diet-related) vs. advanced MMVD since	LA enlargement and LCHF may be secondary there is significant MR today on exam	y to DCM (genetic vs. B6
	<b>B6</b>	
Final Diagnosis: Decreased contractile function with mo	derate to marked LAE r/o genetic vs. diet ind	uced vs. advanced
Heart Failure Classification Score:  ISACHC Classification:  la  lb  l	IIIa ☑ IIIb	

**ACVIM CHF Classification:** 



SV(Teich) ml LV Major an LV Minor an Sphericity Index TAM TWX an LVAd LAX an **LVEDV A-L LAX** ml **LVEDV MOD LAX** ml LVL5 LAX an **B6** LVAs LAX an **LVESV A-L LAX** ml **LVESV MOD LAX** ml **BPM** HR **EF A-L LAX** % **LVEF MOD LAX** % SV A-L IAX ml SV MOD LAX ml CO A-L LAX **Vmin //min** CO MOD LAX Doppler MR Vmax m/s MR maxPG mmHg 5" m/s **IVRT** ms MR Vmax m/s MR Vmean m/s MR maxPG mmHg **B6** MR meanPG mmHg MR VTI an **AV Vmax** m/s AV maxPG mmHg PV Vmax m/s PV maxPG mmHg

TR Vmax

TR maxPG

m/s

mmHg

# Cummings Veterinary Medical Center

B4, B6

Radiology Request & Report

B6 Species: Canir Black Female ( Retriever Coord Birthdate:	(Spayed) Lab	radur	<b>B6</b>	B6 Date of request:	B6
			B6		
Date of exa	i	6 rd/Cage:	Sedation	<b>W</b> eight ( <b>kg</b> ) B4, B6	
✓ Inpatient ☐ Outpatient Time:			■ BAG ■ OBAG		
■ Outp		e.	1/2 dose OBA	G	
■ Emergency			DexDomitor/Butorphanol		
			Anesti sedate/anesthetize		
Examination Desired: Met Check			*Page Dr. B6	f needed*	

### Presenting Complaint and Clinical Questions you wish to answer:

Referred for generalized cardiomegaly, dyspnea. Suspect DCM

Pertinent History: P has a history of elevated liver enzymes, hypothyroidism (thyroxine 0.5 mg PO BID). O reports that appetite started to wax and wane around 1.5 weeks ago, and P has been having difficulty breathing and getting comfortable at night. Visited rDVM this week for this issue as well as bloodwork to monitor ELE - rDVM performed CXR, revealed generalized cardiomegaly. O's were instructed to make cardiology appt., but P's breathing got worse this morning so they came in through the ER today.

### **Findings**

B4, B6

### **B4**, **B6**

### Condusions:

Finalized:

 Moderate generalized cardiomegaly. Overall normal size of the pulmonary vasculature may be secondary to diuretic therapy (if applicable); however as the veins appear larger than the arteries, congestion should be considered. Interstitial pulmonary pattern may be overestimated by expiratory technique and age-related changes, however cardiogenic pulmonary edema cannot be completely ruled out. Repeat thoracic radiographs may be considered to monitor response to treatment.

	<b>B6</b>	
Reviewing:		
Dates Reported:	В6	

## Cummings Veterinary Medical Center

B4, B6

#### Discharge Instructions

B6	<b>B6</b>	B6
Species: Canine Black Female (Spayed) Labrador	DU	<u> </u>
Retriever Cross	<u> </u>	
Birthdate: B6		
В		
Admit Date: B6 12:06:18 PM		
Discharge Date: B6		
Diagnoses: Dilated cardiumyopathy (DOM	) with congestive heart failure	
Case summary:		
Thank you for bringing B6 to Tufts Unive	ersity for investigation of her increased	respiratory rate and effort.
Upon presentation to the ER B6 was no	oticed to have increased respiratory rat	e and effort. She was also noted to have a
small heart murmur and an abnormal sou		

Due to her breathing pattern, she was admitted to the hospital for further management and monitoring. She was started on cardiac medications while in the hospital and we are happy to report that she responded very positively to the cardiac medications. Her respiratory rate and effort went down overnight and she appears much more comfortable this morning.

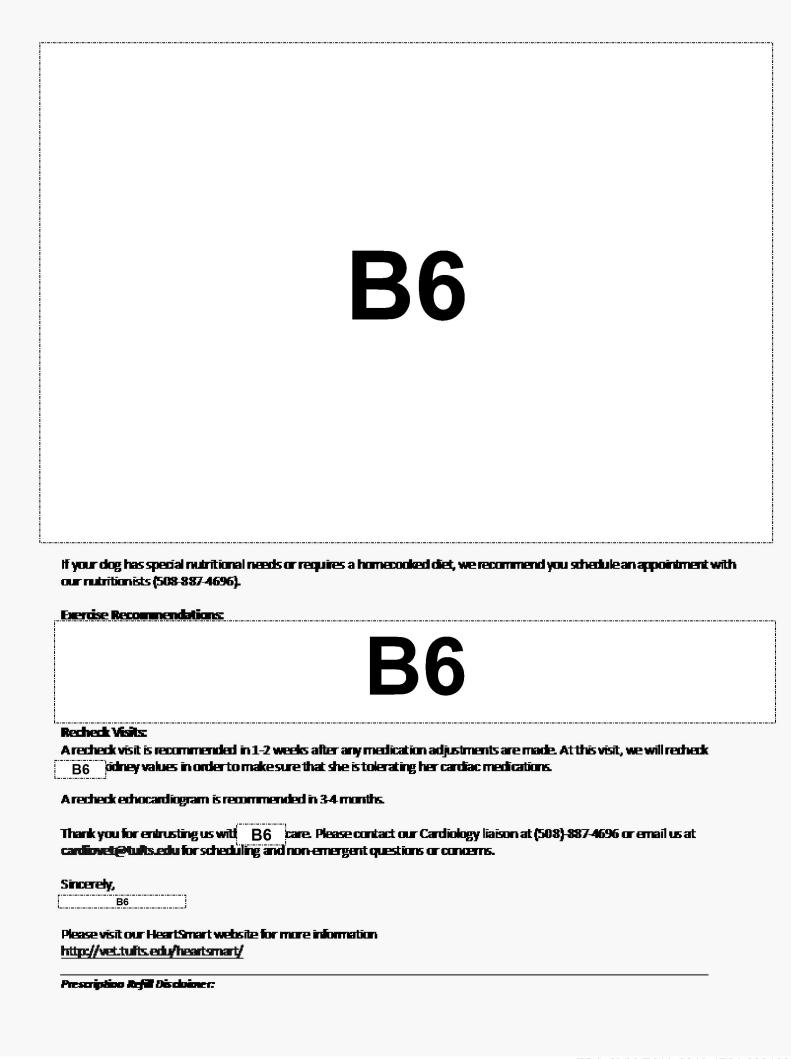
yesterday and revealed that Hazel has a type of heart disease called dilated cardiomyopathy.

has been diagnosed with a primary heart muscle disease called dilated cardiomyopathy (DCM). This disease is more common in large and giant breed dogs and is characterized by thirming of the walls of the heart, reduced cardiac pump function, and enlargement of the upper chambers of the heart. Many dogs with DCM will also have significant arrhythmias which can be life-threatening and also require medical management. The heart enlargement has 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.

**Recommended Medications:** 

Monitoring at home:

**B6** 



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:
M

please call 7-10 days		commended diet(s). If you wish to purchase your jood from us, food is in stock. Alternatively, veterinary diets can be ordered fro
	ies in which our veterinary doctors work w treatment. Please see our website: <u>vet.tu</u>	with you and your pet to investigate a specific disease process or a fits.edu/cvmc/cknicol-studies
	B6	Discharge Instructions

## Cummings Veterinary Medical Center

B4, B6

#### **Notice of Patient Admit**

Date:	<b>B6</b>	12:06:18 PM	Case ■ o: 441599
ļ	R	6	
! !			
	B6	7	
i		!	
			ncy service. Please make note of the following information to facilitate
commu	nication wi	th our team.	
		В6	
The -	f	allem is reviewed that the con-	IPA in DOM CIE

If you have any questions regarding this particular case, please call 508-887-4988 to reach the Cardiology Service. Information is updated daily, by noon.

Thank you for your referral to our Emergency Service.

## Cummings Veterinary Medical Center

B4, B6

**B**6

B6 emale (Spayed)
Canine Labrador Retriever Cross
Black
441599

#### Daily Update From the Cardiology Service

Today's date	В6	
	В6	

Thank you for referring patients to the Foster Hospital for Small Animals at the Cummings School of Tufts University.

Your patient	В6	was admitted and is being cared for by the Cardiology Service
Today, B6		
☑ is in stab	ele condition	n
📃 isstillin	the oxygen	cage
is critica	lly ill	
might be	e discharged	from the hospital today
Today's treatme	nts include:	
bloodwc     bloodwc	rk planned,	/pending
echocan	diography -	
Advance	d DCM - r/a	primary vs. diet induced DCM;
Degener	ative mitral	valve disease;
Active le	ft-sided CHI	- <sup>-</sup> -
ardiac 🔲	catheter pro	cedure planned
ongoing	treatment i	for CHF

#### Additional plans:

ongoing treatment for thrombosis
 ongoing treatment for arrhythmia

Please allow 3-5 business days for reports to be finalized upon patient discharge.

Please call (508) 887-4696 before 5pm or email us at **cardiovet@tufts.edu** if you have any questions. Thank you!

	B6
Senior student:	

# Cummings Veterinary Medical Center AT TUFTS UNIVERSITY B6 B6 Thank you for referring B6 with their p B6 If you have any questions, or concerns, please contact us at 508-887-4988.

**B6** 

Thank you,

В	4,	<b>B6</b>
B6 Canine L Black 441599		e (Spayed) tetriever Cross

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

To: B6

Sent: 3/19/2019 1:32:35 PM

Subject: Redford Limited Ingredient Grain-Free Lamb and Sweet Potato: B6
- EON-382721

Attachments: 2064242-report.pdf

A PFR Report has been received and PFR Event [EON-382721] has been created in the EON System.

A "PDF" report by name "2064242-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report:

**EON Key:** EON-382721

ICSR #: 2064242

EON Title: PFR Event created for Redford Limited Ingredient Grain-Free Lamb and Sweet Potato; 2064242

AE Date	03/12/2019	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Better/Improved/Recovering
Breed	Weimaraner		
Age	8 Years		
District Involved	PFR <b>B6</b> DO		

#### **Product information**

**Individual Case Safety Report Number: 2064242** 

Product Group: Pet Food

**Product Name:** Redford Limited Ingredient Grain-Free Lamb and Sweet Potato **Description:** Diagnosed upon echocardiogram 3/18/19 with dilated cardiomyopathy

Submission Type: Initial

**Report Type:** Adverse Event (a symptom, reaction or disease associated with the product) **Outcome of reaction/event at the time of last observation:** Better/Improved/Recovering

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

Product Name	Lot Number or ID	Best By Date
Redford Limited Ingredient Grain-Free Lamb and Sweet Potato		

Sender information	
<b>B6</b>	
USA	
Owner information  B6	
<b>D</b> U	
To view this PFR Event, please click the lin	ık below:

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.

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

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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.

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

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

DROTSTEI>

To:

From:

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 8:11:44 PM

**Subject:** DCM Taste of the Wild EON-390065

Attachments: Taste of the Wild (various flavors) since Nov 2013: Lisa Freeman - EON-390087; Taste of the

Wild PREY: **B6** EON-390065; Taste of the Wild PREY: **B6** -

EON-390066

#### Everyone,

I know that we aren't forwarding all of these, but since they've added a lot of information, I felt like it's worthwhile to share it with everyone.

ICSR:	2068031				
Type Of Submission:	Followup				
Report Version:	FPSR.FDA.PETF.V.V1				
Type Of Report:	Adverse Event (a symptom,	Adverse Event (a symptom, reaction or disease associated with the product)			
Reporting Type:	Voluntary				
Report Submission Dat	e: 2019-06-10 15:56:37 EDT				
Initial Report Date:	10/09/2018				
Parent ICSR:	2055822				
Follow-up Report to FDA Request:	Yes				
Reported Problem:	Problem Description:	Asymptomatic but is housemate of B6 who was diagnosed with DCM recently (FDA ICSR ID 2055229). Eating same diet until mid-September when switched to Pro Plan Weight Management dry. Note: B6 does not have clear DCM but has reduced contractility. Will recheck in 6 months. Taurine pending - will submit when available.			
	Date Problem Started:	10/02/2018			
	Concurrent Medical Problem:	No			
	Outcome to Date:	: Better/Improved/Recovering			
Product Information:	Product Name:	Taste of the Wild (various flavors) since Nov 2013			
	Product Type:				
	Lot Number:				
	Package Type:	; BAG			
	Product Use Information:			***************************************	
	Manufacturer /Distributor Information:				
	Purchase Location Information:				
Animal Information:	Name:	B6			
	Type Of Species:				
		; Doberman Pinscher			
	Gender:	2			
	Reproductive Status:	ļ			
		33.4 Kilogram			
	Age: Assessment of Prior Health:				
	Number of Animals Given the Product:	2			
	Number of Animals Reacted:	2			
	Owner Information:	Owner Information provided:	Yes		
		Contact:	Name: R6		
			Email:		
		Address			
			<b>B</b> 6		

			B6	
			United States	
	Healthcare Professional Information:	Practice Name:		s School of Veterinary Medicine
		Contact:		Lisa Freeman
				(508) 887-4523
				lisa.freeman@tufts.edu
		Address:	200 Westboro North Grafton Massachusetts 01536 United States	
Sender Information:	Name:	Lisa Freeman		
	Address:	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:	Diet Hx 4-24-19.pdf		
	Description:	Diet history form		
	Туре:	Medical Records		
	Attachment:	echo report 4-24-20	19.pdf	
	Description:	Echo report		
	Type:	Echocardiogram		
	Attachment:	B4, E	36	
	Description:	Lab work		
	Туре:	Laboratory Report		
Attachment:		Doberman DCM Cor	nbo Results For	m.pdf
	Description:	Genetic testing		
		Cenetic testing  Laboratory Report		
		Laboratory Report	odf	
	Туре:	Laboratory Report troponin 5-30-2019.	odf	

#314074

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

	<b>B6</b>			Today's	date: 4 24 19
	How would you assess your pet's appetite? (mark the personal example: Poor_	oint on the line	below that bes	st represents yo _ <i>Excellent</i>	our pet's appetite)
	Poor			_Excellent	
	Have you noticed a change in your pet's appetite over t  Eats about the same amount as usual  Deats less  Seems to prefer different foods than usual  Other	he last 1-2 weel s than usual	ks? (check all □Eats more	that apply) e than usual	
	Over the last few weeks, has your pet (check one)  Lost weight Gained weight Stayed about the	e same weight	Don't know		
•	Please list below <u>ALL</u> pet foods, people food, treats, sna currently eats and that you have fed in the last 2 years.	ack, dental chev	vs, rawhides, a	and any other fo	ood item that your pet
г	Please provide enough detail that we could go to the st	ore and buy the	exact same fo	ood - examples	are shown in the table
	Food (include specific product and flavor)	Form	Amount	How often?	Dates fed
	Nutro Grain Free Chicken, Lentil, & Sweet Potato Adult	dry	1 ½ cup	2x/day	Jan 2016-present
-	85% lean hamburger	microwaved	3 oz	1x/week	June -Aug 2016
	Pupperoni original beef flavor	treat	1/2	1x/day	Sept 2016-present
Ī	Rawhide	treat	6 inch twist	1x/week	Dec 2018-present
t	Pro Plan Sensitive skin / stom	1	1 va cup		
ŀ		1 ary		3x/day	
ŀ		treat	5-6	daily	sep 2018 - pr
ŀ	Hills Ideal Balance duck	treat	5-6	daily	// "
-	Hills Ideal Balance beef	Treat	5-6	dally	//
	baby carrots various veggies			/	
ŀ	Don Older I day				
-	Pro Plan Weight managemer	H dry	1 cup	3x/dau	Sep 2018 - Fel
-	0 0		,	, ,	20
L	*Any additional diet information can be listed on the bac	k of this sheet			
	Do you give any dietary supplements to your pet (for examplements)?	ample: vitamins ich ones and giv Concentration	ve brands and	, fatty acids, or a amounts:	any other  Amount per day
	Antioxidants			,	
	Other (please list):	ture'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  J 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):				

#### **Veterinary Cardiac Genetics Laboratory**



To request swab collection kits, please visit:

#### 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:

Dog's Name:

NCSU Doberman DCM1 Negative (PDK4) Result:

**Result:** 

NCSU Doberman DCM2 Positive Heterozygous

ID #:

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 :	<b>About 40% of dogs with this mutation will develop DCM.</b> Dogs that are positive for only DCM1 will not necessarily develop significant heart disease.	
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 :	<b>About 50% of dogs with this mutation will develop DCM.</b> 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 NG (PDK4) since this will lead to dogs that are highest risk of developing DCM. Dogs 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 development of DCM and should be carefully monitored by your veterinarian for signs of disease. An evaluation by a cardiologist with an echocardiogram and Holter monitor after 3 years 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.



В4		D0
B6 Species: CANINE Breed: DOBERMAN_PINSCH	Date: 04/24/2019 <b>B6</b>	B6
Gender: FEMALE SPAYED Age: 6Y	ii	Account #88933
CARDIOPET proBNP - CAN	INE	
Test Result	Reference Range	Low Normal High
CARDIOPET proBNP - 604 <sup>1</sup>	B6	
Comments:		
	<b>B6</b>	

## B4, B6

GI Lab Assigned Clinic ID: 23523 Species: Canine May 30, 2019 Date Received: GI Lab Accession: **B6 B6** Test Reference Interval Result **Assay Date Ultra-Sensitive Troponin I Fasting B6** ≤0.06 05/31/19 Interpretation: Increased troponin I value. If clinical signs of heart disease are present, additional diagnostic work-up is recommended Patients who are being supplemented with biotin may exhibit a slightly higher ultra-sensitive troponin result (10% or lower); however, the ability of the assay to detect serial increases or decreases of ultra-sensitive troponin is maintained. Comments:

**B4**, **B6** 

From:	PFR Event <pfreventcreation@fda.hhs.gov></pfreventcreation@fda.hhs.gov>
То:	Cleary, Michael *; HQ Pet Food Report Notification; B6
Sent:	6/10/2019 6:08:32 PM
Subject:	Taste of the Wild PREY: B6 - EON-390065
Attachments:	2068021-report.pdf; 2068021-attachments.zip
A PFR Report has been re-	reived and PFR Event [EON-390065] has been created in the EON System.
	2068021-report.pdf" is attached to this email notification for your reference. Ple eived in the report are compressed into a zip file by name "2068021-attachment I notification.
Below is the summary of t	ne report:

**EON Key:** EON-390065

ICSR #: 2068021

**EON Title:** PFR Event created for Taste of the Wild PREY; 2068021

AE Date	B6	Number Fed/Exposed	1
Best By Date	03/12/2020	Number Reacted	1
Animal Species	Dog	Outcome to Date	Died Naturally
Breed	Mixed (Dog)		
Age	B6 Years		
District Involved	PFR- <b>B6</b> DO		

Product information
Individual Case Safety Report Number: 2068021
Product Group: Pet Food
Product Name: Taste of the Wild PREY
<b>Description:</b> On <b>B6</b> night, <b>B6</b> couldn't make it back from his nightly walk, had labored
breathing, and no appetite. His hind legs were shaking. On <b>B6</b> morning <b>B6</b> was brought in to the <b>B6</b>
where he underwent general sedation for a hip/knee X-Ray. The thought
process was that he had injured a hind leg. Under sedation early on, <b>B6</b> experienced abnormal heart rate and
blood pressure readings as well as gum/ tongue color while being monitored. The vet staff pulled him from
sedation, ran a general blood panel (which was unremarkable and otherwise normal - general parameters). The

vet then decided to do a che	est x-ray and found his heart to be 3x t	he normal size. T	hat same day, I took him to	
Be	for a cardio	logist follow up a	s part of their <b>B6</b>	
extension. B6 was diagnos	sed with dilated cardiomyopathy and r	ight ventricular c	ongestive heart failure from an	
echo cardiogram preformed	l by <b>B6</b> He was prescrit opinion of <b>B6</b> that <b>B6</b> had c	oed pimobendan a	and lasix and 1,000 mg of	
taurine 3x a day. It was the	opinion of <b>B6</b> that <b>B6</b> had o	<u>liet- related DCM</u>	. The following week <b>B6</b>	
	o the point of syringe feeding. On			
<b>B6</b> on the recommend	lation of the <b>B6</b> extension Card	liology departmer	nt for a kidney panel before his	
second cardiologist follow	up with another cardiologist, <b>B6</b>	on the same da	y. Unfortunately, <b>B6</b> died of a	
fatal arrhythmia at the cardi	iologist's office 8 days after his initial	diagnosis of susp	ected diet-related DCM and	
right ventricular CHF. The	reason <b>B6</b> was suspected to have di	et related DCM v	vas due to his diet. He was on	
Taste of the Wild PREY, wh	nich is a limited ingredient dry food fo	or the last <b>B6</b> year	rs. Before that, he was on	
Merrick grain-free dog food	d. After reading information on diet re	lated - DCM, I ch	necked the ingredients on <b>B6</b>	
food and lentils was the sec	ond ingredient listed. <b>B6</b> was grain-f	ree his whole life	and on a grain-free diet high	
in lentils for <b>B6</b> years o	f his life. His last 2 bags of Taste of the	ie Wild PREY: Ba	ag 1 (consumed up to the time	
of death): UPC 0-74198-61	368-7 Best by 12/Mar/2020 Possible I	Lot Numbers: 907	72080 PDR0301-19 MSH	
17:27 Bag 2 (consumed 1.5	months before time of death): UPC 0	-74198-61366-3	Best by 08/Mar/2020 Possible	
	B0301-19 JDM 08:09 On a personal n			
cardiologist appointment ar	nd the vet came back in with the result	s, my reaction wa	as "you have to have the wrong	
	!". His resp <u>onse immediately was, "w</u>			
grain-free, he said he had a	very belief <b>B6</b> case was diet-related	d because he was	a mixed breed. We had	
	Wild to ask them if they knew about th		•	
long shot, but please do cor	ntact me to follow up bc I want to know	w if the FDA has	plans to more closely monitor	
•	coming future. I believe that this is ne	•		
	gence on nutrition profiles. The anima			
•	eting pays big dividends and it is comp			
	try where basic items like food are sub			
_	h any additional questions you have. I		L	
	p make a difference. I also want to kno	ow how many cas	ses have been reported.	
<b>Submission Type:</b> Initial				
	ent (a symptom, reaction or disease ass		product)	
	t at the time of last observation: Die	d Naturally		
Number of Animals Treat				
Number of Animals Reacted With Product: 1				
Product Name	Lot Number or ID	Best By Date		
Taste of the Wild PREY	9072080 PDR0301-19 MSH 17:27	03/12/2020		

Sender in	<u>formation</u>	
	<b>B6</b>	
USA		

To view this PFR Event, please click the	link below:
B6	



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Report Details - EON-	390065		
ICSR:	2068021		
Type Of Submission:	Initial		
Report Version:	FPSR.FDA.PETF.V.V1		
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)		
Reporting Type:	Voluntary		
Report Submission Date:	2019-06-10 14:02:21 EDT		
Reporter is the Animal Owner:	Yes		
Reported Problem:	Date Problem Started: Concurrent Medical Problem: Outcome to Date:	Died Naturally	
	Date of Death:	<u> B6</u>	
Product Information:	Product Name:	Taste of the Wild PREY	
	Product Type:	Pet Food	

	Lot Number	Lot Number:	9072080 PDR0301-19 MSH 17:27	
	Lot Nulliber.	Expiration Date:	4	
	LIDO	074198613687		
		; ;		
	Package Type: Package Size:	······		
	Purchase Date:	7		
	Number Purchased:	7		
	Possess Unopened	<u></u>		
	Product:			
	Possess Opened Product:	No		
	Storage Conditions:	Stored in an air-tight	pet food container that was BPA-free	
	Product Use Information:	Description:	1.75 cups fed 2x a day to total a little over 3.75 cups a day. This was taken from the back of the package for a dog in between 60 and 80 lbs.	
		First Exposure Date:	04/01/2019	
		Last Exposure Date:	B6	
		Time Interval between Product Use and Adverse Event:	6 Weeks	
		Product Use Stopped After the Onset of the Adverse Event:	Yes	
		Adverse Event Abate After Product Stop:	No	
		Product Use Started Again:	No	
		Perceived Relatedness to Adverse Event:	Definitely related	
		Other Foods or Products Given to the Animal During This Time Period:	No	
	Manufacturer	Name:	Diamond Pet Food Companies - Taste of the Wild	
	/Distributor Information:	Type(s):	Manufacturer	
		Address:	United States	
		Contact:		
		Possess One or More Labels from This Product:	Yes	
	Purchase Location	Name:		
	Information:	Address:	<b>B6</b>	
			United States	
Animal Information:	Name:	(B6)		
	Tuna Of Chasical	ecies: Dog reed: Mixed (Dog)		
		}		

	Gender:	Male				A COLORADA
	Reproductive Status:	Neutered		***************************************		
	Weight:	Weight: 29.8 Kilogram				
	Age:	<b>B6</b> Years				222
	Assessment of Prior Health:					
	Number of Animals Given the Product:	1				Name and the second of the sec
	Number of Animals Reacted:	1				Throng a party of a
	Owner Information:					and the state of t
	Healthcare Professional	Practice Name:	B6			
	Information:	Contact:	Name:	DC	7	
			Phone:	<b>B6</b>		011
		Address:		, , , , , , , , , , , , , , , , , , ,		005
		Addiess.	B6			
		Type of Veterinarian:	Primary/regular ve	terinarian		U U A A A A A A A A A A A A A A A A A A
		Date First Seen:	В6	••••		The second secon
		Permission to	<sup>9</sup>			2 TO 10 TO 1
		Release Records to FDA:				
		Practice Name:		B6		
		Contact:	Name: Phone:	В6		0.00
		Address:	Be	5		
		Type of Veterinarian:	United States Referred veterinari	an		100 C C C C C C C C C C C C C C C C C C
		Date First Seen:	В6	041114111141111111111111111111111111111		
		Permission to Release Records	i			
		to FDA:				100000000000000000000000000000000000000
Sender Information:	Name: Address:	<b>B6</b>				
	Contact:	Phone: Email:	<u>.</u> В6			
	Permission To Contact Sender:			j		TO THE PARTY NAMED OF THE PARTY
	Preferred Method Of Contact:	Phone				nana gazaria nazaria
	Reported to Other	Manufacturer Store/Place of Purch	ase			nanapuran
Additional Documents:	3					

Attachment:	B6 Report B6 pdf
Description:	
	Medical Records
	B6 B6 odf
Description:	
	Medical Records

#### Visit Summary

Admissic Discharg		Smal. Alive	l Animal Inpatien <u>e</u>	<u>-</u>		B6 Status:	Fina
Client #: Client: Address: City, St:		36	Pat. Pa	nician: ient #: atient: pecies: <u>K9</u> Breed: <u>LABRADO</u>	B6	Sex: MC	9.8KG
	cardiomeg fatiguing week and gagging/c muffled h butorphan	nted for an evaluation aly. For the past easier and less last night had to oughing occasional eart sounds, was sol and radiograph and to VSH.	ation of lethargy 6 months he has benergetic. Has gobe be carried home ally. B6 went to sedated with 100ms revealed marked	peen getting tten signific after a few b B6 cg of dexmede	slower on walk antly worse in locks. He has today tomidine, 4mg	the pas been , had	
<b>Clini</b> 1 2 3 4	cal Diagnos ) Suspect d ) Severe mi ) Mild to m ) Biventric	<b>es</b> iet-associated di tral regurgitatio oderate tricuspid ular failure		chy (nutritio	nal cardiomyop	pathy)	
DISC	arge Summar	Y	B				

sit Summary	B6 Patient:	В6	Page: 2
	DC		
	<b>B6</b>		



#### Visit Summary

Admissi	on: R6	Small Animal Outpatient	В6
Dischar	ge: DO	<u>Alive</u>	Status: Fina
Client #: Client: Address: City, St:		Clinician Patient # B6 Patient Species: K9 Breed: LABRADOR RETRIEVER	Sex: MC
<u>Pert</u>	inent History	<b>Z</b>	
	recent blooms recent blooms recent blooms reathing today (60) currently 1000mg TII	nted for a recheck examination to discuss medication change bod work revealing elevated values, including elevated kidn een anorexic for a week. He is currently being force fed. For rate improved for a few days (40rpm) but was elevated yest rpm). His abdomen appears to be more distended. He was hosped and was treated with fluids and antibiotics.  The receiving pimobendan 7.5mg PO BID, furosemide 60mg PO BID, or cerenia 160mg PO SID, mirtazapine 15mg PO SID and CoQ10 arrested upon presentation.	ey values. is erday and italized at He is taurine
<u>Medi</u>	cal/Surgical B6	Procedures (Billing) 5068 - Misc. Procedure-Card	
	Severe mit	es iet-associated dilated cardiomyopathy (nutritional cardiomy tral regurgitation. Mild to moderate tricuspid regurgitatio ular failure, Death.	
Disc	harge Instruc	ctions	
		<b>B6</b>	
			,

Date

Clinician Signature

From:	Related PFR Event <pfrsignificantactivitycreation@fda.hhs.gov></pfrsignificantactivitycreation@fda.hhs.gov>		
То:	B6 Cleary, Michael *; HQ Pet Food Report Notification; B6		
Sent:	6/10/2019 6:20:41 PM		
Subject:	Taste of the Wild PREY: B6 - EON-390066		
Attachments:	2068022-report.pdf; 2068022-attachments.zip		

A PFR Report has been received and Related PFR Event [EON-390066] has been created in the EON System.

A "PDF" report by name "2068022-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 "2068022-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

**EON Key:** EON-390066

ICSR #: 2068022

EON Title: Related PFR Event created for Taste of the Wild PREY; 2068022

AE Date	B6	Number Fed/Exposed	1
Best By Date	03/12/2020	Number Reacted	1
Animal Species	Dog	Outcome to Date	Died Naturally
Breed	Mixed (Dog)		
Age	B6 Years		
District Involved	PFR <b>B6</b> DO		

Product information	
Individual Case Safety Report N	Number: 2068022
Product Group: Pet Food	
Product Name: Taste of the Wild	PREY
<b>Description:</b> On <b>B6</b> night,	B6 B6 couldn't make it back from his nightly walk, had labored
	nd legs were shaking. On <b>B6</b> morning, <b>B6</b> was brought in to <b>B6</b>
В6	where he underwent general sedation for a hip/knee X-Ray. The thought
process was that he had injured a	hind leg. Under sedation early on, <b>B6</b> experienced abnormal heart rate and
blood pressure readings as well as	gum/ tongue color while being monitored. The vet staff pulled him from

sedation, ran a general blood panel (which was unremarkable and otherwise normal - general parameters). The
vet then decided to do a chest x-ray and found his heart to be 3x the normal size. That same day, I took him to
for a cardiologist follow up as part of their <b>B6</b>
extension. <b>B6</b> was diagnosed with dilated cardiomyopathy and right ventricular congestive heart failure from an
echo cardiogram preformed by B6 He was prescribed pimobendan and lasix and 1,000 mg of
taurine 3x a day. It was the opinion of <b>B6</b> that <b>B6</b> had diet-related DCM. The following week, <b>B6</b>
appetite declined severely to the point of syringe feeding. On <b>B6</b> we brought him back to <b>B6</b>
<b>B6</b> on the recommendation of the <b>B6</b> extension Cardiology department for a kidney panel before his
second cardiologist follow up with another cardiologist, <b>B6</b> on the same day. Unfortunately, <b>B6</b> died of a
fatal arrhythmia at the cardiologist's office 8 days after his initial diagnosis of suspected diet-related DCM and
right ventricular CHF. The reason <b>B6</b> was suspected to have diet related <b>DC</b> M was due to his diet. He was on
Taste of the Wild PREY, which is a limited ingredient dry food for the last B6 years. Before that, he was on
Merrick grain-free dog food. After reading information on diet related - DCM, I checked the ingredients on <b>B6</b>
food and lentils was the second ingredient listed. <b>B6</b> was grain-free his whole life and on a grain-free diet high
in lentils for <b>B6</b> years of his life. His last 2 bags of Taste of the Wild PREY: Bag 1 (consumed up to the time
of death): UPC 0-74198-61368-7 Best by 12/Mar/2020 Possible Lot Numbers: 9072080 PDR0301-19 MSH
17:27 Bag 2 (consumed 1.5 months before time of death): UPC 0-74198-61366-3 Best by 08/Mar/2020 Possible
Lot Numbers: 9068080 PDB0301-19 JDM 08:09 On a personal note: When I had taken <b>B6</b> into his initial
cardiologist appointment and the vet came back in with the results, my reaction was "you have to have the wrong
dog, he's only <b>B6</b> years old!". His response immediately was, "what are you feeding him?" As soon as I said
grain-free, he said he had a very belief <b>B6</b> case was diet-related because he was a mixed breed. We had
reached out to Taste of the Wild to ask them if they knew about this and had heard. Their answer was yes. It's a
long shot, but please do contact me to follow up bc I want to know if the FDA has plans to more closely monitor
dog food companies in the coming future. I believe that this is necessary. These dog food companies have a huge
responsibility to do due-diligence on nutrition profiles. The animal space is highly desirable because it's a
channel where savvy marketing pays big dividends and it is completely unregulated by a government agency. I
don't want to live in a country where basic items like food are subject to the belief that marketing means more
than testing. Please call with any additional questions you have. I'm happy to share <b>B6</b> story and provide as
much details as I can to help make a difference. I also want to know how many cases have been reported.
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: 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 PREY	9072080 PDR0301-19 MSH 17:27	03/12/2020

This report is linked to:

**Initial EON Event Key:** EON-390065

Initial ICSR: 2068021

**Sender information** 

**B6** 

USA

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	B6		
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		B6	
		DU	

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{			
Report Details - EON-	390066		
ICSR:	2068022		
Type Of Submission:	Followup		
Report Version:	FPSR.FDA.PETF.V.V1		
Type Of Report:	Adverse Event (a symptom,	reaction or disease associated with the product)	
Reporting Type:	Voluntary		
Report Submission Date:	2019-06-10 14:11:22 EDT		
Initial Report Date:	06/10/2019		
Reporter is the Animal Owner:	Yes		
Parent ICSR:	2068021		
Follow-up Report to FDA Request:	Yes		
Reported Problem:	Problem Description:  Date Problem Started:	On B6 night B6 B6 couldn't make it back from his nightly walk, had labbred breathing, and no appetite. His hind legs were shaking. On B6 morning, B6 was brought in to the where he underwent general sedation for a hip/knee X-Ray. The thought process was that he had injured a hind leg. Under sedation early on, Be experienced abnormal heart rate and blood pressure readings as well as gum't tongue color while being monitored. The vet staff pulled him from sedation, ran a general blood panel (which was unremarkable and otherwise normal - general parameters). The vet then decided to do a chest x-ray and found his heart to be 3x the normal size. That same day, I took him to for a cardiologist follow up as part of their B6 extension. B6 was diagnosed with dilated cardiomyopathy and right ventricular congestive heart failure from an echo cardiogram preformed by B6 He was prescribed pimobendan and lasix and 1,000 mg of tartine 3x a day. It was the opinion of B6 that 186 had diet-related DCM. The following week, B6 appetite declined severely to the point of syringe feeding. On B6 we brought him back to B6 in the same day. Unfortunately. B6 died of a fatal arrhythmia at the cardiologist solfice 8 days after his initial diagnosis of suspected diet-related DCM and right ventricular CHF. The reason B6 was suspected to have diet related DCM was due to his diet. He was on Taste of the Wild PREY, which is a limited ingredient dry food for the last 3.5 years. Before that, he was on Merrick grain-free dog food. After reading information on diet related - DCM, I checked the ingredients or, B6 jood and lentils was the second ingredient listed B6 was grain-free dog food. After reading information on diet related - DCM, I checked the ingredient dry food for the last 3.5 years. Before that, he was on Merrick grain-free his whole life and on a grain-free diet high in lentils for 3.5/4.5 years of his life. His last 2 bags of Taste of the Wild PREY; Bag 1 (consumed up to the time of death). UPC 0-74198-61368-7 Best by 12/Mar/2020 Possible	
	Concurrent Medical	<u></u>	
	Problem:		

	Outcome to Date: Date of Death:	}			
Product Information:		Taste of the Wild PR	REY		
	Product Type:	e: Pet Food			
	Lot Number:	r: Lot Number: 9072080 PDR0301-19 MSH 17:27			
		Expiration Date: 03/12/2020			
	UPC:	074198613687			
	Package Type:				
	Package Size:				
	Purchase Date:				
	Number Purchased:	2			
	Possess Unopened				
	Product: Possess Opened	No			
	Product:	: Stored in an air-tight pet food container that was BPA-free			
	Product Use				
	Information:	Description:	1.75 cups fed 2x a day to total a little over 3.75 cups a day. This was taken from the back of the package for a dog in between 60 and 80 lbs.		
		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 Started Again:	No		
		Perceived Relatedness to Adverse Event:	Definitely related		
		Other Foods or Products Given to the Animal During This Time Period:			
	Manufacturer	Name:	Diamond Pet Food Companies - Taste of the Wild		
	/Distributor Information:	Type(s):	Manufacturer		
		Address:	United States		
		Contact:			
		Possess One or More Labels from This Product:	Yes		
	Purchase Location	Name:			
	Information:	Address:	<b>B6</b>		

Animal Information:		De l	<u> </u>	*
Ammai imormacion.	Name:	B6		The state of the s
	Type Of Species:	4		
	Type Of Breed: Gender:	J		
	Reproductive Status:	7 ?		
		29.8 Kilogram		
		B6 rears		
	Assessment of Prior	<b>,</b> intratabataantaataantaantaantaantaantaanta	an translation ann translation ann translation and the annian at the annian annian annian annian annian annian	5 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1
	Health:	LXCellett		
	Number of Animals Given the Product:	1		
	Number of Animals Reacted:	1		
	Owner Information:			
	Healthcare Professional	Practice Name:	B6	
	Information:	Contact:		
		3331	Phone: B6	
		<b>A</b>	FROME.	
		Address:	DC	United States
			<b>B6</b>	30 30 30 30 30 30 30 30 30 30 30 30 30 3
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		i	United States	000000000000000000000000000000000000000
		Type of	Primary/regular veterinarian	
		Veterinarian:	i iiiiai yii egalar veterinanan	
		Date First Seen:	В6	
		Permission to	Yes	
		Release Records		
		to FDA:		
		Practice Name:	B6	
		Contact:	Phone: B6	
		Address:	<u> </u>	
			DC	0 t d 0 t c 0 t 5 0 t 5 0 t 5 0 t 5 0 t 5 0 t 6 0 t 7
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			United States	0 to
			Referred veterinarian	
		Veterinarian:		
		Date First Seen:	<u>į̃Li</u>	
		Permission to Release Records	Yes	
		to FDA:		
		Practice Name:	<u> </u>	36
		Contact:	·	- Constitution of the Cons
			Phone: B6	2015 2015 2015 2015 2015 2015 2015 2015
		Address:		
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		Type of	Referred veterinarian	
		Veterinarian:		
			1	STATE OF THE STATE

			<u>-</u>	
		Date First Seen:		
		Permission to Release Records to FDA:	Yes	
Sender Information:	Name:			
	Address:	<b>B6</b>		
	Contact	United States		
	Contact:	Phone: Email:	<b>B6</b>	
	Permission To Contact Sender:	Yes		
	Preferred Method Of Contact:	Phone		
	Reported to Other Parties:	Manufacturer Store/Place of Purch	ase	
Additional Documents:				
	Attachment:	TOTW_1.jpg		
	Description:	: Taste of the Wile PREY Fed to <b>B6</b> at the even of his death		
	Type:	Product Label		
	Attachment:	TOTW_2.jpg		
Description: Taste of the Wild PREY Fed to B6 -6-8 weeks leading up to his death				weeks leading up to his death on <b>B6</b>
	Type:	Type: Product Label		
	Attachment:		In Taurine Level	R6 Amino Acid Lab) ndf
		B6 19039110_ Taurine Level ( B6 mino Acid Lab).pdf  B6 Taurine levels. Echo-cardiogtam can be submitted once recieved.  Medical Records		

		Rcvd:	15-May-2019 12:28 am
<b>B6</b>	Account #: B6	788 Rptd:	29-May-2019 10:55 am
B6		B6	Final
<u> </u>	d: Y <b>Species:</b> Canine Breed: La	brador Retriever	
Pending Tests:	, and the second second		
Test	Result	Reference Range	Units
Gend Out  Taurine Level († B6 Amino  Sample type  Taurine Level	Acid Lab) Plasma  B6		
Plasma normal range: Cat 80 - 120 nmol/ml Dog 60 - 120 nmol/ml	wn risk for Taurine Deficiency		
Cat 300 - 600 nmol/ml	sk for Taurine deficiency		
Testing performed at the Amino A	cids Laboratory, B6		
B6			

(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: 1/28/2019 1:38:48 PM Subject: DCM-Lisa Freeman

Attachments: 4Health grain=free beef and potato: Lisa Freeman - EON-375111; 4Health whitefish and potato

dry: Lisa Freeman - EON-376448; Acana Free Run Poultry dry: Lisa Freeman - EON-374786;

Annamaet chicken and rice dry + Honest kitchen beef: Lisa Freeman - EON-376360;

Homecooked diet - see diet history in medical record: Lisa Freeman - EON-374789; Orijen Adult Original dry (until Aug 2018): Lisa Freeman - EON-375110; Orijen grain free original dry: Lisa Freeman - EON-375114; Orijen Original dry: Lisa Freeman - EON-374783; Taste of the Wild Sierra Mountain dry: Lisa Freeman - EON-376361; Zignature - various flavors (venison: Lisa

Freeman - EON-376446; Zignature kangaroo dry: Lisa Freeman - EON-376363

Here is the Freeman Collection

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

**B6** (BB)





From:







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From:	PFR Event <pfreventcreation@fda.hhs.gov></pfreventcreation@fda.hhs.gov>		
То:	Cleary, Michael *; HQ Pet Food Report Notification;	В6	
Sent:	1/23/2019 11:40:21 PM		
Subject:	Wellness Core Ocean Grain Free Protein-Rich Nutrition EON-377321	В6	
Attachments:	2061666-report.pdf; 2061666-attachments.zip		

2061666-report.pdf; 2061666-attachments.zip

A PFR Report has been received and PFR Event [EON-377321] has been created in the EON System.

A "PDF" report by name "2061666-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 "2061666-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

**EON Key:** EON-377321

ICSR #: 2061666

EON Title: PFR Event created for Wellness Core Ocean Grain Free Protein-Rich Nutrition: 2061666

AE Date	02/15/2015	Number Fed/Exposed	2
Best By Date	10/24/2019	Number Reacted	2
Animal Species	Dog	Outcome to Date	Better/Improved/Recovering
Breed	Retriever - Golden		
Age	7 Years		
District Involved	PFR <b>B6</b> DO		

# **Product information**

**Individual Case Safety Report Number: 2061666** 

Product Group: Pet Food

Product Name: Wellness Core Ocean Grain Free Protein-Rich Nutrition

**Description:** Began feeding Wellness CORE Ocean Dry Kibble Feb. 2015 as main source of nutrition, fed 1 cup 2x per day. Submitted Whole Blood sample to UC Davis Amino Acid Lab for Taurine Testing 6/26/2018. Lab Result 240 Whole Blood Taurine Results which per Dr. Joshua Stern UC Davis DVM Cardiologist is BELOW the 250 minimum range for a Golden Retriever Dog. Per Dr. Stern's order continue feedling this food and supplement each daily meal with taurine rich foods for 3 months then ReTest. Supplemented kibble with 1/2cup

pan fried Ground Sirloin, 1 Hardboiled Eggs and 3 Greek 2% Yogurt for 3months. ReTested Whole Blood Taurine Level October 24, 2018 sent to UC Davis Amino Acid Lab. 10/24/2018 Lab Result Whole Blood Taurine Results 297. Improvement of 57, putting him within the "normal" range Dr. Stern has identified for Golden Retriever Dogs.

**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
Wellness Core Ocean Grain Free Protein-Rich Nutrition	1228J22	10/24/2019

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**B6** 

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

**B6** 

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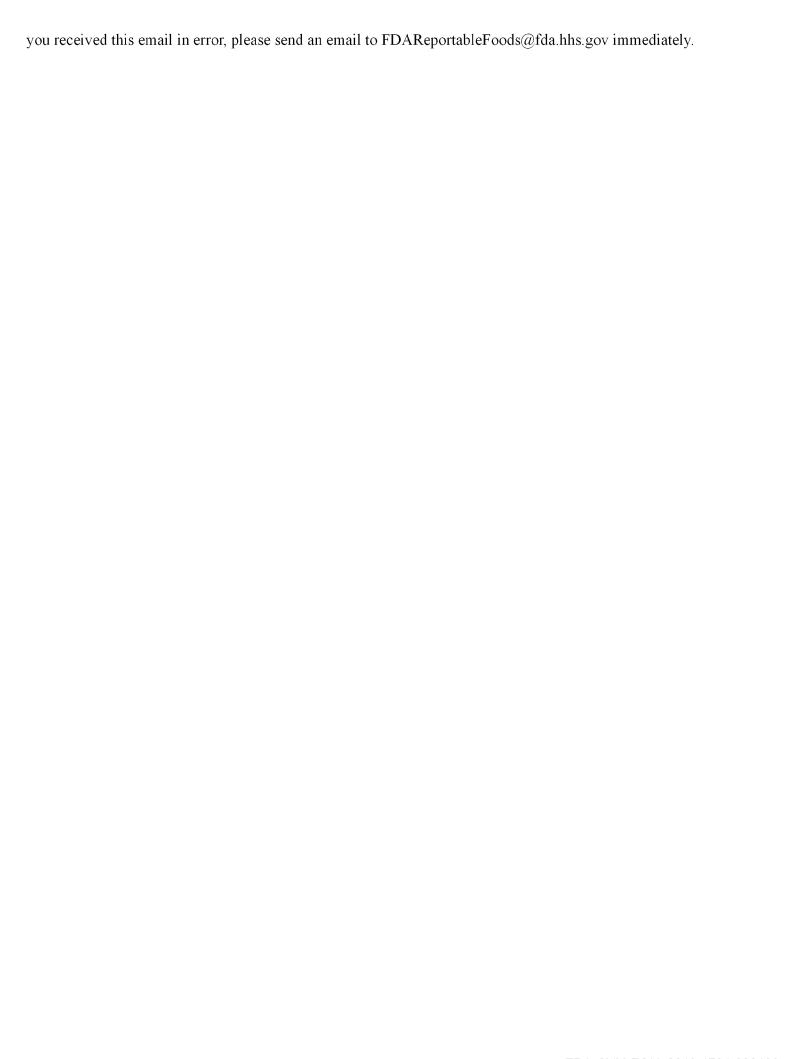
**B6** 

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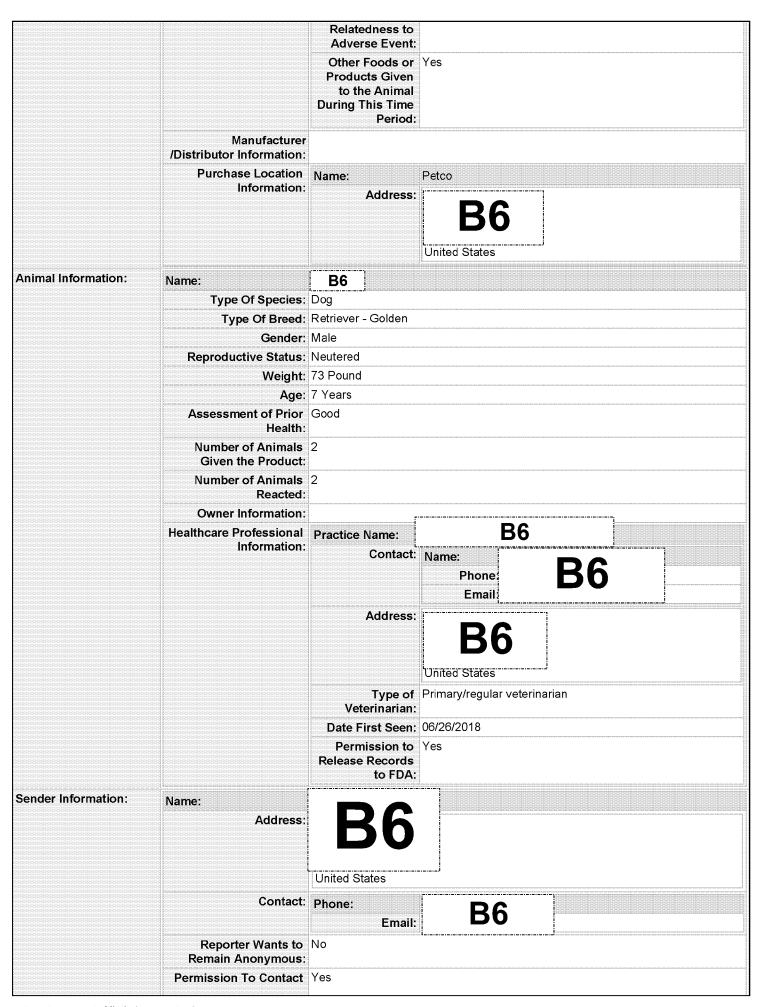
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Report Details - EON-	377321		
ICSR:	2061666		
Type Of Submission:	Initial		
Report Version:	FPSR.FDA.PETF.V.V1		
Type Of Report:	Both		
Reporting Type:	Voluntary		
Report Submission Date:	2019-01-23 18:29:48 EST		
Reporter is the Animal Owner:	Yes		
Reported Problem:	Problem Description:	nutrition, fed 1 cup 2 Amino Acid Lab for Taurine Results which BELOW the 250 min order continue feedlife foods for 3 months to Ground Sirloin, 1 Ha ReTested Whole Blo Acid Lab. 10/24/201	ness CORE Ocean Dry Kibble Feb. 2015 as main source of the per day. Submitted Whole Blood sample to UC Davis Taurine Testing 6/26/2018. Lab Result 240 Whole Blood och per Dr. Joshua Stern UC Davis DVM Cardiologist is a minum range for a Golden Retriever Dog. Per Dr. Stern's ing this food and supplement each daily meal with taurine rich hen ReTest. Supplemented kibble with 1/2cup pan fried ardboiled Eggs and 3 Greek 2% Yogurt for 3months. Bood Taurine Level October 24, 2018 sent to UC Davis Amino 8 Lab Result Whole Blood Taurine Results 297. Improvement thin the "normal" range Dr. Stern has identified for Golden
	Date Problem Started:	02/15/2015	
	Date of Recovery:	10/24/2018	
	2)	Better/Improved/Red	covering
Product Information:	Product Name:	i	an Grain Free Protein-Rich Nutrition
	Product Type:	2 2	an Orall Free Freehand Number
	((	Lot Number:	4000 100
	Lot Number.	Expiration Date:	1228J22 10/24/2019
	UPC:	076344884132	
	Package Type:	BAG	
	Package Size:	12 Pound	
	Purchase Date:	01/04/2019	
	Number Purchased:	1	
	Possess Unopened Product:	No	
	Possess Opened Product:	Yes	
	Storage Conditions:	Bag has a ziplock fre	eshness seal which was opened and resealed after each use.
	Product Use Information:	Description:	Fed 1 cup kibble soaked in warm water 2x per day to Snickers.
		Last Exposure Date:	01/04/2019
		Time Interval between Product Use and Adverse Event:	3 Years
		Product Use Stopped After the Onset of the Adverse Event:	Yes
		Adverse Event Abate After Product Stop:	Yes
		Product Use Started Again:	No
		Perceived	Definitely related



Additional Documents:	Preferred Method Of Contact: Reported to Other Parties:		
		Stole/Flace of Furchase	
At			
	tachment:	B6 ct20182ndTaurineResults_23928.jpg.pdf	
	Description:	Taurine Retest Lab Report after 3 months of adding Taurine Rich Foods to existing kibble which was causing the problem.	
	Туре:	Laboratory Report	
At	tachment:	B6 June2620181stTaurineResultsT_19251.pdf	
	Description:	First Taurine Results, Per Dr. Stern: "Those taurine levels are ok. I would prefer to see over 250. My recommendation would be either diet change and retest after 3 months or add in taurine rich ingredients and retest in 3 months."	
	Туре:	Laboratory Report	
At	tachment:	DrStern Lab Taurine RecommendationsAug2018.pdf	
	Description:	Aug 2018 Letter from Dr. Joshua Stern DVM Cardiologist explaining the Taurine Deficeincy results specifically to Golden Retriever owners with the correct range that Golden Retriever dogs are to be in.	
	Туре:	Letter	

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# STERN CARDIAC GENETICS LABORATORY JOSHUA A. STERN, DVM, PHD, DACVIM (CARDIOLOGY)

sterngenetics@ucdavis.edu; August 9, 2018

# FREQUENTLY REQUESTED INFORMATION REGARDING TAURINE & DILATED CARDIOMYOPATHY IN GOLDEN RETRIEVERS

**Taurine reference ranges for Golden Retrievers:** The Stern Lab suggests that the following clinical reference ranges be used for Golden Retrievers and be considered for other known taurine-sensitive breeds such as Newfoundlands or American Cocker Spaniels. This is primarily based on 3 observations:

- 1. Golden Retrievers with marginal taurine levels (defined below) have been diagnosed with dilated cardiomyopathy and have documented disease reversal after taurine supplementation and diet change.
- 2. Previously published work documents taurine sensitivity in Golden Retrievers.
- 3. The most recently published reference on normal blood taurine values shows higher levels than previously reported.
  - o Normal whole blood taurine: >250nmol/mL
  - Normal plasma taurine: >70nmol/mL
  - o Marginal whole blood taurine: 200-250nmol/mL
  - o Marginal plasma taurine: 60-70nmol/mL
  - Low whole Blood taurine: <200nmol/mL</li>
  - Low plasma taurine: <60nmol/mL</li>

#### References:

Kramer GA, Kittleson MD, Fox PR, Lewis J, Pion PD. Plasma taurine concentrations with normal dogs and in dogs with heart disease. J Vet Intern Med 1995;9:253-258.

Belanger MC, Ouellet M, Queney G, Moreau M. Taurine-deficient dilated cardiomyopathy in a family of golden retrievers. J Am Anim Hosp Assoc 2005;41:284-291.

Kittleson MD, Keene B, Pion PD, Loyer CG, MUST Study Investigators. Results of the multicenter spaniel trial (MUST): taurine- and carnitine-responsive dilated cardiomyopathy in American Cocker Spaniels with decreased plasma taurine concentration. J Vet Intern Med 1197;11:204-211.

Backus RC, Choen G, Pion PD, Good KL, Rogers QR, Fascetti AJ. Taurine deficiency in Newfoundlands fed commercially available complete and balanced diets. J Am Vet Med Assoc 2003;223:1130-1136.

Fascetti AJ, Reed JR, Rogers QR, Backus RC. Taurine deficiency in dogs with dilated cardiomyopathy: 12 cases (1997-2001). J Am Vet Med Assoc 2003;223:1137-1141.

Freeman LM, Michel KE, Brown DJ, Kaplan PM, Stamoulis ME, Rosenthal SL, Keene BW, Rush JE. Idiopathic dilated cardiomyopathy in Dalmatians: nine cases (1990-1995). J Am Vet Med Assoc 1996;209:1592-1596.

Delaney SJ, Kass PH, Rogers QR, Fascetti AJ. Plasma and whole blood taurine in normal dogs of varying size fed commercially prepared food. J Anim Physiol a Anim Nutr 2003;87:236-244.

### Plasma vs. whole blood taurine testing:

If at all possible, we recommend that paired (plasma and whole blood) taurine samples be submitted for analysis. A low value on either or both tests is clinically relevant. If your dog is diagnosed with DCM, submitting paired taurine samples (plasma and whole blood) is imperative. We recommend that the UC Davis Amino Acid Laboratory be used for taurine testing, as this is where the literature utilized for our reference ranges was generated. <a href="https://www.vetmed.ucdavis.edu/labs/amino-acid-laboratory">https://www.vetmed.ucdavis.edu/labs/amino-acid-laboratory</a>. If a single test is submitted the Stern Lab recommends that whole blood be submitted preferentially. This is due to the false elevation of taurine levels that is possible in plasma samples due to sample handling issues. This is an area of some debate between clinicians and conflicting information on preference for plasma vs. whole blood exists. This underscores the value of paired sampling.

Page 1 of 3

#### Clinical Recommendations for Golden Retrievers based on taurine levels:

# If taurine levels test < 200 nmol/mL in whole blood or < 60 nmol/mL in plasma

- An echocardiogram by a board-certified veterinary cardiologist is indicated
- After echocardiogram has been completed, a diet change is recommended.
  - o If DCM is diagnosed, this patient may need a variety of cardiac medications that would be prescribed by the attending cardiologist.
  - o If DCM is diagnosed, prescribed supplementation with oral taurine and l-carnitine is recommended.
  - Reevaluation of taurine levels is warranted after three months of diet change and supplementation.
  - Cardiology reevaluation schedules will be recommended by the attending clinician pending echocardiographic findings.
  - o Many Golden Retrievers with taurine-deficient DCM in our study showed slow and steady improvement over a period of 6-12 months.

# If taurine levels test 200 - 250nmol/mL in whole blood or 60-70nmol/mL in plasma

- An echocardiogram by a board-certified cardiologist is recommended.
- After echocardiogram has been completed, a diet change is recommended.
- We recognize that many dogs in this category may have normal echocardiograms and thus the value of screening should be carefully considered. If the dog is eating a diet that falls within the FDA warning or shares features with the diets identified in our study (see diets of concern section below), we encourage echocardiographic screening with greater enthusiasm.
- If an echocardiogram is not performed, a diet change is still recommended and a taurine level reevaluation after three months on the new diet should be considered.
- If DCM is diagnosed, this patient may need a variety of cardiac medications that would be prescribed by the attending cardiologist.
  - o If DCM is diagnosed, prescribed supplementation with oral taurine and l-carnitine is recommended.
  - Reevaluation of taurine levels is warranted after three months of diet change and supplementation.
  - Cardiology reevaluation schedules will be recommended by the attending clinician pending echocardiographic findings.
  - o Many Golden Retrievers with taurine-deficient DCM in our study showed slow and steady improvement over a period of 6-12 months.

# If taurine levels test > 250nmol/mL in whole blood or > 70nmol/mL in plasma

- Diet change is recommended if you are feeding a diet that falls within the FDA warning or shares features with the diets identified in our study (see diets of concern section below)
- If your pet shows any signs of cardiac disease (trouble breathing, exercise intolerance, fainting/collapse, coughing) we recommend your veterinarian evaluate your pet.

# Diets of Concern & Choosing a diet

The FDA alert called attention to several dietary ingredients that should be considered when evaluating whether your pet is at risk (for example legumes like peas and lentils, white or sweet potatoes). These findings were largely recapitulated in our current study of Golden Retrievers with low taurine levels and DCM. Our lab considers these ingredients to be of greatest concern when present within the first 5 listed ingredients on the dog food bag. Additionally, we noted a high percent of diets in our study were using protein sources other than chicken or beef and labeled as grain-free.

Points to consider when making a diet change:

- Choose a diet that does not contain the concerning components listed above
- Choose a diet that meets the WSAVA Global Nutrition Assessment Guidelines published as consensus by veterinary nutritionists from around the world:
  - o https://www.wsava.org/WSAVA/media/Arpita-and-Emma-editorial/Selecting-the-Best-Food-for-your-Pet.pdf
- FDA alert found here:
  - o <a href="https://www.fda.gov/AnimalVeterinary/NewsEvents/CVMUpdates/ucm613305.htm">https://www.fda.gov/AnimalVeterinary/NewsEvents/CVMUpdates/ucm613305.htm</a>

# Choosing a taurine or l-carnitine supplement:

Selecting supplements should be performed based upon those that match their stated contents and are readily available for absorption. Luckily a previous publication tested multiple taurine and l-carnitine supplements. Based upon this publication our laboratory recommends the following supplements as those meeting our quality criteria. (Bragg et al. 2009 J Am Vet Med Assoc; 234(2))

Tested taurine supplements that test within 5% of stated contents and if applicable disintegrated within 30 minutes

- Mega taurine caps by Twinlab (1000 capsule)
- Taurine by Swanson Health Products (500mg capsule)
- Taurine by NOW foods (500mg capsule)
- Taurine 500 by GNC (500mg tablet)

<u>Tested L-carnitine supplements that test within 5% of stated contents and if applicable disintegrated</u> within 30 minutes

- L-carnitine 500 by Jarrow Formulas (500mg capsule)
- L-carnitine caps by Country Life (500mg capsule)
- Maxi L-carnitine by Solgar Vitamin and Herb (500mg tablet)
- L-carnitine by Puritan's Pride (500mg tablet)

The Stern lab does not recommend the empirical supplementation of taurine or l-carnitine to dogs without evidence of DCM and/or significant deficiency. If DCM is diagnosed we typically recommend dogs over 50lbs receive 1000mg of taurine every 12hrs and dogs under 50lbs receive 500mg of taurine every 12hours. We recommend L-carnitine at a dose of  $\sim 50 \, \mathrm{mg/kg}$  orally with food every 8hrs. Your veterinary cardiologist or family veterinarian should be consulted for prescribing the best dose for your dog.

# Reporting to the FDA:

Understanding the basis of this condition requires a great deal of research and investigation. Clients with affected dogs can contribute their data to help propel this research forward. You can report cases of taurine deficiency, dilated cardiomyopathy, sudden cardiac death, or any combination of these events to the FDA by following the information found here:

https://www.fda.gov/animalveterinary/safetyhealth/reportaproblem/ucm182403.htm

Additional questions or comments: sterngenetics@ucdavis.edu This document last updated: Aug. 20, 2018

Page 3 of 3

From: PFR Event PFR Event

A PFR Report has been received and PFR Event [EON-377324] has been created in the EON System.

A "PDF" report by name "2061667-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 "2061667-attachments.zip" and is attached to this email notification.

2061667-report.pdf; 2061667-attachments.zip

Below is the summary of the report:

**EON Key:** EON-377324

Attachments:

ICSR #: 2061667

EON Title: PFR Event created for Wellness Core Ocean Grain Free Protein-Rich Nutrition; 2061667

AE Date	01/02/2017	Number Fed/Exposed	2
Best By Date	10/24/2019	Number Reacted	2
Animal Species	Dog	Outcome to Date	Better/Improved/Recovering
Breed	Retriever - Golden		
Age	3 Years		
District Involved	PFR- <b>B6</b> DO		

# **Product information**

**Individual Case Safety Report Number: 2061667** 

**Product Group:** Pet Food

Product Name: Wellness Core Ocean Grain Free Protein-Rich Nutrition

**Description:** Began feeding Wellness CORE Ocean Dry Kibble Jan. 2017 as main source of nutrition, fed 1.5 cup 2x per day. Submitted Whole Blood sample to UC Davis Amino Acid Lab for Taurine Testing 6/26/2018. Lab Result 256 Whole Blood Taurine Results which per Dr. Joshua Stern UC Davis DVM Cardiologist is barely above the 250 minimum range for a Golden Retriever Dog. Per Dr. Stern's order continue feedling this food and supplement each daily meal with taurine rich foods for 3 months then ReTest. Supplemented kibble with 1/2cup

pan fried Ground Sirloin, 1 Hardboiled Eggs and 3 Greek 2% Yogurt for 3months. ReTested Whole Blood Taurine Level October 24, 2018 sent to UC Davis Amino Acid Lab. 10/24/2018 Lab Result Whole Blood Taurine Results 348. Improvement of 57, putting him within the "normal" range Dr. Stern has identified for Golden Retriever Dogs.

**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

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

Product Name	Lot Number or ID	Best By Date
Wellness Core Ocean Grain Free Protein-Rich Nutrition	1228J22	10/24/2019

Sen	<u>ider information</u>
	<b>B</b> 6
US	A

 <b>B6</b>	
To view the PFR Event Report, please click the lir	ık below:

**B6** 

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.

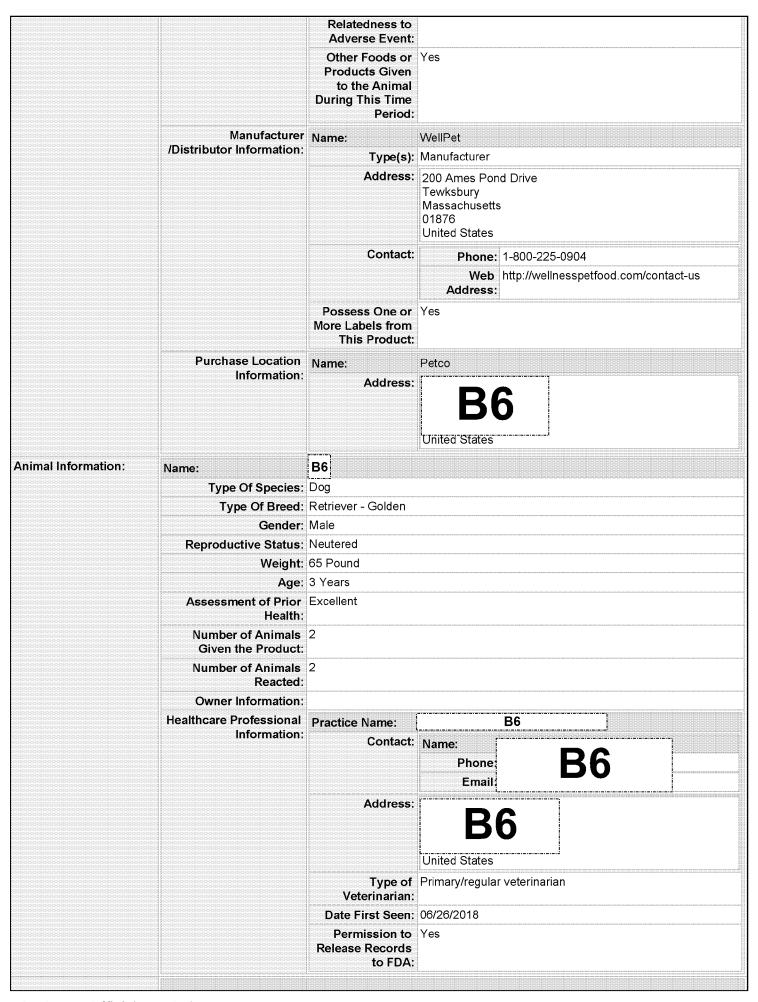
This email message is intended for the exclusive use of the recipient(s) named above. It may contain information that is protected, privileged, or confidential. Any dissemination, distribution, or copying is strictly prohibited.

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

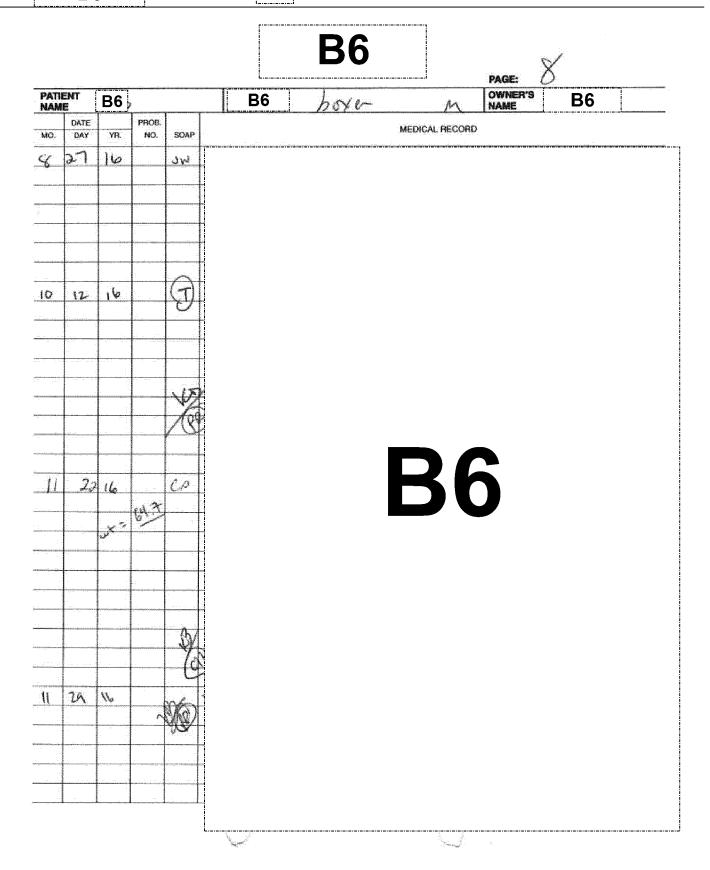


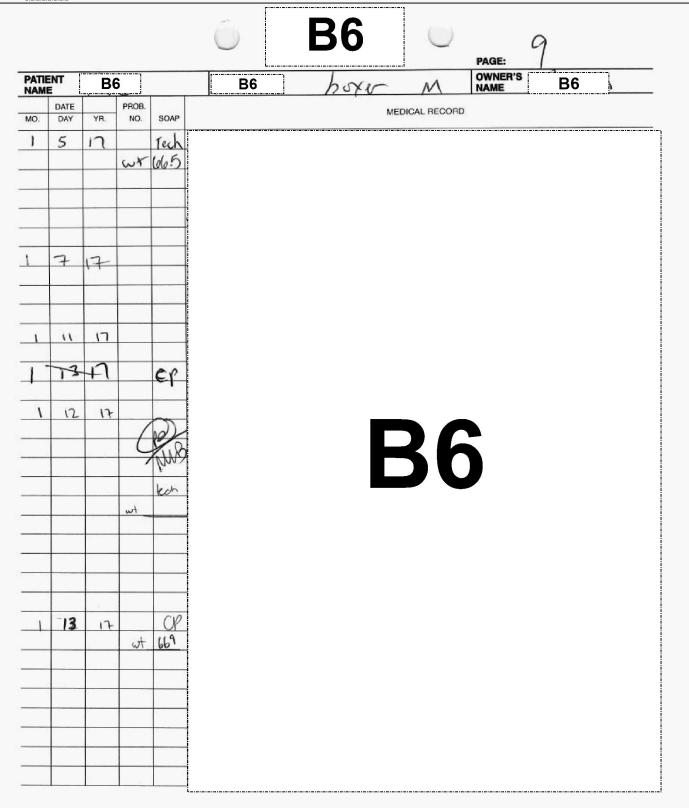
Report Details - EON-	377324		
ICSR:	2061667		
Type Of Submission:	Initial		
Report Version:	FPSR.FDA.PETF.V.V1		
Type Of Report:	Both		
Reporting Type:	Voluntary		
Report Submission Date:	::) :::)		
Reporter is the Animal	Yes	annaan Maaanaan Maaanaan Manaan Manaan Manaan Ma	
Owner:			
Reported Problem:	Problem Description:	nutrition, fed 1.5 cup Amino Acid Lab for Taurine Results white above the 250 minin continue feedling thi for 3 months then Re Sirloin, 1 Hardboiled Blood Taurine Level /2018 Lab Result Wilhim within the "norm	ness CORE Ocean Dry Kibble Jan. 2017 as main source of 2x per day. Submitted Whole Blood sample to UC Davis Taurine Testing 6/26/2018. Lab Result 256 Whole Blood chiper Dr. Joshua Stern UC Davis DVM Cardiologist is barely num range for a Golden Retriever Dog. Per Dr. Stern's order is food and supplement each daily meal with taurine rich foods et et al. Supplemented kibble with 1/2cup pan fried Ground Eggs and 3 Greek 2% Yogurt for 3months. ReTested Whole October 24, 2018 sent to UC Davis Amino Acid Lab. 10/24 nole Blood Taurine Results 348. Improvement of 57, putting fall" range Dr. Stern has identified for Golden Retriever Dogs.
	Date Problem Started:	01/02/2017	
	Date of Recovery:	10/24/2018	
	Concurrent Medical Problem:	No	
	Outcome to Date:	Better/Improved/Red	covering
Product Information:	Product Name:	Wellness Core Ocea	n Grain Free Protein-Rich Nutrition
	Product Type:	Pet Food	
	Lot Number:	Lot Number:	1228J22
		Expiration Date:	10/24/2019
	UPC:	076344884132	3
	Package Type:	BAG	
	Package Size:	12 Pound	
	Purchase Date:	7	
	Number Purchased:	1	
	Possess Unopened	No	
	Product:		
	Possess Opened Product:	Yes	
	Storage Conditions:	Bag has a ziplock fre	eshness seal which was opened and resealed after each use.
	Product Use Information:	Description: Last Exposure Date:	Fed 1.5 cups kibble soaked in warm water 2x per day to Oly. 01/04/2019
		Time Interval between Product Use and Adverse Event:	2 Years
		Product Use Stopped After the Onset of the Adverse Event:	
		Adverse Event Abate After Product Stop:	
		Product Use Started Again:	No
		Perceived	Definitely related

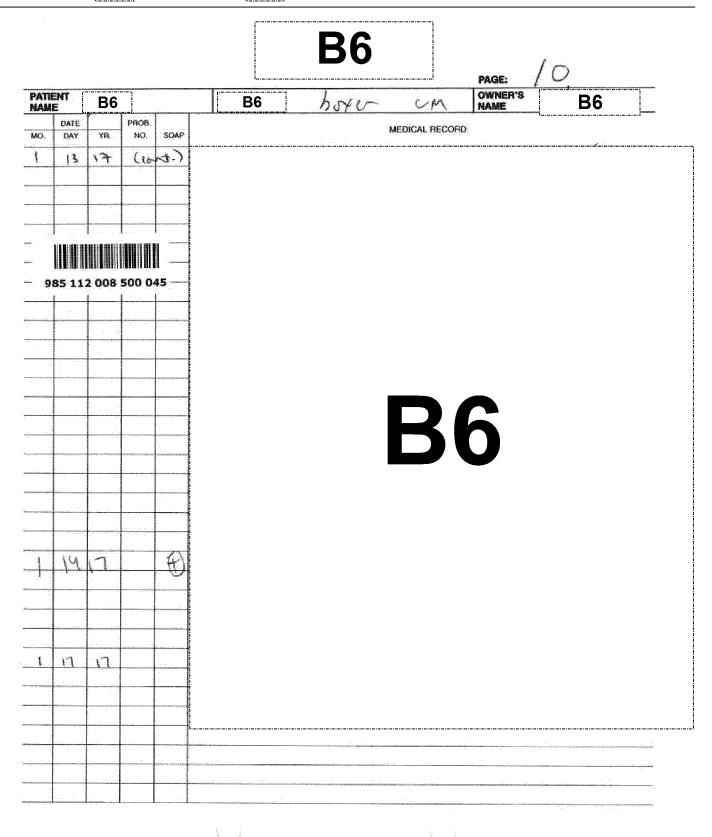


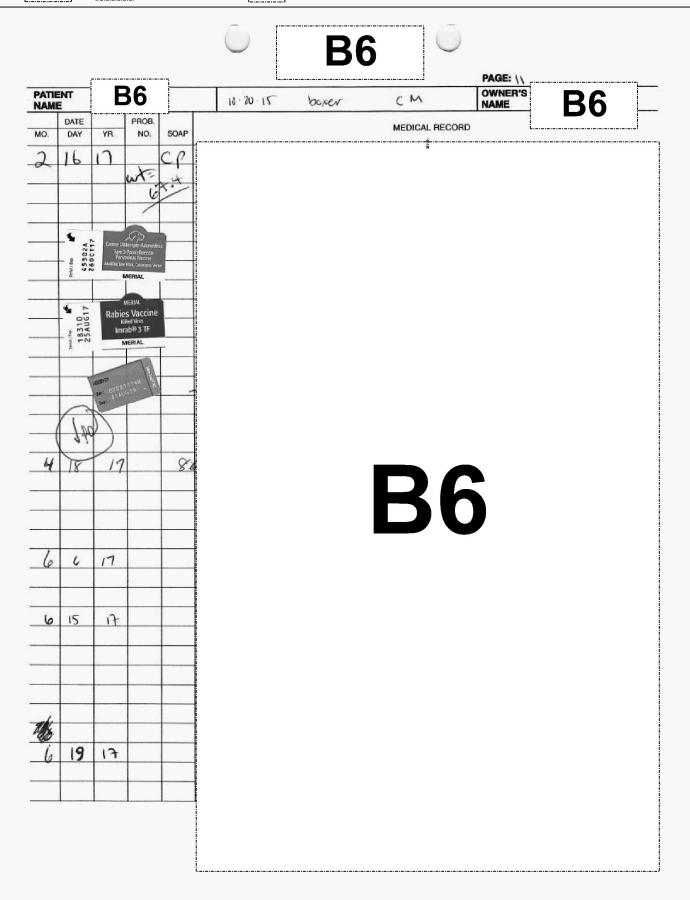
Sender Information:	Name:	B6
	Address:	B6 United States
	Contact:	Phone: B6
	Reporter Wants to Remain Anonymous:	No
	Permission To Contact Sender:	Yes
	Preferred Method Of Contact:	Email
	Reported to Other Parties:	Store/Place of Purchase Other
Additional Documents:		
	Attachment:	B6 June20181stTaurineResults_19250.jpg.pdf
	Description:	First Taurine Results Lab Report June 2018
	Туре:	Laboratory Report
	Attachment:	B6 Dct20182ndTaurineResults_23928.jpg.pdf
		2nd Lab Results for Taurine from UC Davis Vet Amimno Acid Lab
	Type:	Laboratory Report
	Attachment:	DrStern Lab Taurine RecommendationsAug2018.pdf
	Description:	Per email from Dr. Stern:"Those taurine levels are just ok. I would prefer to see it higher than 256. My recommendation would be either diet change & retest after 3 months or add in taurine rich ingredients & retest in 3 months."
	Type:	Letter

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		Other Ph# (	)	(2.1)
Other Ph #()		Email:	В6	
: B6		Gender: M		1/13/17 CP/SAM
ecies: Canine		Breed: 60 xer	_ span (taken)	
DB: <b>B6</b>		Color: bandle		
		36		
crock freezenificant History/Comments:	onia	В6	CAUT	ION:
6/16 AAML Cardio	logy Cx (	2* ( mm 1 N	exreport.	*
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# WAYLAND ANIMAL CLINIC 6 Winter Street Wayland, MA 01778

					Wayland, MA	01778	PAGE: 12		
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**B6** 

Pet: B6

Breed: Boxer Sex: M Color: brindle

**B6** 

Visit Date: June 19, 2017

Dear Dr. B6

I was pleased to see that B6 taurine level came back low, indicating there is a chance we can reverse the changes I saw on echo. I called and left a message for B6 and am copying below an email I sent her about his diet:

Hi B6

You probably already received my message with the news that B6 taurine level came back as low. This is good news because it means there is a chance the heart enlargement and weakened heart muscle appearance may be reversible. Even prior to receiving the bloodwork results I was consulting with a nutritionist who shared my concerns that he could have low taurine related to his diet. She expressed concern not just about the salmon based diet, but about the current diet as well based on the manufacturer/brand. So in addition to the taurine supplement, I recommend we switch B6 to a diet we are sure is complete and balanced according to AAFCO feeding trials or by analysis of the actual diet (not a prediction based on recipe) to ensure it meets AAFCO nutrient profiles (AAFCO is the Association of American Feed Control Officials, a non-profit organization that sets standards for both animal feeds and pet food in the US). That may sounds daunting, but there are a lot of great pet food manufacturers out there who meet these stringent requirements.

There are a lot of diet misconceptions and marketing information that makes diet selection very confusing for pet owners. I highly recommend the website set up by the Tufts veterinary school nutrition team at <a href="www.petfoodology.org">www.petfoodology.org</a>. There are so many wonderful articles on there (I just spent a half hour surfing around because it is such wealth of great info!). I want to draw your

attention to the great article on the risks of raw diets

(http://vetnutrition.tufts.edu/2016/06/grain-free-diets-big-on-marketing-small-on-truth/). In short, since there is concern that [86] may have some food sensitivities, I encourage you to work with one of the nutritionists at either Tufts or [86] to find a diet that will work for him, or at least that we switch him to a diet by a company who has done the research and due diligence to ensure a complete and balanced diet.

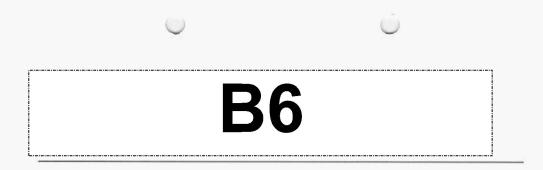
Meanwhile, you should continue the taurine and L-carnitine supplements, and the pimobendan as prescribed. It would be great to see <u>Be</u> back sooner than the 3 month recheck however- to take a quick peek at his heart to see if (hopefully) things are changing for the better, and to recheck a taurine level. I think around 6 weeks from now makes sense, so let me know if you are interested in scheduling this, or if you have any questions.

Best, Dr. B6

Thank you for the referral and your continued support of me if you need any more information regarding B6

Please contact

Sincerely,



# SOAP - Cardiology

Jun 19, 2017

В6	Patient: Species: Breed:	Canine Boxer	DOB: Age: Sex:	B6 Old
Acc. No: 223669	Color: Doctor:	brindle B6	Tag: Weight	: 69.225 lbs. (31.4 kgs.)
Phone: Home - B6		i		

Weight: 31.4 kgs.

#### **Prior Medical History**

As of 6/30/16

-Mildly elevated left and right ventricular outflow tract velocities: suspect normal variant +/- very mild aortic stenosis.

-Impression of mild left atrial enlargement: r/o age-related, other variant of undetermined cause

## Presenting Complaint

Routine recheck

# **Current Medical History**

General Complaints: O states that \( \begin{align\*} \begin{align\*} B6 \) has had 2 episodes since last visit, First episode was awhile ago (o not sure how long) in Vermont. He was running around with daughter and then acting totally out of it, staring at the ground, weak but did not lose consciousness-for around 30 min. Brought to ER in \( \begin{align\*} \begin{align\*} \begin{align\*} B6 \\ \begin{align\*} \be

Coughing?: No Sneezing?: Yes Vomiting: No Polyuria: No Polydipsia: No Diarrhea?: No

Dier?: Was on Go Fresh limited ingredient salmon diet for about a year. A few weeks ago switched to Go Fresh venison and Fresh Now beef, with a raw patty at lunchtime (o unsure brand- something with two people's names)

Appetite: Normal Any collapses or seizures?; Yes

#### **Current Medications**

Do you need any refills today?: No First Cardiac Evaluation?: Yes Referral Radiographs?; No

#### Physical Exam

**B6** 

**Echocardiogram** 



# ECHOCARDIOGRAPHIC DIAGNOSIS:

- ECHOCARDIOGRAPHIC DIAGNOSIS:
  -Dilated cardiomyopathy (severe), r/o idiopathic, secondary to taurine-deficiency, myocarditis, other-Borderline pulmonary hypertension
  -Mildly elevated left ventricular outflow tract velocity (dx 6/2016)

Comparison to previous studies:

There has been significant increase in left atrial size (from 3.86 cm on 2D one year ago), in left ventricular size (from 4.38 cm one year ago) and decrease in %FS (from 30.8% one year ago). MR and TR are new (suspect secondary to annular stretch). The right atrium and ventricle subjectively appear somewhat enlarged as well.

#### Electrocardiogram

**B6** 

#### **Blood Pressure**

**B6** 

#### Final Assessment

- Final Diagnosis:
  -Dilated cardiomyopathy (severe), r/o idiopathic, secondary to taurine-deficiency, myocarditis, other
  -Borderline pulmonary hyperlension
  -Mildly elevated left ventricular outflow tract velocity (dx 6/2016)
  -Normal sinus arrhythmia with no ventricular ectopy

Diagnostic Recommendations:

**B6** 

Therapeutic Recommendations:

Follow-Up:
Recheck 3 months with echocardiogram +/- thoracic radiographs (scheduled for September 11 at 9:30 am)

Consulting Cardiologist B6 DVM; DACVIM (cardiology)

10:29 AM

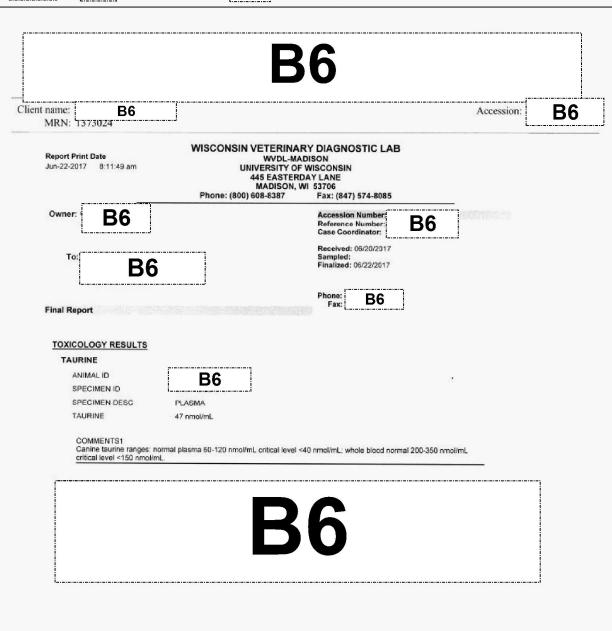
See attached link

rDVM B6 and B6 HX 6/16/16-6/24/17 ( B6 Echo 6/19/17)

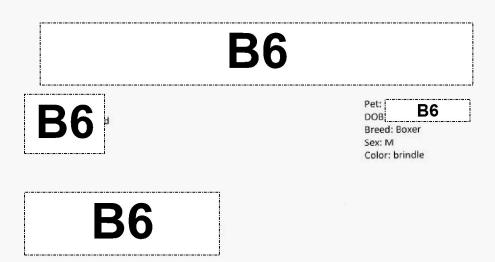
Accession number B6
This report continues... (Final)

SENDOUT

Page 1



Jun-22-2017	8:11:49 am	Accession Number:B6	Page 1 of 1
cession numb			
D OF REPOR	RT (Final)		Page :



Visit Date: June 19, 2017

Please see the accompanying cardiology report for our mutual patient. B6 I was so sad to see that B6 is heart has changed quite a bit in the last year, and he now appears to have severe dilated cardiomyopathy. He had been on a limited ingredient salmon diet, only recently switched to beef and venison based diet, so I hold some hope that this may be a taurine deficiency manifestation (would be much better prognosis for him- so fingers crossed!). We have a taurine level pending, but of course this may not reflect historic deficiency due to his recent diet change. Meanwhile, I have prescribed pimobendan and recommended taurine and L-carnitine supplementation. He has had two episodes of seeming woozy/disoriented and "out of it" after exertion, but they do not sound classic for arrhythmia-related (one episode lasted 30 minutes) and his ECG today was normal. We will continue to monitor for now (perhaps they were related to low output from systolic dysfunction and pimobendan will help). If they recur, we will check a 24 hour holter monitor (with B6 bad luck I wouldn't put it past him to also have a neurologic condition!). Thank you for the referral and your continued support of Please contact me if you need any more information regarding B6

Sincerely,



# SOAP - Cardiology

Jun 19, 2017

D6	Patient: Species:	B6 Canine	DOB: Age:	В6 В6	þld
DU	Breed:	Boxer	Sex:	M	
	Color:	brindle	Tag:		
Acc. No: 223669	Doctor:	B6	Weight:	69.225 lbs.	(31.4 kgs.)
Phone: Home - B6					

Weight: 31.4 kgs.

#### **Prior Medical History**

-Mildly elevated left and right ventricular outflow tract velocities: suspect normal variant +/- very mild aertic stenosis. -Impression of mild left atrial enlargement: r/o age-related, other variant of undetermined cause

## **Presenting Complaint**

Routine recheck

# **Current Medical History**

General Complaints: O states that \$\( \) B6 has had 2 episodes since last visit, First episode was awhile ago (o not sure how long) in \$\( \) B6 h. He was running around with daughter and then acting totally out of it, staring at the ground, weak but did not lose consciousness-for around 30 min. Brought to ER in \$\( \) B6 h. but he was acting normal by the time they got there and they did not find any abnormalities on PE. Thursday am this happened when \$\frac{1}{2}\$ B6 was running with \$\( \) B6 in the back yard, and side swiped a bush, then stood up and seemed drunk/out of it (moving front legs in \( \) Inition ordinated/crossing over fashion), lasted 5 min. then went back to normal. O did notice that on Thursday Gums were very pink during episode (not pale). No BM/urination/hypersalivation during episodes. Yesterday was doing "a ton" of reverse sneezing according to O. Great energy level otherwise. Does now have a good appetite, O has seen a kinesthesiologist due to low appetite. \$\( \) Bis had been on strictly salmon based diet for past year, but they recommended changing/rotating protein sources (now beef and venison)- changed a few weeks ago and he is eating better.

Coughing?: No Sneezing?: Yes Vomiting: No Polyuria: No Polydipsia: No Diarrhea?: No

Diet?: Was on Go Fresh limited ingredient salmon diet for about a year. A few weeks ago switched to Go Fresh venison and Fresh Now beef, with a raw patty at lunchtime (o unsure brand- something with two people's names)

Appetite: Normal

Any collapses or seizures?: Yes

#### **Current Medications**

Do you need any refills today?: No First Cardiac Evaluation?: Yes Referral Radiographs?: No

# **Physical Exam**

**B6** 

# **Echocardiogram**



#### ECHOCARDIOGRAPHIC DIAGNOSIS:

ECHOCARDIOGRAPHIC DIAGNOSIS:

- -Dilated cardiomyopathy (severe), r/o idiopathic, secondary to taurine-deficiency, myocarditis, other
- -Borderline pulmonary hypertension -Mildly elevated left ventricular outflow tract velocity (dx 6/2016)

Comparison to previous studies:
There has been significant increase in left atrial size (from 3.86 cm on 2D one year ago), in left ventricular size (from 4.38 cm one year ago) and decrease in %FS (from 30.8% one year ago). MR and TR are new (suspect secondary to annular stretch). The right atrium and ventricle subjectively appear somewhat enlarged as well.

## Electrocardiogram

**B6** 

#### **Blood Pressure**

**B6** 

#### **Final Assessment**

Final Diagnosis:

- r-mai Diagnosis:

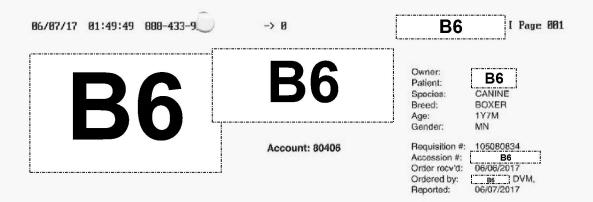
  Initiated cardiomyopathy (severe), r/o idiopathic, secondary to taurine-deficiency, myocarditis, other -Borderline pulmonary hypertension -Mildly elevated left ventricular outflow tract velocity (dx 6/2016) -Normal sinus arrhythmia with no ventricular ectopy

Diagnostic Recommendations

**B6** 

Therapeutic Recommendations:

Follow-Up:
Recheck 3 months with echocardiogram +/- thoracic radiographs (scheduled for September 11 at 9:30 at
Consulting Cardiologist: B6 DVM; DACVIM (cardiology)



### OVA AND PARASITES 3 OR MORE

### **OVA & PARASITES**

NO OVA OR PARASITES SEEN

CYNICLOMYCES GUTTULATUS ALSO KNOWN AS SACCHAROMYCOPSIS GUTTULATA (NON-PATHOGENIC YEAST) PRESENT

In cases of acute or chronic diarrhea in addition to a fecal floatation and antigen testing for ova and parasites consider testing for viral, bacterial and protozoal infectious agents using RealPCR (canine diarrhea panel: test code 2625; feline diarrhea panel: test code 2627).

B6 06/07/2017 FINAL REPORT

PAGE 1 OF 1

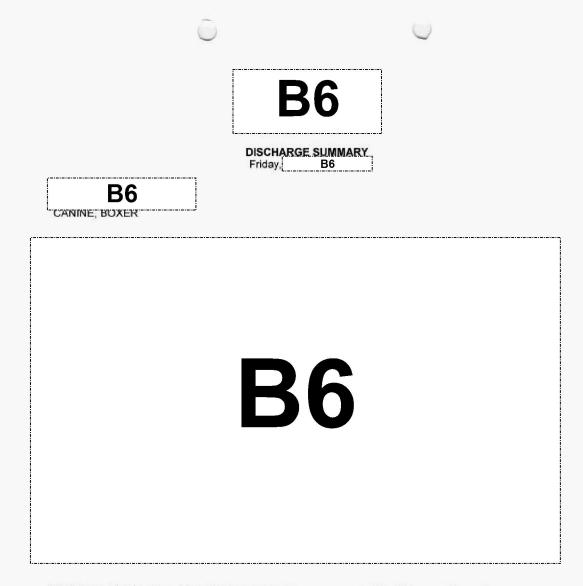
URINE CULT & SUSCEPTIBILITY		
Test	Result	
SOURCE:	DC	
STATUS:	Bb	
COMPLETED CULTURE RESULTS		

URINALYSIS & C+S (MIC)	URINALYSIS	49		
Test	Re	Referenc	e Range Fla	ig Bar Graph

**B6** 01/14/2017

FINAL REPORT

PAGE 1 OF 1



 $<sup>^{\</sup>star\star}$  Your pet had a procedure that may make them groggy for 24-48 hours. If you have any questions or concerns please feel free to call the office.

# **Anesthesia Monitoring**

	-			-a				
	Client Name:	B6		Pet N	ame:	В6		
Procedure: Neo	ter	Breed: Bo	sker			10 Sex	M	Wt: 66.9#
								11.0.400.1
D T. 1 5	TIN 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1							
Dr: CP Tech: B	6 IV Fluid Ty	pe: LRS	Fluid I	Rate_	300	ml hr	Fluid Tot	al $182cc$
Pre op meds:	orb- 0.5α	Ace- 0	100 IT	10	815	AM		
Induction: Propoflo	Reg/28 3	cc (V			-			
Anest Start: 909	SX Start: 93	SX Finish	1: 94S	Anest	h Fini	sh: 945	Extubate	@ 1000
Pre Op T:	ET Tube Siz	e: 9.0 BP (	ouff Size:	M	IVC	atheter si	te: (B)	1 1 1
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Iso % O2								
Heart Rate								
Resp Rate							-	
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CRT MM Color								
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Breath								
Rimadyl 2 r	nl SO given	a) 910 Am						
Buprenex 0.8	ml SO/IV/IM	given @	925 44					
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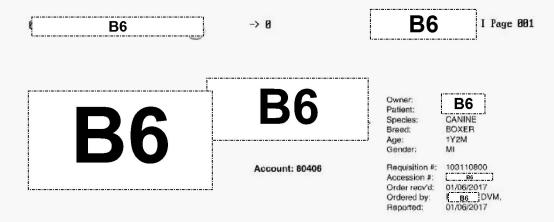
Results to follow upon completion.

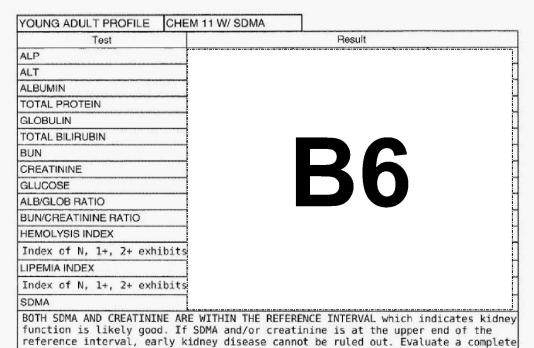
-> Ø **B6** I Page 001 **B6** Owner: Patient: **B6 B6 B6** CANINE Species: Breed: BOXER B6 MI Age: Gender: 103179571 B6 01/12/2017 B6 DVM, 01/12/2017 Requisition #: Account: 80406 Accession #: Order recv'd: Ordered by: Reported; **B6** NOTE FROM NOTE Your microbiology sample has been received.

UA COMPLETION Test Result COLLECTION METHOD COLOR CLARITY SPECIFIC GRAVITY GLUCOSE BILIRUBIN KETONES BLOOD PH **B6** PROTEIN Protein test is performed a test. WBC RBC **BACTERIA** EPI CELL MUCUS CASTS CRYSTALS OTHER SPERM PRESENT UROBILINOGEN

B6 FINAL REPORT

PAGE 1 OF 1

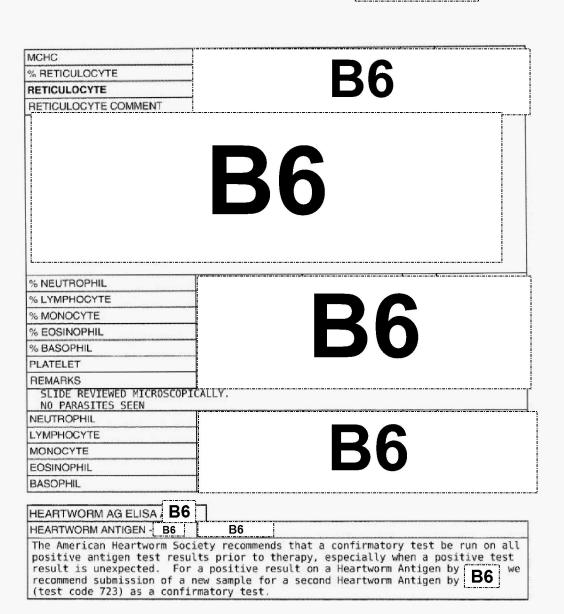




YOUNG ADULT PROFILE	CBC COMPREHENSIVE	
Test		Result
WBC		
RBC		
HGB		
HCT		
MCV		
MCH		
В6		FINAL REPORT - CONTINUED ON NEXT PAGE . PAGE 1

urinalysis to confirm there is no other evidence of kidney disease.

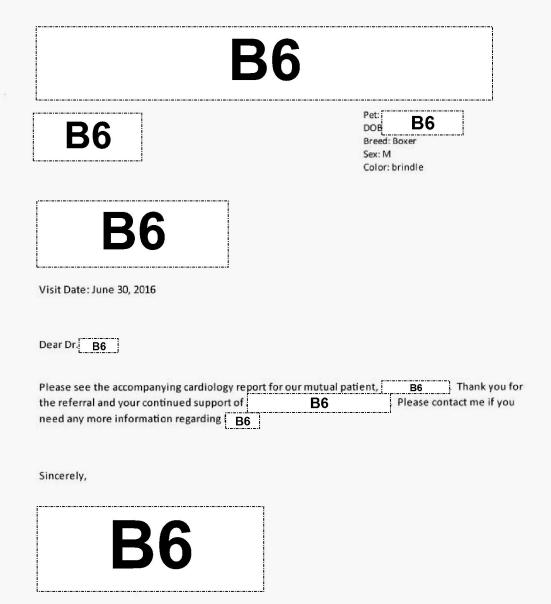
B6 → 8 B6 Page 882



**B6** 

FINAL REPORT

PAGE 2 OF 2



# **SOAP - Cardiology**

# Jun 30, 2016

		Patient	B6	DOB:	В6
<b>B6</b>		Species	:Canine	Age:	В6
DU	United States	Breed:	Boxer	Sex:	М
Ĺ	j	Color:	brindle	Tag:	
Acc. No: 223669		Doctor:	<b>B6</b>	Weight:	55.2 lbs. (25.038 kgs.)
Phone: Home -	B6				

Weight: 55.2 lbs.

## **Prior Medical History**

**B6** 

### **Presenting Complaint**

New patient B6 needs neuter clearance

## **Current Medical History**

General Complaints: Doing well. Good energy, good appetite.

Coughing?: No Sneezing?: No Vomiting: No Polyuria: No Polydipsia: No Diarrhea?: No

Diet?: NowFresh kibble Appetite: Normal

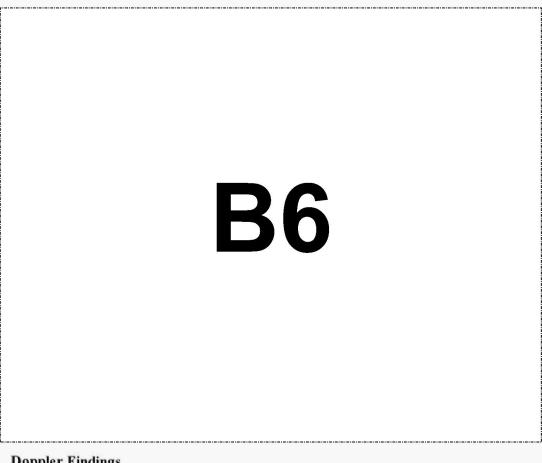
Any collapses or seizures?: No

#### Physical Exam

**B6** 

## Echocardiogram

**B6** 



### **Doppler Findings**

**B6** 

## ECHOCARDIOGRAPHIC DIAGNOSIS:

ECHOCARDIOGRAPHIC DIAGNOSIS:

- -Mildly elevated left and right ventricular outflow tract velocities: suspect normal variant +/- very mild aortic stenosis.
- -Impression of mild left atrial enlargement: r/o age-related, other variant of undetermined cause

**Final Assessment** 

#### Final Diagnosis:

- -Mildly elevated left and right ventricular outflow tract velocities: suspect normal variant +/- very mild aortic stenosis.
- -Impression of mild left atrial enlargement: r/o age-related, other variant of undetermined cause

Diagnostic Recommendations:

No further cardiac testing currently recommended.

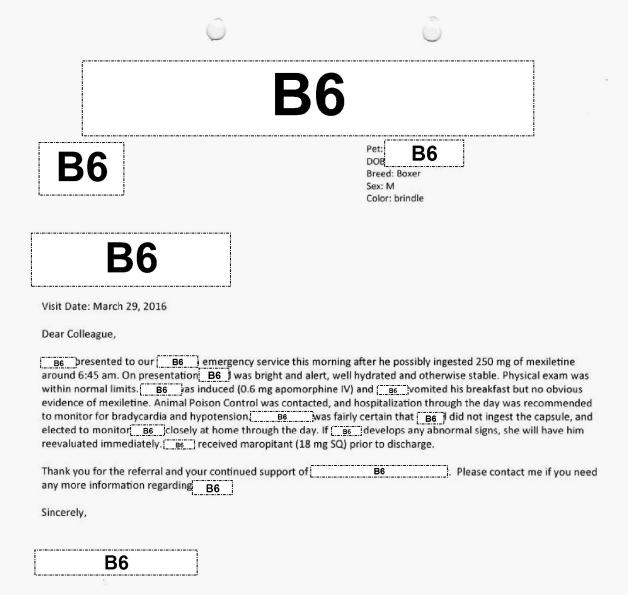
Therapeutic Recommendations:

No cardiac medications currently recommended. B6 appears to be a good anesthetic candidate for future neutering. Out of an abundance of caution (regarding possible mild aortic stenosis), recommend perioperative antibiotics, and avoid agents which would promote tachycardia (ie. use anti-cholinergics only if needed for intraop bradycardia).

Follow-Up:		
Recheck echocardiogram	1	year.

Consulting Cardiologist: B6 DVM; DACVIM (cardiology)

OW	NER B	PATIENT	B6		MITTED:
		Deta	1 1	F	Total
1.	Office	Office Visit Wy			- Total
		☐ After Hours			
_		☐ Forms Completion	1		
2.	Intensive Care				
3.	Vaccinations	☐ D, DH, DHLP, R, P, Bord ☐ FD, FVRC, P, R, FELV			
		☐ FD, FVRC, P, R , FELV			
4.	General	☐ Anal Sacs			
_	Procedures	□ Nail Trim			
_		Injections Organia			
_		☐ Fluid Therapy			
_		☐ IV Cath.			
		□ EKG			
		Transfusion			
		Catheterization (Urinary)			
		☐ Bandaging/Splints			
		☐ Ear Treatment			
		☐ Special Procedure			
5.	Pharmacy	☐ Medication			
_					
_		G Mana Salaa Far	+-+-		
8	Anesthesia	☐ Mass. Sales Tax ☐ Local	<del>                                     </del>		
Ο.	Muestriesia	☐ General	+		
7.	Radiology	Radiograph			
		Procedure, Ultrasound			
8.	Dentistry	☐ Hand Scaling			
		☐ Ultrasonic Scaling			
		☐ Extractions			
9.	Surgery	Q V	-		
0.	Hospitalization	Ward Fee 12 May 15			
_		Prof. Daily Care			-
	Laboratori	Other			
	Laboratory	Azostix			
_		☐ Fecal Flot./Dig. ☐ Blood, HW , FELV test			
_		Profile			
_		☐ CBC Hematology			
_		HT, Wbc, Bun. Glucose, etc.			
		☐ ACTH stim.			
		Urine screen			
		☐ Urinalysis			
		☐ Skin scraping			
		☐ Culture — Sensitivity			
_		☐ Biopsy — Cytology			
		Collection Fee			_
	Missallesson	Other			
2.	Miscellaneous	_ Euthanasia/cremation			
-		Bath			
		<u> </u>	-		



-	-	-			
C.	<i>r</i> 1	Λ	L	311	<b>Text</b>
J	u	$\sim$		-	ICAL

# Mar 29, 2016

	Patient: B6	DOB: B6
DC	Species:Canine	Age: B6 Old
ВО	Breed: Boxer	Sex: M
	Color: brindle	Tag:
Acc. No: 223669	Doctor: B6	Weight: 28.881 lbs. (13.1 kgs.)
Phone: Home - B6	i	··a.

Panting: No Is this patient presenting for trauma?: No

Patient Result - Text: History: 5-6 months old; o has had since puppy. UTD on vaccines. On HW preventative, not yet on flea/tick preventative. No travel history, from B6 . Here previously for pneumonia; also hx of murmur which appears to have resolved at last vet visit. Diet: Fresh now large breed puppy food. Current/chronic meds/supplements: none

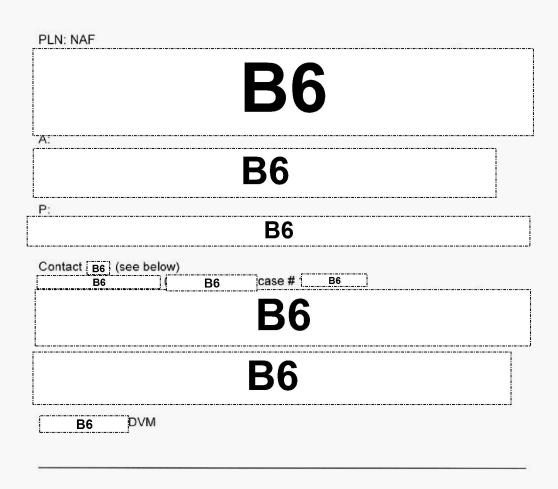
About an hour ago o gave other dog two 250 mg mexiletine tablets with treats; o daughter said she saw B6 ating something that may have been the tablet but o not sure (80% he didn't).

T: 102.0 F P: 128 R: 24 Weight: 18.6 kg

S: BAR, adeq hydration. Normothermic. No overt nausea or discomfort.

0:

EENT: Eyes clear, ears clean AU. No ocular/nasal d/c. Minimal tartar; oral exam wnl.



## **Assessment**

## **Problem List**

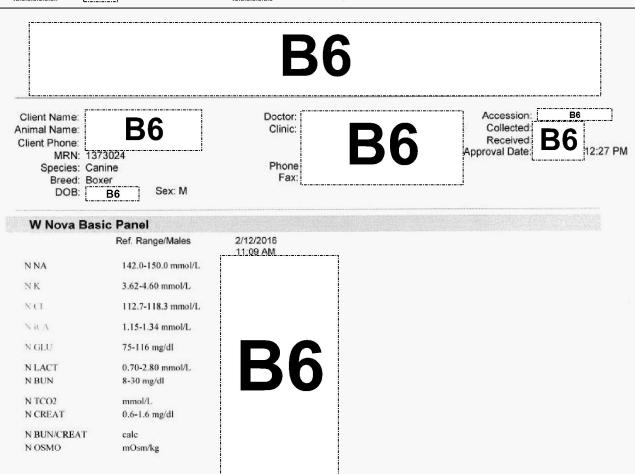
### **Patient Problem List:**

No problems found for period.

# **Diagnosis**

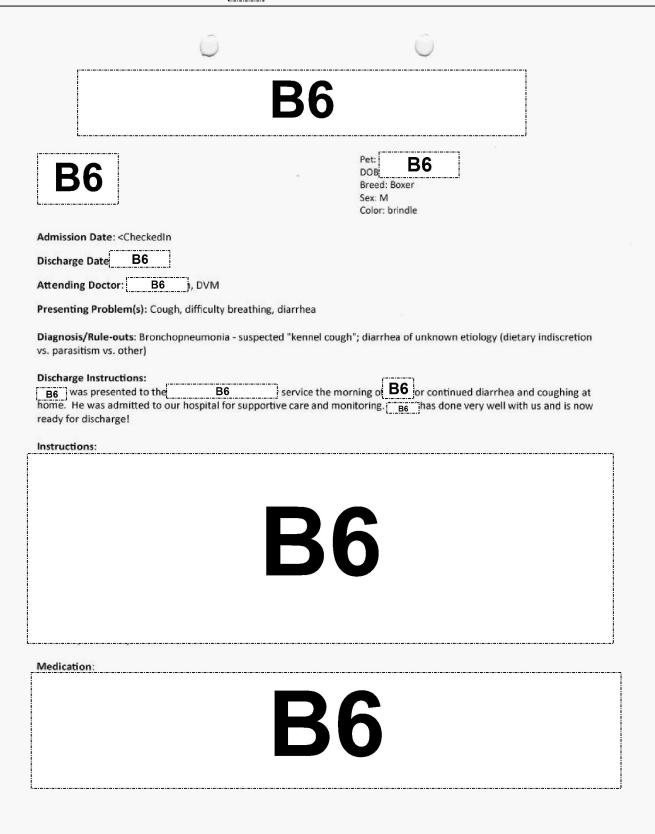
# **Patient Diagnosis:**

No diagnosis found for period.

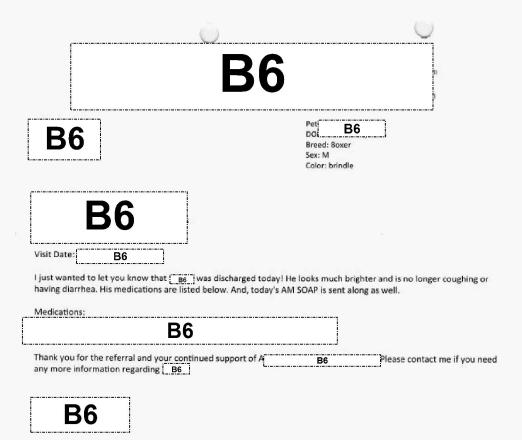


Accession number: B6 BND OF REPORT (Final)

Page 1



<u></u>	
Be	)
Sincerely,	
B6	



B6	

**SOAP - Text** 

**B6** 

**B6** 

Patient: B6
Species: Canine
Breed: Boxer

Color: brindle

Doctor:

Acc. No: 223669

Phone: Home

В6

B6

Weight: 28.881 lbs. (13.1 kgs.)

Weight: 13.1 kgs. Temperature: 101.6 Pulse: 140 Respiration: 28

Panting: No

Is this patient presenting for trauma?: No

Patient Result - Text: Day 2 hospitalization, admitted at noon on B6

B6 was admitted for concerns secondary to increased respiratory effort and cough.

CXR consistent with left lung consolidation secondary to presumed bacterial pneumonia. Overnight, he has done very well and is no longer coughing. He has not had diarrhea (or a bowel movement) since admission. He is receiving medications orally without challenge.

S: BAR, very nice pup, MM pink and moist, CRT < 2 seconds, BCS 5/9

 C: EENT: Eyes clear OU, moderate amount of bilateral mucoid discharge, no aural discharge, normal facial symmetry, underbite which is pronounced, dentition consistent with age

PLN: No peripheral lymphadenopathy CV: I/VI systolic murmur, NSR, f-PSS

Resp: Normal bronchovesicular sounds all fields, possibly slightly decreased sounds on

the left caudal field, no cough noted

ABD: Soft, nonpainful, no organomegaly UG: Externally normal male, testicles descended bilaterally

Integ: Normal hair coat

A:

- 1. Bronchopneumonia, tracheobronchitis
- 2. Diarrhea r/o parasitic vs. dietary indiscretion vs. IBS vs. other
- 3. I/VI systolic murmur innocent vs. pathologic

Current therapy;

**B6** 

Plan:

1. Discharge today with oral medications

B6 DVM

**Assessment** 

**Problem List** 

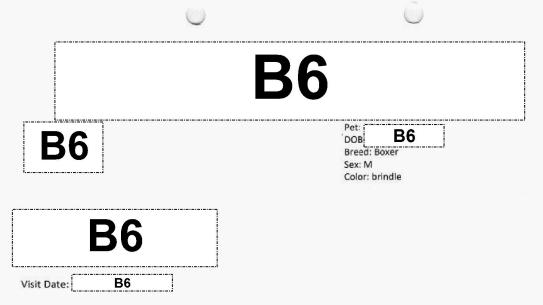
Patient Problem List:

Bronchopneumonia - P6 Diarrhea - B6

## **Diagnosis**

## **Patient Diagnosis:**

No diagnosis found for period.



Dear Colleagues,

was hospitalized in oxygen (mildly dyspnea noted when awake) and started on a high rate of IV fluids, oral doxycycline, IV metronidazole, and IV cerenia. We will keep you update on his progress.

I've attached my SOAP for your records.

B6 , DVM

Weight: 12.9 lbs.

#### **Presenting Complaint**

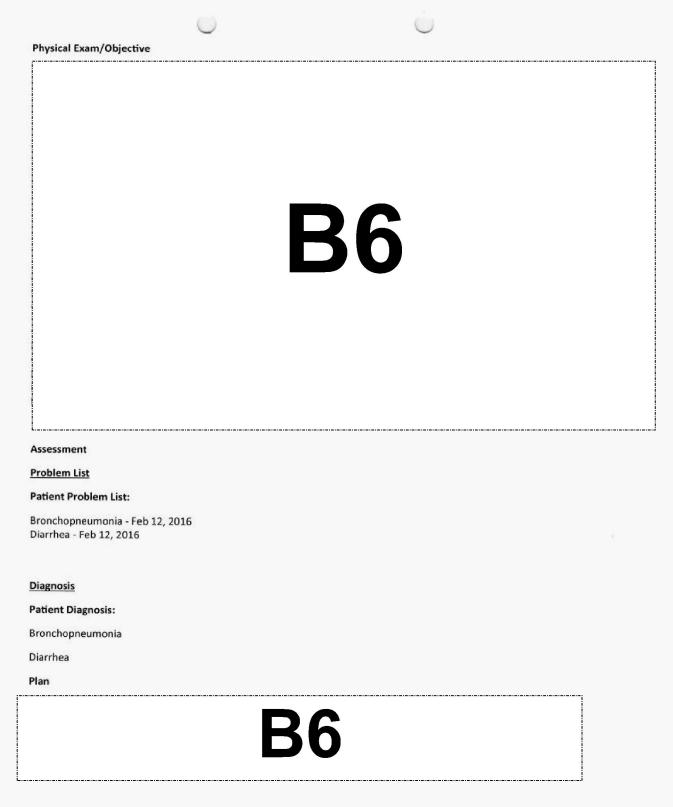
Presenting Complaint: Seen early this morning, concern for continued diarrhea, lethargy and anorexia in the car ride home.

When the owner tried to bring him home, he had absolutely no interest in food, then had a little bit of slightly formed stool in the house, ran outside and had profuse amounts of watery/liquid diarrhea. At the end of the episode was straining as well.

Historically has been a picky eater since they adopted him. A few days ago he began to get progressively more picky-would only finish a bit of his food and leave the rest. However yesterday he had a full appetite and ate everything offered to him.

He started developing a hacking cough around midnight last night - it progressed and became more frequent and the owner got up with him at 3AM today. He had progressed to coughing every few minutes and producing white foamy spittle. No vomiting at all that the owner had noted.

He is a dog that will eat things - he ate a carrot off of a snowman the other day as well as chewed on the twigs that made the arms, He had one vomitus after this (a few days ago) which contained pieces of the carrot and stick but has eaten well since then and had no further upper GI symptoms

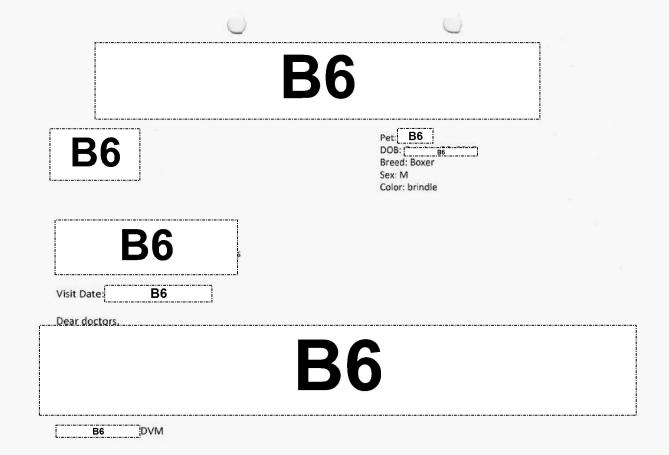


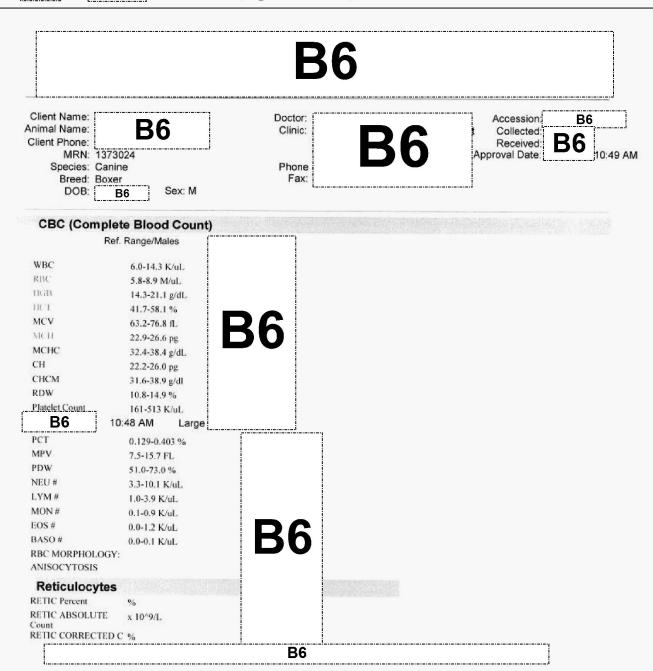
Spoke with owner - due to B6 current state, his lethargy and continued symptoms I recommended hospitalization with supportive care (IV fluids, metronidazole, doxycycline). Discussed possible pneumonia, need for isolation with kennel cough-like symptoms, and oxygen due to mild dyspnea. It is possible that he will not need to be in oxygen shortly, however it is difficult for me to tell at this time. Warned owner that he could get worse before he gets better. A large component of when he can go home will be when he starts to show signs that he eating/drinking/better hydrated. Owner OK with plan.

**B6** 

**B6** 

B6 DVM





Accession number: В6 END OF REPORT (Final)

Page 1

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:** 12/6/2018 3:20:09 AM **Subject:** DCM cases 12/5/2018 2200

Attachments: Acana dog food. Varying diet/formulas over the past 3.5 years.: B6 EON-372923;

Earthborn Meadow Feast dry: Lisa Freeman - EON-372804; Earthborn Meadow Feast dry: Lisa Freeman - EON-372828; Earthborn Meadow Feast dry: Lisa Freeman - EON-372831; Earthborn Meadow Feast dry: Lisa Freeman - EON-372834; Earthborn Meadow Feast dry: Lisa Freeman - EON-372842; Kirkland Signature Nature's Domain Salmon Meal & Sweet Potato Formula for Dogs EON-372864; Pure Vita Holistic Pet Foods Turkey and Sweet Potato

Entree B6 EON-372846; The Honest Kitchen Grain Free Chicken Recipe: B6 EON-372839; Wellness Core Natural Grain Free Dry Dog Food Ocean Whitefish: B6

**B6** EON-372851

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





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Report Details - EON	-372804						
ICSR:	2059619						
Type Of Submission:	Initial						
Report Version:	FPSR.FDA.PETF.V.V1						
Type Of Report:	Adverse Event (a symptom,	reaction or disease associated with the product)					
Reporting Type:	Voluntary						
Report Submission Date	: 2018-12-04 17:08:36 EST						
Reported Problem:	Problem Description:	Littermate diagnosed with reduced cardiac contractility Eating BEG diet (Earthborn) so screened all housemates Echo within normal limits but elevated NT-proBNP and cardiac troponin I Taurine pending Owner changing diet and will recheck in 3 months					
	Date Problem Started:	11/21/2018					
	Concurrent Medical Problem:	Yes					
	Pre Existing Conditions:	History of resection of jejunum and ileum due to intussusception as puppy					
	Outcome to Date:						
Product Information:	Product Name:	Earthborn Meadow Feast dry					
	Product Type:						
	Lot Number:						
	Package Type:						
	Product Use	Description: See diet history					
	Information:	First Exposure 02/01/2018					
		Date:					
	Manufacturer /Distributor Information:						
	Purchase Location Information:						
Animal Information:	Name:	B6					
	Type Of Species:						
		Boxer (German Boxer)					
	Gender:	}					
	Reproductive Status:						
	Pregnancy Status:	<del></del>					
	Lactation Status:						
		27.4 Kilogram					
		3 Years					
	Assessment of Prior Health:	<del></del>					
	Number of Animals Given the Product:	5					
	Number of Animals Reacted:	4					
	Owner Information:	Owner Yes Information					
		provided:  Contact: Name:					
		Phone Email:					
		Address:					
		B6					

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

B4

**Sent:** 12/4/2018 11:04:49 PM

**Subject:** Earthborn Meadow Feast dry: Lisa Freeman - EON-372828

Attachments: 2059621-report.pdf; 2059621-attachments.zip

A PFR Report has been received and PFR Event [EON-372828] has been created in the EON System.

A "PDF" report by name "2059621-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 "2059621-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

**EON Key:** EON-372828

ICSR #: 2059621

EON Title: PFR Event created for Earthborn Meadow Feast dry; 2059621

AE Date	11/20/2018	Number Fed/Exposed	5
Best By Date		Number Reacted	4
Animal Species	Dog	Outcome to Date	Stable
Breed	Boxer (German Boxer)		
Age	3 Years		
District Involved	PFR <b>B6</b> DO		

### **Product information**

**Individual Case Safety Report Number: 2059621** 

**Product Group:** Pet Food

Product Name: Earthborn Meadow Feast dry

**Description:** Eating BEG diet (Earthborn) Echo had subjectively reduced contractility; elevated NT-proBNP and

cardiac troponin I Taurine pending Owner changing diet and will recheck in 3 months

Submission Type: Initial

**Report Type:** Adverse Event (a symptom, reaction or disease associated with the product)

Outcome of reaction/event at the time of last observation: Stable

**Number of Animals Treated With Product: 5** 

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

Product Name	Lot Number or ID	Best By Date
Earthborn Meadow Feast dry		

## **Sender information**

Lisa Freeman 200 Westboro Rd North Grafton, MA 01536 USA

Owner	

**B6** 

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

**B6** 

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

**B6** 

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

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Report Details - EON-	372828			
ICSR:	2059621			
Type Of Submission:	Initial			
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:	2018-12-04 17:59:30 EST			
Reported Problem:	Problem Description:			ad subjectively reduced contractility; elevated faurine pending Owner changing diet and will
	Date Problem Started:	11/20/2018		
	Concurrent Medical			
	Problem:			
	Outcome to Date:	Stable		
Product Information:	Product Name:	Earthborn Meadow F	east dry	
	Product Type:			
	Lot Number:			
	Package Type:	e: BAG		
	Product Use Information:	Description: See diet history in records for more details		
	Manufacturer /Distributor Information:			
	Purchase Location Information:			
Animal Information:	Name:	В6		
	Type Of Species:	i		
		Boxer (German Boxe	er)	
	Gender:			
	Reproductive Status:	3		
	Pregnancy Status:	-4 		
	Lactation Status:	3		
		30.3 Kilogram		
		3 Years		
	Assessment of Prior	3		
	Health:			
	Number of Animals Given the Product:	5		
	Number of Animals Reacted:	4		
	Owner Information:	Owner Information provided:	Yes	
		Contact:	Name: Phone:	D6
			Email:	3 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0
		Address:	B6	
			United States	
	Healthcare Professional Information:	Practice Name: Contact:		gs School of Veterinary Medicine

			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:			
Additional Documents:				
	Attachment:	rpt_medical_record_	preview.pdf	
	Description:	Medical records  Medical Records		



Client: Address B6

Patient: B6

Breed: Boxer
DOB: **B6** 

Species: Canine Sex: Female

**B6** 

**Referring Information** 

**B6** 

**Initial Complaint:** 

Scanned Record

**Initial Complaint:** 

New, boxer 2-3 murmur. ok per Dr

**B6** 

**Initial Complaint:** 

**B6** 

Client: <b>B6</b>			
Initial Complaint:  B6 to over	rsee		
SOAP Text Jun 7 2017 4:07PM	и В6		
6/7/2017 4:30:12 PM	B6		
Initial Complaint: B6			
SOAP Text Nov 29 2017 11:20A	ъм- В6		
Initial Complaint: Recheck B6			
Initial Complaint: Recheck - B6			
SOAP Text Nov 15 2018 2:01P	м- В6		
Disposition/Recommendations	\		

## CUMMINGS Veterinary Medical Center

**B6** 

Client:	B6	
Veterinarian	1:	
Patient ID:	334373	
Visit ID:		

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

## Lab Results Report

	11/15/2018 3:35:43 PM	Accession ID: B6
Test	Results	Reference Range Units
Troponin I Research - FHSA	B6	0 - 0.08 mg/dl
0	4/111	B6
stringsoft		Printed Tuesday, December 04, 2018

Client: **B6** 

Referral and records B6 nimal Medical Center

Referral and records-Dr. **B6 B6**  Client: **B6** 

Referral and records B6

Client: **B6** 

Referral and records-D B6

Client: **B6** Patient: **B6** Referral and records **B6** 

**B6** Patient:

Referral and records **B6 B6**  Signed consent

Signed consent

**B6** Client: Patient: **B6** rDVM Dr. **B6**  rDVM Dr

B6

Client: Patient: **B6** 

rDVM B6

B4, B6

Client **B6** 

rDVM B6

Client: **B6** 

rDVM B6

**B6** 

**B6** 

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## CANINE HOLTER MONITORING REPORT HOLTER MONITOR REPORT **B6**

**B6** 

Page 20/111 **B6** 

Client: **B6**Patient:

В6

**B6** 

Page Laf I

Client: Patient: **B6** 

**B6** 

**B6** 

Client: **B6** 

**B6** 

**B6** 

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Client: **B6**Patient:

B6

## **Holter Monitor Report 11/16/17** CANINE HOLTER MONITORING REPORT HOLTER MONITOR REPORT **B6**

**Holter Monitor Report 11/16/17** 

**Holter Monitor Report 11/16/17** 

**Holter Monitor Report 11/16/17** 

RDVM -

**B6** 

Client: **B6**Patient

RDVM - B6

Client:	RA
Patient:	

RDVM - B6

Client: **B6** 

RDVM - B6

## CANINE HOLTER MONITORING REPORT HOLTER MONITOR REPORT **B6**

Page 50/111

Client: Patient:

**B6** 

Holter report 3/30/18

Client: McIntosh, Maura Patient: Murphy Holter report 3/30/18 **B6** 

Page 59/111

## CANINE HOLTER MONITORING REPORT

## HOLTER MONITOR REPORT

Lab Results B4, B6 **B6** 

76 III

Client: **B6** 

Cardiac Troponin/

**B6** 

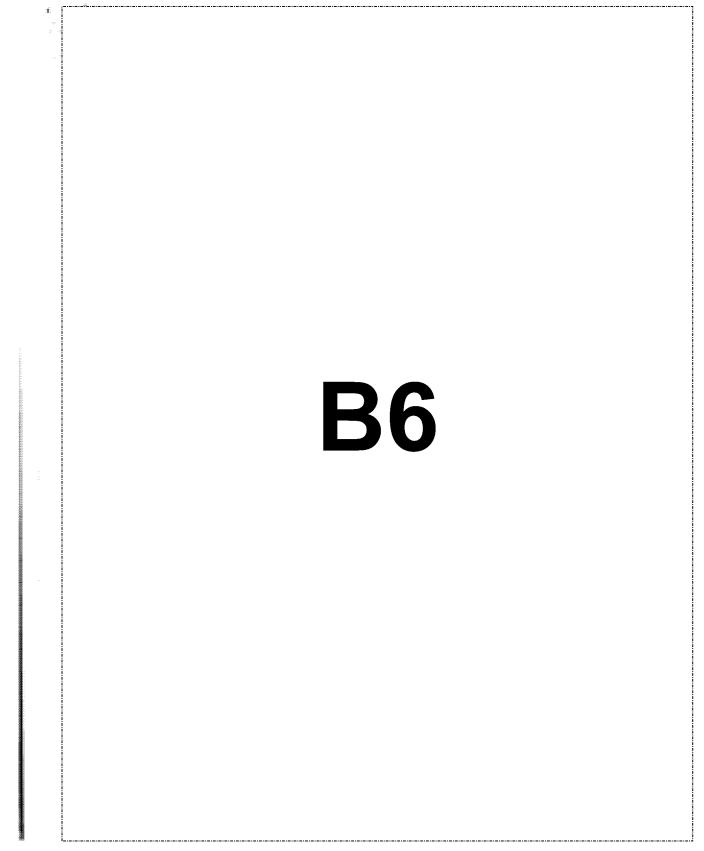
B4, B6

Cardiac Troponin/

**B6** 

B4, B6

**TAURINE Panel 11/15/18** 



**TAURINE Panel 11/15/18** 



Page 75/111

Client: Patient:

**B6** 

## **Best Available Copy**

Diet hx

How would you assess your parts appoints? I thank the pool of the line below that oper tell tell per your perfections of the period of the line below that the period period of the peri		Please answer the folio	WHOSE DISJUICED SH	in alboot wood i		NORTH-
Pope Countries Pope II you'd part's appointed uses the last 1-2 weeker? (Characterist Countries purve amount de laste II Characterist II Characterist III Chara		B6			oday's date	1412152
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Client:
Patient:

**B6** 

## Vitals Results

3/14/2016 3:29:53 PM	Weight (kg)	
10/20/2016 2:23:42 PM	Weight (kg)	
11/29/2017 10:41:26 AM	Weight (kg)	<b>B6</b>
4/5/2018 2:45:48 PM	Weight (kg)	<b>D</b>
11/15/2018 2:01:47 PM	Weight (kg)	

HOLTER MONITOR REPORT

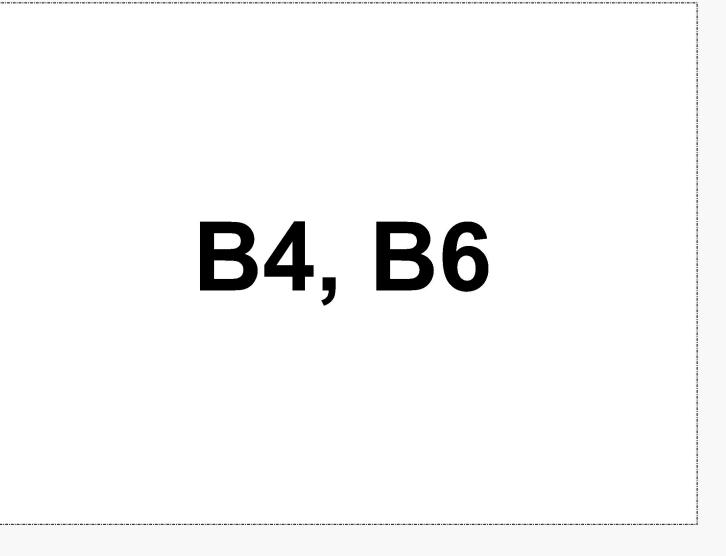
Client: Patient: **B6** 

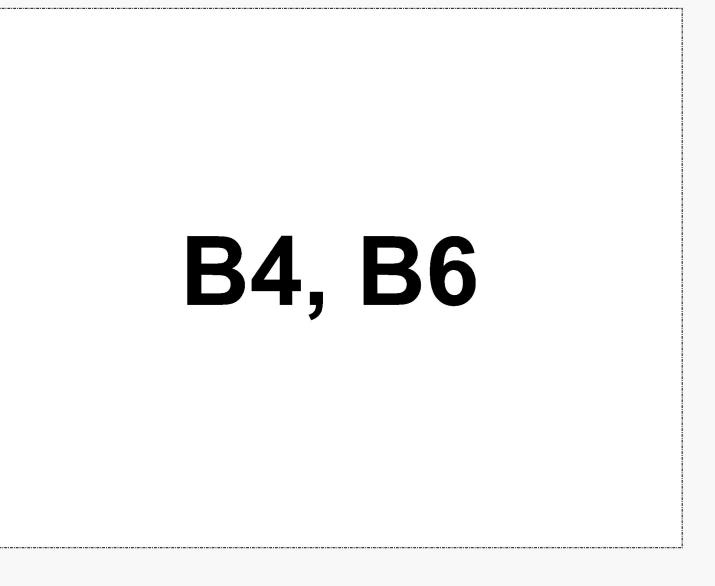
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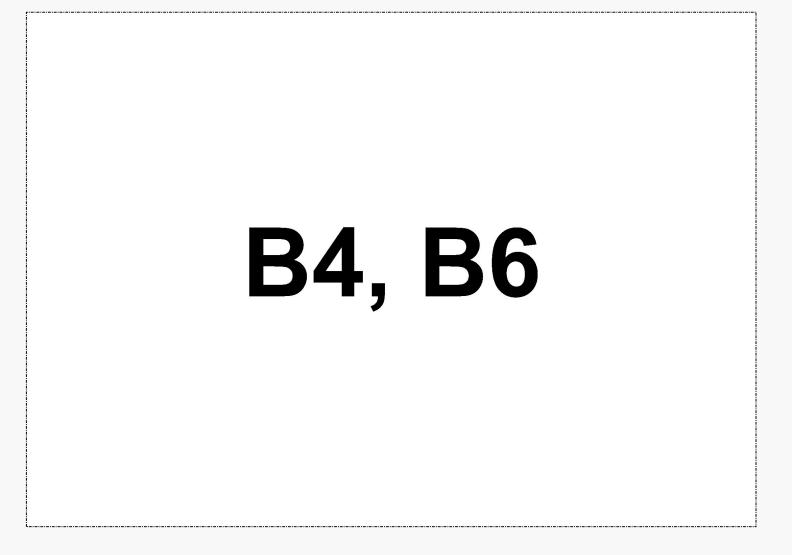
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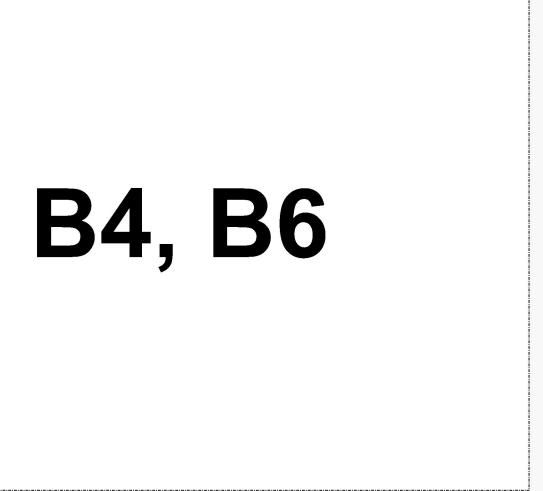
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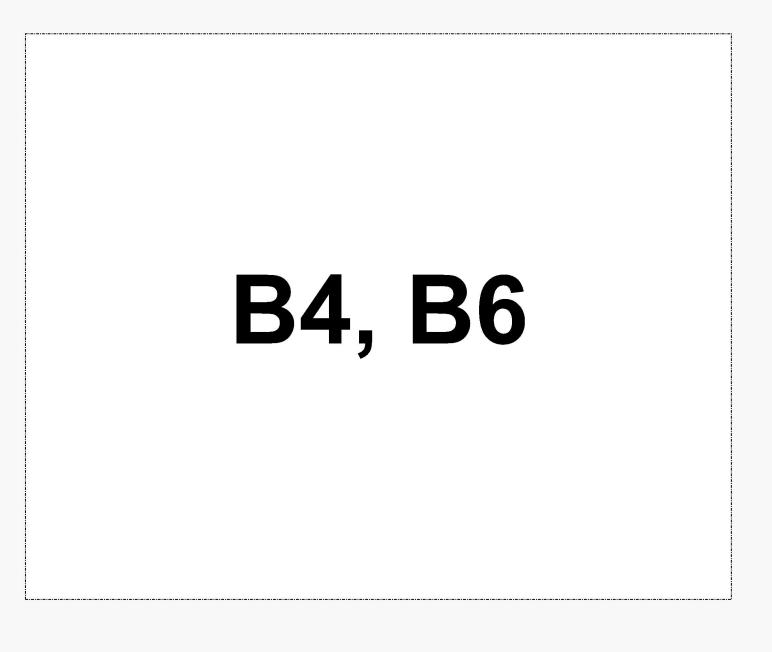
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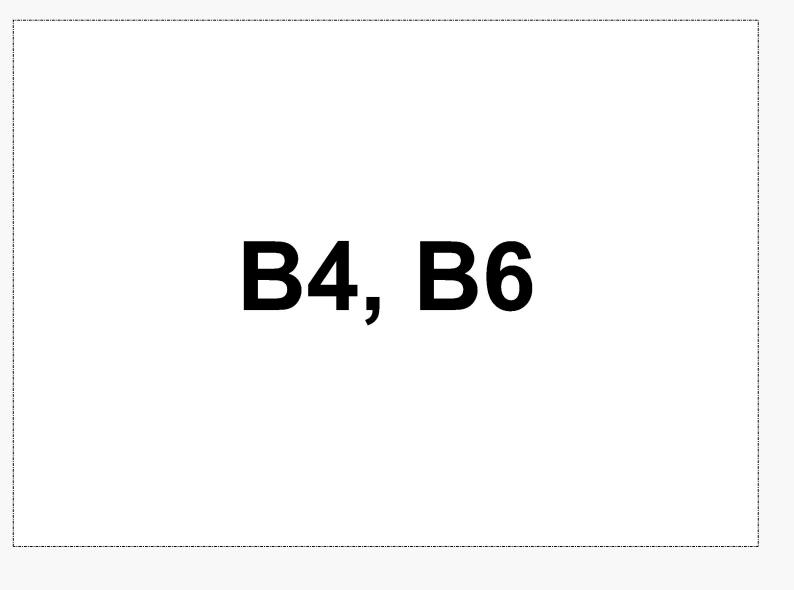












From: PFR Event creation@fda.hhs.gov> To: Cleary, Michael \*; HQ Pet Food Report Notification; **B6** Sent: 12/4/2018 11:12:44 PM Subject: Earthborn Meadow Feast dry: Lisa Freeman - EON-372831 Attachments:

2059622-report.pdf; 2059622-attachments.zip

A PFR Report has been received and PFR Event [EON-372831] has been created in the EON System.

A "PDF" report by name "2059622-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 "2059622-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

**EON Key:** EON-372831

ICSR #: 2059622

**EON Title:** PFR Event created for Earthborn Meadow Feast dry; 2059622

AE Date	11/15/2018	Number Fed/Exposed	5
Best By Date		Number Reacted	4
Animal Species	Dog	Outcome to Date	Stable
Breed	Boxer (German Boxer)		
Age	3 Years		
District Involved	PFR <b>B6</b> DO		

#### **Product information**

**Individual Case Safety Report Number: 2059622** 

**Product Group:** Pet Food

Product Name: Earthborn Meadow Feast dry

**Description:** Daughter diagnosed with reduced cardiac contractility and **B6** 

**B6** Eating BEG diet (Earthborn) so screened all housemates Echo within normal limits but elevated

NT-proBNP and cardiac troponin I Taurine pending Owner changing diet and will recheck in 3 months

**Submission Type:** Initial

**Report Type:** Adverse Event (a symptom, reaction or disease associated with the product)

Outcome of reaction/event at the time of last observation: Stable

**Number of Animals Treated With Product: 5 Number of Animals Reacted With Product: 4** 

Product Name	Lot Number or ID	Best By Date
Earthborn Meadow Feast dry		

#### **Sender information**

Lisa Freeman 200 Westboro Rd North Grafton, MA 01536 USA

Owner	inforn	nation

**B6** 

To view this PFR Event, please click the lin	nk below:
В6	

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

<b>B6</b>	
	-

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-	3			
ICSR:	2059622			
Type Of Submission:	Initial			
Report Version:	FPSR.FDA.PETF.V.V1			
Type Of Report:	3	reaction or disease a	associated with the product)	
Reporting Type:	Voluntary			
Report Submission Date:	2018-12-04 18:08:14 EST			
Reported Problem:	Problem Description:	<b>B6</b> housemates Echo w	with reduced cardiac contractility ( B6 Eating BEG diet (Earthborn) so screened an ithin normal limits but elevated NT-proBNP and cardiac ending Owner changing diet and will recheck in 3 months	
	Date Problem Started:	11/15/2018		
	Concurrent Medical Problem:			
	Outcome to Date:	Stable		
Product Information:	Product Name:	Earthborn Meadow I	Feast dry	
	Product Type:			
	Lot Number:	<u> </u>		
	Package Type:	BAG		
	Product Use Information:	Description:	See diet history in medical record for more info	
	Manufacturer /Distributor Information:			
	Purchase Location Information:			
Animal Information:	Name:	B6		
	Type Of Species:	Dog		
	Type Of Breed:	d: Boxer (German Boxer)		
	Gender:	Female		
	Reproductive Status:	Intact		
	Pregnancy Status:	Not pregnant		
	Lactation Status:	Not lactating		
	Weight:	29.1 Kilogram		
		3 Years		
	Assessment of Prior			
	Health: Number of Animals Given the Product:	5		
	Number of Animals Reacted:	3		
	Owner Information:	Owner Information	Yes	
		provided:		
		Contact:	Phone Email	
		Address:	B6	
			United States	
	Healthcare Professional Information:	Practice Name: Contact:	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	
nder Information:	Name:	Lisa Freeman		
		200 Westboro Rd North Grafton Massachusetts 01536 United States		
	Contact:		5088874523	
			lisa.freeman@tufts.edu	
	Permission To Contact Sender:			
	Preferred Method Of Contact:	Email		
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# Cummings Veterinary Medical Center

**B6** 

Client: Address:

**B6** 

All Medical Records

Patient: **B6**Breed: Boxer

DOB: B6

Species: Canine Sex: Male

(Neutered)

#### **Referring Information**

**B6** 

Client: Patient:

**B6** 

#### **Initial Complaint:**

Scanned Record

**SOAP Text** Nov 20 2018 12:22PM

**B6** 

#### **Initial Complaint:**

DCM Study

**SOAP Text** Nov 20 2018 1:10PM

**B6** 

#### **Disposition/Recommendations**

## **B6**

Client: **B6**Veterinarian:
Patient ID: 433149
Visit ID:

Patient:	B6
Species:	Canine
Breed:	Boxer
Sex:	Male (Neutered)
Age:	B6 Years Old

### Lab Results Report

	11/20/2018 5:45:23 PM	Accession ID: B6	
Test	Results	Reference Range	Units
Troponin I Research - FHSA	B6	0 - 0.08	mg/dl

3/13 **B6**stringsoft

Printed Tuesday, December 04, 2018

Client: **B6** 

CARDIAC TROPONIN

**B6** 

Client: B6

CARDIAC TROPONIN

**B6** 

#### Diet hx

Pet	's name B6			Today's date	20 NOV 2
١.	How would you assess your pet's appetite? (mark the				
	Example: Poor			ellent	ro appointoj
	Poor		Exc	ellent	
	Have you noticed a change in your pet's appetite over the same amount as usual    Seems to prefer different foods than usual    Other	ess than usual	s? (check all that □Eats more tha	apply) n usual	
Ş	Over the last few weeks, has your pet (check one) □Lost weight □Gained weight □Gayed about	the same weight <b>□</b>	IDon't know		
	Please list below <u>ALL</u> pet foods, people food, treats, currently eats. Please include the brand, specific productions are considered to the production of t	snack, dental chews duct, and flavor so v	s, rawhides, and a ve know exactly v	any other food it what you pet is e	em that your p
	Examples are shown in the table - please provide en	ough detail that we	could go to the s	tore and buy the	exact same f
ſ	Food (include specific product and flavor)	Form	Amount	How often?	Fed since
Ī	Nutro Grain Free Chicken, Lentil, & Sweet Potato Add		1 ½ cup	2x/day	Jan 2018
1	85% lean hamburger	microwaved	3 oz	1x/week	Jan 2015
	Pupperoni original beef flavor	treat	1/2	1x/day	Aug 2015
	Rawhide	treat	6 inch twist	1x/week	Dec 2015
F	EARTHBORN - MEADOWPEAST	DRY	~11/20+	2x DAY	FEB 2016
	Taurine	example: vitamins, which ones and give nd/Concentration	e brands and amo	ounts:	other ount per day
	Example: Vitamin C SUPPLEMENT NUPPO - DOC	Nature's Bounty		500 mg table	ets – 1 per da   TBSP)  -2

**ECG** from Cardio

**B6** 

**ECG** from Cardio

**B6** 

**ECG** from Cardio

**Patient History** 

