From: Jones, Jennifer L </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0F6CA12EAA9348959A4CBB1E829AF244-JENNIFER.JO>
To: Reimschuessel, Renate
CC: Peloquin, Sarah
Sent: 6/13/2019 2:35:36 PM
Subject: RE: FDA consumer report - CC-156319 B6

Thank you!

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

From: Reimschuessel, Renate
Sent: Thursday, June 13, 2019 10:31 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Peloquin, Sarah <Sarah.Peloquin@fda.hhs.gov>
Subject: FW: FDA consumer report - CC-156319 B6

06-13-2019 – RR called in response to owner's call. The dog has been on grain free diets since being a puppy. Was fed 5 earth born and Natural balance sweet potato in the past.
Has no clinical signs now, but was in congestive heart failure at diagnosis.
Has been on a heart monitor, has had an echo and will be obtaining 6-month echo in next few weeks.

Owner also volunteered that she would want necropsy done and said she would contact Josh Stern and wanted protocol for the procedure. I suggested Vet-LIRN contact her vet with the info if needed.
RR requested records and diet history (to be written by owner) to be sent via email.
Provided Vet-LIRN procedures for owners.

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

From: Reimschuessel, Renate
Sent: Thursday, June 13, 2019 10:29 AM
To: B6
Subject: FDA consumer report - CC-156319- B6

Dear Ms. B6

Thank you for submitting your consumer complaint to FDA. I'm sorry to hear about B6 heart condition. As we discussed this morning, as part of FDA's investigation we'd like to request:

- **Full Medical Records**
  - Please contact your veterinarians and ask them to email (preferred) or fax (301-210-4685) a copy of B6 **entire** medical history (not just this event) and the cardiologist evaluations, echos and radiographs.

- **Diet history**
  - Please provide me B6 diet history – including his main diet over the years and also any treats and snacks that may be periodically given.

I attached a copy of our Vet-LIRN network procedures. The procedures describe how Vet-LIRN operates and how owners help with our case investigations. With respect to a possible postmortem evaluation, thank you so much for your willingness to participate if B6 were to pass. We can work with your veterinarian and provide the protocols that we are currently following.

Please respond to this email to confirm that you received it.
Sincerely,
Renate Reimschuessel

Renate Reimschuessel V.M.D. Ph.D.
Director: Vet-LIRN
(Veterinary Laboratory Investigation and Response Network)
Center For Veterinary Medicine, FDA,
8401 Muirkirk Road, Laurel, MD 20708
Phone 1-240-402-5404 Fax 301-210-4685
EMAIL: renate.reimschuessel@fda.hhs.gov

Vet-LIRN

http://www.fda.gov/AnimalVeterinary/ScienceResearch/ucm247334.htm

Phish-Pharm

http://www.fda.gov/AnimalVeterinary/ScienceResearch/ToolsResources/Phish-Pharm/default.htm

Aquaculture

http://www.fda.gov/AnimalVeterinary/ScienceResearch/ResearchAreas/ucm130892.htm

06-13-2019 – RR called in response to owner's call. The dog has been on grain free diets since being a puppy. Was fed 5 earth born and Natural balance sweet potato in the past.

Has no clinical signs now, but was in congestive heart failure at diagnosis.

Has been on a heart monitor, has had an echo and will be obtaining 6-month echo in next few weeks.

Owner also volunteered that she would want necropsy done and said she would contact Josh Stern and wanted protocol for the procedure. I suggested Vet-LIRN contact her vet with the info if needed.

RR requested records and diet history (to be written by owner) to be sent via email.

Provided Vet-LIRN procedures for owners.

From: Reimschuessel, Renate </O=FDA/OU=FIRST ADMINISTRATIVE GROUP/CN=RECIPIENTS/CN=RREIMSCH>
To: Carey, Lauren; Jones, Jennifer L; Rotstein, David; Ceric, Olgica; Palmer, Lee Anne; Queen, Jackie L
CC: Nemser, Sarah
Sent: 4/3/2017 11:22:23 AM
Subject: RE: Nature's Variety Instinct Limited Ingredient diet Lamb Meal & Peas Formula: B6 B6 EON-308715

B5

I agree this case is a NFA – but I'm wondering B5

B5

Something to look at during our strategic planning.

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

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From: Carey, Lauren
Sent: Monday, April 03, 2017 7:06 AM
To: Jones, Jennifer L; Rotstein, David; Ceric, Olgica; Palmer, Lee Anne; Queen, Jackie L; Reimschuessel, Renate
Subject: RE: Nature's Variety Instinct Limited Ingredient diet Lamb Meal & Peas Formula: B6 - EON-308715

Interesting! Thanks Jen

From: Jones, Jennifer L
Sent: Monday, April 03, 2017 7:05 AM
To: Rotstein, David; Carey, Lauren; Ceric, Olgica; Palmer, Lee Anne; Queen, Jackie L; Reimschuessel, Renate
Subject: RE: Nature's Variety Instinct Limited Ingredient diet Lamb Meal & Peas Formula: B6 - EON-308715

Just found an article for this: http://www.vetmed.ucdavis.edu/vmb/labs/aal/pdfs/Torres.pdf

"Taurine (Tau) deficiencies have been associated with the feeding of commercial lamb-meal and rice diets to dogs. We hypothesized that the poor digestibility of some lamb-meals may limit sulphur amino acids availability for Tau synthesis and/or increase of Tau degradation in the gut. Urinary Tau increased by 54% when methionine (Met) was supplemented to Diet A (lamb-based died), supporting the suggestion of a low bioavailability of sulphur amino acids and/or an increased fecal loss of Tau in dogs consuming Diet A."

Very interesting report, but I'd agree-NFA. Likely B5

B5

Jennifer Jones, DVM
Veterinary Medical Officer

From: Rotstein, David
Sent: Monday, April 03, 2017 7:02 AM
To: Carey, Lauren; Ceric, Olgica; Jones, Jennifer L; Palmer, Lee Anne; Queen, Jackie L; Reimschuessel, Renate
Subject: RE: Nature's Variety Instinct Limited Ingredient diet Lamb Meal & Peas Formula: B6 - EON-308715

Lauren,

I think NFA. B5

B5

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
CVM OSC/DC/CERT
7519 Standish Place, RM 120
240-402-5613 (Office) (NEW NUMBER)
B6 (BB)

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From: Carey, Lauren
Sent: Monday, April 03, 2017 6:55 AM
To: Ceric, Olgica; Jones, Jennifer L; Palmer, Lee Anne; Queen, Jackie L; Reimschuessel, Renate; Rotstein, David
Subject: FW: Nature's Variety Instinct Limited Ingredient diet Lamb Meal & Peas Formula: B6 - EON-308715

8.5yo Golden Retriever diagnosed with cardiac disease: valvular disease, decreased contractility, CHF. Taurine blood levels very low - cardiologist worried there is a relation to food.

Food is raw ("naturally preserved") so I worry more about bacteria around the dog's diseased valves, but any desire to follow-up for taurine, etc.?

From: PFR Event [mailto:pfreventcreation@fda.hhs.gov]
Sent: Thursday, March 30, 2017 3:56 PM
To: Cleary, Michael *; HQ Pet Food Report Notification B6
Subject: Nature's Variety Instinct Limited Ingredient diet Lamb Meal & Peas Formula: B6 - EON-308715

A PFR Report has been received and PFR Event [EON-308715] has been created in the EON System.

A "PDF" report by name "1064844-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report:

EON Key: EON-308715
ICSR #: 1064844
EON Title: PFR Event created for Nature's Variety Instinct Limited Ingredient diet Lamb Meal & Peas Formula; 1064844

AE Date	03/09/2017	**Number Fed/Exposed**	1
Best By Date		**Number Reacted**	1
Animal Species	Dog	**Outcome to Date**	Stable
Breed	Retriever - Golden		
Age	8.5 Years		
District Involved	PFR-New England DO		

Product information
Individual Case Safety Report Number: 1064844
Product Group: Pet Food
Product Name: Nature's Variety Instinct Limited Ingredient diet Lamb Meal & Peas Formula
Description: Presented to local veterinarian for gagging cough. Regular veterinarian concerned about new heart murmur and large heart on ultrasound and referred to Emergency and Cardiology services at B6. Cardiac workup showed degenerative valvular disease, but also very depressed cardiac contractility and early congestive heart failure. Taurine level (plasma) was checked to rule out taurine deficiency as cause of depressed cardiac contractility and level was extremely low B6 nmol/mL (normal is 60-120 nmol/mL; critical is < 40 nmol/mL). Concerned that diet may not have sufficient precursors to taurine.
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
Nature's Variety Instinct Limited Ingredient diet Lamb Meal & Peas Formula		

Sender information

B6

USA

Owner information

B6

To view this PFR Event, please click the link below:
https://eon.fda.gov/eon//browse/EON-308715

To view the PFR Event Report, please click the link below:
https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jspa?decorator=none&e=0&issueType=12&issueId=323753

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From: Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>
To: B6
Sent: 8/23/2018 3:50:49 PM
Subject: 800.267-FDA Case Investigation for B6 and B6 (EON-308715)
Attachments: 02-Vet-LIRN-NetworkProceduresVets-12.22.2015.pdf; 03-Vet-LIRN-Network ProceduresOwners-12.22.2015.pdf

Good morning Dr. B6
Thank you for submitting your consumer complaint to FDA. I'm sorry to hear about B6 illness.
As part of our investigation, we'd like to request:

- **Full Medical Records**
  - Please email (preferred) or fax (301-210-4685) a copy of B6 **entire** medical history (not just this event), including any referral diagnostics.
- **Have you submitted a report for** B6 I was forwarded the medical records and told from Dr. Lisa Freeman that you may have submitted a complaint. I cannot seem to locate it within our system.

I attached a copy of our Vet-LIRN network procedures. The procedures describe how Vet-LIRN operates and how veterinarians help with our case investigations.
Please respond to this email so that we can initiate our investigation.
Thank you kindly,
Dr. Jones

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

Network Procedures for Veterinary Laboratory Investigation and Response Network Case Investigations

Network Procedures for Veterinarians

1. Introduction

The purpose of this Network Procedure is to facilitate basic interactions between the Vet-LIRN Program Office (VPO) and veterinarians participating in Vet-LIRN case investigations. General procedures such as information flow, sample handling procedures, submission of reports and billing for services are discussed. The focus of most Vet-LIRN case investigations is on diagnostic samples, although occasionally animal food samples will also be submitted. Animal food testing conducted after receiving a consumer complaint is typically handled by FDA's Office of Regulatory Affairs (ORA) Laboratories or accredited laboratories.

1.1 In the case of Vet-LIRN investigations, the government is the client.

1.1.1 The government is requesting assistance in its investigation, and is requesting tests or services to be performed by your clinic during this investigation.

1.1.2 The government will pay for these services.

1.1.3 The owner is helping with the government's investigation of a regulated product.

1.1.4 The goal of the investigation is to determine if the product is at fault and why.

1.1.5 The government's investigation may not provide a definitive diagnosis for the patient's illness.

2. Case Background – Consumer complaint

2.1 Vet-LIRN obtains information about the cases we investigate from 3 main sources,

2.1.1 Consumer complaints (cc) - obtained by FDA Consumer Complaint Coordinators by phone

2.1.2 Electronic consumer complaint submissions through FDA's Food Safety Reporting Portal, and

2.1.3 Vet-LIRN partner laboratories.

NOTE: *Generally, the information received in a consumer complaint* ***is not*** *kept confidential. In most cases, only protected personal information (such as names and addresses) is withheld in an effort to prevent the complaint from being traced back to the individual who submitted it.*

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3. Communications

3.1 VPO will discuss the case with the referring veterinarian and or the owner.

3.2 VPO evaluates the case history and determines a need for follow up testing to determine if the food (or drug) is the cause of the illness or death.

3.3 VPO contacts the appropriate member laboratory(-ies) (chosen based on location and capabilities) and provides initial information

3.3.1 In some cases only partial history is available

3.3.2 Follow up information will be sent as it becomes available.

3.4 VPO proposes the tests to be conducted and prepares billing documents.

3.5 VPO makes arrangements with the veterinarian to obtain and ship samples.

3.5.1 VPO receives test results and forwards the results to the veterinarian who will then communicate the results to the owner.

4. Case history

4.1 A complete medical history is essential,

4.1.1 age, sex, breed, animal's ID/name,

4.1.2 other animals affected,

4.1.3 duration of problem, lesion distribution (diagrams or photos are welcome),

4.1.4 treatment of problem (especially dose and duration of therapy) and response to treatment.

4.1.5 concomitant drugs or dietary supplements administered (not used for treatment of the reaction, but administered for other reasons at the same time or within a short time of the problem occurrence).

4.2 Vet-LIRN Case Numbers:

4.2.1 Include Vet-LIRN case number in all correspondence.

4.2.2 E-mail: include the Vet-LIRN case number as the first part of the subject line. This will help archiving data for each case.

4.3 Electronic submission of medical records and laboratory results is preferred.

4.4 Histories can also be submitted by FAX to Vet-LIRN (301-210-4685).

4.5 Information about follow-up visits related to the investigation and additional laboratory reports should be provided as soon as possible. Phone calls are very useful for

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discussing cases in depth, but should be followed up with the medical records and lab reports.

4.5.1 Due to time difference around the country, email communication is often the best way to assure information is transferred in a timely manner.

5. Services Requested by VPO

5.1 Services typically tests will fall into 3 categories:

5.1.1 Office Examination

5.1.2 Clinical laboratory samples

5.1.3 Pathology

5.2 Office Examination:

5.2.1 To evaluate the current status of the patient.

5.2.2 To obtain samples from the patient for further analysis (blood, urine, feces).

5.3 Clinical Laboratory Samples:

5.3.1 VPO may ask for repeat analysis of new samples to be run either by the veterinary hospital, or by its usual testing laboratory.

5.3.2 Typical tests include clinical hematology, microbial cultures, urinalysis, and fecal examination.

5.3.3 Additional testing may be requested and the samples sent to a Vet-LIRN network laboratory.

5.4 Pathology:

5.4.1 Either submit the entire carcass or conduct a routine necropsy examination. Record your findings in detail and submit. Histopathology and microbiological cultures as appropriate.

5.4.1.1 Describe all lesions – location, color, size, texture.

5.4.1.2 Culture lesions or intestinal contents as deemed appropriate based on the history.

5.4.1.3 Save tissues for histopathology- be sure to use 10:1 formalin to tissue mass.

5.4.2 Histopathology tissues (preserve in 10% neutral buffered formalin 10:1 ratio fixative to tissue):

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5.4.2.1 thyroid, thymus, lung, heart, liver, spleen, adrenal, kidney, pancreas, stomach, duodenum, jejunum, ileum, colon, urinary bladder, skeletal muscle, brain.

5.4.2.2 Request a duplicate set of H&E for submission to VPO for archiving.

5.5 Toxicology:

5.5.1 Freeze and hold tissues if there is any indication that a toxic substance may be involved:

5.5.1.1 brain (for organophosphates and carbamates),

5.5.1.2 eyes, liver, kidney, brain, stomach content, fat,

5.5.1.3 if available, serum, EDTA blood, urine.

5.5.2 Following a review of histopathology, VPO may select tissues to be analyzed and request that tissues be sent to a Vet-LIRN laboratory.

5.5.3 When the case is closed by VPO, samples can be disposed of. When in doubt, please ask.

5.5.3.1 The animal's remains can be disposed of following the laboratories' customary procedures.

6. Sample submissions

6.1 Normally, VPO prefers that the veterinarian, not the pet owner submit samples.

6.2 Arrangements for transport should be made with the VPO (see additional shipping instructions).

6.3 A Vet-LIRN Sample Submission Form, given by VPO to the veterinarian, should be provided to the veterinarian and should accompany all samples being sent to our Vet-LIRN laboratory, listing the recommended tests.

6.4 A Shipping Inventory Sheet, given by VPO to the veterinarian, should also be provided by VPO and should be submitted with all samples. This form will be filled out and faxed to the VPO (301-210-4685) by the receiving Vet-LIRN laboratory.

6.5 Vet-LIRN case numbers should be provided by the VPO and should be included on all samples and reports.

6.5.1 Rarely, an owner will deliver a specimen or an animal for necropsy directly to the participating laboratory. Vet-LIRN should notify the lab to expect the owner if this happens and will provide appropriate forms.

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7. Sample types that Vet-LIRN may request from the Veterinarian

7.1 Entire bodies (fresh or frozen)

7.2 Organs from necropsy (fresh, frozen or formalin fixed)

7.3 Clinical samples (serum, blood, urine, feces, biopsy samples, cultures)

7.4 Food samples (open bag products from home)

8. Reporting

8.1 All reports from Vet-LIRN testing labs are submitted to VPO.

8.2 VPO will forward reports to the veterinarian, who should discuss the results with the owner.

8.3 If appropriate, VPO will forward reports to the owner.

9. Communications with Owners

9.1 General:

9.1.1 VPO usually will have contacted the owner to request permission and assistance in the investigation.

9.1.2 Vet-LIRN's investigation is focused on determining if a regulated product is the cause of the animal's illness. The testing requested by Vet-LIRN may not provide a definitive diagnosis

9.1.3 VPO will provide testing results to the veterinarian for communication to the owner. This ensures that:

9.1.3.1 Owners can be counseled on the interpretation of the test results,

9.1.3.2 Appropriate medical follow-up care based on test results can be recommended by the owner's veterinarian.

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10. Billing

10.1 Vet-LIRN VPO can only pay for services which were requested and approved by VPO. Vet-LIRN cannot pay for treatment, or for diagnostic testing outside of the scope of the investigation.

10.2 Procurement and Billing Process: The following process needs to be followed in order to adhere to government regulations.

10.2.1 The veterinarian must provide estimates so a Purchase Request can be prepared. Estimates should include items such as office visit(s), in-house diagnostic test costs, biopsy or pathology costs and additional charges such as potential shipping charges.

10.2.2 A billing contact must be provided: include name, address, telephone + fax numbers, and email.

10.2.3 Approved Purchase Request is required prior to beginning service.

10.2.4 Additional services may only be initiated after authorized by Vet-LIRN, but must first be approved by VPO with an additional Purchase Request.

10.2.5 Hospitals must provide an invoice to Vet-LIRN upon the completion of work before they can be paid. VPO is tax exempt. Taxes should be removed from all charges. The invoice must include the Vet-LIRN case number.

FDA-CVM-FOIA-2019-1704-005962

Network Procedures for Veterinary Laboratory Investigation and Response Network Case Investigations

Network Procedures for Owners

The purpose of this Network Procedure is to help you, the owner, understand how the Veterinary Laboratory Investigation and Response Network (Vet-LIRN) Program Office conducts case investigations (follow up to consumer complaints).

The following items are explained below:

- General Introduction
- Billing
- Step by Step Process
- Types of Services and Tests

1. General Introduction:

1.1. What is the goal of the case investigation?

The goal of the case investigation is to determine if the product is causing your pet's illness. Our case investigation MAY NOT provide a definitive diagnosis for your pet's illness, although we may rule out several other potential reasons for your pet's illness.

1.2. What is the focus of a case investigation?

Most case investigations focus on diagnostic samples (such as blood, urine or tissue from the pet), although we occasionally request and test pet food samples.

1.3. What is my veterinarian's role during the case investigation?

Your veterinarian helps our investigation into FDA- regulated products by providing information about your pet's medical history and by obtaining any diagnostic samples like blood, urine or tissue.

1.4. What will Vet-LIRN ask of me during a case investigation?

We may ask that your veterinarian perform certain tests or services or provide diagnostic samples to FDA or a Vet-LIRN cooperating laboratory.

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1.5. Will Vet-LIRN pay for tests or services requested?

Yes, we will pay veterinarians or laboratories *for tests or services requested by Vet-LIRN* and approved through our government purchasing system. We cannot, however, reimburse owners for tests already performed or not specifically requested by Vet-LIRN. We recommend that you discuss with your veterinarian which tests and services will be billed to you and which will be covered by Vet-LIRN. For instance, Vet-LIRN may request that your veterinarian perform a urinalysis on your pet while he or she is hospitalized. Vet-LIRN will pay for the collection and testing of the sample, but would not cover the cost of your pet's stay in the hospital.

1.6. Is the information received in the consumer complaint confidential?

Generally, the information received in the consumer complaint is not kept confidential. In most cases, only protected personal information (such as names and addresses) is withheld in an effort to prevent the complaint from being traced back to the individual who submitted it.

2. Billing:

2.1. Will Vet-LIRN pay for bills related to the case investigation?

Vet-LIRN will cover the cost of services and testing that we specifically request. You should understand that Vet-LIRN *CANNOT* reimburse owners for any veterinary bills. Services *MUST* be pre-authorized and paid directly to the veterinarian.

2.2. Will Vet-LIRN pay for testing that was not requested by Vet-LIRN?

No, we will only pay for testing that we request and authorize.

2.3. Will Vet-LIRN pay for treatments or private cremation?

No, we cannot pay for treatment or cremation.

FDA-CVM-FOIA-2019-1704-005964

2.4. If I allow my veterinarian to submit my pet's body for testing, will I be able to have back his or her remains?

Each Vet-LIRN member laboratory has its own procedures for handling remains. Some Vet-LIRN member laboratories offer private cremation services for a fee payable directly to the laboratory. We advise you to discuss directly with the member laboratory the possibilities and costs for obtaining your pet's remains after examination are complete.

3. Step by Step Process:

Vet-LIRN will do the following during a case investigation:

3.1. Assign a case number which MUST be included in all correspondences
3.2. Discuss the case with you and your veterinarian
3.3. Request medical records from your veterinarian
3.4. Coordinate with your veterinarian and you to obtain and submit samples for testing
3.5. Provide results to your veterinarian who will discuss the results with you.

Vet-LIRN requests that:

3.6. Any follow-up veterinary visits related to the investigation are reported to Vet-LIRN
3.7. Additional laboratory reports are reported to Vet-LIRN by your veterinarian.

4. Types of Services and Tests:

4.1. What may a veterinary examination include once the case investigation is started?

A veterinary examination may include:

- an office visit and physical examination to assess your animals current health
- collection of clinical samples from your animal (blood, urine, feces).

4.2. Will your animal be tested more than once?

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It is possible that Vet-LIRN may request additional tests or examinations depending on results from initial testing.

4.3. Will Vet-LIRN need to conduct a necropsy in the event of an animal death?

Yes, if you are willing, we may request that your veterinarian or another Vet-LIRN cooperating laboratory to conduct a necropsy to collect samples for testing. The samples collected may be tested right away or may be held for future testing or archiving. If the veterinarian completes the necropsy then the remains will be handled according the veterinarians normal procedures. If a Vet-LIRN cooperative laboratory completes the necropsy the remains are usually disposed of by that laboratory. Vet-LIRN cannot pay for private cremation. You are welcome to discuss normal procedures with the laboratory.

4.4. Will Vet-LIRN ask for a food sample?

Our main focus is on testing diagnostic tissue or fluid samples from the animal, but we may need to test the food. Please hold all food samples once the consumer complaint is submitted. If needed, we will make arrangements to collect the food.

4.5. What are some general tests that Vet-LIRN may request?

General tests that we may request include, but are not limited to:

- Hematology
- Microbial cultures
- Urinalysis
- Fecal examination
- Necropsy/Histology/Toxicology

4.6. Will I get results from Vet-LIRN requested tests?

Results of testing on your animal's diagnostic tissue or fluid samples will be forwarded to your veterinarian who will be asked to share the results with you.

FDA-CVM-FOIA-2019-1704-005966

From:	Rotstein, David </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0A3B17EBFCF14A6CB8E94F322906BADD-DROTSTEI>
To:	Carey, Lauren; Ceric, Olgica; Glover, Mark; Jones, Jennifer L; Nemser, Sarah; Palmer, Lee Anne; Peloquin, Sarah; Queen, Jackie L; Rotstein, David
Sent:	6/19/2019 12:49:35 PM
Subject:	FW: Acana Free Run Poultry dry: Lisa Freeman - EON-390790
Attachments:	2069328-report.pdf; Acana Free Run Poultry dry: Lisa Freeman - EON-374786; 2069328-attachments.zip

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

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From: Related PFR Event <pfrsignificantactivitycreation@fda.hhs.gov>
Sent: Tuesday, June 18, 2019 12:57 PM
To: Rotstein, David <David.Rotstein@fda.hhs.gov>; B6 Cleary, Michael * <Michael.Cleary@fda.hhs.gov>; HQ Pet Food Report Notification <HQPetFoodReportNotification@fda.hhs.gov>
Subject: Acana Free Run Poultry dry: Lisa Freeman - EON-390790

A PFR Report has been received and Related PFR Event [EON-390790] has been created in the EON System.

A "PDF" report by name "2069328-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 "2069328-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-390790
ICSR #: 2069328
EON Title: Related PFR Event created for Acana Free Run Poultry dry; 2069328

AE Date	08/20/2018	**Number Fed/Exposed**	2
Best By Date		**Number Reacted**	2

Animal Species	Dog	**Outcome to Date**	Recovered Completely
Breed	Doberman Pinscher		
Age	10 Years		
District Involved	PFR-New England DO		

Product information
Individual Case Safety Report Number: 2069328
Product Group: Pet Food
Product Name: Acana Free Run Poultry dry
Description: Housemate was diagnosed with DCM (B6 - previously reported). B6 was asymptomatic but eating same diet (Acana) so was screened 8/20/18 - reduced contractile function. Owner changed diet to Pro Plan Weight Management dry. No improvement on 12/12/18 echo. Will recheck in 3 months WB taurine B6
Submission Type: Followup
Report Type: Adverse Event (a symptom, reaction or disease associated with the product)
Outcome of reaction/event at the time of last observation: Recovered Completely
Number of Animals Treated With Product: 2
Number of Animals Reacted With Product: 2

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

This report is linked to:
Initial EON Event Key: EON-374786
Initial ICSR: 2060599

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

Owner information
B6
USA

To view this Related PFR Event, please click the link below:
https://eon.fda.gov/eon//browse/EON-390790

To view the Related PFR Event Report, please click the link below:
https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jspa?decorator=none&e=0&issueType=10100&issueId=408062&parentIssueTypeId=12

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{

Report Details - EON-390790

ICSR:	2069328		
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:	2019-06-18 12:50:49 EDT		
Initial Report Date:	12/27/2018		
Parent ICSR:	2060599		
Follow-up Report to FDA Request:	Yes		
Reported Problem:	**Problem Description:**	Housemate was diagnosed with DCM (B6 - previously reported). B6 was asymptomatic but eating same diet (Acana) so was screened 8/20/18 - reduced contractile function. Owner changed diet to Pro Plan Weight Management dry. No improvement on 12/12/18 echo. Will recheck in 3 months WB taurine B6	
	Date Problem Started:	08/20/2018	
	Date of Recovery:	06/11/2019	
	Concurrent Medical Problem:	Yes	
	Pre Existing Conditions:	B6	
	Outcome to Date:	Recovered Completely	
Product Information:	**Product Name:**	Acana Free Run Poultry dry	
	Product Type:	Pet Food	
	Lot Number:		
	Package Type:	BAG	
	Product Use Information:	**Description:**	Fed since approximately 9/2016 (see diet history form) Changed to Pro Plan Weight Management Aug 2018
	Manufacturer /Distributor Information:		
	Purchase Location Information:		
Animal Information:	**Name:**	B6	
	Type Of Species:	Dog	
	Type Of Breed:	Doberman Pinscher	
	Gender:	Female	
	Reproductive Status:	Neutered	
	Weight:	38.1 Kilogram	
	Age:	10 Years	
	Assessment of Prior Health:	Excellent	
	Number of Animals Given the Product:	2	
	Number of Animals Reacted:	2	
	Owner Information:	**Owner Information provided:**	Yes
		Contact:	**Name:** B6
			Phone:
			Email:
		Address:	B6

FDA-CVM-FOIA-2019-1704-005970

			B6 United States
	Healthcare Professional Information:	Practice Name:	Tufts Cummings School of Veterinary Medicine
		Contact:	Name: Lisa Freeman Phone: (508) 887-4523 Email: lisa.freeman@tufts.edu
		Address:	200 Westboro Rd North Grafton Massachusetts 01536 United States
Sender Information:	Name:		Lisa Freeman
	Address:		200 Westboro Rd North Grafton Massachusetts 01536 United States
	Contact:	Phone:	5088874523
		Email:	lisa.freeman@tufts.edu
	Permission To Contact Sender:		Yes
	Preferred Method Of Contact:		Email
	Reported to Other Parties:		None
Additional Documents:			
	Attachment:		B6 2019-06-12-1033.pdf
	Description:		Idexx NT pro-BNP
	Type:		Laboratory Report
	Attachment:		Diet hx 6-11-2019.pdf
	Description:		med records
	Type:		Medical Records
	Attachment:		Echo report V9.pdf
	Description:		Echo report
	Type:		Echocardiogram

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

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

Sent: 12/27/2018 3:16:35 PM

Subject: Acana Free Run Poultry dry: Lisa Freeman - EON-374786

Attachments: 2060599-report.pdf; 2060599-attachments.zip

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

A "PDF" report by name "2060599-report.pdf" is attached to this email notification for your reference. Please note that all documents received in the report are compressed into a zip file by name "2060599-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-374786
ICSR #: 2060599
EON Title: PFR Event created for Acana Free Run Poultry dry; 2060599

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

Product information
Individual Case Safety Report Number: 2060599
Product Group: Pet Food
Product Name: Acana Free Run Poultry dry
Description: Housemate was diagnosed with DCM (B6 - previously reported). B6 was asymptomatic but eating same diet (Acana) so was screened 8/20/18 - reduced contractile function. Owner changed diet to Pro Plan Weight Management dry. No improvement on 12/12/18 echo. Will recheck in 3 months WB taurine. B6
Submission Type: Initial
Report Type: Adverse Event (a symptom, reaction or disease associated with the product)

Outcome of reaction/event at the time of last observation: Stable
Number of Animals Treated With Product: 2
Number of Animals Reacted With Product: 2

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

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

Owner information
B6 USA

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

To view the PFR Event Report, please click the link below:
https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jspa?decorator=none&e=0&issueType=12&issueId=391795

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Report Details - EON-374786

ICSR:	2060599		
Type Of Submission:	Initial		
Report Version:	FPSR.FDA.PETF.V.V1		
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)		
Reporting Type:	Voluntary		
Report Submission Date:	2018-12-27 10:09:22 EST		
Reported Problem:	**Problem Description:**	Housemate was diagnosed with DCM (B6 - previously reported). B6 was asymptomatic but eating same diet (Acana) so was screened 8/20/18 - reduced contractile function. Owner changed diet to Pro Plan Weight Management dry. No improvement on 12/12/18 echo. Will recheck in 3 months WB taurine B6	
	Date Problem Started:	08/20/2018	
	Concurrent Medical Problem:	Yes	
	Pre Existing Conditions:	B6	
	Outcome to Date:	Stable	
Product Information:	**Product Name:**	Acana Free Run Poultry dry	
	Product Type:	Pet Food	
	Lot Number:		
	Package Type:	BAG	
	Product Use Information:	**Description:**	Fed since approximately 9/2016 (see diet history form) Changed to Pro Plan Weight Management Aug 2018
	Manufacturer /Distributor Information:		
	Purchase Location Information:		
Animal Information:	**Name:**	B6	
	Type Of Species:	Dog	
	Type Of Breed:	Doberman Pinscher	
	Gender:	Female	
	Reproductive Status:	Neutered	
	Weight:	38.1 Kilogram	
	Age:	10 Years	
	Assessment of Prior Health:	Excellent	
	Number of Animals Given the Product:	2	
	Number of Animals Reacted:	2	
	Owner Information:	**Owner Information provided:**	Yes
		Contact:	**Name:** B6 **Phone:** **Email:**
		Address:	B6 United States
	Healthcare Professional Information:	**Practice Name:**	Tufts Cummings School of Veterinary Medicine
		Contact:	**Name:** Lisa Freeman

FDA-CVM-FOIA-2019-1704-005974

		Phone:	(508) 887-4523
		Email:	lisa.freeman@tufts.edu
	Address:	200 Westboro Rd North Grafton Massachusetts 01536 United States	

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

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

Cummings Veterinary Medical Center at Tufts University

Foster Hospital for Small Animals

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

All Medical Records

Client: B6
Address:

Patient: B6
Breed: Doberman
DOB: B6

Species: Canine
Sex: Female (Spayed)

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

Referring Information

B6

Client: B6
Patient:

Initial Complaint:
Cardiology Study Appointment

SOAP Text Aug 20 2018 1:58PM - B6

Initial Complaint:
Recheck - B6 - DCM study

SOAP Text Dec 12 2018 12:23PM - B6

Disposition/Recommendations

FDA-CVM-FOIA-2019-1704-005976

FDA-CVM-FOIA-2019-1704-005977

Cummings Veterinary Medical Center AT TUFTS UNIVERSITY

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

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

Patient:	B6
Species:	Canine
Breed:	Doberman
Sex:	Female (Spayed)
Age:	B6

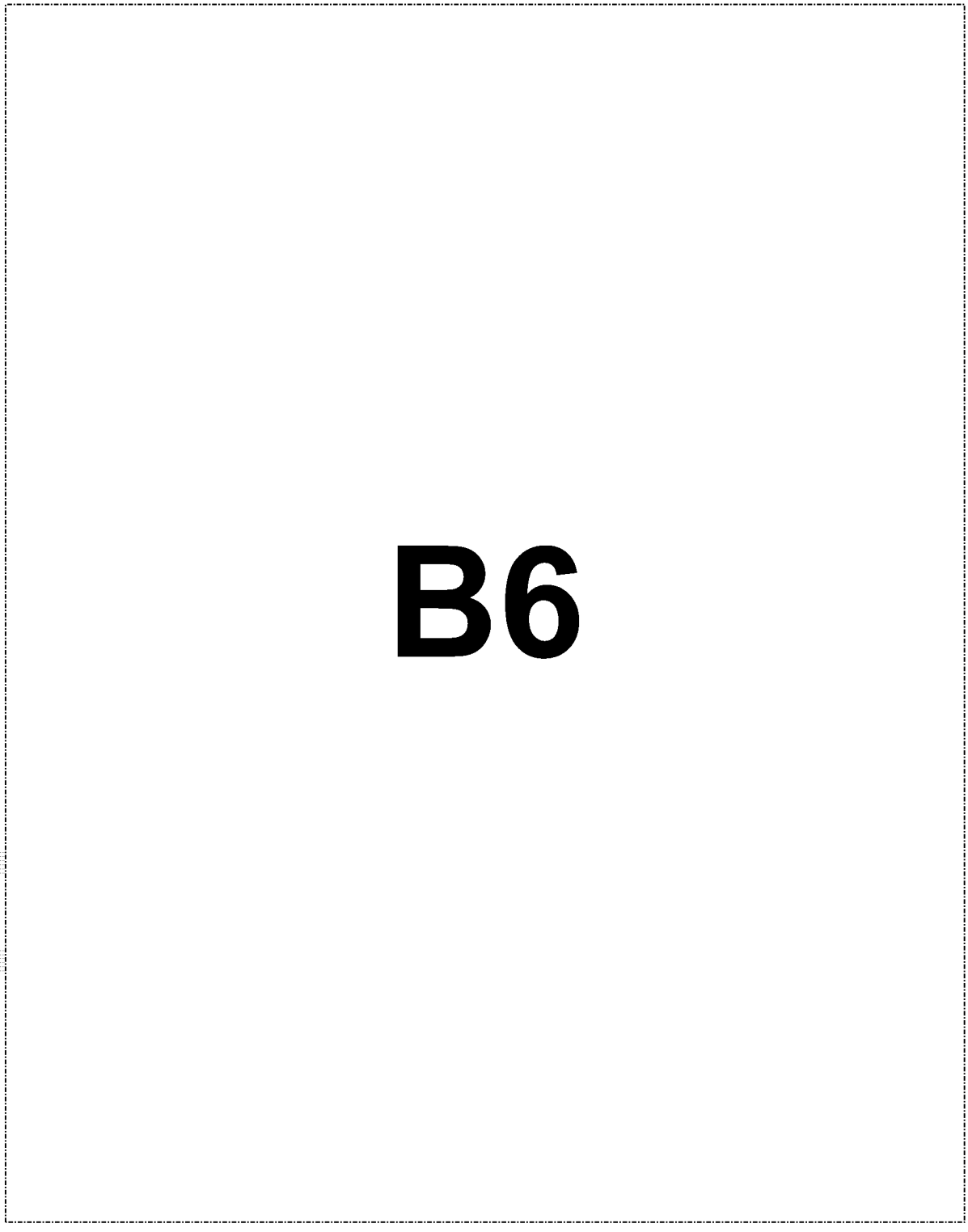
Lab Results Report

Accession ID:

Test	Results	Reference Range	Units

FDA-CVM-FOIA-2019-1704-005978

UCDavis Taurine Level



FDA-CVM-FOIA-2019-1704-005979

Lab Results IDEXX CARDIOPET proBNP 12/12/18

FDA-CVM-FOIA-2019-1704-005980

Diet history 12/12/18

CARDIOLOGY DIET HISTORY FORM

Please answer the following questions about your pet.

Pet's name: B6 Today's date: 12/12/2018

1. How would you assess your pet's appetite? On a scale of 1-10 with 1 being poor and 10 being excellent: 10

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

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

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

Food (include specific product and flavor) | Form | Amount | How often? | Fed since
Examples are shown in the table – please provide enough detail so we know exactly what you are feeding your pet.

Food (include specific product and flavor)	Form	Amount	How often?	Fed since
Blue Buffalo Life Protection Formula Adult Chicken & Brown Rice Recipe	dry	2 cups	Twice	Jan 2018
Milk Bone Dog Biscuits	semi-moist	1 oz	Occasional	Jan 2018
Purina ONE Lean Beef Recipe	wet	3	Twice	Aug 2018
Rawhide	treat	3 small bones	Occasional	Jan 2018
Purina Pro Plan Healthy Weight 2	dry	1 cup	Once	August 2018
Purina Pro Plan Healthy Weight 2	dry	1 cup	Once	Sept 2018
Blue Buffalo Tidy Cat Multi-Cat Clumping Cat Litter	dry	1 cup	Once per day	August 2018
Organic Milk from Trader Joe's	beverage	1 teaspoon	Once a week	Since Nov
Organic Whole Oats	beverage	1 to 2 teaspoons	Once a week	Since
Banana	banana	1/2 banana or less	Once a week	Since Dec
Pet Heroes Assortment	dental	1 bone	Occasionally	Since Dec

Any additional diet information can be listed at the bottom of this page.

5. Do you give any dietary supplements to your pet? (By example: vitamins, glucosamine, fatty acids, or any other supplements)? (x) Yes ( ) No If yes, please list which ones and give a complete description:

	Yes/No	Brand/Concentration	Amount per day
Taurine	( ) Yes ( ) No		
Carnitine	( ) Yes ( ) No		
Antioxidants	( ) Yes ( ) No		
Multivitamin	( ) Yes ( ) No		
Fish oil	(x) Yes ( ) No	Nutri-Vet Omega-3 Plus	1 pump per 10 lbs of body weight
Coenzyme Q10	( ) Yes ( ) No		
Other (please list):			
Example: Vitamin C		Antonio's Brand	500 mg tablets – 1 per day (1 tablet per 10 lbs)
Thiamin		4 mg	

6. How do you administer pills to your pet?
   - [ ] I do not give any medications
   - [ ] I put them directly in my pet's mouth without food
   - [ ] I put them in my pet's dog food
   - [ ] I put them in a Pill Pocket or similar product
   - [x] I put them in Spoon Diet Topper (Like Pet Greenies) or Wet food or peanut butter and she loves it. I've tried to get her down every way to a

Additional diet or supplement information: _____

Information below to be completed by the veterinarian:

Current body weight: _____ kg Current body condition score (1-9): _____

Muscle Condition: None (normal muscle) ( ) Mild (muscle loss) ( ) Moderate (marked loss) ( ) Severe (severe loss) ( )

FDA-CVM-FOIA-2019-1704-005981

Client: **B6**
Patient:

Diet history 8/20/18

CARDIOLOGY DIET HISTORY FORM

Please answer the following questions about your pet

Pet's name: **B6** Owner's name: **B6** Today's date: 8/20/18

1. How would you assess your pet's appetite? (mark the point on the line below that best represents your pet's appetite)

Example: Poor ——— Excellent

Poor ——— Excellent

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

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

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

Food (include specific product and flavor) Form Amount How often? Fed since
Examples are shown in the table – please provide enough detail that we could go to the store and buy the exact same food.

Food (include specific product and flavor)	Form	Amount	How often?	Fed since
Acana Grain Free Chicken, Lamb & Sweet Potato Adult dog food	dry	1 ½ cups	2 times per day	Jan 2018
Fromm Gold Holistic Chicken Entree	Canned/wet	3 oz	1 time per day	Jan 2018
Fromm Gold Holistic Beef Entree	Canned/wet	3 oz	1 time per day	Jan 2018
Pumpkin	Raw	¼	Twice per day	Jan 2018
Mixed Fruit (Blueberry, Banana, Strawberry)	Raw	4 each total	1 time per day	Jan 2018
Blended with Greek Yogurt		1.5 cups	2x/day	8/20/18
Apple cobbler Crumble		Sprinkled on top	1 time per day	
Blueberry		¼ cup	Sprinkled on top	
Green Beans		1 tablespoon	Mixed into food	
Carrots		1 tablespoon	Mixed into food	
Cucumber		¼ cup	1 time per day	

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

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

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

6. How do you administer pills to your pet?
☐ I do not give any medications
☐ I put them directly in my pet's mouth without food
☐ I put them in my pet's regular food
☐ I put them in a pill Pocket or similar product
☐ I put them in foods that I know my pet likes: No Medication | banana | Canned food

FDA-CVM-FOIA-2019-1704-005982

Client:
Patient: B6

Vitals Results

8/20/2018 1:25:17 PM	Weight (kg)	38.1000

FDA-CVM-FOIA-2019-1704-005983

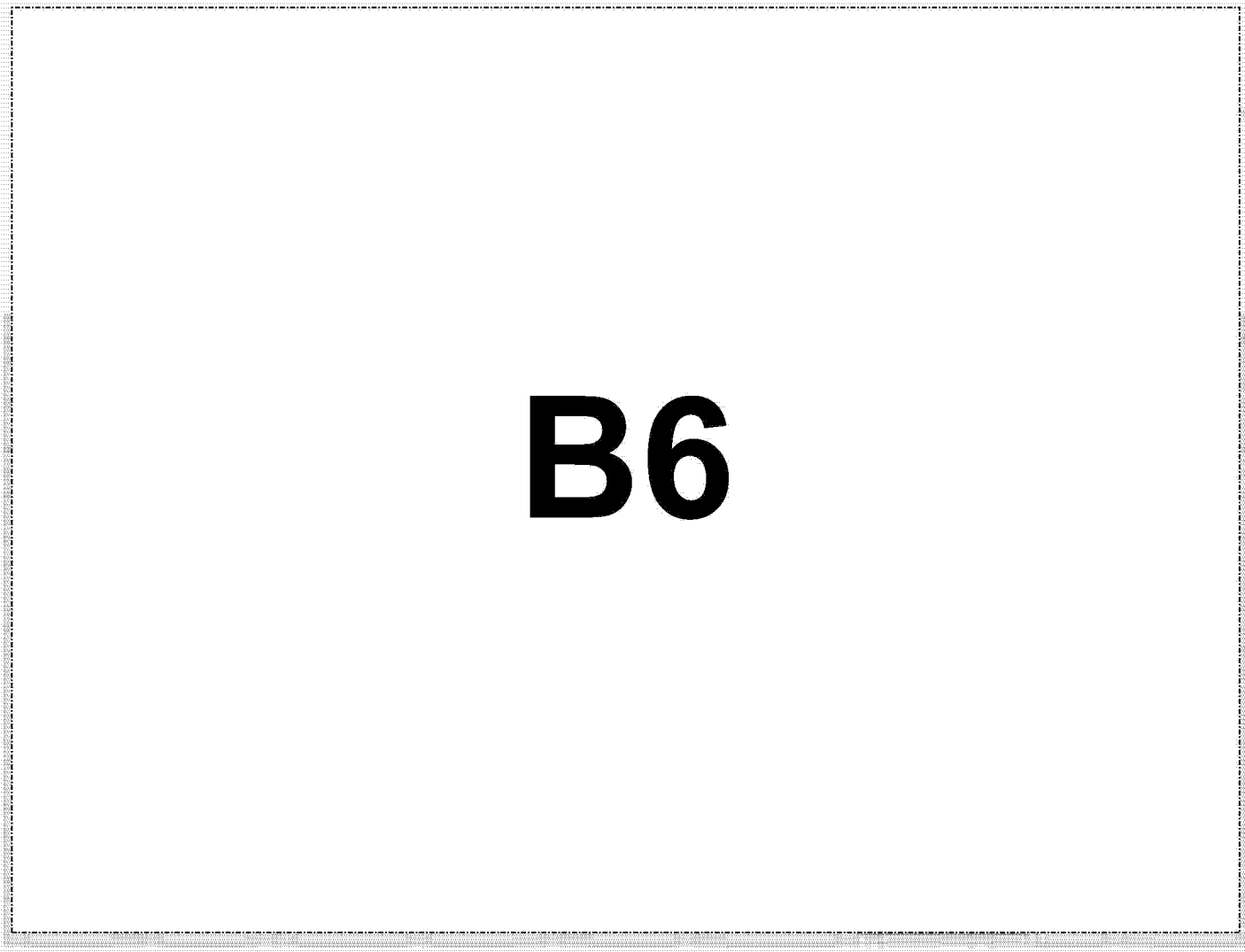
ECG from Cardio

FDA-CVM-FOIA-2019-1704-005984

ECG from Cardio

FDA-CVM-FOIA-2019-1704-005985

ECG from Cardio

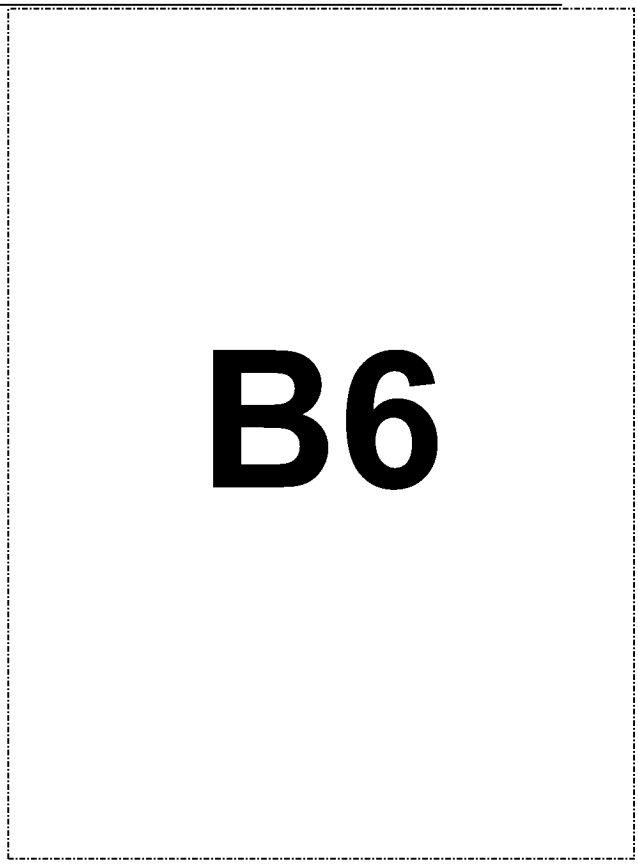


FDA-CVM-FOIA-2019-1704-005986

Client: B6
Patient:

Patient History

08/20/2018 12:48 PM	UserForm
08/20/2018 01:07 PM	Treatment
08/20/2018 01:20 PM	UserForm
08/20/2018 01:25 PM	Vitals
08/20/2018 01:26 PM	Purchase
08/20/2018 01:27 PM	Purchase
08/20/2018 01:27 PM	Purchase
10/17/2018 09:42 AM	Appointment
12/11/2018 07:22 PM	Appointment
12/12/2018 11:04 AM	UserForm
12/12/2018 11:07 AM	Treatment
12/12/2018 11:59 AM	Purchase
12/12/2018 11:59 AM	Purchase
12/12/2018 12:09 PM	UserForm
12/12/2018 12:24 PM	Purchase
12/12/2018 12:47 PM	Appointment



FDA-CVM-FOIA-2019-1704-005987

Cummings
Veterinary Medical Center
AT TUFTS UNIVERSITY

Foster Hospital for Small Animals
56 Winward Street
North Grafton, MA 01536
Telephone: (508) 839-5395
Fax (508) 839-7956
http://vetmed.tufts.edu/

Discharge Instructions

Patient
Name: B6
Species: Canine
Breed/Sex: Female (Spayed) Doberman
Birthdate: B6

Owner
Name: B6
Address: B6

Patient ID: B6

Attending Cardiologist:
B6

Cardiology Resident:
B6

Student: B6
Cardiology Technician:
B6

B6

FDA-CVM-FOIA-2019-1704-005988

B6

Cummings
Veterinary Medical Center
AT TUFTS UNIVERSITY
Cardiology Liaison: 508.887-4670

B6

Patient ID: B6
B6 Center
B6 Canine Old Female (5 year 4) Doberman Black/Tan

Cardiology Appointment Report

Date: 8/20/2018

Attending Cardiologist:

B6

Cardiology Resident:

B6

Cardiology Technician:

B6

Student: B6

B6

B6

B6

Assessment and recommendations:
Normal cardiac structure, although the contractile function is mildly decreased. This may be indicative of early cardiomyopathy. Taurine levels were submitted for analysis, and the patient will be switched off of the grain free diet. If contractile function is not improved at the 4 month rechecked despite change in diet, then we should submit a NT-proBNP to help us diagnose if the changes is indicated of primary DCM and not diet related.

Final Diagnosis:
Mild MMVD
R/O diet related vs. primary DCM related mild decrease in contractile function vs normal variation

Heart Failure Classification Score:
ISACHC Classification:
☑ IIa ☐ IIIa

☐ Ib ☐ IIb
☐ II

ACVIM Classification:
☐ A ☐ C
☒ B1 ☐ D
☐ B2

M-Mode

IVSd	cm
LVIDd	cm
LVPWd	cm
IVSs	cm
LVIDs	cm
LVPWs	cm
%FS	%
Ao Diam	cm
LA Diam	cm
LA/Ao	
Max LA	cm

M-Mode Normalized

IVSdN	(0.29 - 0.52)
LVIDdN	(1.35 - 1.73)
LVPWdN	(0.33 - 0.53)
IVSsN	(0.43 - 0.71) !
LVIDsN	(0.79 - 1.14) !
LVPWsN	(0.53 - 0.78) !
Ao Diam N	(0.68 - 0.89)
LA Diam N	(0.64 - 0.90)

2D

SA LA	cm
Ao Diam	cm
SA LA / Ao Diam	
LVId A4C	cm
LVEDV MOD A4C	ml
LVLs A4C	cm
LVESV MOD A4C	ml
LVEF MOD A4C	%
SV MOD A4C	ml

Doppler

MV E Vel	m/s
MV Dec T	ms
MV A Vel	m/s
MV E/A Ratio	
E'	m/s

B6

A'		m/s
E/E'		
PV Vmax		m/s
PV maxPG		mmHg
AV Vmax		m/s
AV maxPG		mmHg

B6

FDA-CVM-FOIA-2019-1704-005994

Cummings
Veterinary Medical Center
AT TUFTS UNIVERSITY

Foster Hospital for Small Animals
56 Wilfred Street
North Grafton, MA 01536
Telephone: (508) 839-5395
Fax (508) 839-7956
http://vet.tufts.edu/

Discharge Instructions

Patient
Name: B6
Species: Canine
Breed/Sex/Age: Female (Spayed) Doberman
B6

Owner
Name: B6
Address: B6

Patient ID: B6

Attending Cardiologist:
John E. Rush DVM, MS, DACVIM (Cardiology), DACVECC
B6

Cardiology Resident:
B6

Cardiology Technician:
B6

Student: B6

B6

B6

Cummings
Veterinary Medical Center
AT TUFTS UNIVERSITY
Cardiology Liaison: 508.887.4676

B6

Patient ID: B6
B6 Gender
B6 Years Old Female (Spayed) Doberman Black/Tan

Cardiology Appointment Report

Date: 12/12/2018

Attending Cardiologist:
John E. Rush DVM, MS, DACVIM (Cardiology), DACVECC
B6

Cardiology Resident:
B6

Cardiology Technician:
B6

Student: B6

B6

B6

B6

B6

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

Heart Failure Classification Score:
ISACHC Classifications:

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

ACVIM Classifications:

- ☐ A
- ☐ B1
- ☑ B2
- ☐ C
- ☐ D

M Mode	
IVSd	cm
LVIDd	cm
LVPWd	cm
IVSs	cm
LVIDs	cm
LVPWs	cm
LDV(Teich)	ml
LSV(Teich)	ml
EF(Teich)	%
%FS	%
SV(Teich)	ml
Ao Diam	cm
LA Diam	cm
LA/Ao	
Max LA	cm

2D	
SA LA	cm
Ao Diam	cm
SA LA / Ao Diam	
IVSd	cm
LVIDd	cm
LVPWd	cm
LDV(Teich)	ml
IVSs	cm
LVIDs	cm

B6

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LVPWs		cm
LSV(Teich)		ml
LF(Teich)		%
%FS		%
SV(Teich)		ml
LVId A4C		cm
LVEDV MOD A4C		ml
LVIs A4C		cm
LVESV MOD A4C		ml
LVEF MOD A4C		%
SV MOD A4C		ml
	B6	
Doppler		
MV E Vel		m/s
MV DecT		ms
MV Dec Slope		m/s
MV A Vel		m/s
MV E/A Ratio		
E'		m/s
E/E'		
A'		m/s
AV Vmax		m/s
AV maxPG		mmHg
PV Vmax		m/s
PV maxPG		mmHg

FDA-CVM-FOIA-2019-1704-006001

Cummings
Veterinary Medical Center
AT TUFTS UNIVERSITY

B6

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

B6
B6 Female (Spayed)
Canine Doberman Black/Tan
B6

8/24/2018

Dear D B6

Thank you for referring B6 with their p B6

If you have any questions, or concerns, please contact us at (508) 887-4088.

Thank you,

B6

Cummings
Veterinary Medical Center
AT TUFTS UNIVERSITY

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

B6
B6 emale (Spayed)
Canine Doberman Black/Tan
B6

B6

12/19/2018

Dear Dr B6

Thank you for referring B6 with their pe B6

If you have any questions, or concerns, please contact us at (508) 887-4088.

Thank you,

B6

#426154

CARDIOLOGY DIET HISTORY FORM

Please answer the following questions about your pet

Pet's name: **B6** Owner's name: **B6** Today's date: 6/11/19

1. How would you assess your pet's appetite? (mark the point on the line below that best represents your pet's appetite)

Example: **Poor** ——|—— **Excellent**

Poor ——|—— **Excellent**

35kg

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

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

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

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

Food (include specific product and flavor)	Form	Amount	How often?	Fed since
Nutro Grain Free Chicken, Lentil, & Sweet Potato Adult	*dry*	*1 ½ cup*	*2x/day*	*Jan 2018*
85% lean hamburger	*microwaved*	*3 oz*	*1x/week*	*Jan 2015*
Pupperoni original beef flavor	*treat*	*½*	*1x/day*	*Aug 2015*
Rawhide	*treat*	*6-inch twist*	*1x/week*	*Dec 2015*
Purina Pro Plan focus ~~Heart~~ Weight Management	Kibble	2½ cups	2x/day	Aug. 2018
Hills beef/barley canned	can	1 tablespoon Topping	2x/day	Aug 2018
banana	organic	½ banana	few times/wk	2008
blueberry, Apple, watermelon	organic	taste snack	"	"
pumpkin	organic canned	"	"	"
peanut butter	"	2 teaspoons	"	"

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

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

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

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

B6

FDA-CVM-FOIA-2019-1704-006004

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

B6

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

Cardiology Appointment Report
IN DCM DIET STUDY

Date: 6/11/2019

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

B6

Cardiology Resident:

B6

Cardiology Technician:

B6

Student: B6

Presenting Complaint:
Recheck DCM study
Mild MMVD
Mild decreased contractile function r/o diet related vs primary DCM vs normal variation

B6

Diet and Supplements:
Purina Pro Plan (weight management) 2 cups BID, Hills Beef and barley canned 1 heaping tablespoon BID, fruit, pumpkin, and salt free sugar free peanut butter as snacks

Cardiovascular History:

Prior CHF diagnosis? N
Prior heart murmur? N
Prior ATE? N
Prior arrhythmia? Sinus arrythmia, ventricular arrythmia dx via holter monitor
Monitoring respiratory rate and effort at home? pants a lot, no increased effort
Cough? no, occasional cough from licking dust (has done forever)
Shortness of breath or difficulty breathing? N
Syncope or collapse? N
Sudden onset lameness? limping Left front after jumping off a wall to chase chipmunk
Exercise intolerance? N

Current Medications Pertinent to CV System:

B6

Muscle condition:

- [x] Normal
- [ ] Mild muscle loss
- [ ] Moderate cachexia
- [ ] Marked cachexia

Cardiovascular Physical Exam:

Murmur Grade:

- [x] None
- [ ] I/VI
- [ ] II/VI
- [ ] III/VI
- [ ] IV/VI
- [ ] V/VI
- [ ] VI/VI

Jugular vein:

- [x] Bottom 1/3 of the neck
- [ ] Middle 1/3 of the neck
- [ ] 1/2 way up the neck
- [ ] Top 2/3 of the neck

Arterial pulses:

- [ ] Weak
- [ ] Fair
- [ ] Bounding
- [ ] Pulse deficits

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

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

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

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

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

Problems:

Mild MMVD

Mild decreased contractile function r/o diet related vs primary DCM vs normal variation

Hx elevated proBNP

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

B6

Mitral inflow:
- [ ] Summated
- [ ] Normal
- [x] Delayed relaxation
- [ ] Pseudonormal
- [ ] Restrictive

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B6

Assessment and recommendations:

The patient continues to be asymptomatic at home and is doing great. The echocardiogram today is slightly improved compared to the previous one on the basis of a smaller LVIDd and improved FS on m-mode. There has been a drastic improvement when we compare today's echocardiogram with the first one performed back in August 2018. Once again, it is impossible to say if the improvement is secondary to the diet change vs. the addition of B6 but the amount of improvement visualized as well as the constant improvement might be a vote in favor of diet-related changes. No arrhythmia was visualized today. An NT-proBNP was submitted today. Continue with the current dose of B6 with no change. The patient is officially done with the DCM study and any further rechecks should be covered by the owner. A recheck echocardiogram with ECG is recommended in 6 months or sooner if the patient develops clinical signs consistent with worsening heart disease.

Final Diagnosis:

- Very early DMVD with no LAE
- Improved contractile function after change of food and B6 supplementation.

Heart Failure Classification Score:

ISACHC Classification:

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

ACVIM Classification:

- ☐ A
- ☑ B1
- ☐ B2
- ☐ C
- ☐ D

M-Mode

B6

IVSd	cm
LVIDd	cm
LVPWd	cm
IVSs	cm
LVIDs	cm
LVPWs	cm
EDV(Teich)	ml
ESV(Teich)	ml
EF(Teich)	%
%FS	%
SV(Teich)	ml
Ao Diam	cm
LA Diam	cm
LA/Ao	
EPSS	cm

M-Mode Normalized

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IVSdN		(0.290 - 0.520)
LVIDdN		(1.350 - 1.730) !
LVPWdN		(0.330 - 0.530)
IVSsN		(0.430 - 0.710)
LVIDsN		(0.790 - 1.140)
LVPWsN		(0.530 - 0.780)
2D		
SA LA		cm
Ao Diam		cm
SA LA / Ao Diam		
IVSd		cm
LVIDd		cm
LVPWd		cm
EDV(Teich)		ml
IVSs		cm
LVIDs		cm
LVPWs		cm
ESV(Teich)		ml
EF(Teich)		%
%FS		%
SV(Teich)		ml
LV Majpr		cm
LV Minor		cm
Sphericity Index		
LVLd A4C		cm
LVEDV MOD A4C		ml
LVLs A4C		cm
LVESV MOD A4C		ml
LVEF MOD A4C		%
SV MOD A4C		ml
Doppler		
MV E Vel		m/s
MV DecT		ms
MV Dec Slope		m/s
MV A Vel		m/s
MV E/A Ratio		
E'		m/s
E/E'		
A'		m/s
S'		m/s
AV Vmax		m/s
AV maxPG		mmHg
PV Vmax		m/s
PV maxPG		mmHg

B6

FDA-CVM-FOIA-2019-1704-006009

IDEXX

B6

PET OWNER:	B6	**Tufts University Attn: Lisa Freeman**		LAB ID:	2301638777
SPECIES:	Canine	200 Westboro Rd.		ORDER ID:	889337
BREED:	Doberman Pinscher	North Grafton, MA 01536		COLLECTION DATE:	**6/10/19**
GENDER:	Female	508-839-5395		DATE OF RECEIPT:	**6/11/19**
AGE:	B6	ACCOUNT #:	B6	DATE OF RESULT:	**6/12/19**
PATIENT ID:		ATTENDING VET:	B6		

IDEXX Services:

Chemistry

6/11/19 (Order Received)
6/12/19 10:33 AM (Last Updated)

TEST		RESULT	REFERENCE VALUE
Cardiopet proBNP (Canine)	a	B6	0 - 900 pmol/L

B6

B6

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

FDA-CVM-FOIA-2019-1704-006010

IDEXX

B6

PET OWNER:	B6	**Tufts University Attn: Lisa Freeman**		LAB ID:	2301638777
SPECIES:	Canine	200 Westboro Rd.		ORDER ID:	889337
BREED:	Doberman Pinscher	North Grafton, MA 01536		COLLECTION DATE:	**6/10/19**
GENDER:	Female	508-839-5395		DATE OF RECEIPT:	**6/11/19**
AGE:	10 Years	ACCOUNT #:	B6	DATE OF RESULT:	**6/12/19**
PATIENT ID:		ATTENDING VET:	B6		

IDEXX Services:

Chemistry

6/11/19 (Order Received)
6/12/19 10:33 AM (Last Updated)

TEST		RESULT	REFERENCE VALUE	
Cardiopet proBNP (Canine)	a	B6	0 - 900 pmol/L	B6

a **B6**

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

FDA-CVM-FOIA-2019-1704-006011

IDEXX

B6

PET OWNER:	B6	**Tufts University Attn: Lisa Freeman**		LAB ID:	2301638777
SPECIES:	Canine	200 Westboro Rd.		ORDER ID:	889337
BREED:	Doberman Pinscher	North Grafton, MA 01536		COLLECTION DATE:	**6/10/19**
GENDER:	Female	508-839-5395		DATE OF RECEIPT:	**6/11/19**
AGE:	10 Years	ACCOUNT #:	B6	DATE OF RESULT:	**6/12/19**
PATIENT ID:		ATTENDING VET:	B6		

IDEXX Services:

Chemistry

6/11/19 (Order Received)
6/12/19 10:33 AM (Last Updated)

TEST		RESULT	REFERENCE VALUE	
Cardiopet proBNP (Canine)	a	B6	0 - 900 pmol/L	B6

a B6

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

FDA-CVM-FOIA-2019-1704-006012

From: Rotstein, David </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS /CN=0A3B17EBFCF14A6CB8E94F322906BADD-DROTSTEI>

To: Jones, Jennifer L; Queen, Jackie L; Palmer, Lee Anne; Carey, Lauren; Peloquin, Sarah

Sent: 9/24/2018 11:23:36 AM

Subject: Fwd: Taste of the Wild-Last 1-2 bags (for 2 dogs) before diagnosis were Southwest Canyon flavor-Before that: Lisa Freeman - EON-366516

Attachments: 2055229-report.pdf; 2055229-attachments.zip

From: PFR Event <pfreventcreation@fda.hhs.gov>
Date: September 22, 2018 at 6:40:54 PM EDT
To: Cleary, Michael * <Michael.Cleary@fda.hhs.gov>, HQ Pet Food Report Notification <HQPetFoodReportNotification@fda.hhs.gov>
B6
Subject: Taste of the Wild-Last 1-2 bags (for 2 dogs) before diagnosis were Southwest Canyon flavor-Before that: Lisa Freeman - EON-366516

A PFR Report has been received and PFR Event [EON-366516] has been created in the EON System.

A "PDF" report by name "2055229-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 "2055229-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-366516
ICSR #: 2055229
EON Title: PFR Event created for Taste of the Wild Last 1-2 bags (for 2 dogs) before diagnosis were Southwest Canyon flavor Before that fed 3-4 bags of Pine Forest Before that had been feeding Pacific Stream for several years; 2055229

AE Date	09/08/2018	**Number Fed/Exposed**	2
Best By Date		**Number Reacted**	1
Animal Species	Dog	**Outcome to Date**	Stable
Breed	Doberman Pinscher		

Age	B6 Years		
District Involved	PFR-New England DO		

Product information
Individual Case Safety Report Number: 2055229
Product Group: Pet Food
Product Name: Taste of the Wild Last 1-2 bags (for 2 dogs) before diagnosis were Southwest Canyon flavor Before that, fed 3-4 bags of Pine Forest Before that, had been feeding Pacific Stream for several years
Description: DCM and CHF Probably primary DCM in predisposed breed but given diet history, some possibility of diet-associated DCM Taurine WNL
Submission Type: Initial
Report Type: Adverse Event (a symptom, reaction or disease associated with the product)
Outcome of reaction/event at the time of last observation: Stable
Number of Animals Treated With Product: 2
Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Taste of the Wild Last 1-2 bags (for 2 dogs) before diagnosis were Southwest Canyon flavor Before that, fed 3-4 bags of Pine Forest Before that, had been feeding Pacific Stream for several years		

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

Owner information
B6
USA

To view this PFR Event, please click the link below:
https://eon.fda.gov/eon//browse/EON-366516

To view the PFR Event Report, please click the link below:
https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jspa?decorator=none&e=0&issueType=12&issueId=383430

==========

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-366516

ICSR:	2055229		
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:	2018-09-22 18:33:37 EDT		
Reported Problem:	**Problem Description:**	DCM and CHF Probably primary DCM in predisposed breed but given diet history, some possibility of diet-associated DCM Taurine WNL	
	Date Problem Started:	09/08/2018	
	Concurrent Medical Problem:	No	
	Outcome to Date:	Stable	
Product Information:	**Product Name:**	Taste of the Wild Last 1-2 bags (for 2 dogs) before diagnosis were Southwest Canyon flavor Before that, fed 3-4 bags of Pine Forest Before that, had been feeding Pacific Stream for several years	
	Product Type:	Pet Food	
	Lot Number:		
	Package Type:	BAG	
	Product Use Information:	**Description:**	Owner has given consent to have FDA contact her for any additional questions
	Manufacturer /Distributor Information:		
	Purchase Location Information:		
Animal Information:	**Name:**	**B6**	
	Type Of Species:	Dog	
	Type Of Breed:	Doberman Pinscher	
	Gender:	Male	
	Reproductive Status:	Neutered	
	Weight:	34.2 Kilogram	
	Age:	**B6** Years	
	Assessment of Prior Health:	Excellent	
	Number of Animals Given the Product:	2	
	Number of Animals Reacted:	1	
	Owner Information:	**Owner Information provided:**	Yes
		Contact:	**Name:** **B6**
			Phone:
			Email:
		Address:	**B6** United States
	Healthcare Professional Information:	**Practice Name:**	Tufts Cummings School of Veterinary Medicine
		Contact:	**Name:** Lisa Freeman
			Phone: (508) 887-4523

FDA-CVM-FOIA-2019-1704-006016

		Email:	lisa.freeman@tufts.edu
		Address:	200 Westboro Rd North Grafton Massachusetts 01536 United States
Sender Information:	**Name:**	Lisa Freeman	
	Address:	200 Westboro Rd North Grafton Massachusetts 01536 United States	
	Contact:	**Phone:**	5088874523
		Email:	lisa.freeman@tufts.edu
	Permission To Contact Sender:	Yes	
	Preferred Method Of Contact:	Email	
Additional Documents:			
	Attachment:	discharge B6 pdf	
	Description:	Discharge	
	Type:	Medical Records	
	Attachment:	bnp.pdf	
	Description:	BNP	
	Type:	Laboratory Report	
	Attachment:	cardio appointment 9-20-18.pdf	
	Description:	Cardio appt 9-20-18	
	Type:	Echocardiogram	
	Attachment:	cardio consult 9-8-18.pdf	
	Description:	cardio consult 9-8-18	
	Type:	Echocardiogram	
	Attachment:	discharge B6 pdf	
	Description:	Discharge	
	Type:	Medical Records	

FDA-CVM-FOIA-2019-1704-006017

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

B6

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

Cardiology Appointment Report

Date: 9/20/2018

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

B6

Cardiology Resident:
B6

Cardiology Technician:
B6

Student: B6 V19

Presenting Complaint:
Recheck of DCM with active CHF

General Medical History:
Has been his normal self, went on one 20 min walk since he was last here and had no trouble at all.
PU/PD (due to lasix)

Diet and Supplements:
Fromm Mature: 4 cups a day

Cardiovascular History:
Prior CHF diagnosis? Yes
Prior heart murmur? Yes, grade III/VI
Prior ATE?, N
Prior arrhythmia? Y, VPCs
Monitoring respiratory rate and effort at home? N, but havent noticed any labored breathing
Cough? N
Shortness of breath or difficulty breathing? N
Syncope or collapse? N
Sudden onset lameness? N
Exercise intolerance? N

Current Medications Pertinent to CV System:

B6

Muscle condition:

- [x] Normal
- [ ] Mild muscle loss
- [ ] Moderate cachexia
- [ ] Marked cachexia

Cardiovascular Physical Exam:

Murmur Grade:

- [ ] None
- [ ] I/VI
- [ ] II/VI
- [ ] III/VI
- [x] IV/VI
- [ ] V/VI
- [ ] VI/VI

Murmur location/description:

Jugular vein:

- [x] Bottom 1/3 of the neck
- [ ] Middle 1/3 of the neck
- [ ] 1/2 way up the neck
- [ ] Top 2/3 of the neck

Arterial pulses:

- [ ] Weak
- [ ] Fair
- [x] Good
- [ ] Strong
- [ ] Bounding
- [ ] Pulse deficits
- [ ] Pulsus paradoxus
- [ ] Other:

Arrhythmia:

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

FDA-CVM-FOIA-2019-1704-006019

Gallop:

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

Pulmonary assessments:

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

Abdominal exam:

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

Problems:

Differential Diagnoses:

Diagnostic plan:

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

Assessment and recommendations:

Final Diagnosis:

Heart Failure Classification Score:

ISACHC Classification:

- [ ] Ia
- [ ] Ib
- [ ] II
- [ ] IIIa
- [ ] IIIb

ACVIM Classification:

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

FDA-CVM-FOIA-2019-1704-006020

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

B6

Patient ID: B6
B6 Canine
B6 Years Old Male (Neutered)
Doberman Pinscher
Black/Tan BW: Weight (kg) 32.00

Cardiology Consultation

Date: 9/8/2018
Weight: Weight (kg) 32.00
Requesting Clinician: B6

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

B6

Cardiology Resident:

B6

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

Patient location: ER

Presenting complaint and important concurrent diseases: 8 y.o doberman presenting for aoute onset soft cough after exercise and at rest, worse at night. Owners report coughing episodes have been getting more frequent over the past 3 days. Grade IV/VI right sided systolic murmur ausoulted on exam. Had scheduled appointment to be seen with cardiology 9/20/18 based on arrhythmia heard at rDVM.

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

Physical Examination

B6

Cardiovascular Physical Exam
Murmur Grade:
☐ None
☐ I/VI
☐ IV/VI
☐ V/VI

- [ ] II/VI
- [x] III/VI
- [ ] VI/VI

B6

Jugular vein:
- [x] Bottom 1/3 of the neck
- [ ] Middle 1/3 of the neck
- [ ] Top 2/3 of the neck
- [ ] 1/2 way up the neck

Arterial pulses:
- [ ] Weak
- [ ] Fair
- [x] Good
- [ ] Strong
- [ ] Bounding
- [ ] Pulse deficits
- [ ] Pulsus paradoxus
- [ ] Other (describe):

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

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

Pulmonary assessments:
- [ ] Eupneic
- [x] Mild dyspnea
- [ ] Marked dyspnea
- [ ] Normal BV sounds
- [ ] Pulmonary Crackles
- [ ] Wheezes
- [ ] Upper airway stridor
- [ ] Other auscultatory findings:

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

Echocardiogram Findings:

B6

Mitral inflow:
- [ ] Summated
- [x] Normal
- [ ] Delayed relaxation
- [ ] Pseudonormal
- [ ] Restrictive

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ECG findings:

B6

Assessment and recommendations: Findings consistent with DCM and active congestive heart failure. Simpson and sphericity index revealed advanced LV dilation and enlarged LA are consistent with advanced DCM. Recommend B6 in order to improve systolic function, cardiac output and decrease LA pressure. TR revealed mild PHT, for which we expect that treating CHF will help to improve pulmonary circulation. B6 can be considered in the future, but not for now. Radiographs revealed interstitial pattern consistent with incipient pulmonary edema. B6 s recommended in B6 B6 recommended. Telemetry monitoring during hospitalization as patient had maov isolated ventricular ectopies during the exam. In case of couplets, triplets, NSVT or R/T, recommend B6 low sodium diet (ideally a main stream brand) should be started and explain to owners that grain free diet is contra-indicated at this point. Kidney levels should be evaluated in daily basis during hospitalization and recheck ECG tomorrow in case arrythmias are still frequent.

Treatment plan:

B6

Final Diagnosis:

L-CHF secondary to DCM

Addendum:

9/9/18 - Patient did well overnight, rare episodes of cough and respiratory rate stayed stable

B6

B6 Recheck is scheduled in 9 days. Recheck echo or radiographs, ECG, and blood work in 3-4 months.

Heart Failure Classification Score:

ISACHC Classification:

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

ACVIM CHF Classification:

- ☐ A
- ☐ B1
- ☐ B2
- ☑ C
- ☐ D

FDA-CVM-FOIA-2019-1704-006023

Cummings
Veterinary Medical Center
AT TUFTS UNIVERSITY

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

Emergency & Critical Care Liaison: (508) 887 - 4745

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

Owner Name:
Address: B6

Patient ID: B6

Emergency Clinician: B6
Consulting Clinician:

ER Supervisor: B6

Discharge Instructions

Admit Date: 9/8/2018 10:52:58 AM
Check Out Date: 9/8/2018

Case Summary
Diagnosis:
1. Dilated cardiomyopathy with active congestive heart failure.

Case Summary:
Thank you for bringing B6 to Tufts ER for evaluation of his persistent cough. You reported that he suddenly developed a cough three days ago and that it is worse after exercise or when he is resting at night. On presentation he was bright and alert. His vital signs (heart rate, respiratory rate, and temperature) were all within normal limits. He had an audible bilateral heart murmur. He coughed when his trachea was palpated lightly.

Based on his breed and clinical presentation, we opted to do radiographs and have an emergency consult with the cardiology department because of concerns of dilated cardiomyopathy (DCM). This is a common condition for this breed. Also, grain-free diets may predispose animals to developing dilated cardiomyopathy or make a pre-existing disease to get worse.

On his cardiology consult, ultrasound showed significantly decreased contraction of the heart, confirming dilated cardiomyopathy. EKG showed occasional abnormal heartbeats originating from the ventricle. Based on the results of his radiographs and cardiology consult, Ryche was started on diuretics to relieve some of the fluid building up in his lungs. He was also started on pimobendan, which increases the strength of heart contractions. As grain free diet can affect absorption of some nutrients, Taurine supplementation was started. He was placed on an EKG overnight to determine if any arrhythmias are present.

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Patient Care Instructions:

1. Exercise restrictions: Do not allow B6 to overexert himself. He may still go for short walks and play with his sister but avoid strenuous activity like hiking or chasing squirrels which may overexert his heart.

2. Diet: We recommend to discontinue the grain free diet - a sheet that has suggestions for diet and low sodium treats can be found on the HeartSmart web site (http://vet.tufts.edu/heartsmart/diet/). We recommend as dry options:

- Royal Canin Early Cardiac;
- Royal Canin Boxer;
- Purina ProPlan Adult Weight Management.

Medications:

B6

Recheck Visits: Please come in for your scheduled cardiology appointment on September 20th at 1PM as a re-check appointment.

Thank you for entrusting us with B6 's care. Please contact our Cardiology liaison at (508)-887-4696 or email us at cardiowt@tufts.edu for scheduling and non-emergent questions or concerns.

Please visit our HeartSmart website for more information
http://vet.tufts.edu/heartsmart/

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

Ordering Food:

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

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

---

Case: B6 Owner: B6 **Discharge Instructions**

Cummings
Veterinary Medical Center
AT TUFTS UNIVERSITY

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

Discharge Instructions

Patient
Name: B6
Species: Canine
Black/Tan Male (Neutered) Doberman Pinscher
Birthdate: B6

Owner
Name: B6
Address: B6

Patient ID: B6

Attending Cardiologist:
John E. Rush DVM, MS, DACVIM (Cardiology), DACVECC
B6

Cardiology Resident:
B6

Cardiology Technician:
B6

Student: B6 V'19

Admit Date: 9/20/2018 1:05:31 PM
Discharge Date: 9/20/2018

Diagnoses:
1. Dilated cardiomyopathy (DCM)– stable
2. Congestive heart failure– resolved

Case summary:
Thank you for bringing in B6 for his recheck appointment with us today. He is such a sweet boy! We are so happy to hear he has been doing so well on his medications and has not had any coughing, difficulty breathing, or exercise intolerance. We are so glad B6 is responding so well to his medications and is feeling so comfortable.

Today we performed a recheck quick ultrasound of his heart, an ECG to recheck his ventricular arrythmias, and took some blood to recheck his kidney values since being on the furosemide for 10 days. His heart seems to be contracting a little stronger than it was previously. His left ventricle was still dilated, but his left atrium was smaller today since his last visit, which means he is improving on his current medications. He did not have any arrythmias when we performed his EOG today. The blood work results are normal and we would like to continue him on his current medication doses (see list below), and also continue exercise restricting him to only leash walks.

Monitoring at home:
- We would like you to monitor B6 's breathing rate and effort at home, ideally during sleep or at a time of rest. The doses of drugs will be adjusted based on the breathing rate and effort.
- In general, most dogs with heart failure that is well controlled have a breathing rate at rest of less than 35 breaths per minute. In addition, the breathing effort, noted by the amount of belly wall motion used for each breath, is

fairly minimal if heart failure is controlled.

- An increase in breathing rate or effort will usually mean that you should give an extra dose of B6 If difficulty breathing is not improved by within 60 -90 minutes after giving extra B6 then we recommend that a recheck exam be scheduled and/or that your dog be evaluated by an emergency clinic.
- There are instructions for monitoring breathing, and a form to help keep track of breathing rate and drug doses, on the Tufts HeartSmart web site (http://vet.tufts.edu/heartsmart/at-home-monitoring/).
- We also want you to watch for weakness or collapse, a reduction in appetite, worsening cough, or distention of the belly as these findings indicate that we should do a recheck examination.
- If you have any concerns, please call or have your dog evaluated by a veterinarian. Our emergency clinic is open 24 hours/day.

Recommended Medications:

B6

Diet suggestions:

We suggest B6 to be in one of the diets we recommended (see list). 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:

Leash walking only is ideal, and short walks to start. Once the heart failure is better controlled, then slightly longer walks are acceptable. However, if you find that B6 is lagging behind or needs to stop on a walk then this was too long a walk and shorter walks are advised in the future. Repetitive or strenuous high energy activities (repetitive ball chasing, running fast off-leash, etc.) are generally not advised at this stage of heart failure.

Recheck Visits:

A recheck echocardiogram for B6 is recommended in 3-4 months.
B6 has an appointment with us on October 2nd at 4 pm.)

Thank you for entrusting us with B6 care. Please contact our Cardiology liaison at (508)-887-4696 or email us at cardiovet@tufts.edu for scheduling and non-emergent questions or concerns.

Please visit our HeartSmart website for more information
http://vet.tufts.edu/heartsmart/

Prescription Refill Disclaimer:

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

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Clinical Trials:

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

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FDA-CVM-FOIA-2019-1704-006028

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

All Medical Records

Client: B6
Address: B6

Patient: B6
Breed: Pit Bull
DOB: B6

Species: Canine
Sex: Male (Neutered)

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

B6

Referring Information

B6

Client: B6
Patient:

Initial Complaint:
Scanned Record

Initial Complaint:
Cardiology New - will be here at 1:30 PM

SOAP Text Jan 3 2019 1:03PM - B6

Disposition/Recommendations

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FDA-CVM-FOIA-2019-1704-006030

Cummings Veterinary Medical Center at Tufts University

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

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

Patient:	B6
Species:	Canine
Breed:	Pit Bull
Sex:	Male (Neutered)
Age:	B6

Lab Results Report

Accession ID:

Test	Results	Reference Range	Units

FDA-CVM-FOIA-2019-1704-006031

B6

FDA-CVM-FOIA-2019-1704-006032

B6

FDA-CVM-FOIA-2019-1704-006033

B6

FDA-CVM-FOIA-2019-1704-006034

B6

FDA-CVM-FOIA-2019-1704-006035

B6

FDA-CVM-FOIA-2019-1704-006036

B6

FDA-CVM-FOIA-2019-1704-006037

B6 3/17/18 3 year Rabies Cert

B6

FDA-CVM-FOIA-2019-1704-006038

diet history 1/3/19

B6

FDA-CVM-FOIA-2019-1704-006039

diet history 1/3/19

B6

FDA-CVM-FOIA-2019-1704-006040

B6

FDA-CVM-FOIA-2019-1704-006041

B6

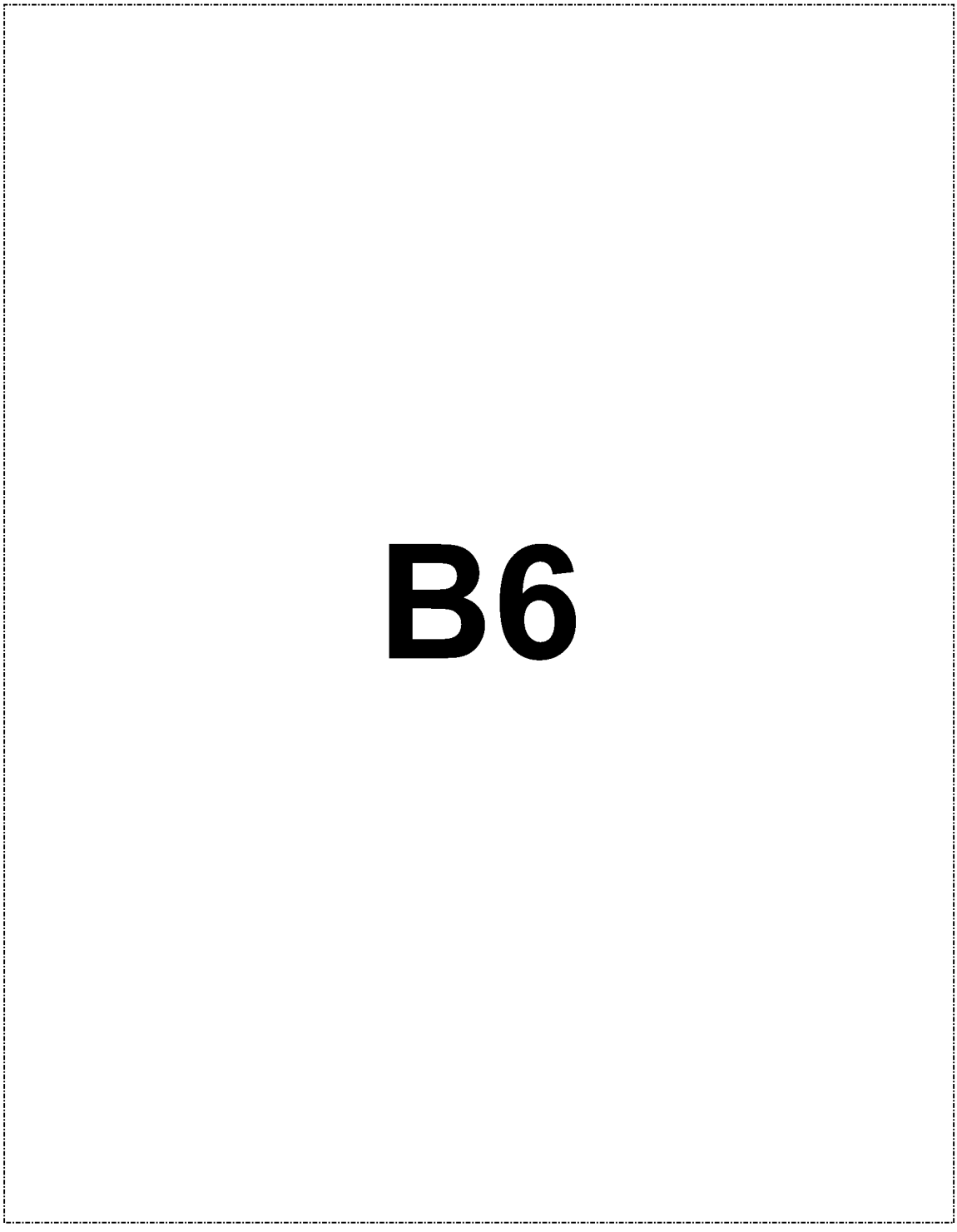
FDA-CVM-FOIA-2019-1704-006042

B6

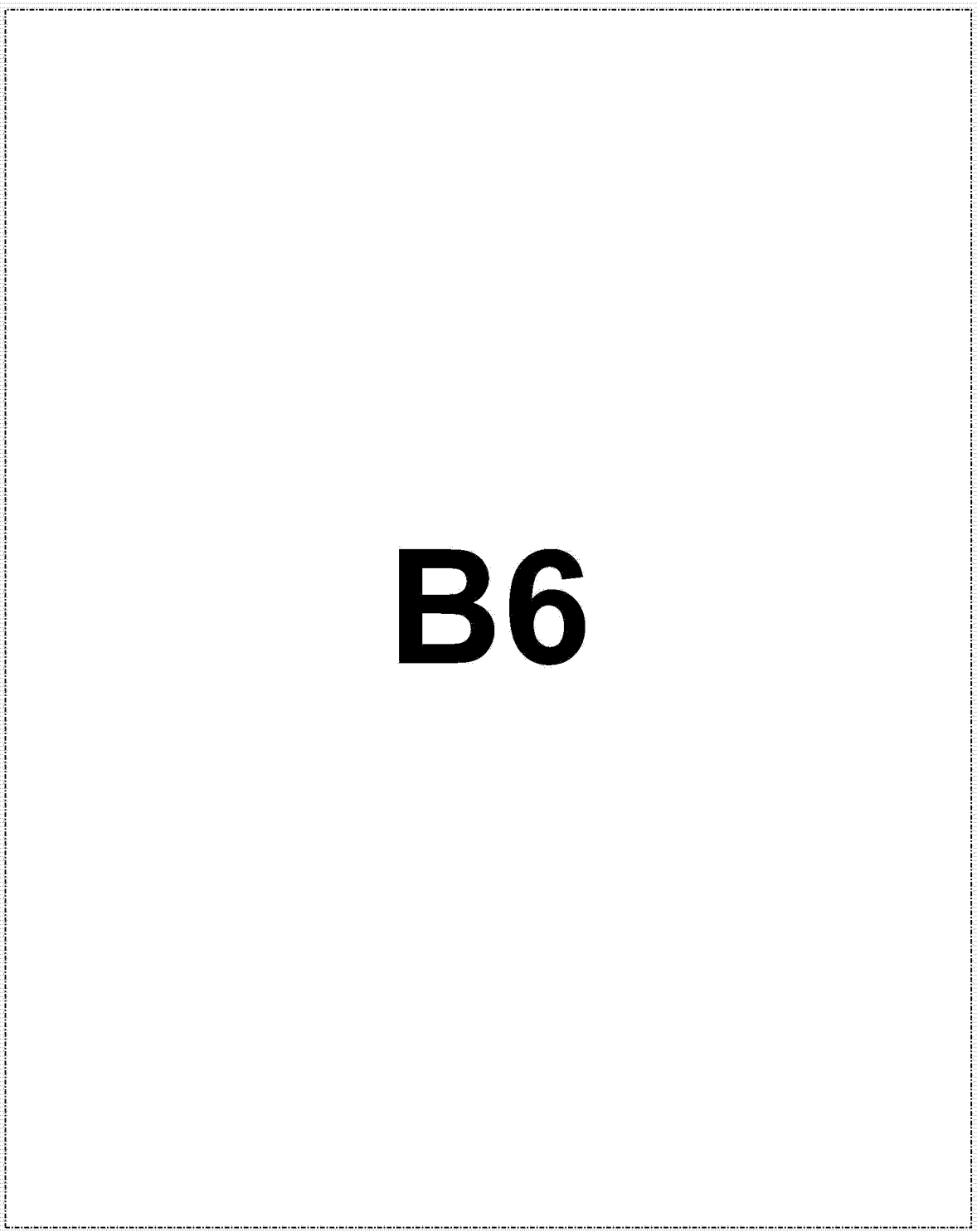
FDA-CVM-FOIA-2019-1704-006043

B6

FDA-CVM-FOIA-2019-1704-006044



FDA-CVM-FOIA-2019-1704-006045



FDA-CVM-FOIA-2019-1704-006046

B6

FDA-CVM-FOIA-2019-1704-006047

B6

FDA-CVM-FOIA-2019-1704-006048

B6

FDA-CVM-FOIA-2019-1704-006049

B6

FDA-CVM-FOIA-2019-1704-006050

B6

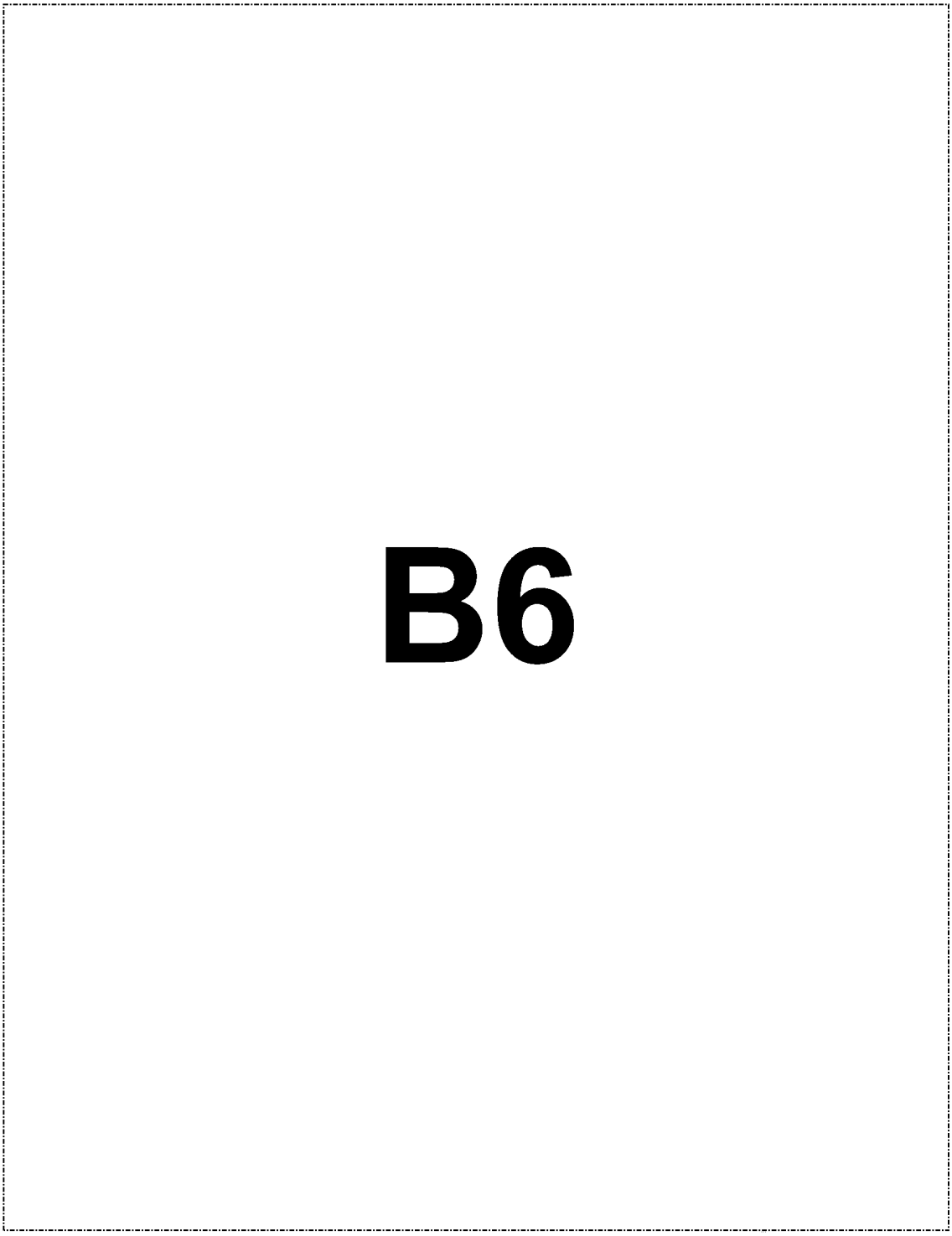
FDA-CVM-FOIA-2019-1704-006051

B6

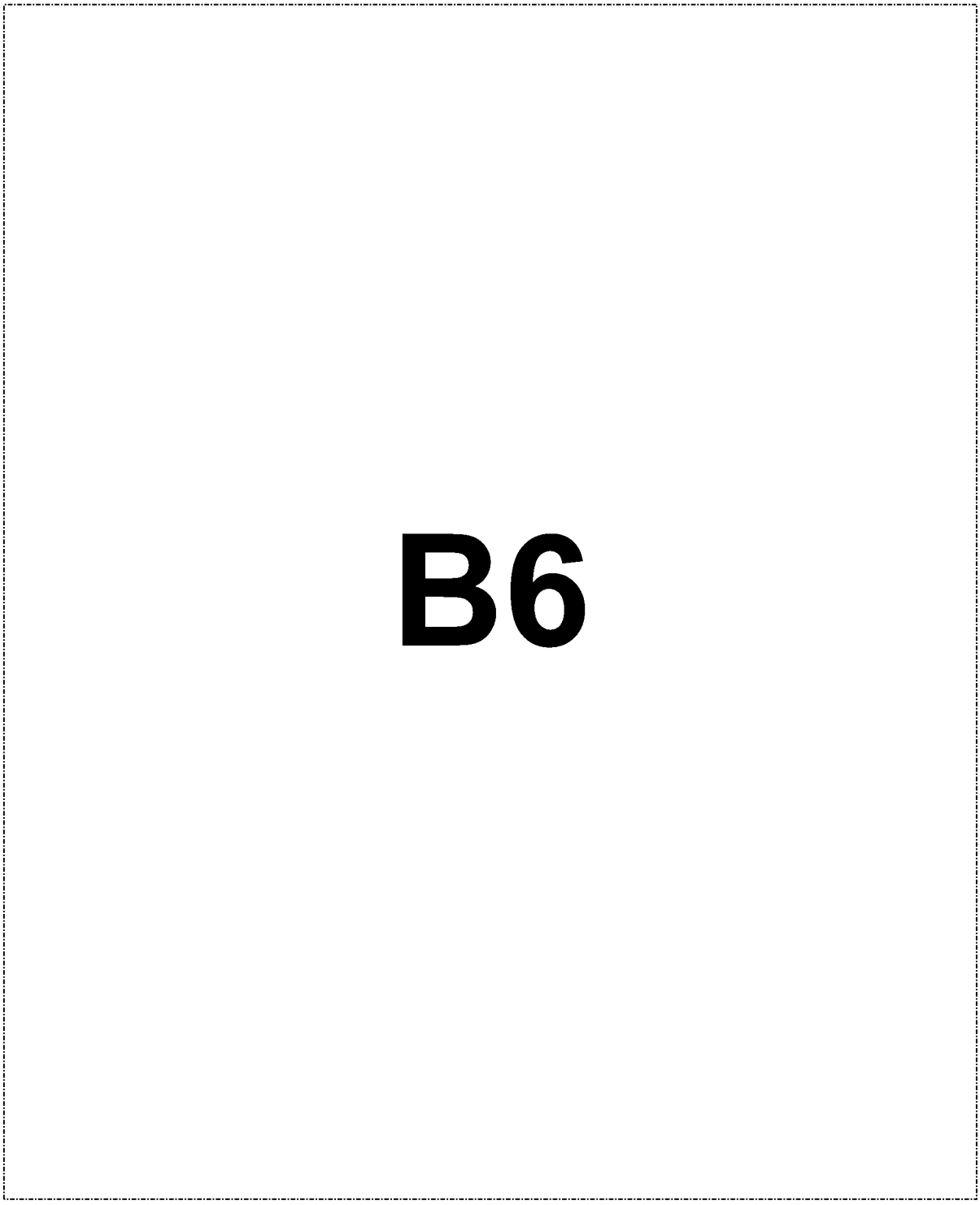
FDA-CVM-FOIA-2019-1704-006052

B6

FDA-CVM-FOIA-2019-1704-006053



FDA-CVM-FOIA-2019-1704-006054



FDA-CVM-FOIA-2019-1704-006055

B6

FDA-CVM-FOIA-2019-1704-006056

FDA-CVM-FOIA-2019-1704-006057

IDEXX BNP - 1/3/2019

FDA-CVM-FOIA-2019-1704-006058

CBC/CHEM - 1/3/2019

B6

FDA-CVM-FOIA-2019-1704-006059

CBC/CHEM - 1/3/2019

B6

B6

B6

FDA-CVM-FOIA-2019-1704-006060

Diet history 1/3/19

B6

FDA-CVM-FOIA-2019-1704-006061

Diet history 1/3/19

FDA-CVM-FOIA-2019-1704-006062

Lab Results IDEXX Leptospirosis Panel (MAT) 1/4/19

FDA-CVM-FOIA-2019-1704-006063

B6 ospital UA results- 1/7/19

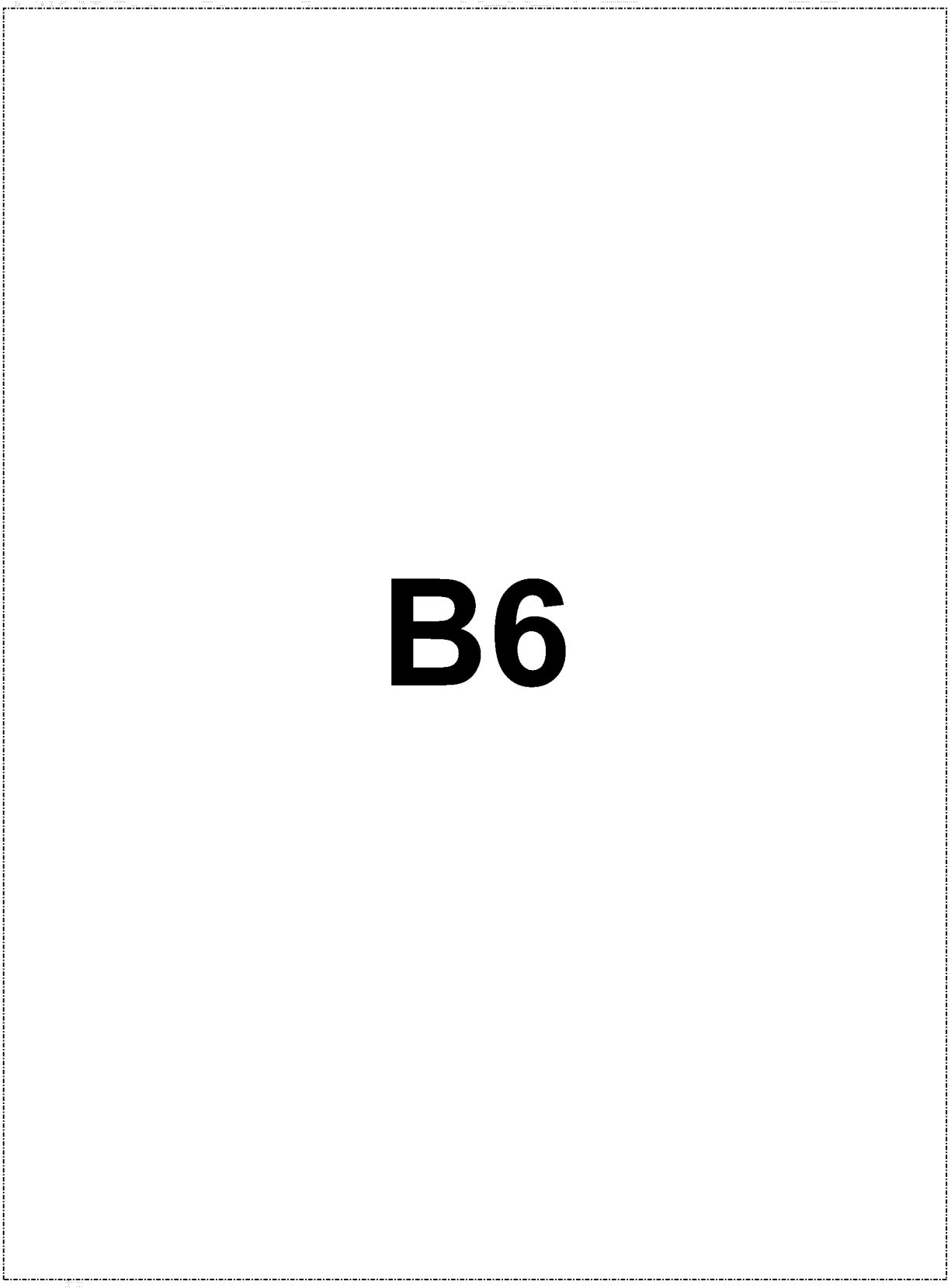
B6

FDA-CVM-FOIA-2019-1704-006064

B6

FDA-CVM-FOIA-2019-1704-006065

IDEXX Chemistry 1/8/19



FDA-CVM-FOIA-2019-1704-006066

IDEXX Chemistry 1/8/19

B6

FDA-CVM-FOIA-2019-1704-006067

Taurine Panel send out 1/3/2019

B6

FDA-CVM-FOIA-2019-1704-006068

Client: B6
Patient:

Vitals Results

1/3/2019 1:44:42 PM	Weight (kg)
1/3/2019 1:44:49 PM	Heart Rate (/min)

B6

Patient History

01/02/2019 12:50 PM	Appointment
01/03/2019 01:06 PM	UserForm
01/03/2019 01:16 PM	Treatment
01/03/2019 01:44 PM	Vitals
01/03/2019 01:44 PM	Vitals
01/03/2019 03:07 PM	Deleted Reason
01/03/2019 03:09 PM	Purchase
01/03/2019 03:10 PM	UserForm
01/03/2019 03:25 PM	Purchase
01/03/2019 03:25 PM	Purchase
01/03/2019 03:33 PM	Prescription
01/03/2019 03:33 PM	Prescription
01/03/2019 03:38 PM	Prescription
01/03/2019 03:47 PM	Purchase
01/03/2019 04:08 PM	Appointment
01/04/2019 06:18 PM	Purchase

B6

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Cummings
Veterinary Medical Center
AT TUFTS UNIVERSITY

Foster Hospital for Small Animals
55 W Lead Street
North Grafton, MA 01536
Telephone: (508) 839-5395
Fax: (508) 839-7911
http://vetmed.tufts.edu/

Discharge Instructions

Patient
Name: B6
Species: Canine
Breed/Type: Male (Neutered) Pit Bull
Birthdate: B6

Owner
B6

Patient ID: B6

Attending Cardiologist:
Adam J. Rush DVM, MS, DACVIM (Cardiology), DACVECC
B6

Cardiology Resident:
B6

Cardiology Technician:
B6

Student: B6

B6

B6

B6

Cummings
Veterinary Medical Center
AT TUFTS UNIVERSITY

Foster Hospital for Small Animals
55 Winhead Street
North Grafton, MA 01536
Telephone: (508) 839-5395
Fax: (508) 839-7954
http://vet.tufts.edu/

B6

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B6

Cummings
Veterinary Medical Center
AT TUFTS UNIVERSITY
Cardiology Liaison: 508.887.4670

B6

Patient ID: B6
B6 Canine
B6 (Neutered) Pit Bull
Brindle/White

Cardiology Appointment Report
ENROLLED IN DCM STUDY

Date: 1/3/2019

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

B6

Cardiology Resident:
B6

Cardiology Technician:
B6

Student: B6

B6

B6

B6

B6

M-Mode		
IVSd		cm
LVIDd		cm
LVPWd		cm
IVSs		cm
LVIDs		cm
LVPWs		cm
EDV(Teich)		ml
ESV(Teich)		ml
EF(Teich)		%
%FS		%
SV(Teich)		ml
Ao Diam		cm
LA Diam		cm
LA/Ao		
Max LA		cm
EPSS		cm
M-Mode Normalized		
IVSdN		(0.290 - 0.520)
LVIDdN		(1.350 - 1.730) !
LVPWdN		(0.330 - 0.530)
IVSsN		(0.430 - 0.710)
LVIDsN		(0.790 - 1.140) !
LVPWsN		(0.530 - 0.780) !
Ao Diam N		(0.680 - 0.890) !
LA Diam N		(0.640 - 0.900) !
2D		
SA LA		cm
Ao Diam		cm
SA LA / Ao Diam		
IVSd		cm
LVIDd		cm
LVPWd		cm
EDV(Teich)		ml
IVSs		cm
LVIDs		cm
LVPWs		cm
ESV(Teich)		ml
EF(Teich)		%
%FS		%
SV(Teich)		ml
LV Major		cm
LV Minor		cm
Sphericity Index		
LVId LAX		cm
LVAd LAX		cm
LVEDV A-L LAX		ml

B6

FDA-CVM-FOIA-2019-1704-006079

LVEDV MOD LAX		ml
LVLs LAX		cm
LVAs LAX		cm
LVESV A-L LAX		ml
LVESV MOD LAX		ml
HR		BPM
EF A-L LAX		%
LVEF MOD LAX		%
SV A-L LAX		ml
SV MOD LAX		ml
CO A-L LAX		l/min
CO MOD LAX		l/min
Doppler		
MR Vmax		m/s
MR maxPG		mmHg
MV E Vel		m/s
MV DecT		ms
MV Dec Slope		m/s
MV A Vel		m/s
MV E/A Ratio		
E'		m/s
E/E'		
A'		m/s
AV Vmax		m/s
AV maxPG		mmHg
PV Vmax		m/s
PV maxPG		mmHg

B6

Cummings
Veterinary Medical Center
AT TUFTS UNIVERSITY

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

B6

B6 Male (Neutered)
Canine: Pit Bull Bandy/Blue
B6

1/4/2019

Dear B6

Thank you for referring B6 with their pet B6

If you have any questions, or concerns, please contact us at (508) 887-4088.

Thank you,

B6

From: Related PFR Event <pfrsignificantactivitycreation@fda.hhs.gov>

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

Sent: 3/26/2019 6:25:57 PM

Subject: 4Health whitefish and potato dry: Lisa Freeman - EON-383414

Attachments: 2064645-report.pdf; 2064645-attachments.zip

A PFR Report has been received and Related PFR Event [EON-383414] has been created in the EON System.

A "PDF" report by name "2064645-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 "2064645-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-383414
ICSR #: 2064645
EON Title: Related PFR Event created for 4Health whitefish and potato dry, 4Health salmon and potato adult dog food; 2064645

AE Date	01/03/2019	**Number Fed/Exposed**	3
Best By Date		**Number Reacted**	1
Animal Species	Dog	**Outcome to Date**	Died Euthanized
Breed	Pit Bull		
Age	7.5 Years		
District Involved	PFR-New England DO		

Product information
Individual Case Safety Report Number: 2064645
Product Group: Pet Food
Product Name: 4Health whitefish and potato dry, 4Health salmon and potato adult dog food
Description: Eating BEG diet Syncopal episodes - identified arrhythmia recently Owner changing diet and will recheck in 3 months Elevated BNP B6 ; taurine and troponin pending 2 other dogs in household eating same diet - they have not been screened yet
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 Euthanized
Number of Animals Treated With Product: 3
Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
4Health salmon and potato adult dog food		
4Health whitefish and potato dry		

This report is linked to:
Initial EON Event Key: EON-376448
Initial ICSR: 2061217

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

Owner information
B6
B6 USA

To view this Related PFR Event, please click the link below:
https://eon.fda.gov/eon//browse/EON-383414

To view the Related PFR Event Report, please click the link below:
https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jspa?decorator=none&e=0&issueType=10100&issueId=400512&parentIssueTypeId=12

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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-383414

ICSR:	2064645	
Type Of Submission:	Followup	
Report Version:	FPSR.FDA.PETF.V.V1	
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)	
Reporting Type:	Voluntary	
Report Submission Date:	2019-03-26 14:13:37 EDT	
Initial Report Date:	01/15/2019	
Parent ICSR:	2061217	
Follow-up Report to FDA Request:	Yes	
Reported Problem:	**Problem Description:**	Eating BEG diet Syncopal episodes - identified arrhythmia recently. Owner changing diet and will recheck in 3 months Elevated BNP B6 taurine and troponin pending 2 other dogs in household eating same diet - they have not been screened yet
	Date Problem Started:	01/03/2019
	Concurrent Medical Problem:	Yes
	Pre Existing Conditions:	Dental disease, kidney disease, anxiety, history of cruciate tear
	Outcome to Date:	Died Euthanized
	Date of Death:	B6
Product Information:	**Product Name:**	4Health salmon and potato adult dog food
	Product Type:	Pet Food
	Lot Number:	
	Product Use Information:	**Description:** Alternates with other product listed
	Manufacturer /Distributor Information:	
	Purchase Location Information:	
	Product Name:	4Health whitefish and potato dry
	Product Type:	Pet Food
	Lot Number:	
	Product Use Information:	**Description:** Alternates with other listed 4Health product
	Manufacturer /Distributor Information:	
	Purchase Location Information:	
Animal Information:	**Name:**	B6
	Type Of Species:	Dog
	Type Of Breed:	Pit Bull
	Gender:	Male
	Reproductive Status:	Neutered
	Weight:	33.4 Kilogram
	Age:	7.5 Years
	Assessment of Prior Health:	Good
	Number of Animals Given the Product:	3
	Number of Animals Reacted:	1

FDA-CVM-FOIA-2019-1704-006085

Owner Information:	**Owner Information provided:**	Yes	
	Contact:	**Name:**	B6
		Phone:	
		Email:	
	Address:	B6	
		United States	
	Healthcare Professional Information:	**Practice Name:**	Tufts Cummings School of Veterinary Medicine
		Contact: **Name:**	Lisa Freeman
		Phone:	(508) 887-4523
		Email:	lisa.freeman@tufts.edu
		Address:	200 Westboro Rd North Grafton Massachusetts 01536 United States
Sender Information:	**Name:**	Lisa Freeman	
	Address:	200 Westboro Rd North Grafton Massachusetts 01536 United States	
	Contact:	**Phone:**	5088874523
		Email:	lisa.freeman@tufts.edu
	Permission To Contact Sender:	Yes	
	Preferred Method Of Contact:	Email	
	Reported to Other Parties:	None	
Additional Documents:			
	Attachment:	Med record 1.pdf	
	Description:	Medical record	
	Type:	Medical Records	
	Attachment:	Med record 4.pdf	
	Description:	Medical record	
	Type:	Medical Records	
	Attachment:	Med record 2.pdf	
	Description:	Medical record	
	Type:	Medical Records	
	Attachment:	Med record 3.pdf	
	Description:	Medical record	
	Type:	Medical Records	

Cummings Veterinary Medical Center
AT TUFTS UNIVERSITY

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

All Medical Records

Client:
Address: B6

Patient: B6
Breed: Pit Bull
DOB: B6

Species: Canine
Sex: Male (Neutered)

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

B6

Referring Information

B6

Client:
Patient: B6

Initial Complaint:
Scanned Record

Initial Complaint:
Cardiology New - will be here at 1:30 PM

SOAP Text Jan 3 2019 1:03PM - B6

Disposition/Recommendations

FDA-CVM-FOIA-2019-1704-006087

FDA-CVM-FOIA-2019-1704-006088

Cummings Veterinary Medical Center AT TUFTS UNIVERSITY

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

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

Patient:	B6
Species:	Canine
Breed:	Pit Bull
Sex:	Male (Neutered)
Age:	B6 Years Old

Lab Results Report

Accession ID:

Test	Results	Reference Range	Units

stringsoft

Printed Tuesday, March 26, 2019

FDA-CVM-FOIA-2019-1704-006089

INVOICE

B6

FOR: B6

Printed: 12-31-18 at 2:26p
Date: 12-29-18
Account: 10080
Invoice: 106408

Date	For	Qty	Description	Price	Discount	Net Price
12-29-18	B6	1	Office Call - Brief Exam			B6

Eating/drinking:
C/S/V/D:
Meds/suppl:
FT/HWP:
Indoor/outdoor (cats):
Major medical hx:
Concerns:

B6

Heart- NMA, irregularly irregular rhythm, femoral pulses deficits

B6

Assessment -

B6

Ddx - DCM, atrial fibrillation, PSVT

Plan -

B6

O reports intermittent, more frequent syncopal episodes recently. Sometimes

FDA-CVM-FOIA-2019-1704-006090

fainting, but other times appears nauseated and unstable. Strongly recommended referral to cardiologist for complete work up including ECHO, ECG, BP, proBNP and complete thoracic radiograph series. VHS = 10.5 based on prior radiograph taken in hospital

12-29-18 1 Ultrasound - In House B6

Old balance	Charges	Payments	New balance
B6			

A minimum Service Charge of $5.00 per month in addition to a 1.5% monthly finance charge will be applied to all balances after 30 days.

Patient	Total charges
B6	

B6

Doctor's Instructions

Office Call - Brief Exam

Our Regular Business Hours are Mon,Tues,Wed and Fri 9am-5pm, Thurs 9am-7pm and Sat 9am-12pm
In Case of an Emergency After Hours:
B6 in collaboration with B6. Keep B6 B6 provide shared coverage for local emergencies from 5pm-10pm Mon-Fri. Please call our office at B6 and you will be directed to the appropriate hospital providing coverage at that time.
In order to ensure the most comprehensive care for your pet, all overnight, weekend and holiday emergencies are referred to the closest fully staffed 24 hour emergent facilities by all of the B6 area animal hospitals.
B6 is located in B6 is located in B6 B6

FDA-CVM-FOIA-2019-1704-006091

PET OWNER'S COPY

B6

B6

Certificate of Rabies Vaccination

RSA 436:101I, REQUIRES THE FOLLOWING OWNER STATEMENT.

I, B6 SWEAR

THAT TO MY KNOWLEDGE THIS DOG HAS NOT BITTEN ANYONE WITHIN 10 DAYS.

This is to certify that this date 3/17/2015, a (dog) (cat) (ferret) (wolf)
belonging to B6
mailing address B6
and residing in B6
was vaccinated with Boehringer-Ingelheim Rabvac 3 killed vax
(brand) (type)
serial no. 1215388A rabies vaccine,
Breed Pitbull mix Age 4yrs Sex NM
Weight 76.6# Tag No. _____
Animal's Name B6
Markings of animal _____
Re-vaccination Due
Date 3/17/2018 B6
(Veterinarian)

Retain this certificate. A charge for replacement may be made.

The Veterinarian signing this certificate is licensed by the State of B6 and has the approval of the Department of Agriculture for the issuance of Health Certificates and Rabies Vaccinations.

FDA-CVM-FOIA-2019-1704-006092

INVOICE

B6

FOR: B6

Printed: 12-31-18 at 2:44p
Date: 12-29-18
Account: 10080
Invoice: 106408

Date	For	Qty	Description	Price	Discount	Net Price
12-29-18	B6	1	Office Call - Brief Exam			B6

Eating/drinking:
C/S/V/D:
Meds/suppl:
FT/HWP:
Indoor/outdoor (cats):
Major medical hx:
Concerns:

B6

Heart- NMA, irregularly irregular rhythm, femoral pulses deficits

B6

Assessment -

B6

Ddx - DCM, atrial fibrillation, PSVT

Plan -

B6

O reports intermittent, more frequent syncopal episodes recently. Sometimes

FDA-CVM-FOIA-2019-1704-006093

B6

Patient Chart

Printed: 12-31-18 at 2:30p

CLIENT INFORMATION

Name B6
Address

Significant Other B6

PATIENT INFORMATION

Name	B6	**Species**	Canine
Sex	Male, Neutered	**Breed**	American Pit Bull
Birthday	B6	**Age**	7y
ID		**Rabies**	6696
Color	Tan & White	**Weight**	74.20 lbs
Reminded	03-08-18	**Codes**	

⚠ **03-22-18 11:23a: CAUTION!! B6 excellent handler**

Reminders for B6 Last done

HEALTH HISTORY SUMMARY

Date	Diagnosis
12-20-12	B6

B6 weight history (in lbs)

MEDICAL HISTORY

Date	By	Code	Description	Qty (Variance)	Photo
09-20-18	B6	1DOCI	Doctors' Instructions		

B6 did very well for his x-ray.

FDA-CVM-FOIA-2019-1704-006094

Patient Chart for: B6 Client: B6
Date: 12-31-18, Time: 2:30p Page: 2

Date	By	Code	Description	Qty (Variance)	Photo

B6

09-20-18 B6 1RADL1 Radiology 1 view
Lateral chest - on inspiration - heart size within normal, lungs show some fibrosis - no sign of pneumonia, etc

1OC Office Call Exam
Eating/drinking: yes
C/S/V/D: coughing - sometimes to the point where he collapses
Meds/suppl:
FT/HWP:
Indoor/outdoor (cats):
Major medical hx:

B6

Heart- NMA, NSR, femoral pulses are strong and synchronous - just very fast

B6

B6

Age: 7y

(Additional history not shown)

FDA-CVM-FOIA-2019-1704-006095

Client: B6
Patient:

B6 3/17/18 3 year Rabies Cert

PET OWNER'S COPY

B6

B6

Certificate of Rabies Vaccination

RSA 436:1011, REQUIRES THE FOLLOWING OWNER STATEMENT.

I, B6 SWEAR

THAT TO MY KNOWLEDGE THIS DOG HAS NOT BITTEN ANYONE WITHIN 10 DAYS.

This is to certify that this date 3/17/18, a (dog) (cat) (ferret) (wolf)
belonging to B6
mailing address B6
and residing in B6
was vaccinated with Rabvac 3 (brand) KV (type)
serial no. 4150443A rabies vaccine,
Breed Pitbull mix Age 7yrs Sex NM
Weight 80 lbs Tag No B6
Animal's Name B6
Markings of animal tan & white
Re-vaccination Due Date 3/17/21 B6

Retain this certificate. A charge for rep
made.

The Veterinarian signing this certificate is licensed by the State of B6 and has the approval of the Department of Agriculture for the issuance of Health Certificates and Rabies Vaccinations.

B6

FDA-CVM-FOIA-2019-1704-006096

Client: Patient: **B6**

diet history 1/3/19

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

Pet's name: B6 Owner's name: B6 Today's date: 1/3/19

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

   Poor ——|—— **Excellent**

2. Have you noticed a change in your pet's appetite over the last 1-2 weeks? (check all that apply)
   ☒Eats about the same amount as usual ☐Eats less than usual ☐Eats more than usual
   ☐Seems to prefer different foods than usual ☒Other seems more hesitant to eat but once encouraged, he eats his meal. Elevating his bowl has helped.

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

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

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

Food (include specific product and flavor)	Form	Amount	How often?	Fed since
Nutro Grain Free Chicken, Lentil, & Sweet Potato Adult	*dry*	*1 ½ cup*	*2x/day*	*Jan 2018*
85% lean hamburger	*microwaved*	*3 oz*	*1x/week*	*Jan 2015*
Pupperoni original beef flavor	*treat*	*½*	*1x/day*	*Aug 2015*
Rawhide	*treat*	*6 inch twist*	*1x/week*	*Dec 2015*
4Health adult Kibble (alternating proteins - lamb, fish)	dry	1¼ C	Twice daily	12/18
WHITEFISH + POTATO OR SALMON + POTATO ADULT				

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

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

		Brand/Concentration	Amount per day
Taurine	☐Yes ☐No		
Carnitine	☐Yes ☐No		
Antioxidants	☐Yes ☐No		
Multivitamin	☐Yes ☐No		
Fish oil	☐Yes ☐No		
Coenzyme Q10	☐Yes ☐No		
Other (please list):			
Example: Vitamin C		*Nature's Bounty*	*500 mg tablets – 1 per day*
Multi powder			½ tbsp twice daily (just for flavor)
CBD oil - 4 drops	BID		

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

FDA-CVM-FOIA-2019-1704-006097

diet history 1/3/19

Has been eating 4health grain free (alternating proteins) for multiple years, just recently switched to regular kibble (w/grain)

has ~~was~~ been fed a very wide variety of canned food, only used to give medications - about 2 ~~tablespoons~~ twice daily

- pedigree
- pure balance
- 4 health

FDA-CVM-FOIA-2019-1704-006098

B6

Patient Chart

Printed: 01-02-19 at 5:09p

CLIENT INFORMATION

Name B6
Address

Significant Other B6

PATIENT INFORMATION

Name	B6	**Species**	Canine
Sex	Male, Neutered	**Breed**	American Pit Bull
Birthday	B6	**Age**	7y
ID		**Rabies**	6696
Color	Tan & White	**Weight**	74.20 lbs
Reminded	03-08-18	**Codes**	

⚠ **03-22-18 11:23a: CAUTION!!** B6 **excellent handler**

B6

Date	Diagnosis
12-20-12	B6

Horton's weight history (in lbs)

03-22-18	74.20
12-15-17	73.40

MEDICAL HISTORY

Date	By	Code	Description	Qty (Variance)	Photo
01-02-19	B6	NOTES	Notes		
	B6 01-02-19 at 4:40p: emailed chart to liaisons@tuffs.edu				

B6

12-29-18	B6	1IHUL	Ultrasound - In House	

FDA-CVM-FOIA-2019-1704-006099

Date	By	Code	Description	Qty (Variance)	Photo

Decreased contractility
No pleural or pericardial effusion
Left ventricle appears subjectively dilated with decreased fractional shortening
Irregular rhythm audible and noted on u/s
Needs cardio consult with specialist ASAP

12-29-18 B6 1OCB Office Call - Brief Exam

Eating/drinking:
C/S/V/D:
Meds/suppl:
FT/HWP:
Indoor/outdoor (cats):
Major medical hx:

B6

Heart- NMA, irregularly irregular rhythm, femoral pulses deficits

B6

Assessment -

B6

Ddx - DCM, atrial fibrillation, PSVT

Plan -

B6

O reports intermittent, more frequent syncopal episodes recently. Sometimes fainting, but other times appears nauseated and unstable. Strongly recommended referral to cardiologist for complete work up including ECHO, ECG, BP, proBNP and complete thoracic radiograph series. VHS = 10.5 based on prior radiograph taken in hospital

12-29-18 B6 VISIT Patient check-in

B6 12-29-18 at 11:01a: urgent- check heart- having a episode. Having a tough time hearing HR

Age: 7y

FDA-CVM-FOIA-2019-1704-006100

Patient Chart for B6 Client: B6
Date: 01-02-19, Time: 5:09p Page: 3

Date	By	Code	Description	Qty (Variance)	Photo
12-16-18					
12-18-18					
12-13-18					
12-05-18					
09-20-18					

B6

1RADL1 Radiology 1 view
Lateral chest - on inspiration - heart size within normal, lungs show some fibrosis - no sign of pneumonia, etc

1OC Office Call Exam
Eating/drinking: yes
C/S/V/D: coughing - sometimes to the point where he collapses
Meds/suppl:
FT/HWP:

FDA-CVM-FOIA-2019-1704-006101

Patient Chart for B6 Client: B6
Date: 01-02-19, Time: 5:09p Page: 4

Date	By	Code	Description	Qty (Variance)	Photo

Indoor/outdoor (cats):
Major medical hx:
Concerns:

B6

Heart- NMA, NSR, femoral pulses are strong and synchronous - just very fast

B6

09-20-18 B6 VISIT Patient check-in
B6 09-19-18 at 4:53p: Chest x-ray, HWT - O will have him wait in car and will let us know they are here.
B6 may help us take rad

Age: 7y

09-19-18

07-13-18

B6

07-09-18

07-09-18 B6 MHRX DECLINED B6
B6

FDA-CVM-FOIA-2019-1704-006102

Client: B6
Patient:

RDVM B6 **hospital records**

Patient Chart for B6 Client: B6
Date: 01-02-19, Time: 5:09p

Date	By	Code	Description	Qty (Variance)	Photo
05-04-18			B6		
05-04-18					
03-26-18	B6	SCAN	B6		
03-26-18		CC	Client Communication		
03-26-18					
03-23-18			B6		
03-22-18					
03-22-18					

IDXREQ IDEXX LabREXX Requisition #33342114-2164

Test	Result	Flag	Normal Range Low	Normal Range High	Measure

FDA-CVM-FOIA-2019-1704-006103

Client: B6
Patient:

RDVM B6

Patient Chart for B6 Client: B6
Date: 01-02-19, Time: 5:09p

Date	By	Code	Description			Qty (Variance)	Photo
CHEM 27 w/ SDMA 03-22-18 8:38a							
ALP				5	160	U/L	
ALT				18	121	U/L	
AST				16	55	U/L	
CREATINE KINASE				10	200	U/L	
GGT				0	13	U/L	
AMYLASE				337	1469	U/L	
LIPASE				138	755	U/L	
ALBUMIN				2.7	3.9	g/dL	
TOTAL PROTEIN				5.5	7.5	g/dL	
GLOBULIN				2.4	4.0	g/dL	
TOTAL BILIRUBIN				0.0	0.3	mg/dL	
BILIRUBIN CONJUG				0.0	0.1	mg/dL	
BUN				9	31	mg/dL	
CREATININE	B6		H	**0.5**	**1.5**	**mg/dL**	
CHOLESTEROL				131	345	mg/dL	
GLUCOSE				63	114	mg/dL	
CALCIUM				8.4	11.8	mg/dL	
PHOSPHORUS				2.5	6.1	mg/dL	
TCO2 (BICARBONA				13	27	mmol/L	
CHLORIDE				108	119	mmol/L	
POTASSIUM				4.0	5.4	mmol/L	
SODIUM				142	152	mmol/L	
ALB/GLOB RATIO				0.7	1.5		
BUN/CREATININE R							
BILIRUBIN UNCONJ				0.0	0.2	mg/dL	
NA/K RATIO				28	37		
HEMOLYSIS INDEX							

B6

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

RESULTS MAY BE AFFECTED BY THE PRESENCE OF HEMOLYSIS.

LIPEMIA INDEX B6

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

ANION GAP	B6		11	26	mmol/L
SDMA			0	14	ug/dL

B6

SDMA IS WITHIN THE REFERENCE INTERVAL AND CREATININE IS INCREASED. This combination of

B6

Test	Result	Flag	Normal Range Low	Normal Range High	Measure
T4 03-22-18 8:38a					
T4	B6		1.0	4.0	ug/dL

B6

Interpretive ranges:
<1.0 Low
1.0-4.0 Normal
>4.0 High
2.1-5.4 Therapeutic

B6

FDA-CVM-FOIA-2019-1704-006104

Client:
Patient: B6

RDVM B6 **hospital records**

Patient Chart for: B6
Date: 01-02-19, Time: 5:09p

Client: B6
Page: 7

Date	By	Code	Description	Qty (Variance)	Photo

B6

Test	Result	Flag	Normal Range Low	Normal Range High	Measure
CBC STANDARD 03-22-18 8:38a					
WBC	B6		4.9	17.6	K/uL
RBC			5.39	8.70	M/uL
HGB			13.4	20.7	g/dL
HCT			38.3	56.5	%
MCV			59	76	fL
MCH			21.9	26.1	pg
MCHC			32.6	39.2	g/dL
% RETICULOCYTE					%
RETICULOCYTE			10	110	K/uL
% NEUTROPHIL					%
% LYMPHOCYTE					%
% MONOCYTE					%
% EOSINOPHIL					%
% BASOPHIL					%
PLATELET			143	448	K/uL
NEUTROPHIL			2940	12670	/uL
LYMPHOCYTE		**L**	**1060**	**4950**	**/uL**
MONOCYTE			130	1150	/uL
EOSINOPHIL			70	1490	/uL
BASOPHIL			0	100	/uL

B6

AUTOMATED CBC

Test	Result	Flag	Normal Range Low	Normal Range High	Measure
UPC IF INDICATED 03-22-18 8:38a					
UPC IF INDICATED					

A urine protein-to-creatinine ratio (UPC) was not indicated because there was either a negative SSA protein or an active urine sediment (presence of gross hematuria, >100 RBC/hpf, >5 WBC/hpf or bacteria).

Test	Result	Flag	Normal Range Low	Normal Range High	Measure
URINALYSIS 03-22-18 8:38a					
COLLECTION MET	B6				
COLOR					
CLARITY					
SPECIFIC GRAVIT					
GLUCOSE					
BILIRUBIN					
KETONES					
BLOOD					
PH					
PROTEIN					

B6

Protein test is performed and confirmed by the sulfosalicylic acid test.

WBC	B6		0	5	HPF

FDA-CVM-FOIA-2019-1704-006105

Patient Chart for B6 Client: B6
Date: 01-02-19, Time: 5:09p Page: 8

Date	By	Code	Description	Qty (Variance)	Photo

RBC HPF
BACTERIA
EPI CELL
MUCUS
CASTS
CRYSTALS
UROBILINOGEN

B6

Test	Result	Flag	Normal Range Low	Normal Range High	Measure

NOTE FROM IDEXX 03-22-18 8:38a
NOTE
Sample submitted in non-IDEXX glass tube. IDEXX no longer supports the use of glass collection tubes in order to minimize safety concerns. Plastic collection tubes can be ordered at no charge online at order.idexx.com or through the Inside Sales Center at 888-79-IDEXX using product number 98-0003497-00.

03-22-18 B6 1SPR Senior Profile w/Reflex UA #26639999
1DOCI Doctors' Instructions

Today we have checked B6 over for a specific medical condition. His physical exam is normal aside from B6 from previous B6 am submitting some labwork to screen for underlying conditions that would be contributing to his new anxiety.

B6

Please call if any questions or concerns regarding the findings on the physical exam.

1OC Office Call Exam
Eating/drinking: Normal Blue Buffalo
C/S/V/D: No
Meds/suppl: B6
B6
FT/HWP:
Indoor/outdoor (cats):
Major medical hx: bilateral TTA ~1 yo, aggression/reactivity as a puppy
Concerns: Extreme progressive anxiety when left alone.

B6

FDA-CVM-FOIA-2019-1704-006106

Patient Chart for B6 Client: B6
Date: 01-02-19, Time: 5:09p Page: 9

Date	By	Code	Description	Qty (Variance)	Photo

B6

Heart- NMA, NSR, femoral pulses are strong and synchronous

B6

B6

03-22-18 B6 VISIT Patient check-in
HLD: 03-20-18 at 2:56p: extreme anxiety, meds not helping

Age: 6y **Weight:** 74.20

03-17-18 B6 1RD3-3 Rabies Defensor 3 - 3 yr.

03-05-18 MHRX B6

B6

03-05-18 B6 CC Client Communication

B6

FDA-CVM-FOIA-2019-1704-006107

Patient Chart for B6 Client: B6
Date: 01-02-19, Time: 5:09p Page: 10

Date	By	Code	Description	Qty (Variance)	Photo
02-19-18	B6	CC	Client Communication		

B6 02-19-18 at 12:32p: O just needs enough to get her through until she can get some from B6

02-19-18

12-28-17

12-15-17

B6

MHRX B6

B6

12-15-17 B6 NOTES B6

12-15-17 1OC Office Call Exam

B6

Heart/Lungs-No murmur or arrhythmia heard; HR 90

FDA-CVM-FOIA-2019-1704-006108

Patient Chart for B6 Client: B6
Date: 01-02-19, Time: 5:09p Page: 11

Date	By	Code	Description	Qty (Variance)	Photo
12-15-17			B6		
12-04-17					
03-27-15	B6	PHARM	Pharmacy Refills		
03-17-15					
02-07-15					
11-26-14			B6		
11-20-14					
11-20-14					
02-13-14					

FDA-CVM-FOIA-2019-1704-006109

Patient Chart for B6 Client: B6
Date: 01-02-19, Time: 5:09p Page: 12

Date	By	Code	Description	Qty (Variance)	Photo
02-06-14	B6				
03-19-13	B6	CC	Client Communication		
02-19-13	B6				
02-18-13	B6				
	B6	CC	Client Communication		
01-17-13	B6	NOTES	Scan of history form Mass Referral Attachments\10080\ B6 \0117201309282598 8.pdf		
01-09-13	B6				
01-09-13	B6				
12-20-12	B6				

B6 02-18-13 at 4:31p: B6 is concerned that B6 improved -

Today, B6 has been given a physical exam. Everything was within normal limits.

B6 was given booster vaccines according to specific needs and lifestyle.

Recommendations from today's examination:
Keep up the good work.

Please call if any questions or concerns regarding the findings on the physical exam.

B6

FDA-CVM-FOIA-2019-1704-006110

Patient Chart for B6 Client: B6
Date: 01-02-19, Time: 5:09p Page: 13

Date	By	Code	Description	Qty (Variance)	Photo
12-20-12	B6	VISIT	Patient check-in		
	B6				
Age					
12-11-12					
12-07-12					
12-07-12					
12-06-12					
	B6				
11-30-12					
11-09-12					
11-09-12	B6	CC	Client Communication		
B6	11-09-12 at 8:51a	B6			
	B6				
10-29-12					
	B6				
10-29-12	B6	CC	Client Communication		
	B6				
10-29-12					

FDA-CVM-FOIA-2019-1704-006111

Client:
Patient: B6

RDVM B6 **hospital records**

Patient Chart for B6 Client: B6
Date: 01-02-19, Time: 5:09p

Date	By	Code	Description	Qty (Variance)	Photo
10-19-12	B6				
10-19-12			Attachments\10080\ B6 .pdf		
10-17-12	B6	NOTES	Notes		
	B6				
	B6				
10-17-12	OTC	NOTES	Scan of MVR report		
	Est B6				
			Attachments\10080 B6 10172012114422397.pdf		
10-06-12	B6				
10-04-12	OTC	NOTES	Notes		
	B6		10-04-12 at 3:53p: see scanned records from B6		
			Attachments\10080 B6 .pdf		
10-03-12	B6				
	B6				
10-03-12	B6	NOTES	Scan from B6		
			Attachments\10080 B6 22018088.pdf		
09-24-12	CC		Client Communication		
	B6				
	FNOTES	By: B6	Please Call		
	B6				

FDA-CVM-FOIA-2019-1704-006112

Patient Chart for: B6 Client: B6
Date: 01-02-19, Time: 5:09p Page: 15

Date	By	Code	Description	Qty (Variance)	Photo
09-19-12			B6		
09-18-12					
09-18-12	B6		Patient check-in		
	B6				
	Age: 17m				
09-18-12	B6	CC	Client Communication		
09-07-12			B6		
09-04-12					

FDA-CVM-FOIA-2019-1704-006113

Patient Chart for B6 Client: B6
Date: 01-02-19, Time: 5:09p Page: 16

Date	By	Code	Description	Qty (Variance)	Photo
09-04-12	B6				
08-31-12	B6	CC	Client Communication		
08-30-12					
08-27-12	B6				

Please contact our office with any concerns or questions. B6

Thank you,

B6

B6

FDA-CVM-FOIA-2019-1704-006114

Patient Chart for: B6 Client: B6
Date: 01-02-19, Time: 5:09p Page: 17

Date	By	Code	Description	Qty (Variance)	Photo
	B6				
08-27-12	B6	1OCB	Office Call - Brief Exam		
		VISIT	Patient check-in		

B6

B6

Age: 16m

06-14-12

B6

FDA-CVM-FOIA-2019-1704-006115

Client: B6
Patient:

IDEXX BNP - 1/3/2019

IDEXX Reference Laboratories

Client: B6 Patient: B6

IDEXX VetConnect 1-888-433-9987

Client: B6
Patient:
Species: CANINE
Breed: AMERICAN_PIT_BU
Gender: MALE NEUTERED
Age: 0Y

Date: 01/03/2019
Requisition: [illegible]
Accession: B6
Ordered by: B6

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

Account: B6

CARDIOPET proBNP - CANINE

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

Comments:
1

B6

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

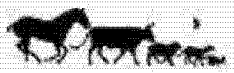
Result is greater than: B6

Page 1 of 1

FDA-CVM-FOIA-2019-1704-006116

Client: B6
Patient:

CBC/CHEM - 1/3/2019



Tufts Cummings School Of Veterinary Medicine

200 Westboro Road
North Grafton, MA 01536

DUPLICATE

Name/DOB: B6
Patient ID: B6
Phone number:
Collection Date: 1/3/2019 3:35 PM
Approval date: 1/4/2019 10:42 AM

Sex: CM
Age: 7
Species: Canine
Breed: Pit Bull

Provider: B6
Order Location: V320559: Investigation into
Sample ID: 1901030138

CBC, Comprehensive, Sm Animal (Research)

DNOYES		B6	Ref. Range/Males
WBC (ADVIA)			4.40-15.10 K/uL
RBC (Advia)			5.80-8.50 M/uL
Hemoglobin (ADVIA)			13.3-20.5 g/dL
Hematocrit (Advia)			39-55 %
MCV (ADVIA)			64.5-77.5 fL
MCH (ADVIA)			21.3-25.9 pg
MCHC (ADVIA)			31.9-34.3 g/dL
RDW (ADVIA)	L		11.9-15.2
Platelet Count (Advia)			173-486 K/uL
01/03/19 5:49 PM		B6	
Mean Platelet Volume (Advia)		B6	8.29-13.20 fl
01/03/19 4:20 PM		B6	
Platelet Crit		B6	0.129-0.403 %
01/03/19 4:20 PM		B6	
Reticulocyte Count (Advia)		B6	0.20-1.60 %
Absolute Reticulocyte Count (Advia)			14.7-113.7 K/uL

Microscopic Exam of Blood Smear (Advia)

DNOYES		B6	Ref. Range/Males
Seg Neuts (%)	H		43-86 %
Lymphocytes (%)			7-47 %
Monocytes (%)			1-15 %
Eosinophils (%)			0-16 %
Seg Neutrophils (Abs) Advia			2.80-11.50 K/ul
Lymphs (Abs) Advia	L		1.00-4.80 K/uL
Mono (Abs) Advia			0.10-1.50 K/uL
Eosinophils (Abs) Advia			0.00-1.40 K/uL
WBC Morphology		B6	
RBC Morphology			

Research Chemistry Profile - Small Animal (Cobas)

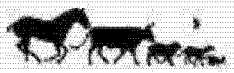
ABLASOTTO		B6	Ref. Range/Males
Glucose			67-135 mg/dL
Urea	H		8-30 mg/dL
Creatinine	H		0.6-2.0 mg/dL
Phosphorus			2.6-7.2 mg/dL

Sample ID: 1901030138/1
This report continues... (Final)

Reviewed by: _____

FDA-CVM-FOIA-2019-1704-006117

CBC/CHEM - 1/3/2019



Tufts Cummings School Of Veterinary Medicine

200 Westboro Road
North Grafton, MA 01536

DUPLICATE

Name/DOB: B6
Patient ID:
Phone number:
Collection Date: 1/3/2019 3:35 PM
Approval date: 1/4/2019 10:42 AM

Sex: CM
Age: 7
Species: Canine
Breed: Pit Bull

Provider: B6
Order Location: V320559: Investigation into
Sample ID: 1901030138

Research Chemistry Profile - Small Animal (Cobas) (cont'd)

ABLASOTTO B6

		Ref. Range/Males
Calcium 2	H	9.4-11.3 mg/dL
Magnesium 2+	L	1.8-3.0 mEq/L
Total Protein		5.5-7.8 g/dL
Albumin		2.8-4.0 g/dL
Globulins		2.3-4.2 g/dL
A/G Ratio		0.7-1.6
Sodium	H	140-150 mEq/L
Chloride		106-116 mEq/L
Potassium		3.7-5.4 mEq/L
tCO2(Bicarb)		14-28 mEq/L
AGAP	H	8.0-19.0
NA/K		29-40
Total Bilirubin		0.10-0.30 mg/dL
Alkaline Phosphatase		12-127 U/L
GGT		0-10 U/L
ALT	H	14-86 U/L
AST		9-54 U/L
Creatine Kinase		22-422 U/L
Cholesterol		82-355 mg/dL
Triglycerides		30-338 mg/dl
Amylase		409-1250 U/L
Osmolality (calculated)	H	291-315 mmol/L

Sample ID: 1901030138/2
END OF REPORT (Final)

Reviewed by: _____
Page 2

FDA-CVM-FOIA-2019-1704-006118

Client:
Patient: **B6**

Diet history 1/3/19

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

Pet's name: **B6** Owner's name: **B6** Today's date: 1/3/19

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

   Poor ——|—— **Excellent**

2. Have you noticed a change in your pet's appetite over the last 1-2 weeks? (check all that apply)
   ☒Eats about the same amount as usual ☐Eats less than usual ☐Eats more than usual
   ☐Seems to prefer different foods than usual ☒Other seems more hesitant to eat but once encouraged, he eats his meal. Elevating his bowl has helped

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

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

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

Food (include specific product and flavor)	Form	Amount	How often?	Fed since
Nutro Grain Free Chicken, Lentil, & Sweet Potato Adult	*dry*	*1 ½ cup*	*2x/day*	*Jan 2018*
85% lean hamburger	*microwaved*	*3 oz*	*1x/week*	*Jan 2015*
Pupperoni original beef flavor	*treat*	*½*	*1x/day*	*Aug 2015*
Rawhide	*treat*	*6 inch twist*	*1x/week*	*Dec 2015*
4Health adult Kibble (alternating proteins - lamb, fish)	dry	1¼C	Twice daily	12/18
↓ WHITEFISH + POTATO OR SALMON + POTATO ADULT				

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

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

		Brand/Concentration	Amount per day
Taurine	☐Yes ☐No		
Carnitine	☐Yes ☐No		
Antioxidants	☐Yes ☐No		
Multivitamin	☐Yes ☐No		
Fish oil	☐Yes ☐No		
Coenzyme Q10	☐Yes ☐No		
Other (please list):			
Example: Vitamin C		*Nature's Bounty*	*500 mg tablets – 1 per day*
Multi powder			(1 tbsp twice daily just for flavor)
CBD oil - 4 drops	BID		

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

FDA-CVM-FOIA-2019-1704-006119

Client:
Patient: **B6**

Diet history 1/3/19

Has been eating 4health grain free (alternating protiens) for multiple years, just recently switched to regular kibble (w/grain)

has ~~was~~ been fed a very wide variety of canned food, only used to give medications - about 2 tablespoons twice daily

- pedigree
- pure balance
- 4 health

FDA-CVM-FOIA-2019-1704-006120

Client: B6
Patient: B6

Lab Results IDEXX Leptospirosis Panel (MAT) 1/4/19

IDEXX VetConnect 1-888-433-9987

Client: B6
Patient: B6
Species: CANINE
Breed: AMERICAN_PIT_BU
Gender: MALE NEUTERED
Age: B6

Date: 01/04/2019
Requisition #: 462544
Accession #: B6
Ordered by: B6

TUFTS UNIVERSITY
200 WESTBORO RD
NORTH GRAFTON, Massachusetts 01536-1828
508-839-5395

Account: B6

LEPTOSPIROSIS PANEL (MAT)

Test	Result	Reference Range	Units	Normal	Flag
L. BRATISLAVA	B6				
L. CANICOLA					
L. GRYPPOTYPHOSA					
L. ICTEROHAEMORRHAGIAE					
L. POMONA					
L. AUTUMNALIS					

Comments

B6

FDA-CVM-FOIA-2019-1704-006121

Client: B6
Patient: B6

B6 **UA results- 1/7/19**

Patient Info:
Name: B6
Record No: B6
Owner: B6
Doctor: B6

Species: Dog
Breed: American Pit Bul
Age: 7Y
Sex: N

Hospital: B6

Accession No	Doctor	Owner	Patient Name
B6	B6	B6	B6

Test	Results	Adult Reference Range	L	Normal	H
SPECIAL URINE PRO/CREAT RATIO				Date given: 01-07-19 T11:30a	
URINE CREATININE	B6	-			
URINE PROTEIN		-			
URINE PRO/CREAT RATIO		-			
COLOR		-			

B6

Additional interpretive guidelines and management recommendations are available in our online directory on www.vetconnectplus.com or www.iris-kidney.com.

UPC IF INDICATED				Date given: 01-07-19 T11:30a	
UPC IF INDICATED		-			

B6

URINALYSIS				Date given: 01-07-19 T11:30a	
COLLECTION METHOD	B6				
COLOR					
CLARITY					
SPECIFIC GRAVITY					
GLUCOSE					
BILIRUBIN					
KETONES					
BLOOD					
PH					
PROTEIN					
UROBILINOGEN					
WBC					

FDA-CVM-FOIA-2019-1704-006122

Client: B6
Patient: B6

B6 **UA results- 1/7/19**

Accession No.	Doctor	Owner	Patient Name
B6	B6	B6	B6

Test	Results	Adult Reference Range	L	Normal	H
RBC	B6	-			
BACTERIA		-			
EPI CELL		-			
MUCUS		-			
CASTS		-			
CRYSTALS		-			

FDA-CVM-FOIA-2019-1704-006123

Client: B6
Patient:

IDEXX Chemistry 1/8/19

01/08/2019 15:59 B6 B6 PAGE 02

B6

B6

Date: 1/8/19

To: Tufts Foster Hospital

Attn: Cardiology / B6

Fax Number: B6

NUMBER OF PAGES (including this cover page) _____

MESSAGE: Results attached of VA results for B6 (obtained via cysto)

FDA-CVM-FOIA-2019-1704-006124

Client: B6
Patient:

IDEXX Chemistry 1/8/19

01/08/2019 15:59 B6 B6 PAGE 01
pg 1 of 2
01-08-2019 6:19 AM

IDEXX Reference Laboratories
Division of IDEXX Laboratories
www.idexx.com

One IDEXX Drive
Westbrook, Maine 04092
United States

IDEXX Reference Laboratories
Customer Support
888 433 9987

B6

PET OWNER: B6

B6

ACCESSION #: B6
REQUISITION #: T1559272B2
DATE OF COLLECTION: 01/08/2019
DATE OF RECEIPT: 01/08/2019
DATE OF REPORT: 01/08/2019

SPECIES: CANINE
BREED: PIT BULL, AMERICAN
GENDER: MALE NEUTERED
AGE: B6

ACCOUNT #: B6
ORDERED BY: B6

IDEXX SERVICES: 3970 SPECIAL URINE PRO/CREAT RATIO, Z326 UA WITH UPC REFLEX

CHEMISTRY

TEST	RESULT	REF.RANGE/UNITS
Urine Protein: Creatinine Ratio If Indicated	B6	
Urine Creatinine	B6	mg/dL
Urine Protein		mg/dL
Urine Protein: Creatinine Ratio		
Color [a]		

URINALYSIS

TEST	RESULT	REF.RANGE/UNITS
Collection	B6	
Color		
Clarity		
Specific Gravity		
pH		
Urine Protein		
Glucose		
Ketones		
Blood / Hemoglobin		
Bilirubin		
Urobilinogen		
White Blood Cells		(0 - 5) HPF
Red Blood Cells		HPF
Bacteria		
Epithelial Cells		
Mucus		
Casts		
Crystals		

NOTES

CHEMISTRY

a
Renal proteinuria:
UPC <0.2 non-proteinuric
UPC 0.2-0.5 borderline proteinuric
UPC >0.5 proteinuric
The urine protein:creatinine ratio (UPC) should be interpreted along with a

Get deeper insights: For complete access to this patient's diagnostic results, including historic values and images, login to www.vetconnectplus.com
Final report generated January 08, 2019
PAGE 1 of 2

FDA-CVM-FOIA-2019-1704-006125

Client: B6
Patient:

Taurine Panel send out 1/3/2019

26456 PL ✓
26457 WB ✓

Amino Acid Laboratory Sample Submission Form

Amino Acid Laboratory, 1089 Veterinary Medicine Drive, Davis, Ca 956
Telephone: 530-752-5058, Fax: 530-752-4698
Email: ucd.aminoacid.lab@ucdavis.edu
www.vetmed.ucdavis.edu/labs/amino-acid-laboratory

19081030139
B6
B6 | pit Race
1/3/2019 3:36 PM
SHIP w ICE PACKS,TAURINE PANEL
Lithium Heparin
B6

Veterinarian Contact: B6

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

Address: 200 Westboro Road, North Grafton MA 015369

Email: Clinpath@tufts.edu cardiovet@tufts.edu

Telephone: 508-887-4699 **Fax:** 508-839-7938

Billing Contact: B6 **Email:** B6

Billing Contact Phone: B6 **Tax ID:**

Patient Name: B6 **Species:** Canine

Breed: Pit Bull **Owner's Name:**

Current Diet :

Sample type: Plasma Whole Blood Urine Food Other

Test: Taurine Complete Amino Acids Other:

Taurine Results (lab use only)

Plasma: B6 Whole Blood: B6 Urine: Food:

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

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

FDA-CVM-FOIA-2019-1704-006126

Amino Acid Labs Taurine Panel 1/3/19

Amino Acid Laboratory Sample Submission Form

Amino Acid Laboratory, 1089 Veterinary Medicine Drive, Davis, Ca 956
Telephone: 530-752-5058, Fax: 530-752-4698
Email: ucd.aminoacid.lab@ucdavis.edu
www.vetmed.ucdavis.edu/labs/amino-acid-laboratory

190103013
B6
B6 pit Race
1/3/2019 3:36 PM
SHIP w ICE PACKS,TAURINE PANEL
Lithium Heparin
B6

Veterinarian Contact: B6

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

Address: 200 Westboro Road, North Grafton MA 015369

Email: Clinpath@tufts.edu

Telephone: 508-887-4669 Fax: 508-839-7936

Billing Contact: B6 Email: B6

Billing Contact Phone: B6 Tax ID:

Patient Name: B6 Species:

Breed: Owner's Name:

Current Diet :

Sample type: Plasma Whole Blood Urine Food Other

Test: Taurine Complete Amino Acids Other:

Taurine Results (lab use only)

Plasma: B6 Whole Blood: B6 Urine: Food:

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

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

FDA-CVM-FOIA-2019-1704-006127

UNIVERSITY OF CALIFORNIA, DAVIS

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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.

- Normal whole blood taurine: >250nmol/mL
- Normal plasma taurine: >70nmol/mL

- Marginal whole blood taurine: 200-250nmol/mL
- Marginal plasma taurine: 60-70nmol/mL

- Low whole Blood taurine: <200nmol/mL
- Low plasma taurine: <60nmol/mL

References:

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. 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.

FDA-CVM-FOIA-2019-1704-006128

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 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 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.
    - 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 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.

FDA-CVM-FOIA-2019-1704-006129

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:
  - https://www.fda.gov/AnimalVeterinary/NewsEvents/CVMUpdates/ucm613305.htm

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)

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

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

The 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 ~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

FDA-CVM-FOIA-2019-1704-006130

UCDAVIS VETERINARY MEDICINE

CARDIOLOGY SERVICE UPDATES: DOG FOOD & DILATED CARDIOMYOPATHY

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

FDA Alerts found here:
https://www.fda.gov/AnimalVeterinary/NewsEvents/CVMUpdates/ucm613305.htm
https://www.fda.gov/AnimalVeterinary/ResourcesforYou/AnimalHealthLiteracy/ucm616279.htm

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

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

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

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

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

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

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

FDA reporting guidelines found here: https://www.fda.gov/AnimalVeterinary/SafetyHealth/ReportaProblem/ucm182403.htm

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

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

FDA-CVM-FOIA-2019-1704-006131

Client: B6
Patient:

Texas A&M GI Lab Troponin Result 1/24/19

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

Website User ID: Cardiovet@tufts.edu OR clinpath@tufts.edu

GI Lab Assigned Clinic ID: 11405

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

Phone: 508 887 4669
Fax: 9 508 839 7936
Animal Name: B6
Owner Name:
Species: Canine
Date Received: Jan 24, 2019

Tufts University-Clinical Pathology Lab Tracking Number:
GI Lab Accession: B6

Test	Result	Reference Interval	Assay Date
Ultra-Sensitive Troponin I Fasting	B6	≤0.06	01/24/19

B6

Comments:

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

FDA-CVM-FOIA-2019-1704-006132

Gastrointestinal Laboratory
Dr. J.M. Steiner
Department of Small Animal Clinical Sciences
Texas A&M University
4474 TAMU
College Station, TX 77843-4474
Website User ID: Cardiovet@tufts.edu OR clinpath@tufts.edu

GI Lab Assigned Clinic ID: 11405

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

Phone: 508 887 4669
Fax: 9 508 839 7936
Animal Name: B6
Owner Name:
Species: Canine
Date Received: Jan 24, 2019

Tufts University-Clinical Pathology Lab Tracking Number:

GI Lab Accession: B6

Test	Result	Reference Interval	Assay Date
Ultra-Sensitive Troponin I Fasting	B6	≤0.06	01/24/19

B6

Comments:

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

FDA-CVM-FOIA-2019-1704-006133

Client: B6
Patient: B6

B6 **Catalyst One 1/29/19**

Client: B6
Patient Name: B6
Species: Canine
Breed:

Gender:
Weight:
Age:
Doctor: B6

B6

Test	Results	Reference Interval	LOW	NORMAL	HIGH
Catalyst One (January 29, 2019 2:46 PM)					
GLU	B6	74 - 143			
CREA		0.5 - 1.8			HIGH
BUN		7 - 27			HIGH
BUN/CREA					
PHOS		2.5 - 6.8			
CA		7.9 - 12.0			
TP		5.2 - 8.2			
ALB		2.3 - 4.0			
GLOB		2.5 - 4.5			
ALB/GLOB					
ALT		10 - 125			HIGH
ALKP		23 - 212			
GGT		0 - 11			
TBIL		0.0 - 0.9			
CHOL		110 - 320			
AMYL		500 - 1500			
LIPA		200 - 1800			

B6

1/29/19
78.4lbs

Specific Gravity
B6

Printed: January 29, 2019 2:46 PM

Page 1 of1

IDEXX LABORATORIES

FDA-CVM-FOIA-2019-1704-006134

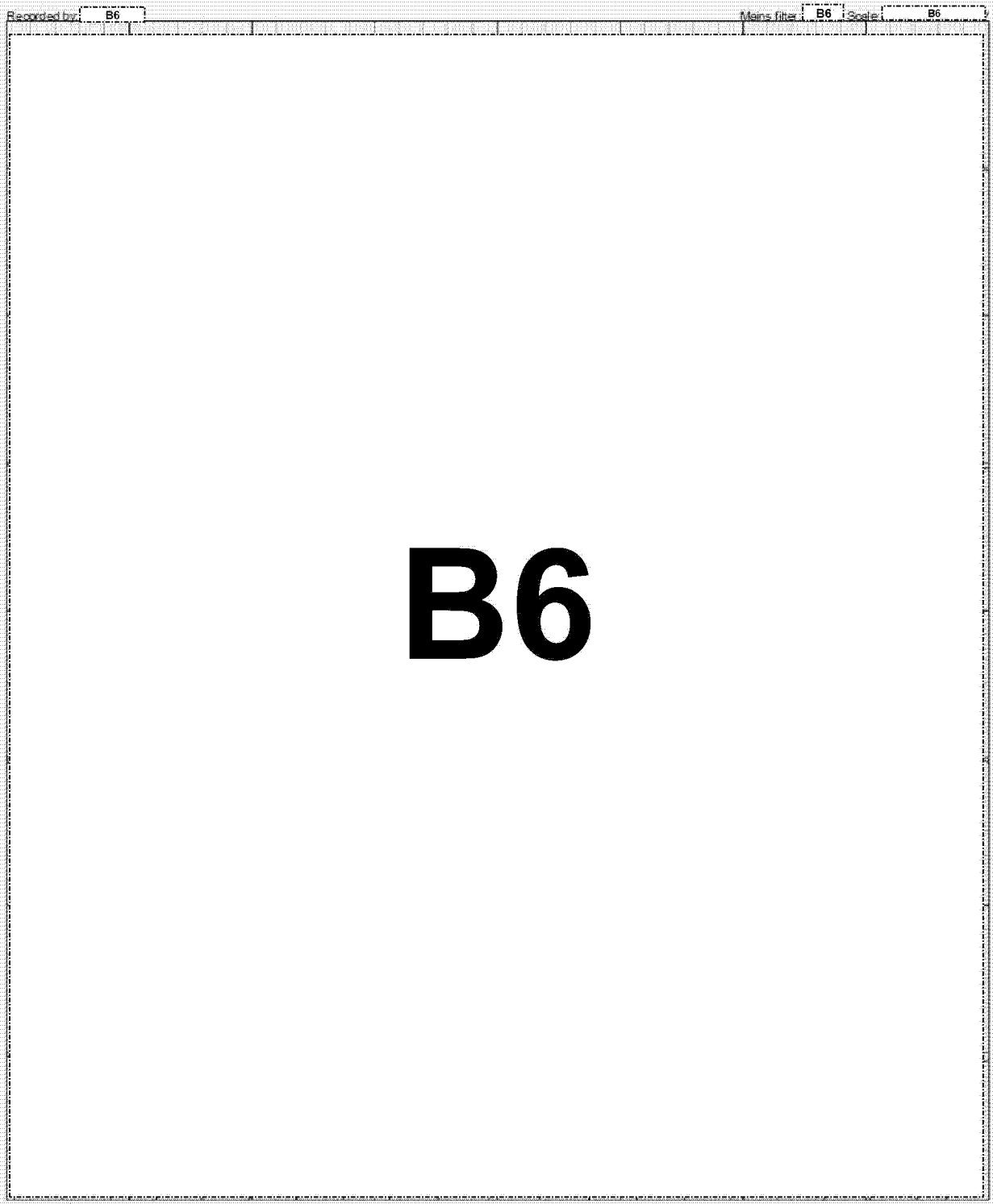
Client:
Patient: **B6**

Alivecor ECG

Patient: B6
Breed/Species American Pit Bull Terrier / Dog
Recorded: Sunday, February 10, 2019 at 10:01:55 PM
Heart Rate: 163 bpm **Duration:** 1 min 7 s

AliveCor

Recorded by: B6 Mains filter: B6 Scale: B6



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FDA-CVM-FOIA-2019-1704-006135

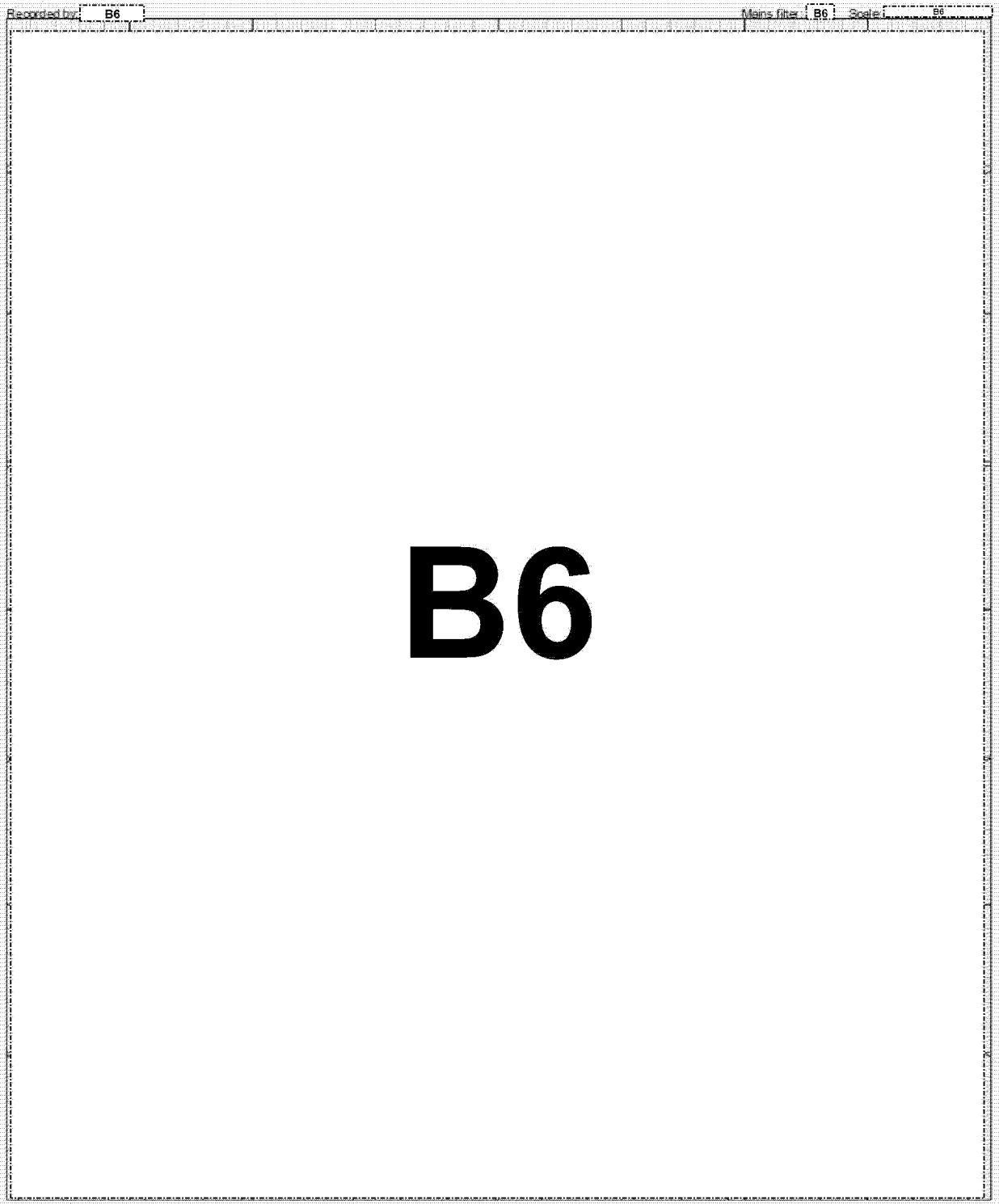
Client:
Patient: **B6**

Alivecor ECG

Patient: B6
Breed/Species American Pit Bull Terrier / Dog
Recorded: Sunday, February 10, 2019 at 10:01:55 PM
Heart Rate: 163 bpm **Duration:** 1 min 7 s

AliveCor

Recorded by: B6 Mains filter: B6 Scale: B6



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FDA-CVM-FOIA-2019-1704-006136

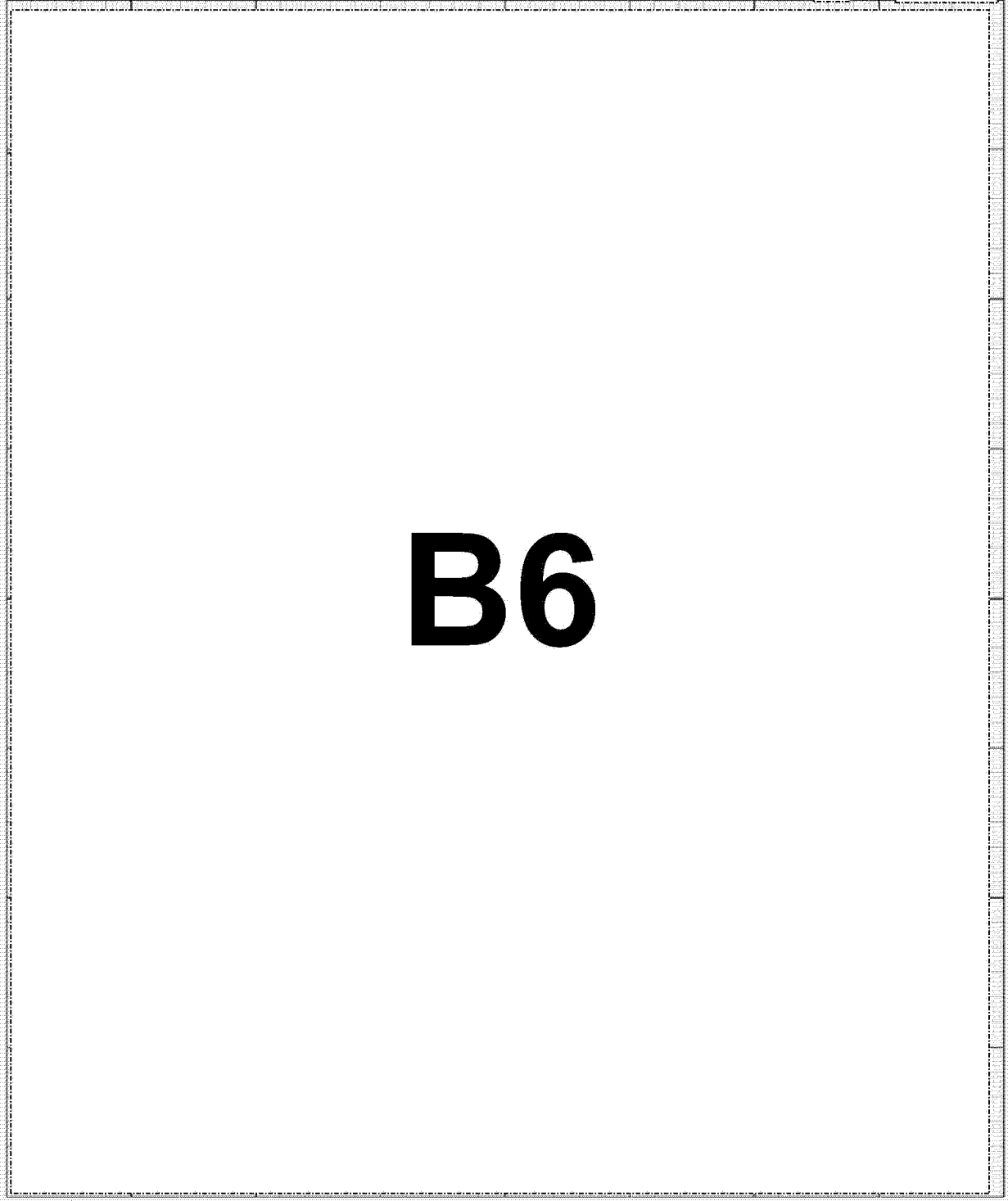
Client:
Patient: **B6**

Alivecor ECG

Patient: B6
Breed/Species American Pit Bull Terrier / Dog
Recorded: Sunday, February 10, 2019 at 10:01:55 PM
Heart Rate: 163 bpm **Duration:** 1 min 7 s

AliveCor

Recorded by: B6 Mains filter: B6 Scale: B6



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FDA-CVM-FOIA-2019-1704-006137

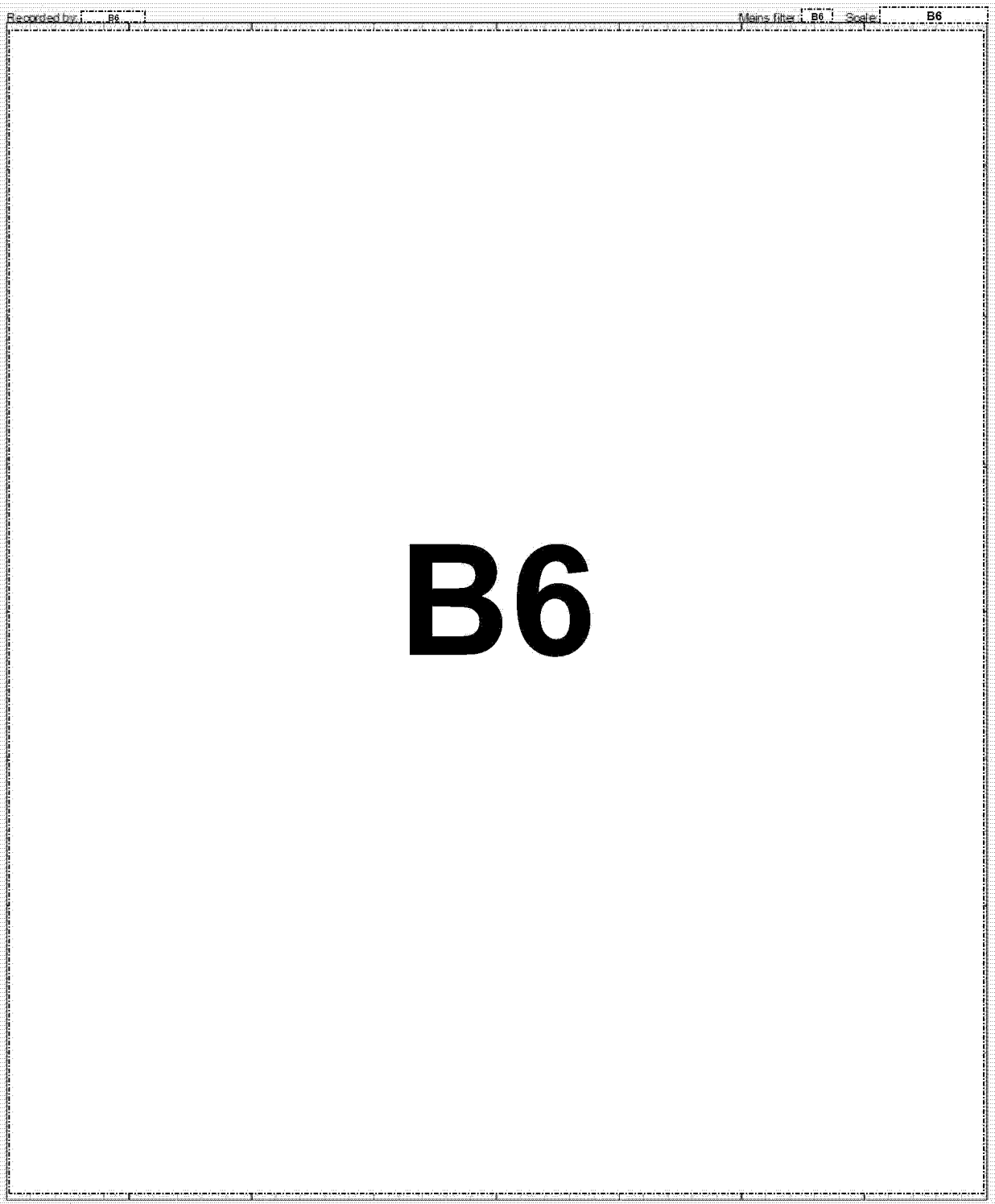
Client:
Patient: **B6**

Alivecor ECG

Patient: B6
Breed/Species American Pit Bull Terrier / Dog
Recorded: Sunday, February 10, 2019 at 10:01:13 PM
Heart Rate: 158 bpm **Duration:** 16 s

AliveCor

Recorded by: B6 Mains filter: B6 Scale: B6



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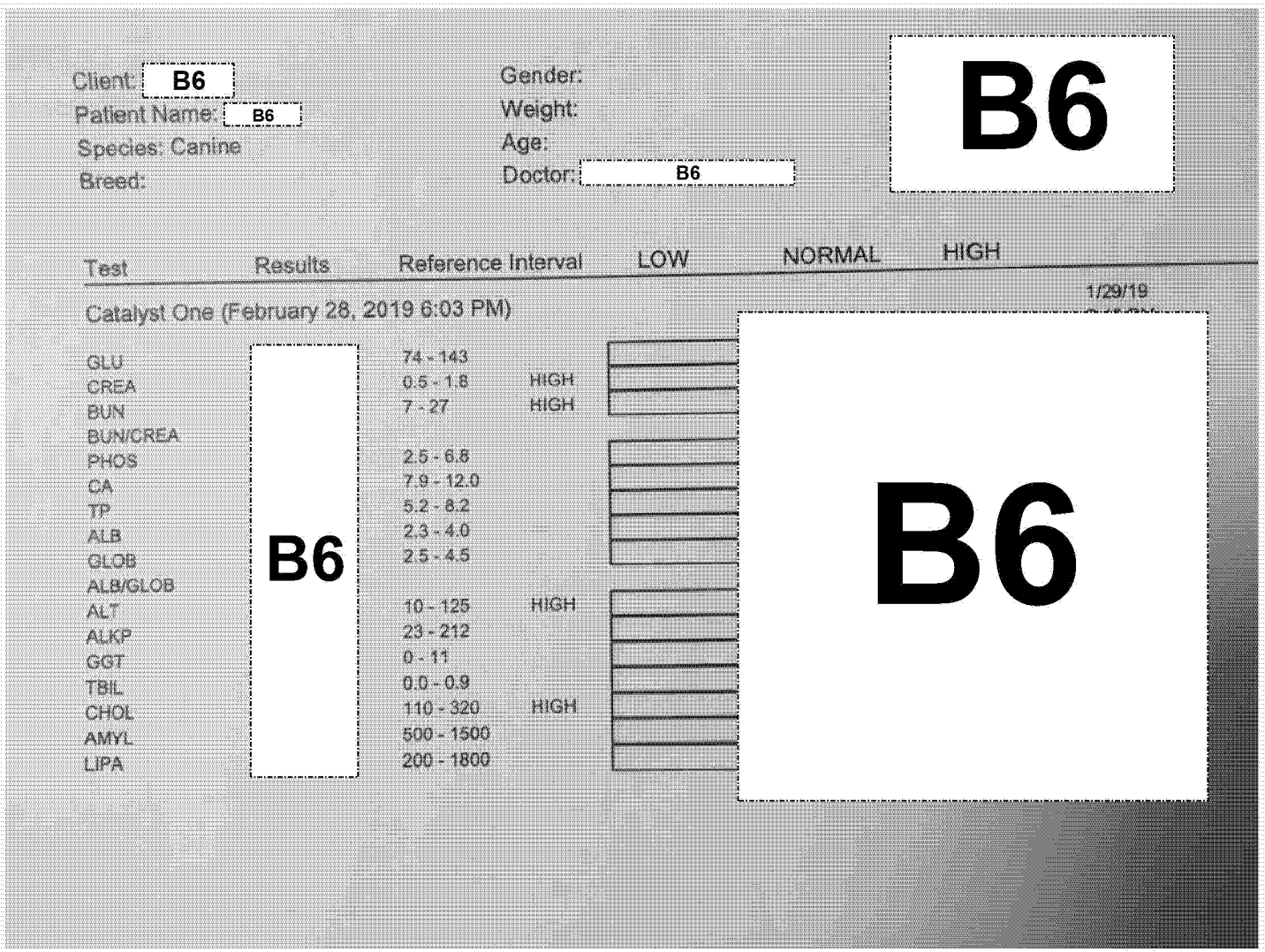
FDA-CVM-FOIA-2019-1704-006138

Client: B6
Patient:

Bloodwork from B6



FDA-CVM-FOIA-2019-1704-006139

Client:
Patient: B6

Vitals Results

B6

1/3/2019 1:44:42 PM	Weight (kg)
1/3/2019 1:44:49 PM	Heart Rate (/min)

FDA-CVM-FOIA-2019-1704-006140

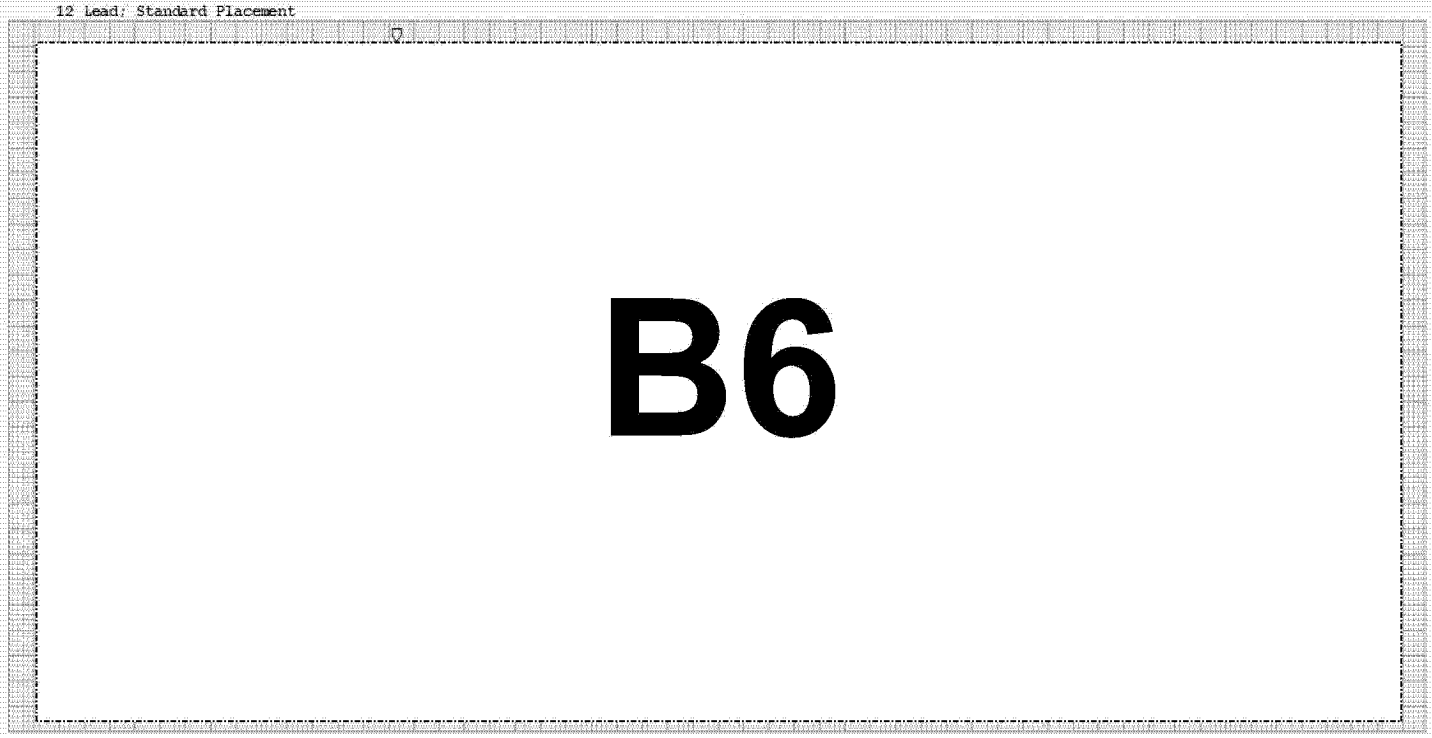
Client: B6
Patient:

ECG from cardio

B6 1/3/2019 3:28:10 PM

Tufts University
Tufts Cummings School of Vet Med
Cardiology

12 Lead; Standard Placement



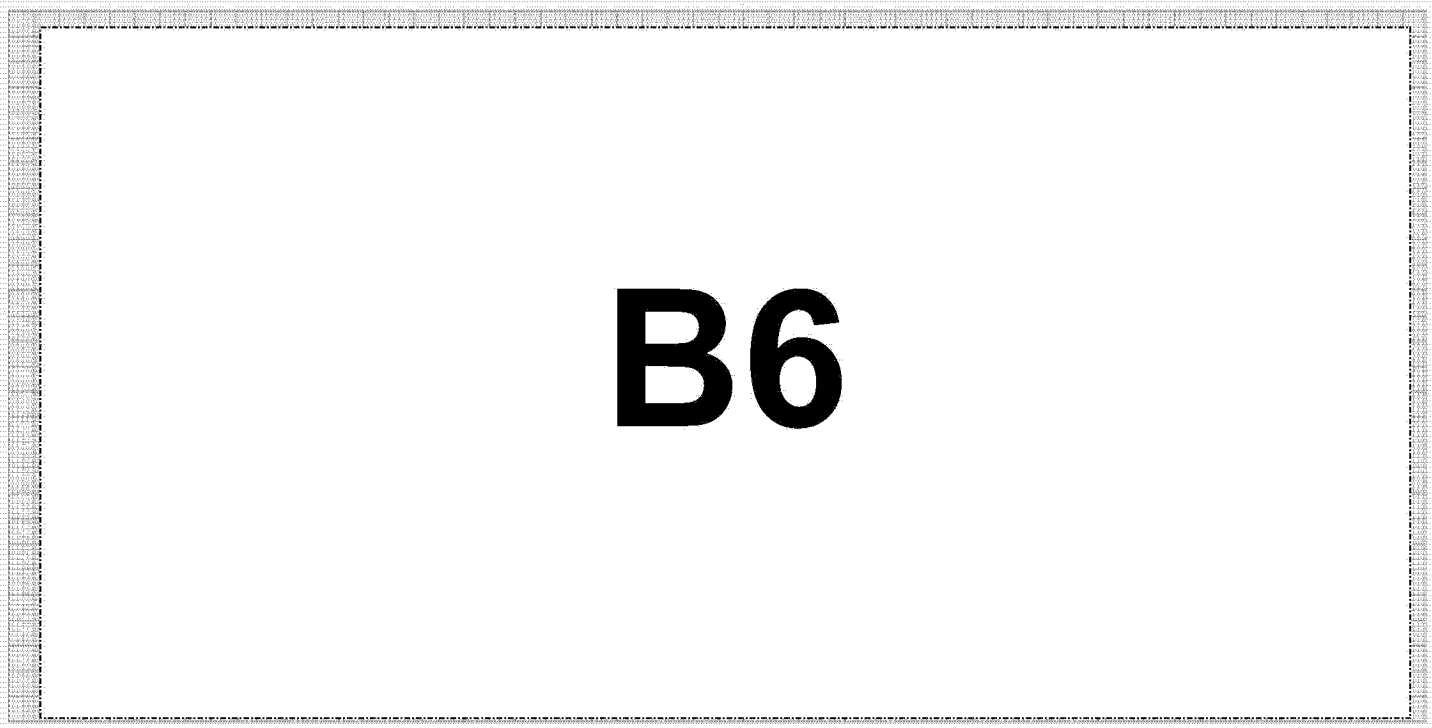
FDA-CVM-FOIA-2019-1704-006141

Client: B6
Patient:

ECG from cardio

B6

Tufts University
Tufts Cummings School of Vet Med
Cardiology



FDA-CVM-FOIA-2019-1704-006142

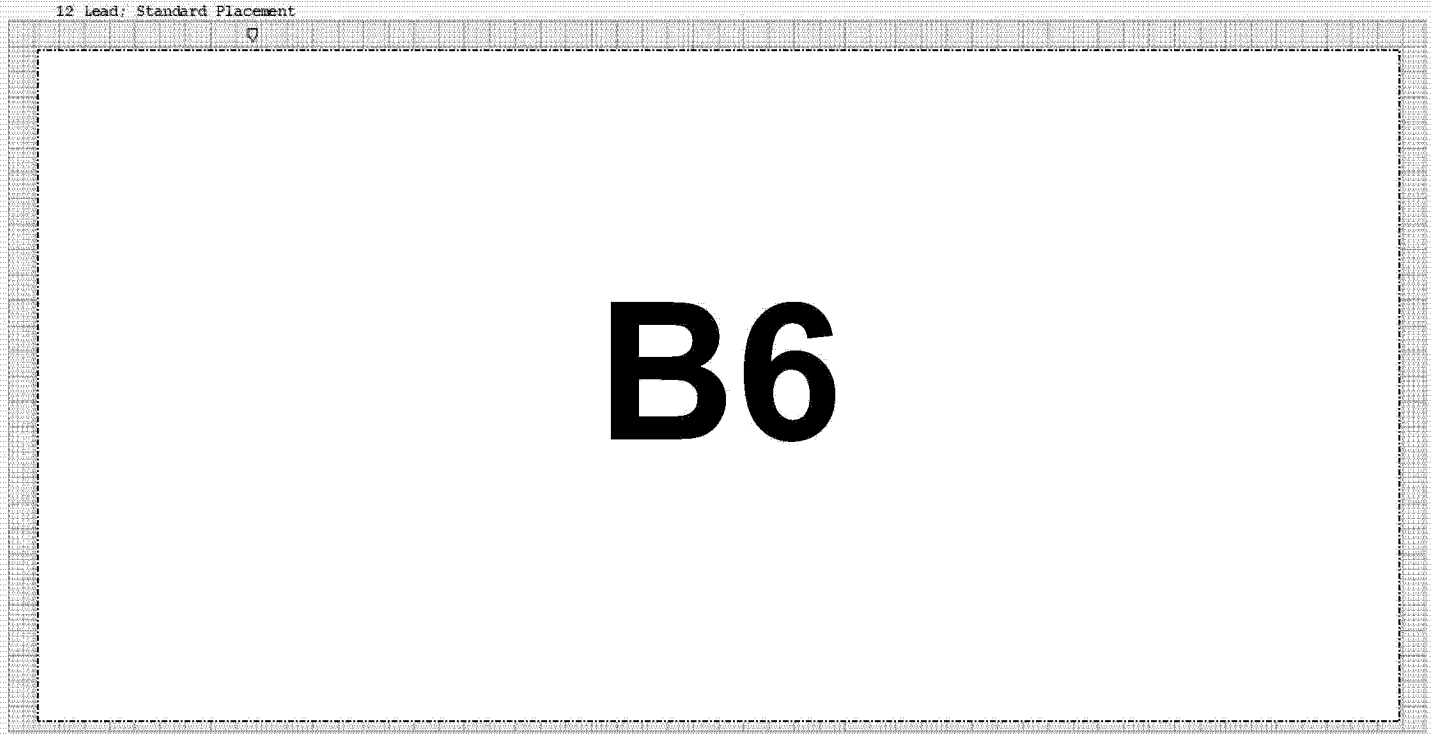
Client: B6
Patient:

ECG from cardio

B6

1/3/2019 3:28:46 PM
Tufts University
Tufts Cummings School of Vet Med
Cardiology

12 Lead; Standard Placement



FDA-CVM-FOIA-2019-1704-006143

Client: B6
Patient:

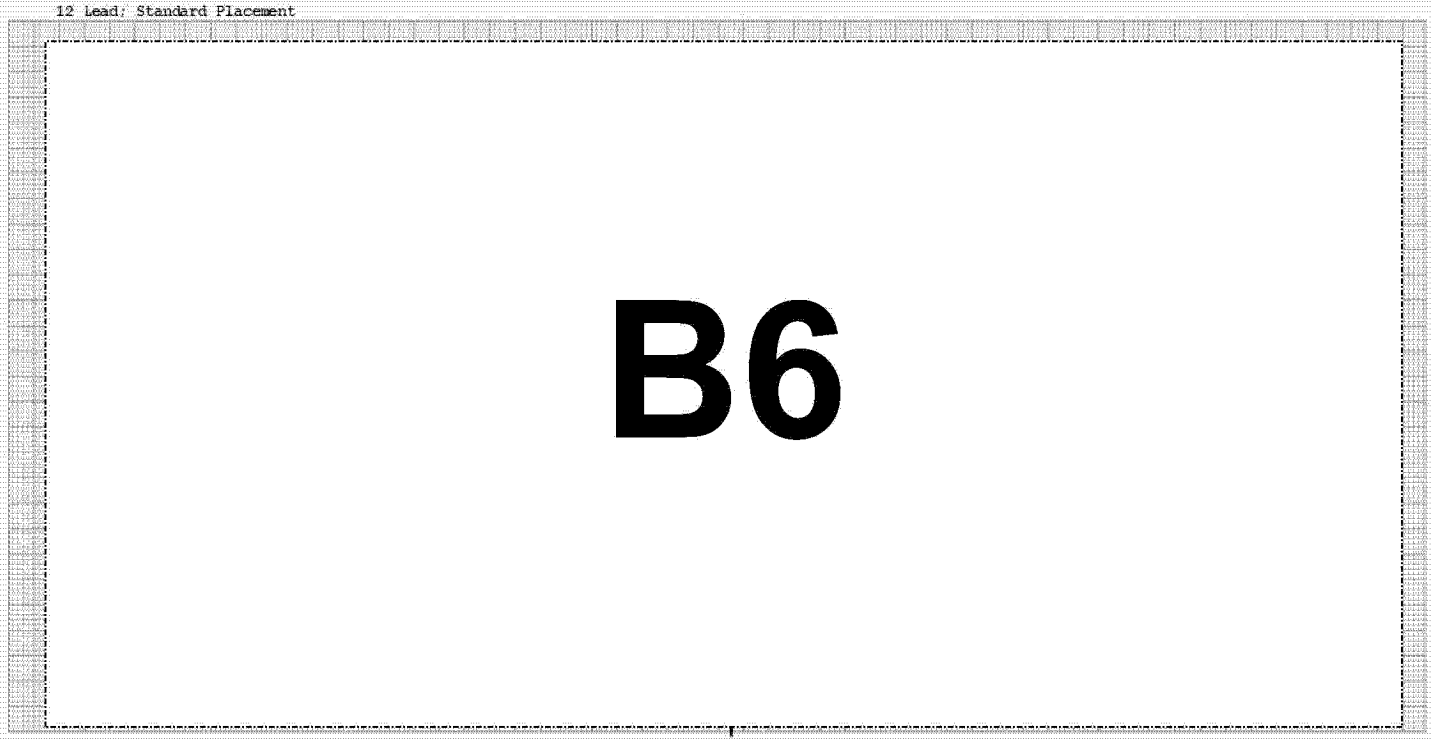
ECG from cardio

B6

1/3/2019 3:29:45 PM

Tufts University
Tufts Cummings School of Vet Med
Cardiology

12 Lead; Standard Placement



FDA-CVM-FOIA-2019-1704-006144

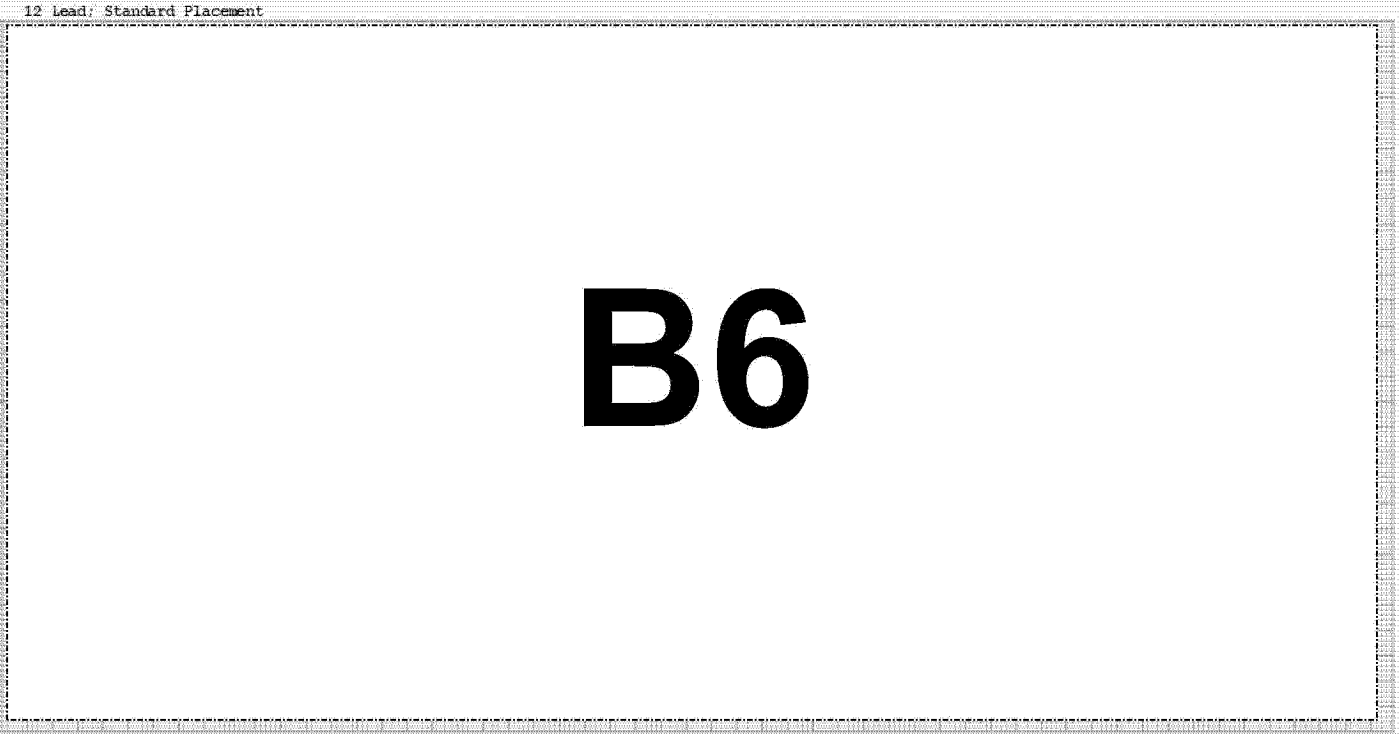
Client: B6
Patient:

ECG from cardio

B6 1/3/2019 3:30:38 PM

Tufts University
Tufts Cummings School of Vet Med
Cardiology

12 Lead; Standard Placement

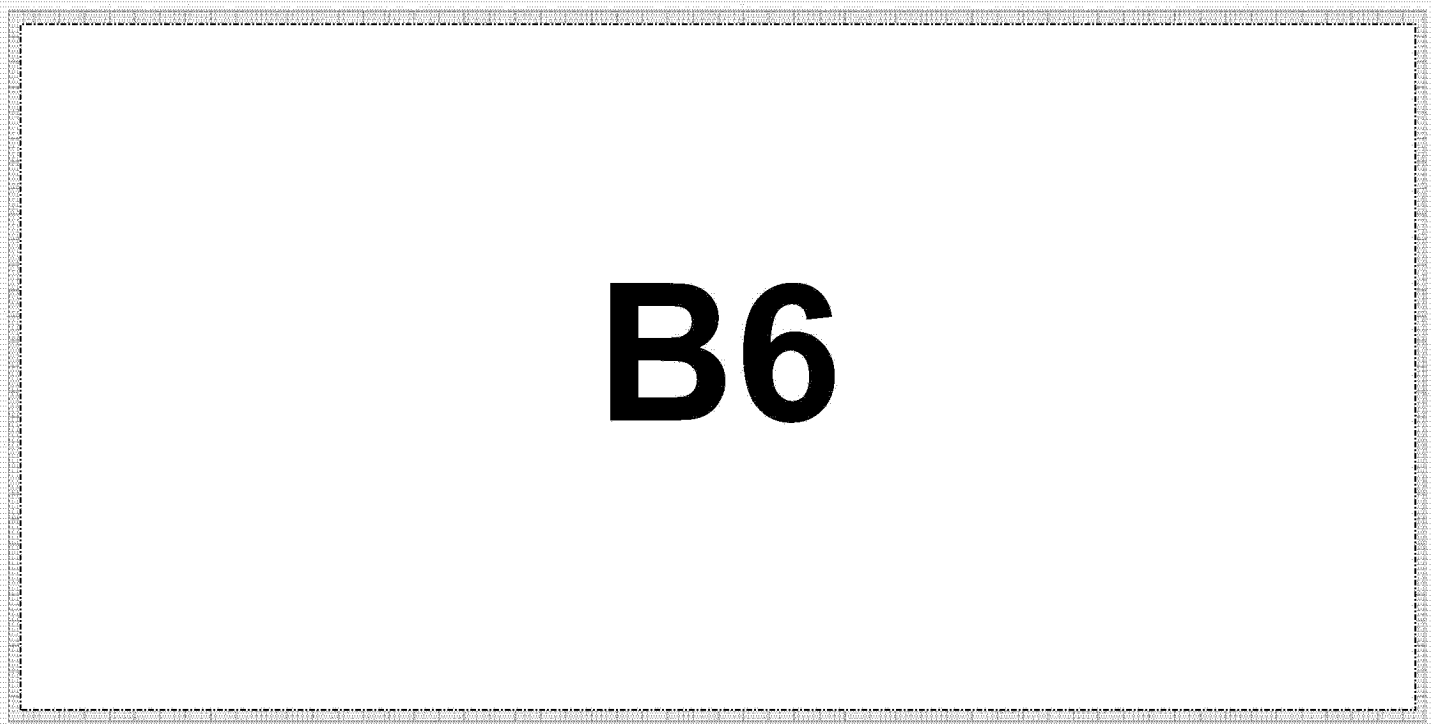


FDA-CVM-FOIA-2019-1704-006145

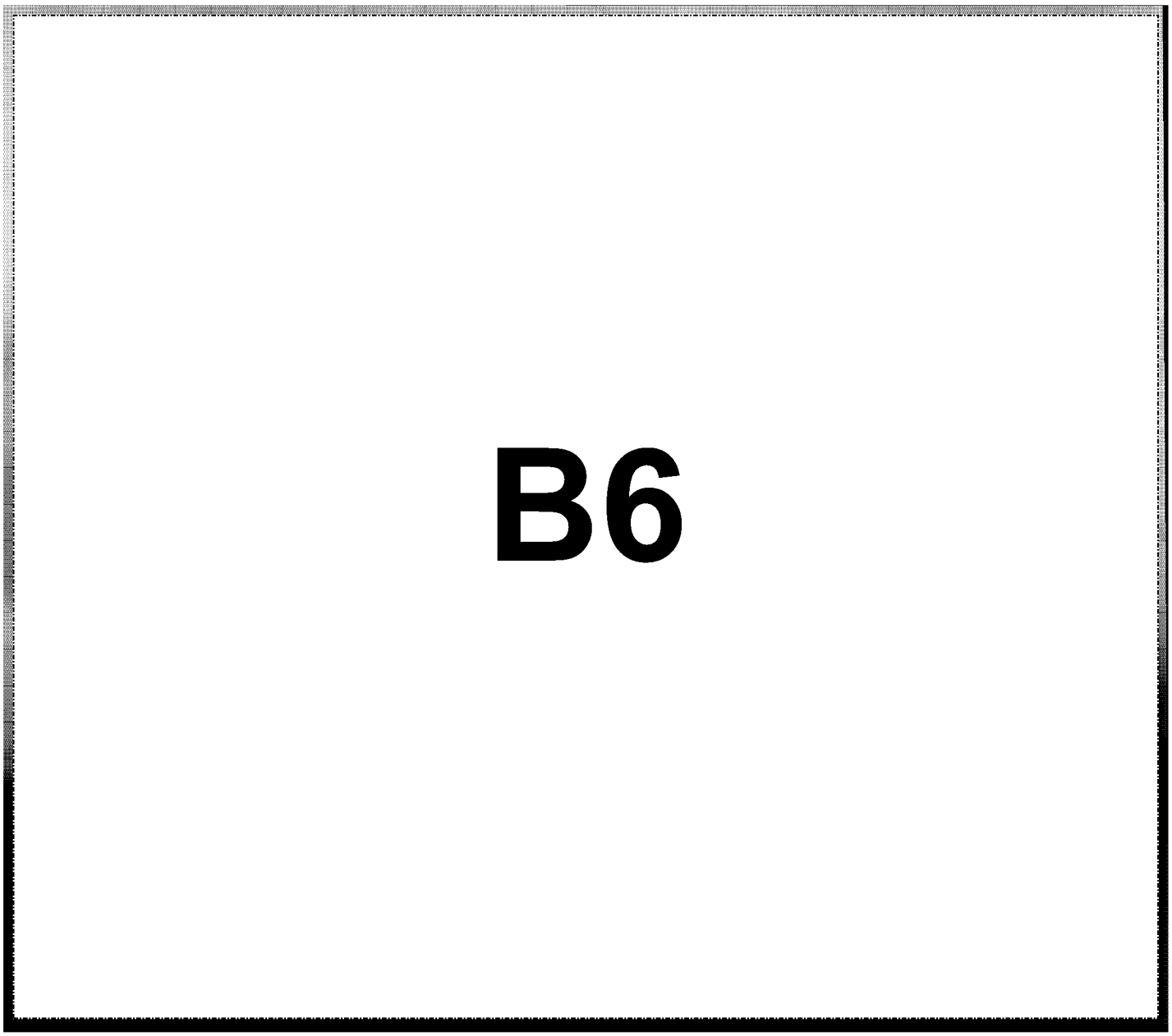
Client: B6
Patient:

ECG from cardio

Tufts University
Tufts Cummings School of Vet Med
Cardiology

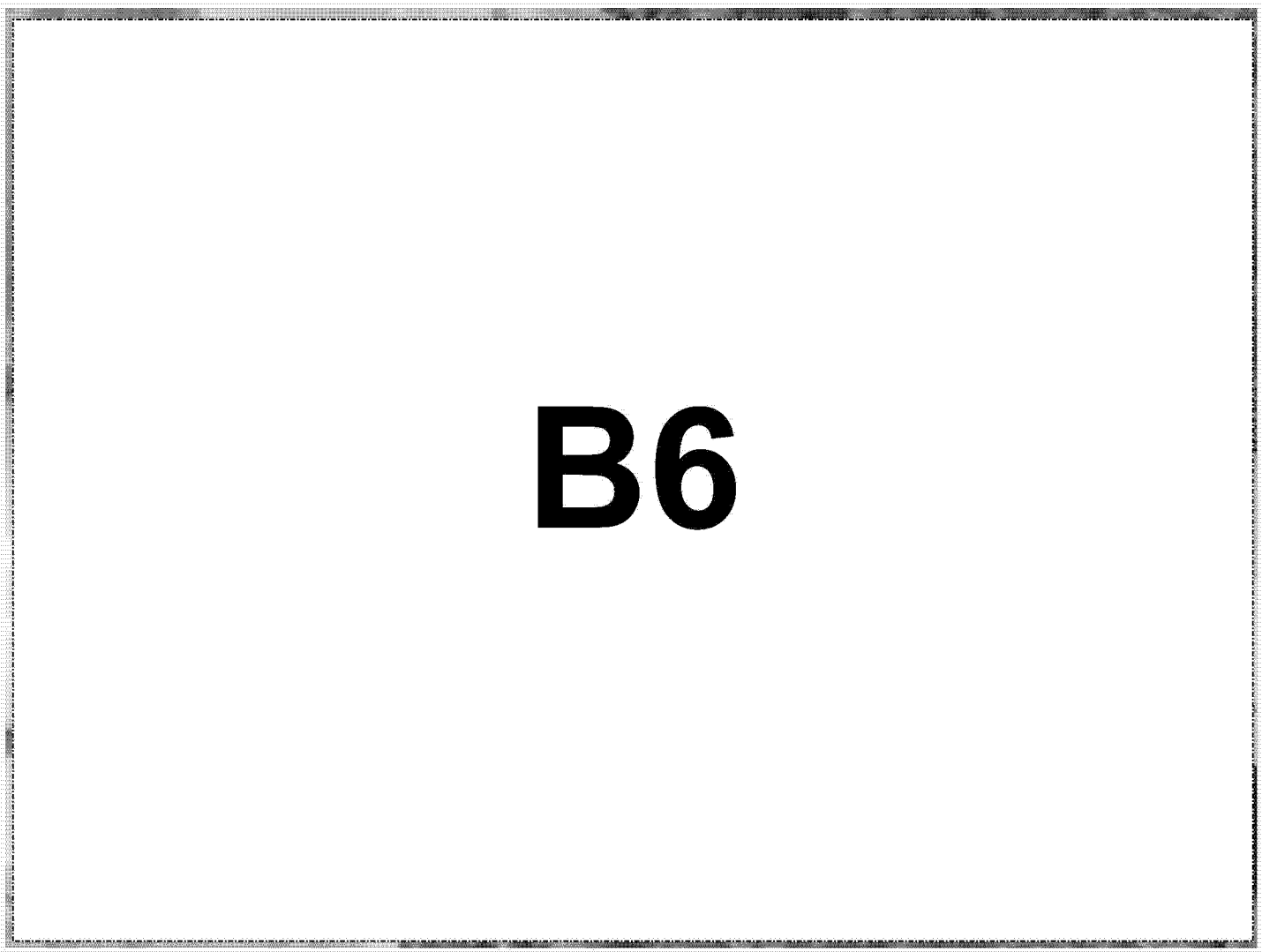


FDA-CVM-FOIA-2019-1704-006146



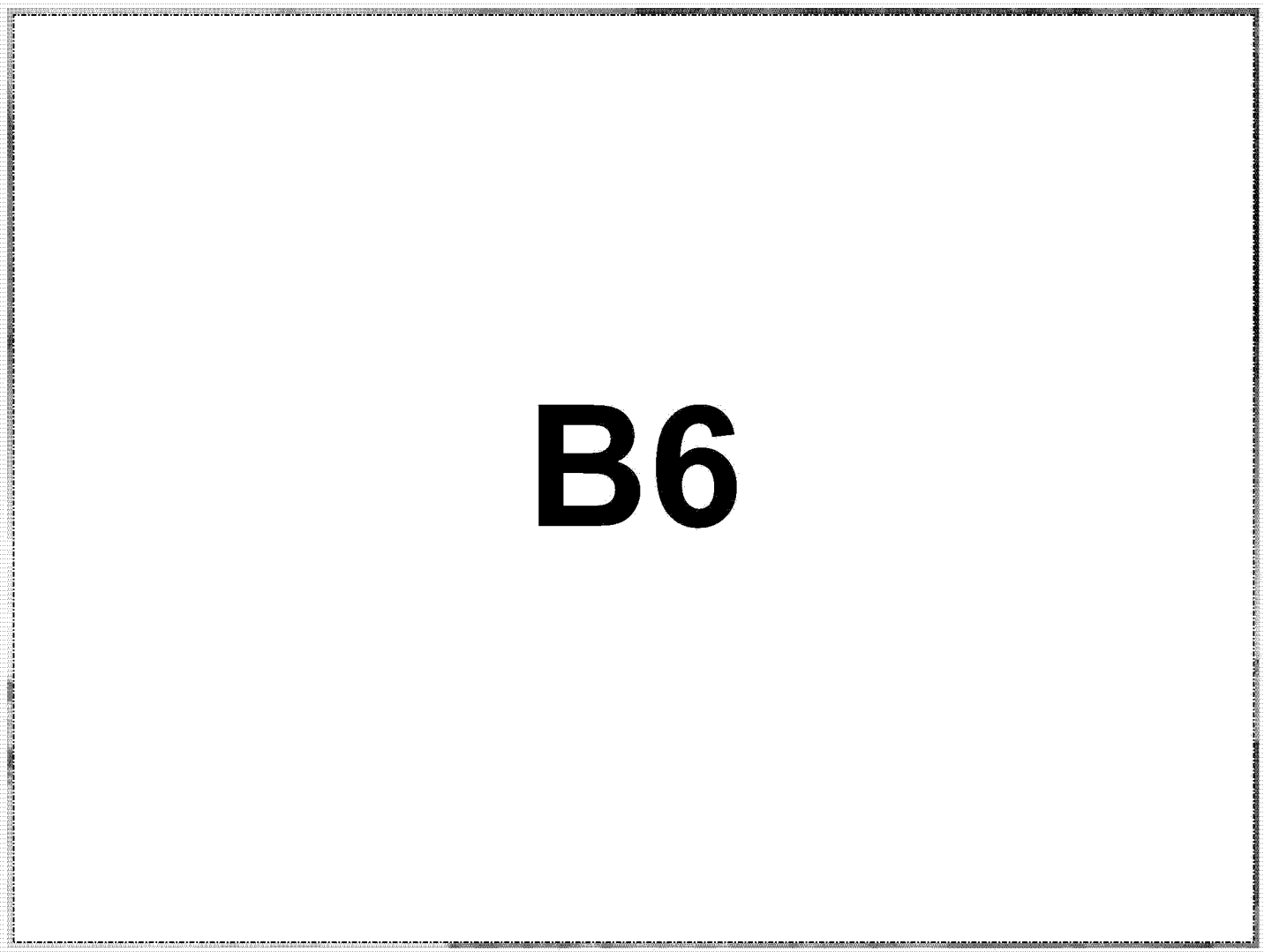
FDA-CVM-FOIA-2019-1704-006147

Urine strip



FDA-CVM-FOIA-2019-1704-006148

Urine strip



FDA-CVM-FOIA-2019-1704-006149

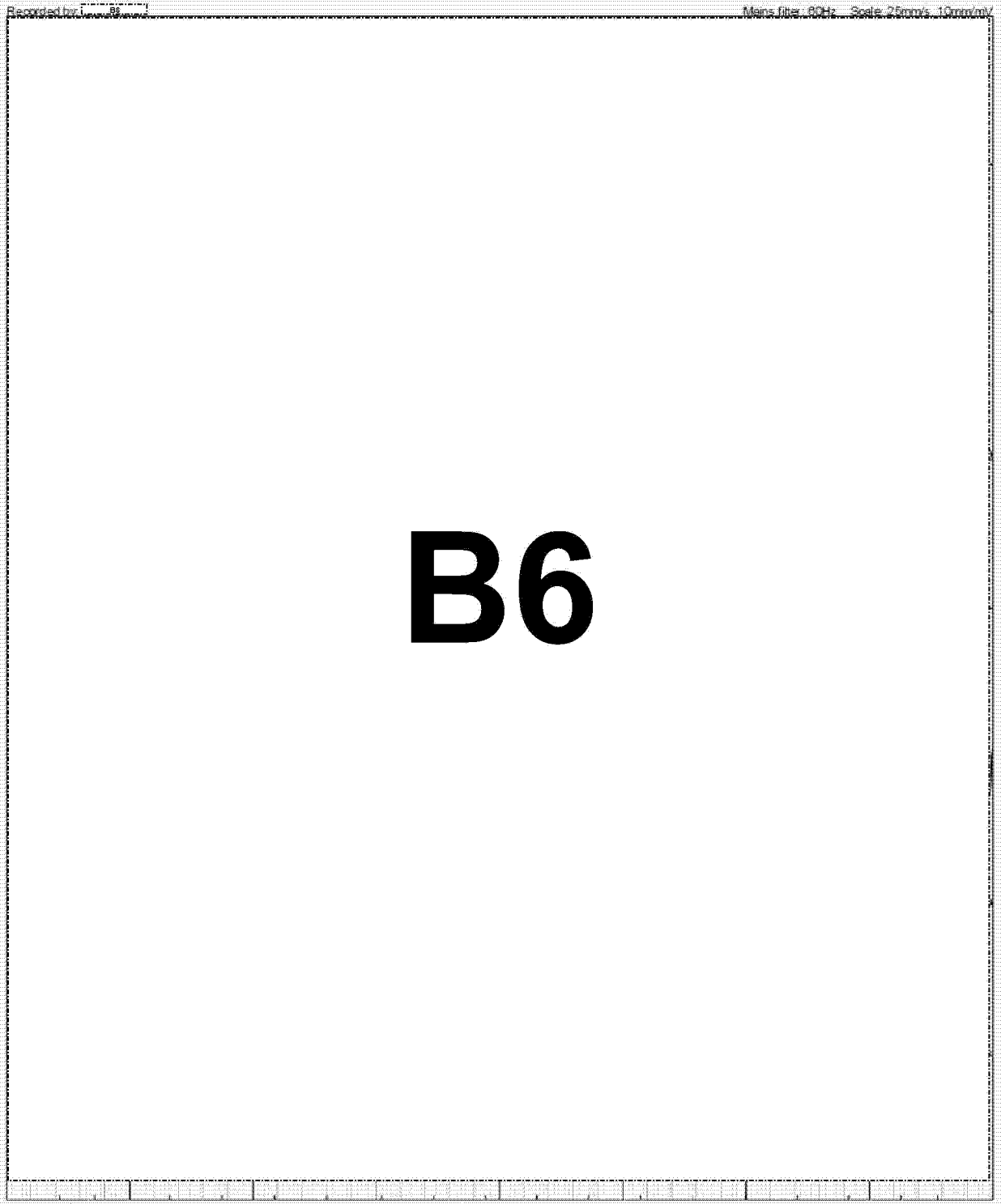
Client:
Patient: **B6**

Alivecor from cardio

Patient: B6
Breed/Species American Pit Bull Terrier / Dog
Recorded: Monday, January 7, 2019 at 11:29:27 PM
Heart Rate: 140 bpm **Duration:** 34 s

AliveCor

Recorded by: B6 Mains filter: 60Hz Scale: 25mm/s, 10mm/mV



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FDA-CVM-FOIA-2019-1704-006150

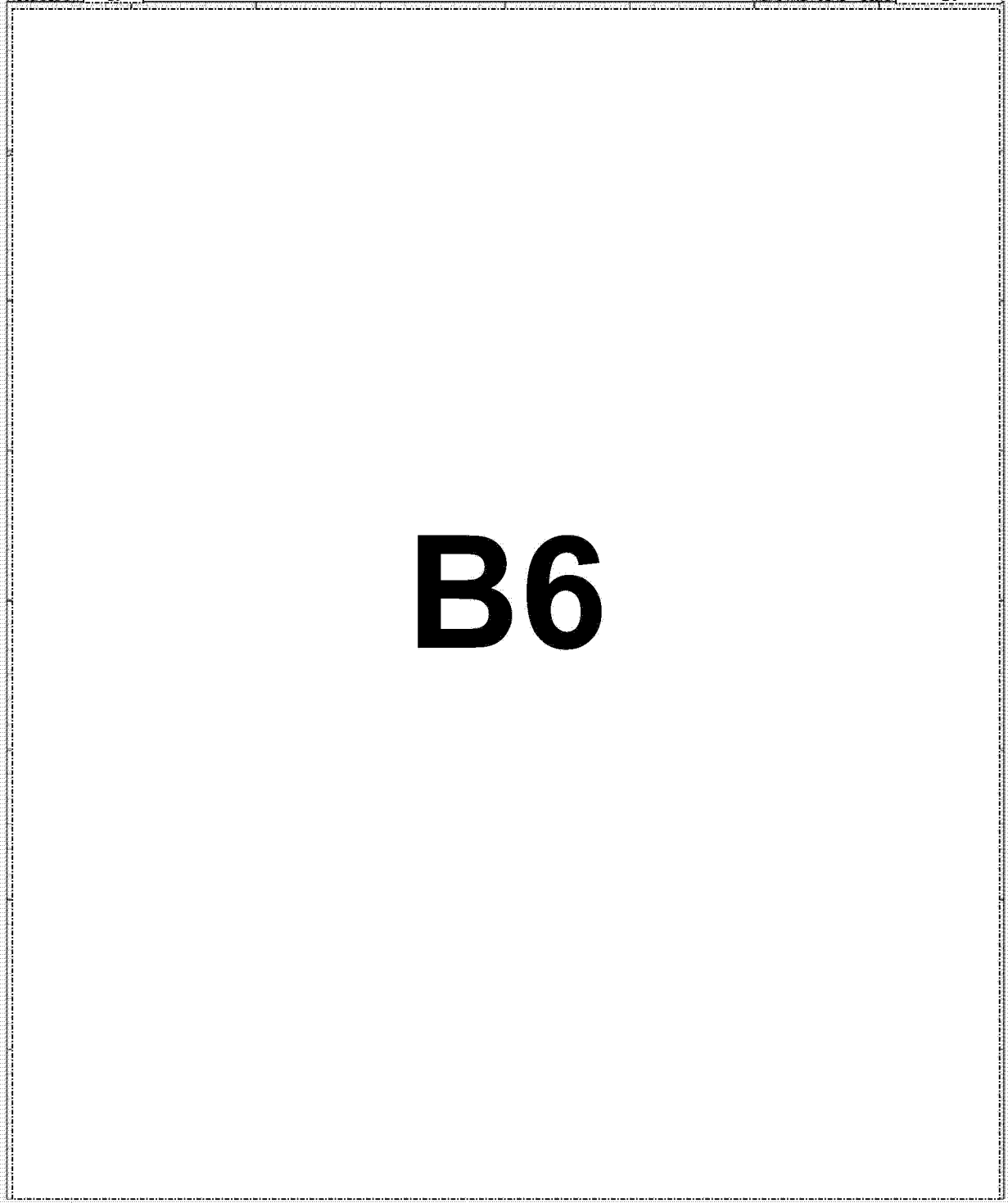
Client:
Patient: **B6**

Alivecor from cardio

Patient: B6
Breed/Species American Pit Bull Terrier / Dog
Recorded: Monday, January 7, 2019 at 11:29:27 PM
Heart Rate: 140 bpm **Duration:** 34 s

AliveCor

Recorded by: B6 Mains filter: B6 Scale: B6



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FDA-CVM-FOIA-2019-1704-006151

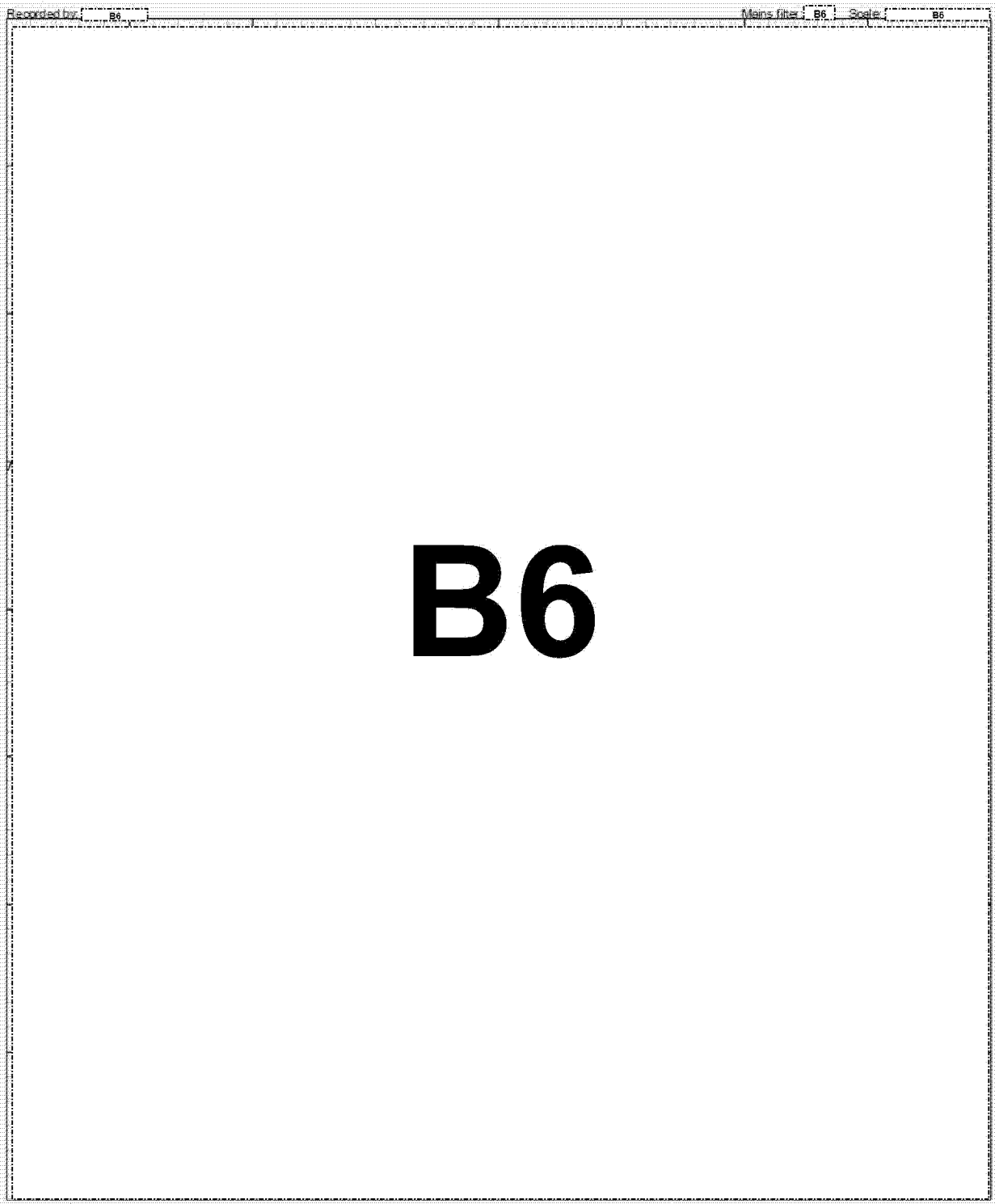
Client:
Patient: **B6**

Alivecor ECG

Patient: B6
Breed/Species American Pit Bull Terrier / Dog
Recorded: Tuesday, January 29, 2019 at 9:23:52 PM
Heart Rate: 126 bpm **Duration:** 1 min 32 s

AliveCor

Recorded by: B6 Mains filter: B6 Scale: B6



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FDA-CVM-FOIA-2019-1704-006152

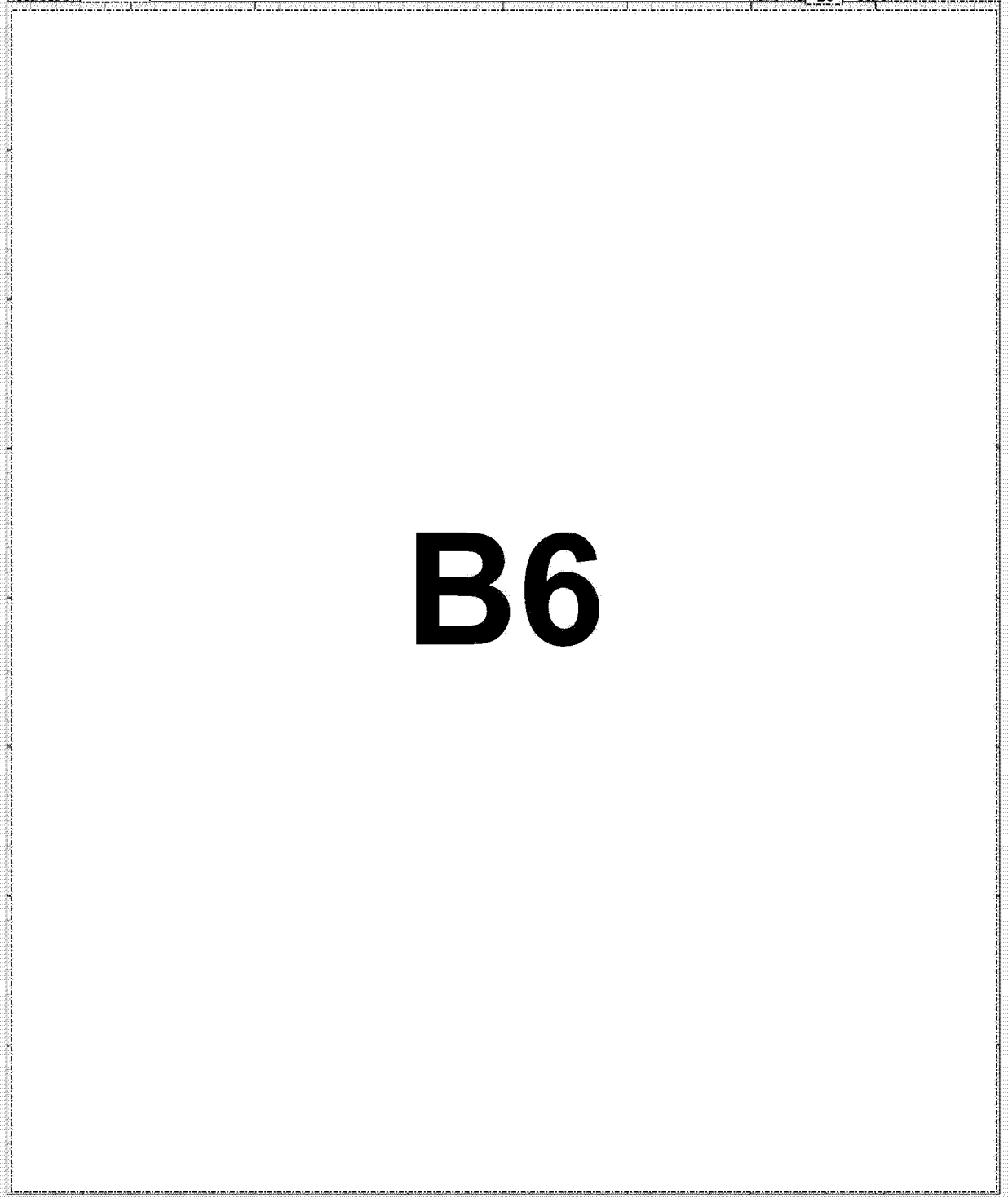
Client:
Patient: **B6**

Alivecor ECG

Patient: B6
Breed/Species American Pit Bull Terrier / Dog
Recorded: Tuesday, January 29, 2019 at 9:23:52 PM
Heart Rate: 126 bpm **Duration:** 1 min 32 s

AliveCor

Recorded by: B6 Mains filter: B6 Scale: B6



(c) Copyright 2012, AliveCor Inc.AliveECG Vet v2.1.4.17, Report v2.0.0, UUID: 53DDF828-7D9E-4AF1-8D12-3714B40D6F49

FDA-CVM-FOIA-2019-1704-006153

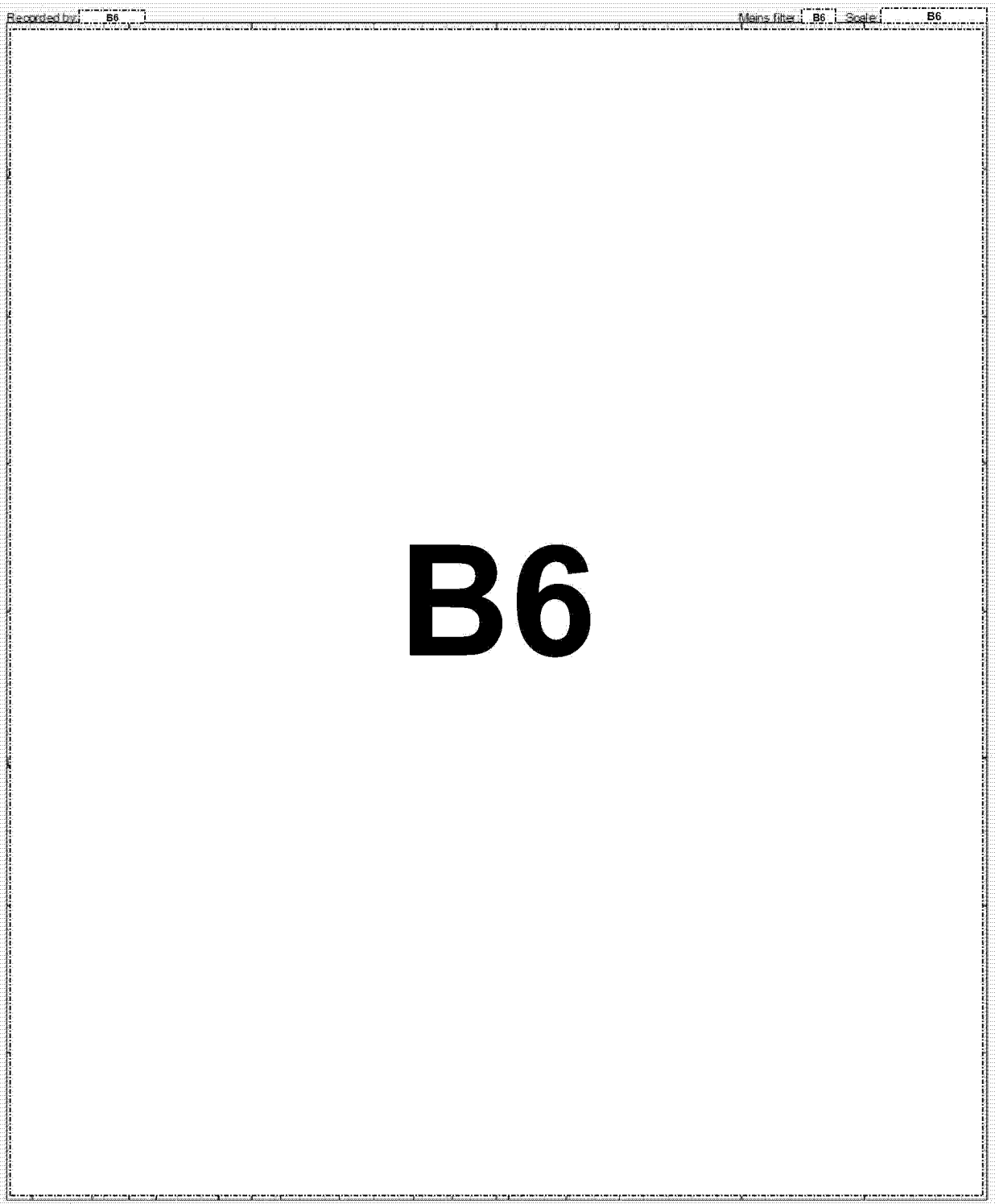
Client:
Patient: **B6**

Alivecor ECG

Patient: B6
Breed/Species American Pit Bull Terrier / Dog
Recorded: Tuesday, January 29, 2019 at 9:23:52 PM
Heart Rate: 126 bpm **Duration:** 1 min 32 s

AliveCor

Recorded by: B6 Mains filter: B6 Scale: B6



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FDA-CVM-FOIA-2019-1704-006154

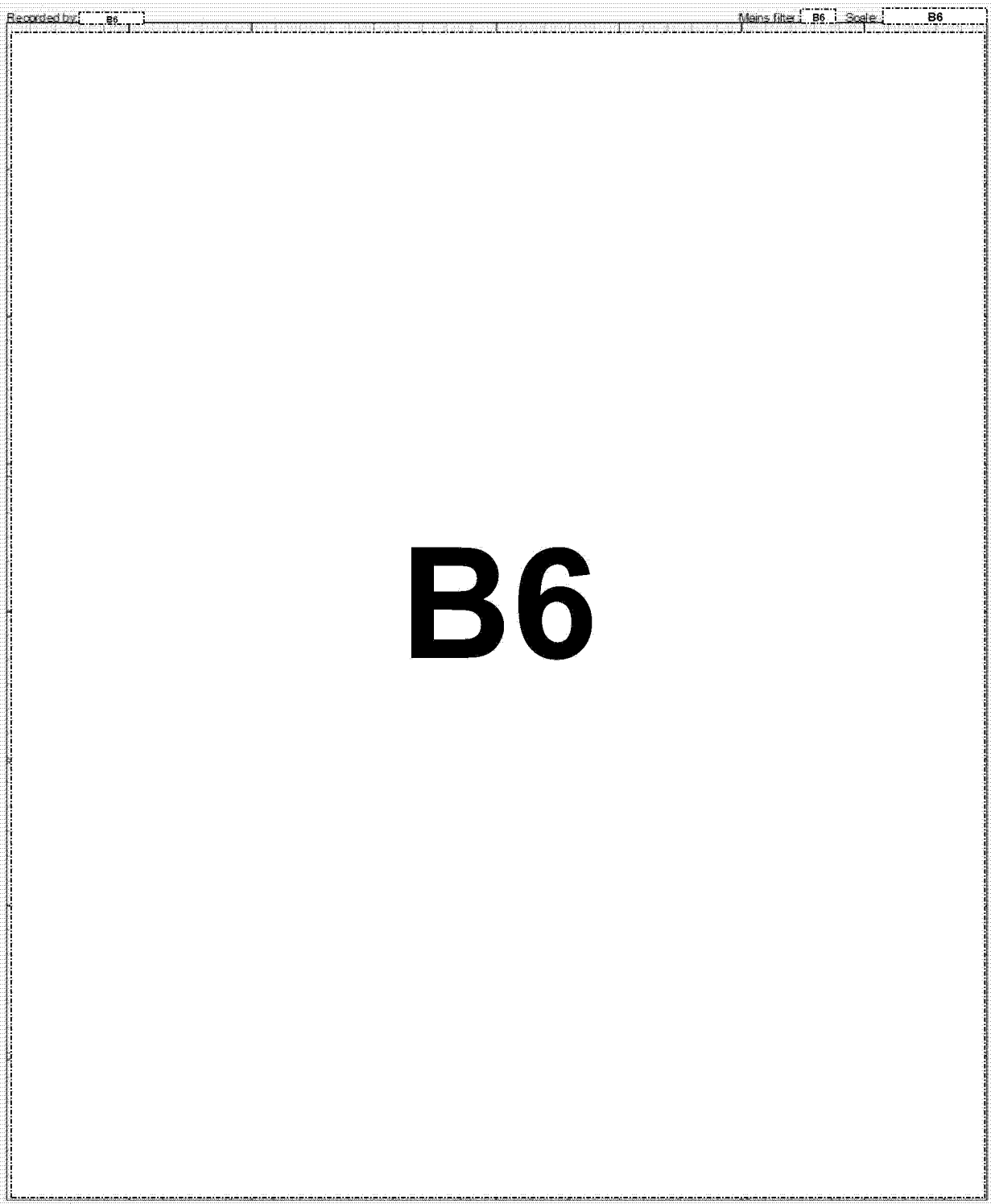
Client:
Patient: **B6**

Alivecor ECG

Patient: B6
Breed/Species American Pit Bull Terrier / Dog
Recorded: Saturday, March 2, 2019 at 5:44:52 PM
Heart Rate: 93 bpm **Duration:** 1 min

AliveCor

Recorded by: B6 Mains filter: B6 Scale: B6



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FDA-CVM-FOIA-2019-1704-006155

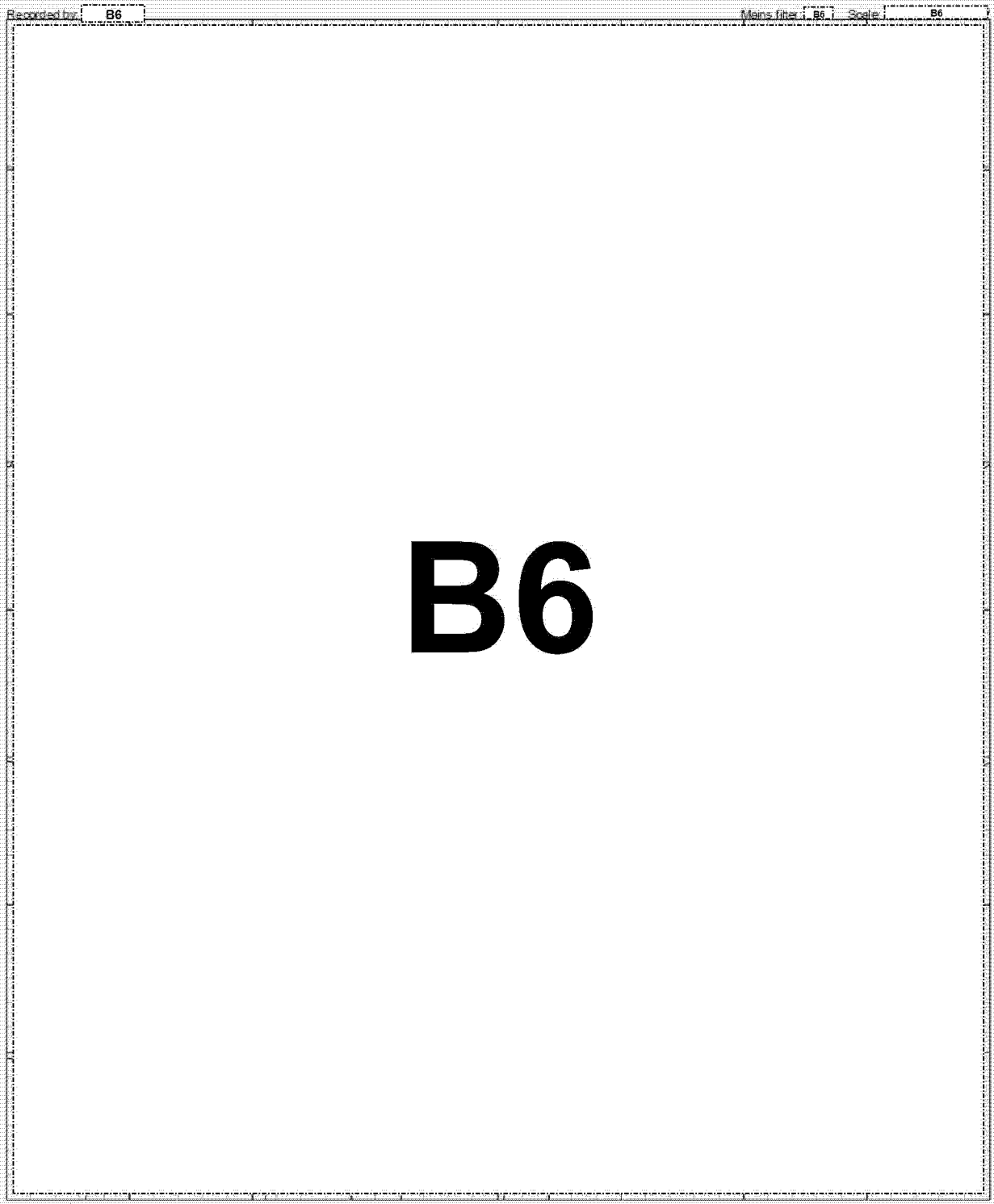
Client:
Patient: **B6**

Alivecor ECG

Patient: B6
Breed/Species American Pit Bull Terrier / Dog
Recorded: Saturday, March 2, 2019 at 5:44:52 PM
Heart Rate: 93 bpm **Duration:** 1 min

AliveCor

Recorded by: B6 Mains filter: B6 Scale: B6



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FDA-CVM-FOIA-2019-1704-006156

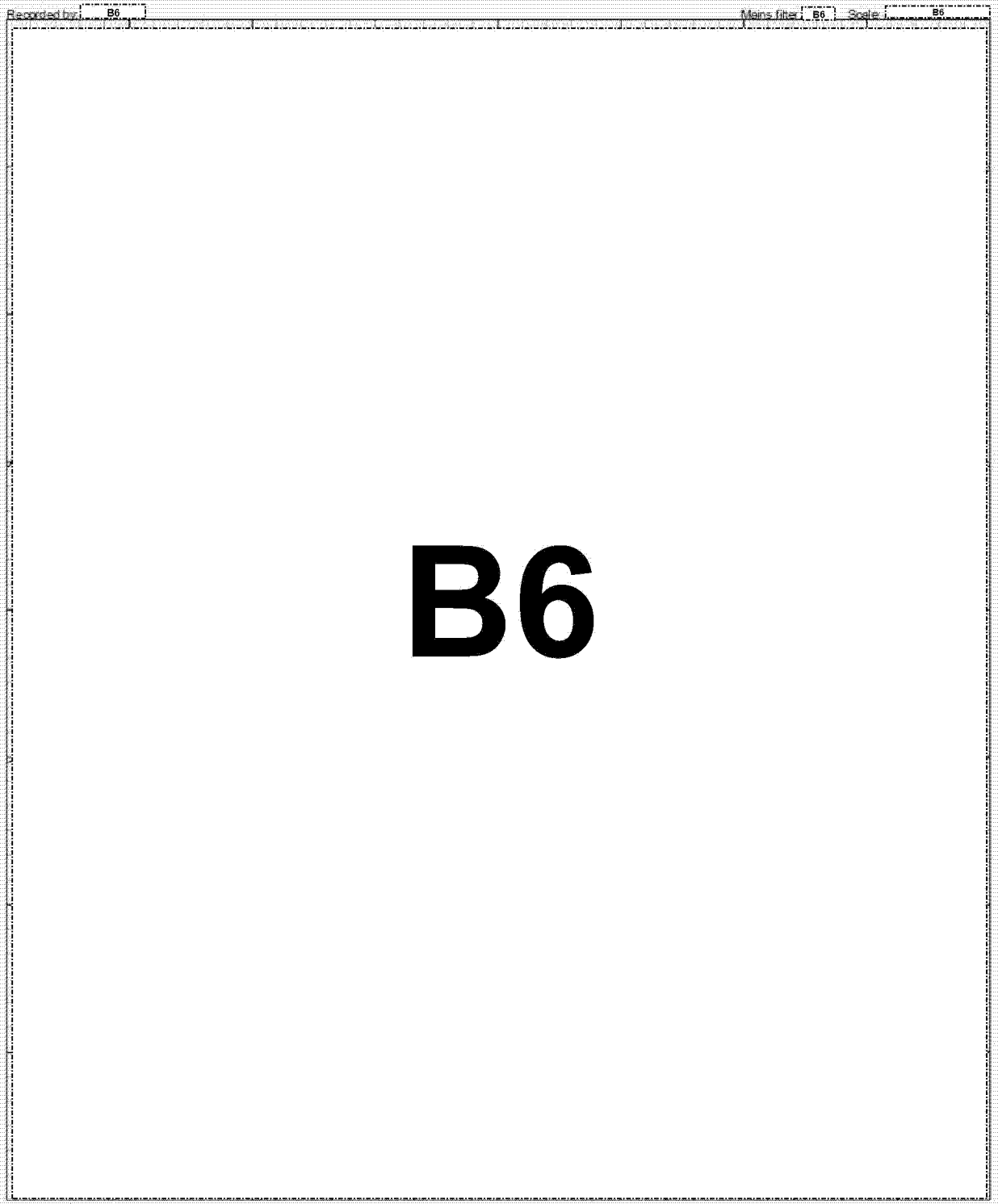
Client:
Patient: B6

Alivecor ECG from cardio

Patient: B6
Breed/Species American Pit Bull Terrier / Dog
Recorded: Friday, March 22, 2019 at 8:37:00 AM
Heart Rate: 95 bpm **Duration:** 1 min 38 s

AliveCor

Recorded by: B6 Mains filter: B6 Scale: B6



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FDA-CVM-FOIA-2019-1704-006157

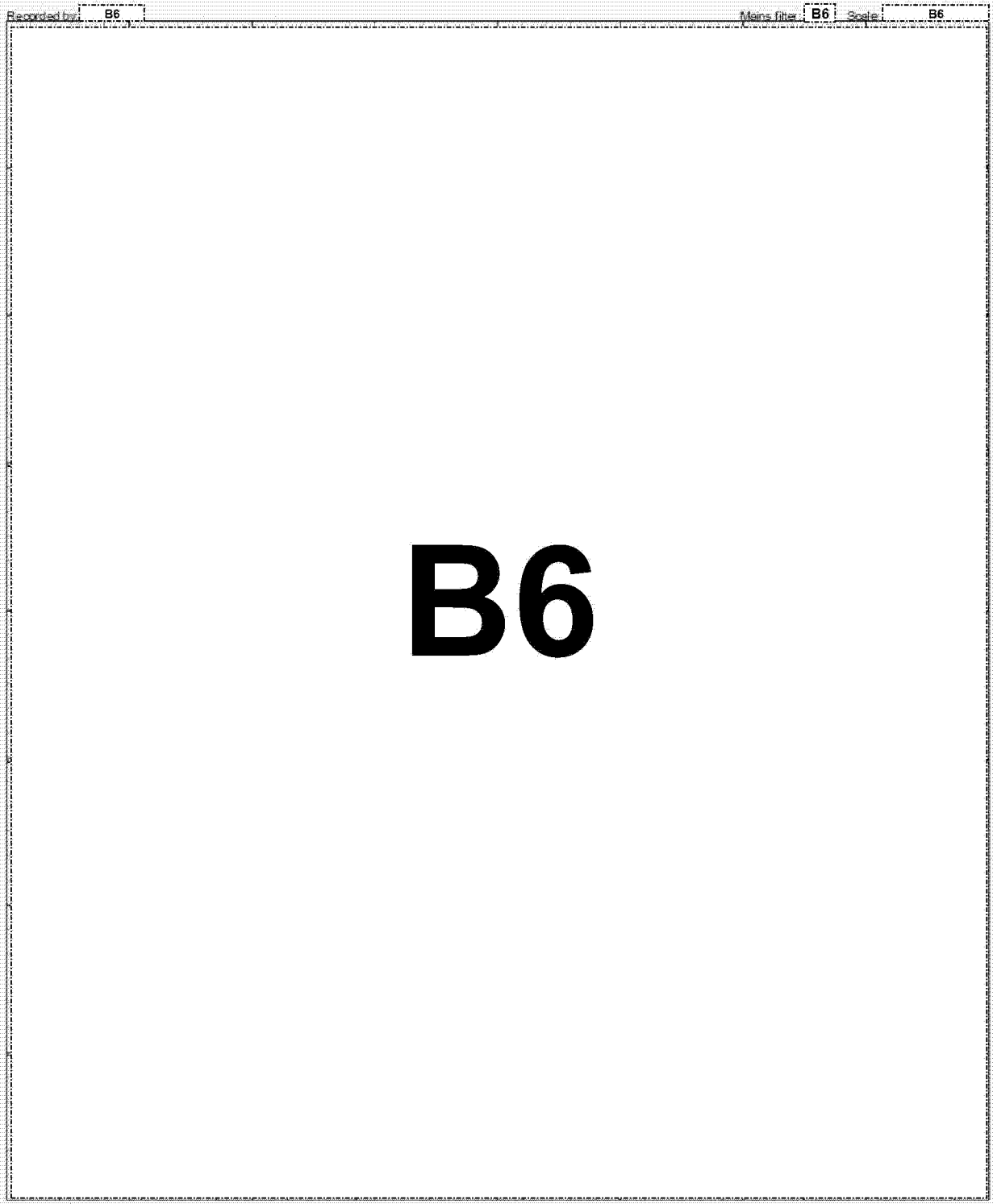
Client:
Patient: **B6**

Alivecor ECG from cardio

Patient: B6
Breed/Species American Pit Bull Terrier / Dog
Recorded: Friday, March 22, 2019 at 8:37:00 AM
Heart Rate: 95 bpm **Duration:** 1 min 38 s

AliveCor

Recorded by: B6 Mains filter: B6 Scale: B6



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FDA-CVM-FOIA-2019-1704-006158

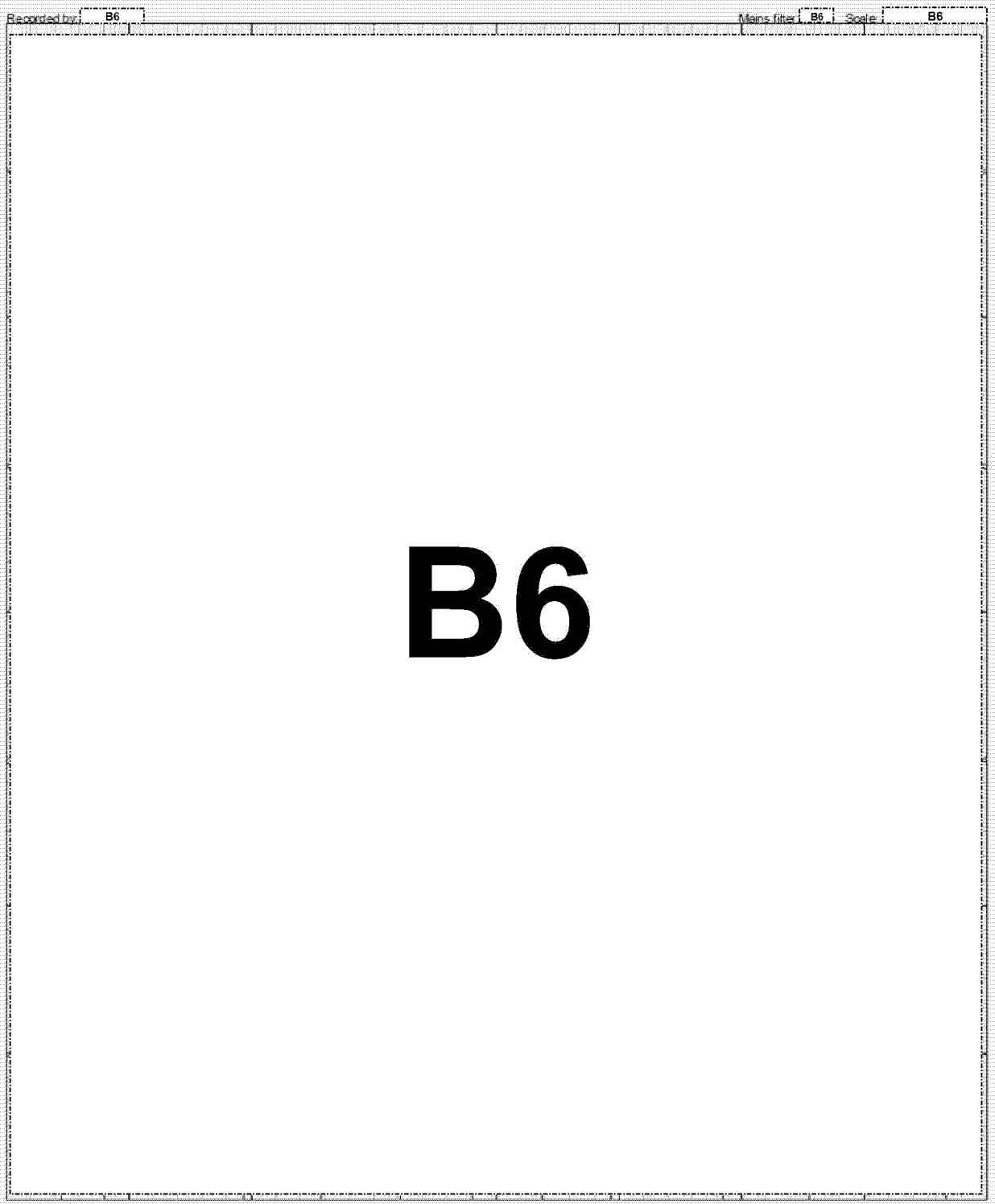
Client:
Patient: **B6**

Alivecor ECG from cardio

Patient: B6
Breed/Species American Pit Bull Terrier / Dog
Recorded: Friday, March 22, 2019 at 8:37:00 AM
Heart Rate: 95 bpm **Duration:** 1 min 38 s

AliveCor

Recorded by: B6 Mains filter: B6 Scale: B6



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FDA-CVM-FOIA-2019-1704-006159

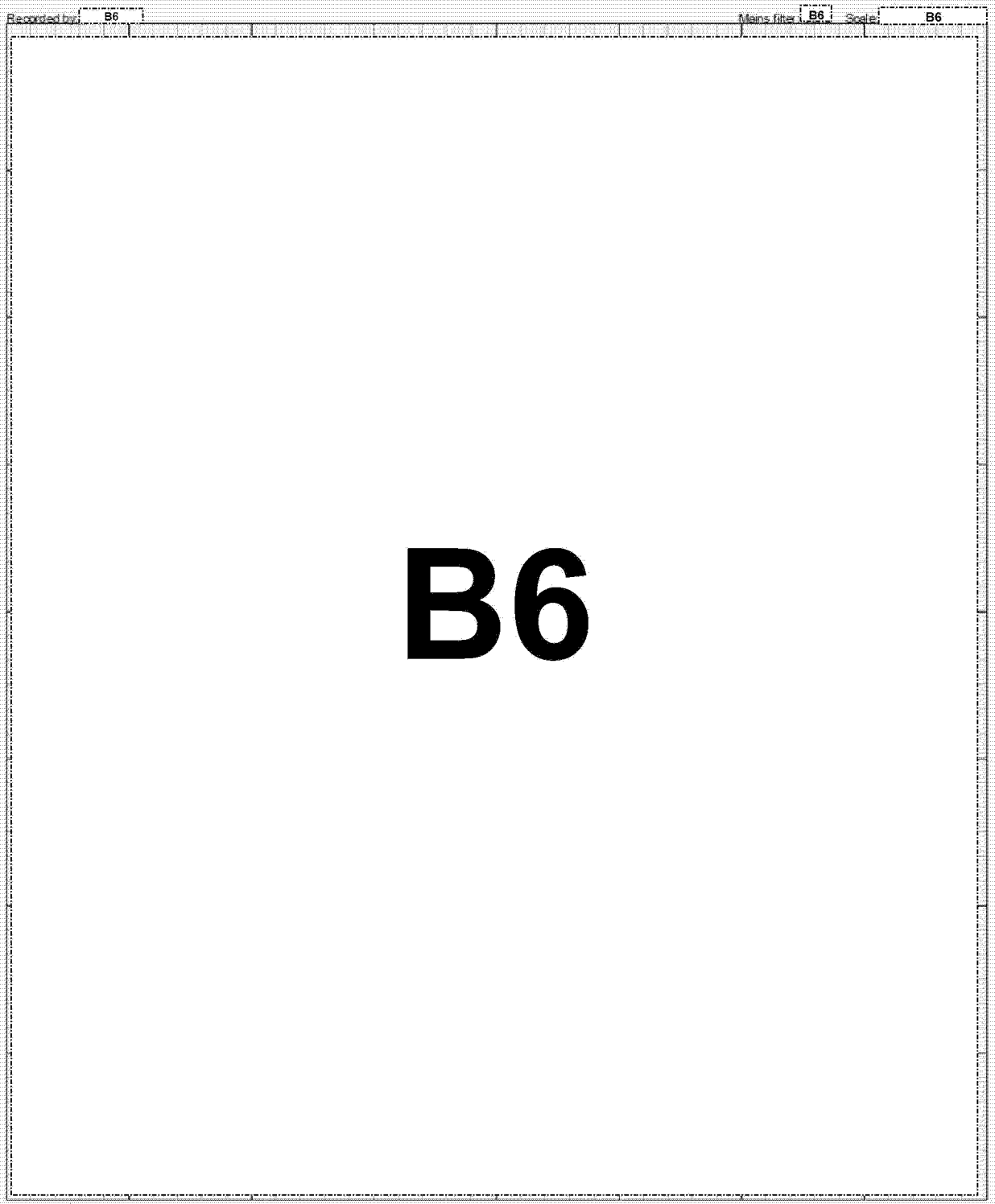
Client:
Patient: **B6**

Alivecor ECG from cardio

Patient: B6
Breed/Species American Pit Bull Terrier / Dog
Recorded: Friday, March 22, 2019 at 8:37:00 AM
Heart Rate: 95 bpm **Duration:** 1 min 38 s

AliveCor

Recorded by: B6 Mains filter: B6 Scale: B6



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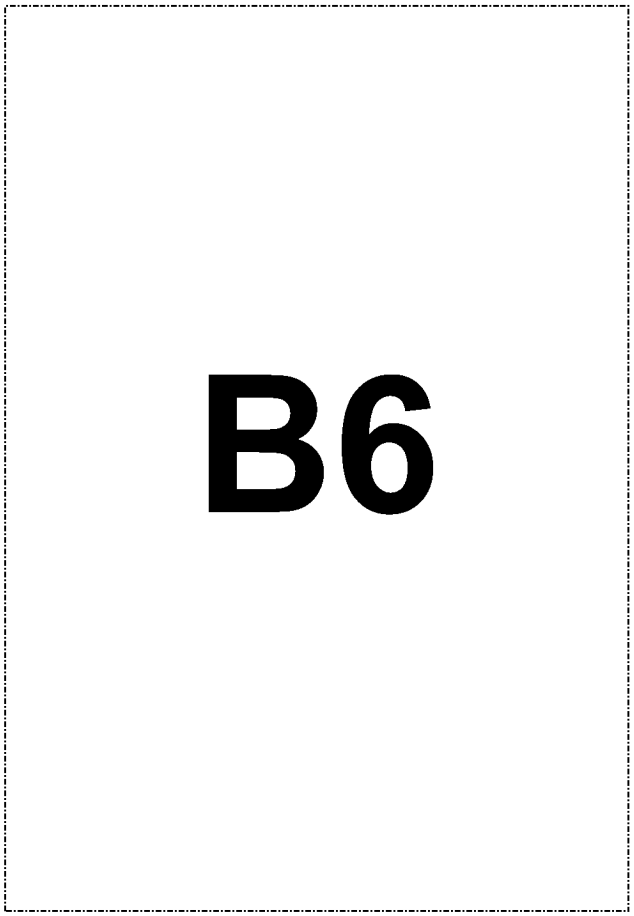
FDA-CVM-FOIA-2019-1704-006160

Client: B6
Patient:

Patient History

01/02/2019 12:50 PM	Appointment
01/03/2019 01:06 PM	UserForm
01/03/2019 01:16 PM	Treatment
01/03/2019 01:44 PM	Vitals
01/03/2019 01:44 PM	Vitals
01/03/2019 03:07 PM	Deleted Reason
01/03/2019 03:09 PM	Purchase
01/03/2019 03:10 PM	UserForm
01/03/2019 03:25 PM	Purchase
01/03/2019 03:25 PM	Purchase
01/03/2019 03:33 PM	Prescription
01/03/2019 03:33 PM	Prescription
01/03/2019 03:38 PM	Prescription
01/03/2019 03:47 PM	Purchase
01/03/2019 04:08 PM	Appointment
01/04/2019 06:18 PM	Purchase
01/17/2019 11:15 AM	Appointment
03/26/2019 10:01 AM	Appointment



Patient Account History	Description	Qty	price	Extended	Disc	Pmt

FDA-CVM-FOIA-2019-1704-006161

Client:
Patient: **B6**

Patient Account History	Description	Qty	price	Extended	Disc	Pmt
Thursday, 03 January 2019 15:09	Appointment: Cardiology Study	1.000	0.000	0.0000	0.0000	0.0000

FDA-CVM-FOIA-2019-1704-006162

Client: B6
Patient:

Patient Account History	Description	Qty	price	Extended	Disc	Pmt

Thursday, 03 January 2019 15:33

B6

FDA-CVM-FOIA-2019-1704-006163

From: Darcy Adin <dbadin@ncsu.edu>
To: Jones, Jennifer L
CC: B6 B6
Sent: 1/25/2019 10:01:01 PM
Subject: Sample?

Hi Jen,

I hope you are doing well - not sure how the partial government shutdown is impacting your area specifically?

B6 was able to collect fresh frozen myocardium from one of our presumed diet induced DCM cases and we are wondering if we should hang on to this in a -80 freezer or send you the sample for testing? This is an almost 2yr MI Yorkie mix that was diagnosed in April 2018 and was eating Castor and Pollux Organic GF Small Breed. The owners tried to change the diet to a grain based Royal canin diet but because of lack of interest he was changed to Primal (raw and grain free). He represented in September 2018 for CHF and was then changed to Fromm Adult Gold Small breed, grain-based supplemented with boiled chicken and rice. Progressive disease was noted at each exam echocardiographically with no improvement in systolic function. His whole blood taurine was B6 but he was still supplemented with taurine.

Thanks for your thoughts!
Take care
Darcy

From: B6
To: Jones, Jennifer L
CC: Darcy Adin; B6
Sent: 1/30/2019 5:37:03 PM
Subject: Re: Sample?

Dear Jennifer

So glad to hear from you, that you are no longe B6 and lastly that you are interested in the tissue we collected.

The final necropsy report may take a few weeks. I will have B6 submit the complaint this week.

Would you like us to wait to send the sample until we get the final postmortem report? The sample is sitting at -80 C right now.

Please make the box to:
NC State University College of Veterinary Medicine
Attn: B6
1060 William Moore Dr.
Raleigh, NC 27607

Thanks so much
B6

On Wed, Jan 30, 2019 at 11:37 AM Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov> wrote:
Hi Darcy,
Thank you for the kind words. Yes, B6 I apologize for the delay.

We are definitely interested in the case. We'd just need a complaint submitted through the Safety Reporting Portal found here: https://www.safetyreporting.hhs.gov/

After you submit the report, please send me the ICSR number (confirmation of report submission). We can send you a box to collect the tissue. Was there also a full necropsy report with medical records you could share as well? Those can be attached to the report you submit.
Please let me know if you have questions.
Thank you again for your help,
Jen

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

-----Original Message-----
From: Darcy Adin <dbadin@ncsu.edu>
Sent: Friday, January 25, 2019 5:01 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: B6
Subject: Sample?

Hi Jen,

I hope you are doing well - not sure how the partial government shutdown is impacting your area specifically?

B6 was able to collect fresh frozen myocardium from one of our presumed diet induced DCM cases and we are wondering if we should hang on to this in a -80 freezer or send you the sample for testing? This is an almost 2yr MI Yorkie mix that was diagnosed in April 2018 and was eating Castor and Pollux Organic GF Small Breed. The owners tried to change the diet to a grain based Royal canin diet but because of lack of interest he was changed to Primal (raw and grain free). He represented in September 2018 for CHF and was then changed to Fromm Adult Gold Small breed, grain-based supplemented with boiled chicken and rice. Progressive disease was noted at each exam echocardiographically with no improvement in systolic function. His whole blood taurine was B6 but he was still supplemented with taurine.

Thanks for your thoughts!
Take care
Darcy

--

B6

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

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

Sent: 1/31/2019 4:41:12 PM

Subject: Castor & Pollux Organix Grain Free B6 - EON-378184

Attachments: 2062004-report.pdf; 2062004-attachments.zip

A PFR Report has been received and PFR Event [EON-378184] has been created in the EON System.

A "PDF" report by name "2062004-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 "2062004-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-378184
ICSR #: 2062004
EON Title: PFR Event created for Castor & Pollux Organix Grain Free, Primal Freeze Dried Nuggets for dogs; 2062004

AE Date	B6	**Number Fed/Exposed**	1
Best By Date		**Number Reacted**	1
Animal Species	Dog	**Outcome to Date**	Died Euthanized
Breed	Terrier - Yorkshire		
Age	1 Years		
District Involved	PFR-Atlanta DO		

Product information
Individual Case Safety Report Number: 2062004
Product Group: Pet Food
Product Name: Castor & Pollux Organix Grain Free, Primal Freeze Dried Nuggets for dogs
Description: B6 a 1-year-old intact male Yorkshire terrier mix, was presented to the NCSU ER in the early morning hours of B6 and was subsequently transferred to the NCSU Cardiology Service for respiratory distress and suspected congestive heart failure. B6 was observed to have labored breathing the morning of B6 although his owner is unsure exactly when it started. He vomited clear frothy foam after coughing multiple times throughout the day and he had a decreased appetite. B6 was taken to B6

B6 that evening for further evaluation. At B6, a CBC showed a marked thrombocytopenia (automated, no smear performed) and thoracic radiographs showed an enlarged heart, a moderate diffuse unstructured interstitial pattern perihilar and caudodorsal lung lobes, and a mildly distended cranial lobar vein. Congestive heart failure was suspected and B6 B6 B6 was subsequently referred to NCSU for further cardiac workup. B6 other medical problems include recent vomiting and diarrhea. He vomits every once in a while, most recently a couple of weeks ago after eating houseplants. He also had a bad bout of diarrhea after eating the plants. He was taken to his primary veterinarian who prescribed medications and a probiotic. The vomiting resolved and his feces normalized until about 2 days ago when they became soft again.

Submission Type: Initial

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

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

Number of Animals Treated With Product: 1

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Primal Freeze Dried Nuggets for dogs		
Castor & Pollux Organix Grain Free		

Sender information

B6

USA

Owner information

B6

To view this PFR Event, please click the link below:
https://eon.fda.gov/eon//browse/EON-378184

To view the PFR Event Report, please click the link below:
https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jspa?decorator=none&e=0&issueType=12&issueId=395193

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Report Details - EON-378184

ICSR:	2062004	
Type Of Submission:	Initial	
Report Version:	FPSR.FDA.PETF.V.V1	
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)	
Reporting Type:	Voluntary	
Report Submission Date:	2019-01-31 11:24:47 EST	
Reported Problem:	**Problem Description:**	B6, a 1-year-old intact male Yorkshire terrier mix, was presented to the NCSU ER in the early morning hours of B6 and was subsequently transferred to the NCSU Cardiology Service for respiratory distress and suspected congestive heart failure. B6 was observed to have labored breathing the morning of B6 although his owner is unsure exactly when it started. He vomited clear frothy foam after coughing multiple times throughout the day and he had a decreased appetite. B6 was taken to B6 that evening for further evaluation. At B6, a CBC showed a marked thrombocytopenia (automated, no smear performed) and thoracic radiographs showed an enlarged heart, a moderate diffuse unstructured interstitial pattern perihilar and caudodorsal lung lobes, and a mildly distended cranial lobar vein. Congestive heart failure was suspected and B6 B6 was subsequently referred to NCSU for further cardiac workup. B6 other medical problems include recent vomiting and diarrhea. He vomits every once in a while, most recently a couple of weeks ago after eating houseplants. He also had a bad bout of diarrhea after eating the plants. He was taken to his primary veterinarian who prescribed medications and a probiotic. The vomiting resolved and his feces normalized until about 2 days ago when they became soft again.
	Date Problem Started:	B6
	Concurrent Medical Problem:	No
	Outcome to Date:	Died Euthanized
	Date of Death:	B6
Product Information:	**Product Name:**	Primal Freeze Dried Nuggets for dogs
	Product Type:	Pet Food
	Lot Number:	
	Package Type:	BAG
	Package Size:	14 Ounce
	Possess Unopened Product:	No
	Possess Opened Product:	No
	Storage Conditions:	Unknown
	Product Use Information:	**Description:** Oral
		Last Exposure Date: 09/08/2018
		Time Interval between Product Use and Adverse Event: 3 Months
		Product Use Stopped After the Onset of the Adverse Event: Yes
		Adverse Event Abate After Product Stop: No
		Product Use Started Again: No
		Perceived Definitely related

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		Relatedness to Adverse Event:	
		Other Foods or Products Given to the Animal During This Time Period:	No
	Manufacturer /Distributor Information:		
	Purchase Location Information:		
	Product Name:	Castor & Pollux Organix Grain Free	
	Product Type:	Pet Food	
	Lot Number:		
	Package Type:	BAG	
	Number Purchased:	1	
	Possess Unopened Product:	No	
	Possess Opened Product:	No	
	Storage Conditions:	Unknown	
	Product Use Information:	Description:	Oral administration
		First Exposure Date:	07/01/2017
		Last Exposure Date	B6
		Time Interval between Product Use and Adverse Event:	9 Months
		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:	Yes
	Manufacturer /Distributor Information:		
	Purchase Location Information:		
Animal Information:	Name:	B6	
	Type Of Species:	Dog	
	Type Of Breed:	Terrier - Yorkshire	
	Gender:	Male	
	Reproductive Status:	Intact	
	Weight:	3.51 Kilogram	
		1 Years	

FDA-CVM-FOIA-2019-1704-006171

	Age:			
	Assessment of Prior Health:	Good		
	Number of Animals Given the Product:	1		
	Number of Animals Reacted:	1		
	Owner Information:	Owner Information provided:	Yes	
		Contact:	Name: B6 Phone: Email:	
		Address:	B6 United States	
	Healthcare Professional Information:	Practice Name:	NC State College of Veterinary Medicine	
		Contact:	Name: B6 Phone: Email:	
		Address:	1060 William Moore Dr Raleigh North Carolina 27607 United States	
		Practice Name:	B6	
		Contact:	Name: B6 Phone: Email:	
		Address:	B6 United States	
		Type of Veterinarian:	Referred veterinarian	
		Date First Seen:	04/02/2018	
		Permission to Release Records to FDA:	Yes	
Sender Information:	Name:	B6		
	Address:	1060 William Moore Dr Raleigh North Carolina 27607 United States		
	Contact:	Phone: Email:	B6	
	Permission To Contact Sender:	Yes		
	Preferred Method Of Contact:	Email		

FDA-CVM-FOIA-2019-1704-006172

Additional Documents:		
	Attachment:	B6 - Necropsy.pdf
	Description:	Necropsy report
	Type:	Necropsy Report
	Attachment:	B6 - Chest Radiographs.pdf
	Description:	Chest x-ray reports
	Type:	Radiographs
	Attachment:	B6 - Echo Reports.pdf
	Description:	Echo Reports (3)
	Type:	Echocardiogram
	Attachment:	B6 - rDVM Medical Record.pdf
	Description:	Medical record
	Type:	Medical Records
	Attachment:	B6 - Discharges.pdf
	Description:	Medical records
	Type:	Medical Records

FDA-CVM-FOIA-2019-1704-006173

B6

Diagnostic Imaging

Radiology Report:

Report Lookup

Accession #: B6 **Search**

Status: Final

View: View Image View Video

B6

B6

Patient ID:	B6	**Exam:**	THORAX CARDIAC DV | 710
Pet Name:		**Acc#:**	B6
Surname:		**Exam Date:**	B6
DOB:		**Status:**	FINAL
Species:	CANINE	**Clinician:**	
Secondary Acc#:		**Affiliation:**	B6
Breed:	YORKSHIRE TERRIER	**2nd Clinician:**	
Gender:	MALE		

History:

B6 6:07 AM resp distress, DCM B6

Assessment:

1. Severe generalized cardiomegaly with left atrial and auricular enlargement, mild pulmonary venous congestion, and bilateral asymmetric severe interstitial to alveolar pulmonary pattern.
   Consistent with left-sided congestive heart failure associated with history of dilated cardiomyopathy.
2. Hepatomegaly.
   Considerations include vacuolar change, congestion, hepatitis, or neoplasia.

Report:

Three-view thoracic radiographs dated B6 are available for interpretation. The study is compared to examinations on 9/17/2018 and prior.

There is similar severe generalized cardiomegaly with increased dimension in three orthogonal planes and specific focal bulging in the region of the left atrium and auricle. The right caudal lobar vein is mildly enlarged and the remainder of the pulmonary vessels are poorly defined. A severe bilateral asymmetric interstitial to alveolar pulmonary pattern is present within the cranioventral, perihilar, and caudodorsal lung more severely affecting the right side. The pleural space is normal. No mediastinal abnormalities are identified.

The hepatic silhouette extends caudal to the costal arch and beyond the collimated field of view. The included osseous structures are normal.

B6

Transcribed By:	B6
Transcribed Date:	
Interpreting Radiologist:	B6
Finalized Date:	01/29/2019
Dx Code:	

FDA-CVM-FOIA-2019-1704-006174

B6

Diagnostic Imaging

Radiology Report:

Report Lookup

Accession #: B6 Search

Status: Final

View: View Image View Video

B6

B6

Patient ID:	B6	**Exam:**	THORAX CARDIAC DV | 710
Pet Name:		**Acc#:**	B6
Surname:		**Exam Date:**	09/17/2018
DOB:		**Status:**	FINAL
Species:	CANINE	**Clinician:**	
Secondary Acc#:		**Affiliation:**	B6
Breed:	YORKSHIRE TERRIER	**2nd Clinician:**	
Gender:	MALE		

History:
09/17/2018 10:53 AM Dilated cardiomyopathy - suspect dietary induced, Congestive heart failure (4/1/18, recurrence 9/8/18) ,Chronic intermittent diarrhea (B6

Assessment:

1. Similar marked cardiomegaly and left atrial enlargement with perihilar and right caudal lung lobe unstructured interstitial pattern; consistent with dilated cardiomyopathy and left-sided congestive heart failure.

Report:
Three-view thoracic radiographs dated 9/17/18 are available and are compared to 9/9/18 and prior.

The previously described marked cardiomegaly and left atrial and left auricular enlargement is similar to prior. There is mild distention of the cranial lobar pulmonary veins relative to their corresponding arteries. An unstructured interstitial pattern is present in the perihilar region and within the right caudal lung lobe. There is no evidence of intrathroacic lymphadenopathy. The pleural space is normal.

The cranial abdominal structures are normal. No musculoskeletal abnormalities are identified.

B6

Transcribed By:	B6
Transcribed Date:	09/17/2018
Interpreting Radiologist:	B6
Finalized Date:	09/18/2018
Dx Code:	

B6

FDA-CVM-FOIA-2019-1704-006175

B6

Diagnostic Imaging

Radiology Report:

Report Lookup

Accession #: B6 Search

Status: Final

View: View Image View Video

B6

B6

Patient ID:	B6	**Exam:**	THORAX CARDIAC DV | 710
Pet Name:		**Acc#:**	B6
Surname:		**Exam Date:**	09/09/2018
DOB:		**Status:**	FINAL
Species:	CANINE	**Clinician:**	
Secondary Acc#:		**Affiliation:**	B6
Breed:	YORKSHIRE TERRIER	**2nd Clinician:**	
Gender:	MALE		

History:
09/09/2018 8:47 AM severe DCM, CHF in April 2018 and recurrence 9/8/2018. Has received B6 over the course of past 24 hours. B6

Assessment:
1. Similar cardiomegaly and pulmonary venous distention, with marked improvement in prior unstructured interstitial pulmonary pattern consistent with response to furosemide therapy.

Report:
Orthogonal projections of the thorax dated 9/9/2018 are compared to the most recent study dated 9/8/2018.

The prior described generalized cardiomegaly with left atrial enlargement and pulmonary venous distension is similar. The previous caudodorsal and perihilar unstructured interstitial pattern is improved consistent with furosemide treatment. There remains a mild perihilar unstructured interstitial pulmonary pattern. The liver remains mildly enlarged. The remainder of the abdomen, and included musculoskeletal structures, are normal.

B6

Transcribed By:	B6
Transcribed Date:	09/10/2018
Interpreting Radiologist:	B6
Finalized Date:	09/12/2018
Dx Code:	

B6

FDA-CVM-FOIA-2019-1704-006176

B6

Diagnostic Imaging

Radiology Report:

Report Lookup

Accession #: B6 Search

Status: Final

View: View Image View Video

B6

B6

Patient ID:	B6	**Exam:**	THORAX CARDIAC DV | 710
Pet Name:		**Acc#:**	B6
Surname:		**Exam Date:**	09/08/2018
DOB:		**Status:**	FINAL
Species:	CANINE	**Clinician:**	B6
Secondary Acc#:		**Affiliation:**	
Breed:	YORKSHIRE TERRIER	**2nd Clinician:**	
Gender:	MALE		

History:
09/08/2018 9:10 AM increased resp effort B6

Assessment:

1. Progressive generalized cardiomegaly with severe left sided enlargement, progressive pulmonary venous distention with unstructured interstitial pulmonary pattern; consistent with progression of prior reported dilated cardiomyopathy with evidence of cardiac decompensation with pulmonary edema.

Report:
Orthogonal projections of the thorax (4 images) dated 9/8/2018 are compared to the most recent study 4/16/2018.

The previously described generalized cardiomegaly and left atrial enlargement is progressive. There is increased dorsal tracheal deviation and caudodorsal soft tissue bulging in the lateral projection, and progressive soft tissue bulging at the 2-3 o'clock position in the dorsoventral projection, consistent with left auricular enlargement. The cardiac silhouette is also larger in the cranial-caudal direction in the lateral projections. The pulmonary lobar veins remain distended as compared to the corresponding arteries. There is a moderate unstructured interstitial pattern within the caudodorsal lung fields and perihilar region, most noticeable within the right caudal lung lobe.
The stomach is moderately distended with gas and heterogeneous soft tissue opaque material. The liver is mildly enlarged extending caudal to the costal margin. The included musculoskeletal structures are normal.

B6

Transcribed By:	B6
Transcribed Date:	09/10/2018
Interpreting Radiologist:	B6
Finalized Date:	09/11/2018
Dx Code:	

FDA-CVM-FOIA-2019-1704-006177

B6

Diagnostic Imaging

Radiology Report:

Report Lookup

Accession #: B6 Search

Status: Final

View: View Image View Video

B6

B6

Patient ID:	B6	**Exam:**	THORAX 3 VIEW VD | 700
Pet Name:		**Acc#:**	B6
Surname:		**Exam Date:**	04/16/2018
DOB:		**Status:**	FINAL
Species:	CANINE	**Clinician:**	B6
Secondary Acc#:		**Affiliation:**	
Breed:	YORKSHIRE TERRIER	**2nd Clinician:**	
Gender:	MALE		

History:
04/16/2018 10:35 AM DCM; CHF B6

Assessment:

1. Similar generalized cardiomegaly with left atrial and left auricular enlargement, with mild caudal lobar venous distention, and right caudodorsal unstructured interstitial pattern- consistent with reported dilated cardiomyopathy; given the reported clinical improvement, the unstructured interstitial pattern may represent mild subclinical residual edema or may represent chronic pulmonary changes secondary to prior insult.

Report:
The study is comprised of 3 orthogonal projections of the thorax dated 4/16/2018, this compared prior study dated 4/2/2018.

The previously described generalized cardiomegaly with left atrial and auricular enlargement is similar. There is mild left caudal lobar venous distention. There is a mild unstructured interstitial pattern within the dorsal aspect of the right caudal lung lobe. There are no abnormalities within the pleural space. There is no evidence of intrathoracic lymphadenopathy. The stomach is moderately distended with amorphous heterogeneous soft tissue opacity material that contains mineral opacity foci.

B6

Transcribed By:	B6
Transcribed Date:	04/16/2018
Interpreting Radiologist:	B6
Finalized Date:	04/16/2018
Dx Code:	

FDA-CVM-FOIA-2019-1704-006178

B6

Diagnostic Imaging

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Report Lookup **Accession #:** B6 Search

Status: Final

View: View Image View Video

B6

B6

Patient ID:	B6	**Exam:**	THORAX CARDIAC DV | 710
Pet Name:		**Acc#:**	B6
Surname:		**Exam Date:**	B6
DOB:		**Status:**	FINAL
Species:	CANINE	**Clinician:**	B6
Secondary Acc#:		**Affiliation:**	
Breed:	YORKSHIRE TERRIER	**2nd Clinician:**	
Gender:	MALE		

History:

B6 8:11 AM DCM, CHF B6

Assessment:

1. Moderate cardiomegaly and left auricular enlargement with resolution of the prior caudodorsal unstructured interstitial pattern, compatible with positive response to treatment for dilated cardiomyopathy and left-sided congestive heart failure.

Report:

Three-view thoracic radiographs dated B6 are available for interpretation. The study is compared to radiographs acquired by the referring veterinarian prior.

The cardiac silhouette is moderately enlarged characterized by widening of the cardiac silhouette with concurrent dorsal displacement of the intrathoracic trachea and carina. A soft tissue opacity bulge is present at the 2-3 o'clock position of the cardiac silhouette in the dorsoventral projection in the region of the left auricle. The pulmonary lobar vasculature is normal in size with no evidence of venous distention. The prior caudodorsal unstructured interstitial pattern is resolved in the current study and the pulmonary parenchyma is normal. No abnormalities are identified in the pleural space or mediastinum.

Cranial abdominal serosal contrast is adequate. The stomach is mildly distended with heterogeneous soft tissue opacity compatible with ingesta.

B6

Transcribed By:	B6
Transcribed Date:	
Interpreting Radiologist:	B6
Finalized Date:	04/04/2018
Dx Code:	

FDA-CVM-FOIA-2019-1704-006179

NC State University
Veterinary Hospital
1052 William Moore Drive
Raleigh, NC 27607
Discharge Comments

Fax: Admin
Fax: Referral
B6

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

Client
B6

Patient
B6
YORKSHIRE TERRIER
M
MIX
CANINE

Case # B6
3.8 kg

Attending DVM
Student
Discharging DVM
Referring DVM
B6

Admission Date/Time B6 01:02 AM **Discharge Date/Time** B6 018 03:00 PM **Discharge Status:**

CASE SUMMARY

DIAGNOSIS:
1. Dilated cardiomyopathy - suspect dietary induced
2. Congestive heart failure B6
3. Chronic intermittent diarrhea

HISTORY:
B6 a 1-year-old intact male Yorkshire terrier mix, was presented to the NCSU ER in the early morning hours o B6 nd was subsequently transferred to the NCSU Cardiology Service for respiratory distress and suspected congestive heart failure.

B6 was observed to have labored breathing the morning o B6 although his owner is unsure exactly when it started. He vomited clear frothy foam after coughing multiple times throughout the day and he had a decreased appetite. B6 was taken to B6 B6 that evening for further evaluation. At B6 a CBC showed a marked thrombocytopenia (automated, no smear performed) and thoracic radiographs showed an enlarged heart, a moderate diffuse unstructured interstitial pattern perihilar and caudodorsal lung lobes, and a mildly distended cranial lobar vein. Congestive heart failure was suspected and B6) and B6 B6 was subsequently referred to NCSU for further cardiac workup.

B6 other medical problems include recent vomiting and diarrhea. He vomits every once in a while, most recently a couple of weeks ago after eating houseplants. He also had a bad bout of diarrhea after eating the plants. He was taken to his primary veterinarian who prescribed medications and a probiotic. The vomiting resolved and his feces normalized until about 2 days ago when they became soft again.

B6 was obtained in July from friends who were rehoming him due to moving. He is reportedly up to date on vaccines and receives monthly heartworm prevention, albeit not regularly. Since July, his diet has been Castor & Pollux Organix grain free small breed formula kibble and canned chicken/veggie recipe.

PHYSICAL EXAM FINDINGS (on presentation to SNTR)
B6

3.51

Hydration: adequate

B6

RESULTS OF DIAGNOSTIC TESTS:
B6

3. A/T FAST: No pericardial, pleural, or peritoneal effusion. Increased B-lines bilaterally.

4. Echocardiogram (4/2/18)
a. Dilated cardiomyopathy
b. Severe LV dilation with severely reduced systolic function
c. Moderate mitral regurgitation
d. Moderate to severe LA enlargement
e. Moderate RV dilation
f. Moderate tricuspid regurgitation
g. Mild to moderate RA enlargement
h. ECG: Sinus rhythm with frequent supraventricular premature complexes

5. Chest radiographs (4/2/18): *final report pending*
a. Severe generalized cardiomegaly
b. Prior unstructured interstitial pattern resolved - consistent with response to therapy for L. CHF

B6

8. Whole blood taurine: results pending

ASSESSMENT:

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

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

Changes in the muscle of the heart in dogs with DCM can lead to fibrosis and remodeling of the myocardium (heart muscle), which can lead to secondary arrhythmias (abnormal heart rhythm) caused by abnormal impulse conduction. Normally, electrical signals are sent through conductive pathways that signal the heart to contract in a synchronous manner. The diseased heart muscle can also initiate abnormal electrical impulses that do not utilize the normal conduction pathways of the heart. As we discussed, arrhythmias occur commonly in dogs with DCM, with some dogs experiencing sudden death as a result. B6 ECG shows evidence of mild arrhythmias at this time. In the future, we would like to perform a test called a holter monitor. This is a 24 hour ECG that B6 would wear home to analyze his heart rhythm.

Although we cannot cure DCM, we hope to manage B6 clinical signs with medical therapy as outlined below. The average survival for DCM patients after an episode of heart failure is 6-12 months. However, as we discussed, given B6 young age and small breed - we suspect his DCM is secondary to his diet. If this is the case, his heart structure and function may show improvement with taurine supplementation and diet change.

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

INSTRUCTIONS FOR CARE

MEDICATIONS:

B6

B6

MONITORING

1. Please monitor B6 for signs of congestive heart failure. This would include lethargy, change and worsening of the cough, difficulty breathing (increased respiratory rate/effort), and episodes of collapse or fainting. If you note any of these signs, please contact us and have B6 evaluated by a veterinarian.

2. Please begin to monitor B6 resting respiratory rate. This should be performed when B6 is resting or sleeping. You can count his respiratory rate by counting the number of breaths he takes over 15 seconds - then multiplying that number by 4 to obtain the number of breaths per minute. A normal respiratory rate is less than 30-40 breaths per minute. If you note that his respiratory rate is increasing, please contact us.

ACTIVITY:

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

DIET:

As we discussed, we would like to change B6 diet due to a concern for dietary induced DCM. We would recommend feeding him a commercial brand (Purina, Hills, Iams) diet going forward.

NEXT APPOINTMENT:

1. We would like B6 to have a recheck appointment in 1-2 weeks for a recheck exam, blood pressure, renal panel, chest radiographs and holter monitor. A holter monitor is a 24 hours ECG monitor that will be worn home with a vest.

2. We will contact you with the results of the taurine levels.

3. We would otherwise like to see B6 back in 3-4 months for a recheck exam, blood pressure, renal panel, and echocardiogram. A repeat echocardiogram will tell us if B6 heart function has improved.

COMMENTS:

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

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

Owner: B6

Clinician: B6

Student: B6

Clinicians:
Dr. Darcy Adin

B6

Residents:

B6

Clinical Technicians:

B6

Client Services:

B6

Research Technician

B6

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

NC State University
Veterinary Hospital
1052 William Moore Drive
Raleigh, NC 27607

Fax: Admin
Fax: Referral

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

Discharge Comments

Client	Patient		Attending DVM	
B6	B6	Case # B6	Student	B6
	YORKSHIRE TERRIER		Discharging DVM	
	M	3.8 kg	Referring DVM	
	MIX			
	CANINE			

Admission Date/Time: APR 16, 2018 09:30 AM **Discharge Date/Time:** APR 16, 2018 11:23 AM **Discharge Status:**

CASE SUMMARY

DIAGNOSIS:
1. Dilated cardiomyopathy - suspect dietary induced
2. Congestive heart failure B6
3. Chronic intermittent diarrhea

HISTORY:
B6 is a 1-year-old male Yorkshire terrier mix who presented to NCSU Cardiology on 4/16/18 for a recheck of his previously diagnosed dilated cardiomyopathy. B6 first presented to NCSU ER's on B6 and was subsequently transferred to the NCSU Cardiology Service for respiratory distress and suspected congestive heart failure. B6 was observed to have labored breathing the morning of B6 vomited after coughing multiple times throughout the day and he had a decreased appetite. Prior to presentation at NCSU, B6 where they performed thoracic radiographs which showed an enlarged heart, a moderate diffuse unstructured interstitial pattern perihilar and caudodorsal lung lobes, and a mildly distended cranial lobar vein. Congestive heart failure was suspected and B6 was given B6 B6 was subsequently referred to NCSU for further cardiac workup. B6 was hospitalized at NCSU in the ICU and treated with B6 Thoracic radiographs were performed the next day which showed moderate cardiomegaly and left auricular enlargement with resolution of the prior caudodorsal unstructured interstitial pattern. An echocardiogram was performed which showed changes consistent with severe dilated cardiomyopathy. B6 ECG showed sinus rhythm with frequent supraventricular premature complexes. B6 responded well to medications and was discharged the following day. The cause of DCM is unknown, but given his history of eating grain-free diets this was presumed a top differential. Additionally, he was not found to be taurine deficient.

Since discharge B6 has been doing great at home. He has been able to go on walks and tolerates them well. He has a great appetite, and his diet has been switched to Royal Canin wet food, as well as a tablespoon of Organix grain-free that he was fed prior to his admission to the ER (as he is transitioning to a grain based diet). He also receives a plethora of fruit and vegetables. B6 had a few episodes of mucoid diarrhea since being discharged, and has a history of chronic diarrhea. His current medications include B6 mg tablets 0.5 tablet by mouth every 12 hours, B6 1.25 mg tablets) 1 tablet by mouth every 12 hours, B6

B6

PHYSICAL EXAM FINDINGS:

B6

4. HOLTER MONITOR - Pending

ASSESSMENT:
Thank you for bringing B6 back to NCSU, he was an absolute sweetheart to work with today! As you know, B6 has been previously diagnosed with dilated cardiomyopathy and today we wanted to assess his response to the medications he was discharged with.

B6 blood pressure was within normal limits today. Additionally, his kidneys appear to be handling the heart medications appropriately which is great news. The chest x-rays today show that B6 heart remains enlarged (which is expected) but fortunately there is no evidence of congestive heart failure today. Overall, we are very happy with how B6 is doing at home and with the results of tests today! We are, however, starting a new medication called B6 today. This medication has a few benefits, including cardioprotective effects that can be useful for congestive heart failure and heart disease.

While we are thrilled that B6 is doing well, we know that the underlying disease may be progressive. Because of this, continued monitoring is critical and please continue to monitor B6 for signs of worsening of heart failure such as increased exercise intolerance, labored breathing, increased coughing or fainting. Call NCSU Cardiology or your referring veterinarian if any of these signs occur. Also, please continue to take a respiratory (breathing) rate when he is resting. This can be done by counting the number of breaths he takes in 15 seconds and multiplying by 4 (to get the total breaths per minute). This number should remain less than 40 at rest.

INSTRUCTIONS FOR CARE MEDICATIONS:

B6

NEXT APPOINTMENT:
1. Please have B6 kidney values and electrolytes checked in 1-2 weeks after starting the new B6 medication. This can be with NCSU as a quick test or with your primary veterinarian.

2. We would like B6 to have a recheck appointment in 3-4 months for a recheck exam, blood pressure, renal panel, chest radiographs and echocardiogram. Additionally, if B6 current pending Holter has concerns this may be changed. If you notice signs of worsening heart disease as described above, please contact us or have him seen sooner.

COMMENTS:

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

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

B6 B6 B6

Clinicians:
Dr. Darcy Adin

B6

Residents:

B6

Clinical Technicians:

B6

Research Technician
B6

Client Services:
B6

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

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Veterinary Hospital
1052 William Moore Drive
Raleigh, NC 27607

Discharge Comments

Fax: Admin
Fax: Referral

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

Client	Patient		Attending DVM
B6	B6	Case # B6	Student
	YORKSHIRE TERRIER		Discharging DVM
	M	3.8 kg	Referring DVM
	MIX		
	CANINE		

B6

Admission Date/Time: SEP 08, 2018 08:18 AM **Discharge Date/Time:** SEP 09, 2018 04:00 PM **Discharge Status:**

CASE SUMMARY
DIAGNOSIS:
1. Dilated cardiomyopathy - suspect dietary induced
2. Congestive heart failure B6 ecurrence 9/8/18)
3. Chronic intermittent diarrhea

HISTORY:
B6 s a 1 year old male intact Yorkshire Terrier mix that presented to NCSU SAES on 9/8/18 for evaluation of coughing and increased respiratory effort. B6 has a history of diet induced cardiomyopathy and congestive heart failure that were originally diagnosed in April 2018. Based on B6 history, clinical signs, and initial diagnostics, he was diagnosed with progressive heart disease and congestive heart failure. B6 was stabilized with oxygen therapy as well as aggressive treatment with B6 B6 He was subsequently transferred to the Cardiology service 9/9/18 for continued care and evaluation.

B6 was first diagnosed with dilated cardiomyopathy in April 2018. He was found to be in congestive heart failure at that time. He was initiated on triple therapy: B6 Due to the severe degree of cardiac dilation, poor systolic function, signalment, and a history of a grain free diet, diet-induced cardiomyopathy was the primary differential. B6 responded well to medications in the hospital and was discharged on B6 B6 B6 B6 taurine supplementation, and recommendations for a grain-containing diet.

He had tolerated these medications well. However, B6 did not consistently show interest in the new diet. Therefore, B6 has been on a different diet. Primal is a raw, freeze-dried grain-free formula for the past several months. Since B6 last discharge, he has reportedly been doing well. He is a picky eater, but drinks plenty of water. The owner notices that B6 sleeps a lot at home but this is not necessarily abnormal for him. The week of presentation to the NCSU SAES, B6 was playing vigorously with a visiting dog the owner was pet-sitting. On 9/7 the owner took both dogs out on a walk on which they ran intermittently for short bursts, but B6 was stopping intermittently and was breathing heavily. That night, B6 was coughing and had increased respiratory effort, and had a few episodes of standing, swaying, and closing eyes, but no actual collapse. B6 was presented to the NCSU SAES on the morning of 9/8/2018.

B6 was obtained in July 2017 from friends who were rehoming him due to moving. He is reportedly up to date on vaccines (received Rabies last week at B6), and intermittently receives monthly heartworm prevention.
Current medications include: B6 B6

PHYSICAL EXAM FINDINGS 9/8/18:

B6

DIAGNOSTICS 9/8/18:

B6

B6

3. Thoracic radiographs: Markedly enlarged globoid heart with evidence of perihilar edema, pulmonary venous distention and elevation of the carina, consistent with congestive heart failure. *Final radiology report pending.

PHYSICAL EXAM FINDINGS 9/9/18:

B6

4. Thoracic radiographs: Markedly enlarged globoid heart with slight decrease in size and decrease in elevation of the carina from previous, decreased perihilar edema, decreased pulmonary venous distention, consistent with significant improvement of previously documented congestive heart failure. *Final radiology report pending.

ASSESSMENT:

Thank you for entrusting us with B6 care. He was in respiratory distress and diagnostic tests provided evidence that he had progression of his heart disease and recurrence of left-sided congestive heart failure. The goal of a hospital stay during this crisis is to alleviate the fluid build up in the lungs. B6 responded well to oxygen therapy, diuretics, anti-anxiety medications, as well as medications to improve heart function and forward pumping.Our goal before sending him home is to reduce the fluid in his lungs, make sure he is comfortable and maintaining a normal heart rate and breathing pattern, and gradually decrease the in-hospital interventions.

Overall he has tolerated our interventions very well. Today's radiographs showed significant improvement in his lungs and even some improvement in his heart size, and B6 is maintaining a normal breathing pattern and heart rate. As B6 progressed into congestive heart failure on his current medications, this indicates we need to increase his dosages of diuretic and B6 It is also concerning that B6 heart is further dilated than in April. The only variable that has not changed in his treatment was the diet. As we discussed, we are still learning about the grain-free diets and their apparent link to dilated cardiomyopathy. B6 is a very young, small breed dog. It is older, large breed dogs that normally get dilated cardiomyopathy. There is no other underlying condition known to cause a heart to appear as B6 Therefore, we believe his heart disease is caused by the diet. We do not know if the grain-free diet is lacking essential elements for normal and healthy heart function, or rather these diets contain ingredients that are in someway harmful. Therefore, we recommend complete transition to any commercially available diet that is grain-containging. You can make the transition over the course of a week or so, but we would strongly encourage B6 not be on his current diet as his heart disease has continued to progress.

Overnight, both these parameters increased suddenly while he was resting, and he responded well to the injection of B6 followed by reinstating a constant rate infusion of B6 T-fast ultrasound and chest radiographs taken this morning revealed marked improvement of the fluid patterns in his lungs. Since his heart rate and respirations had been stable for several hours, his was transitioned from his constant infusion of B6 and started on B6 As he remained stable over the next hours, we subsequently discontinued his oxygen supplementation and continue to monitor him. We are happy to see that he is maintaining well with oral medications and breathing room air (no extra oxygen).

While we are thrilled that B6 is doing well, we know that the underlying disease may be progressive. As B6 has experienced recurrent congestive heart failure, we are increasing the frequency of the B6 and the B6 three times a day. We will keep the B6 and the taurine at the same doses and frequencies. And we would like to implement the B6 medication once daily. (More details on medication directions below.) At this time, we need to balance the needs of B6 heart with those of his kidneys. This can be a delicate task, but overall, his heart disease is the one which puts him at the most risk at this time. This drug regimen (including the B6) will have the most helpful impact on his heart disease, and poses only slight risks to his kidneys.

INSTRUCTIONS FOR CARE MEDICATIONS:

B6

B6

DIET

It is imperative that B6 be fed a grain-containing diet in order to fully help this disease from progressing. Any brand-name food you can purchase at a grocery or pet store is acceptable, as long as it is not advertised to be grain free. We do not yet know exactly what about these diets is causing DCM in young, non-predisposed breeds, but there has been a significant increase of this diagnosis across the country in breeds who are not genetically disposed to getting it, and the single correlation between these cases is a "grain-free" diet. At this point we do not know whether, or how much, B6 heart will improve, but other dogs in his same situation who have switched to a grain-containing diet have had improvement.

We can also discuss a personalized nutrition consult with our Nutrition Service if you are interested in a home cooked diet. If you would like to pursue this option, please reach out to B6. A consultation for homemade diets costs around B6

MONITORING

Please continue to monitor B6 for signs of worsening of heart disease or of failure such as increased exercise intolerance, labored breathing, increased coughing or fainting. Please avoid strenuous exercise or situations which place undue stress on B6 Call NCSU Cardiology or your referring veterinarian if any of these signs occur. Also, please continue to take a respiratory (breathing) rate when he is resting. This can be done by counting the number of breaths he takes in 15 seconds and multiplying by 4 (to get the total breaths per minute). This number should remain less than 40 at rest.

PLAN FOR REEVALUATION:

B6

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

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

B6 Owner

B6 DVM

B6 2019

Clinicians:

B6

Residents:

B6

Clinical Technicians:

B6

Client Services:

B6

Research Technician

B6

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

NC State University
Veterinary Hospital
1052 William Moore Drive
Raleigh, NC 27607

Discharge Comments

Fax: Admin
Fax: Referral

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

Client	Patient		Attending DVM	
B6	B6	Case # B6	Student	B6
	YORKSHIRE TERRIER		Discharging DVM	
	M	3.8 kg	Referring DVM	
	MIX			
	CANINE			

Admission Date/Time: SEP 17, 2018 10:25 AM **Discharge Date/Time:** SEP 17, 2018 01:13 PM **Discharge Status:**

CASE SUMMARY

DIAGNOSIS:
1. Dilated cardiomyopathy - suspect dietary induced - progressive
2. Congestive heart failure (B6 recurrent 9/8/18)
3. Chronic intermittent diarrhea and varying appetite

HISTORY:
B6 is a 1.5 year old male Yorkshire Terrier mix that was presented to the NCSU Cardiology Service on 9/17/18 for a 1 week recheck evaluation after recurrent congestive heart failure secondary to diet induced DCM.

B6 was first diagnosed with dilated cardiomyopathy and congestive heart failure in April 2018. Due to the severe degree of cardiac dilation, poor systolic function, signalment, and a history of a grain free diet - diet-induced cardiomyopathy was the primary differential. B6 responded well to medications in the hospital and was discharged on B6 B6. His owners were also instructed to transition him to a balanced diet containing grains. A recheck evaluation 1 week later showed resolution of congestive heart failure, and B6 was doing well at home. A holter monitor showed no ventricular ectopy. His medications were continued at their prior doses, and the addition of B6 was recommended.

From April through September 2018 B6 overall did well at home. He was taking his medications well (with the exception of B6 which was not started). B6 had a great energy level at home. B6 was initially eating a Royal Canin diet, however due to lack of interest his owners transitioned him to a raw/grain free diet called Primal (raw, freeze-dried, grain free). He was eating this diet from May-September 2018. On 9/7/18 B6 was noted to stop intermittently while walking, and was breathing heavily. That night, B6 was coughing and had increased respiratory effort, and had a few episodes of standing, swaying, and closing eyes, but no actual collapse. B6 was presented to the NCSU SAES on the morning of 9/8/2018. He was diagnosed with progressive DCM, and recurrent congestive heart failure. He was managed overnight and responded well to treatment. He was discharged the following morning on B6 B6 B6 B6 B6 B6.

Over the past week B6 has overall been doing well at home. He was initially lethargic after returning home, but returned to normal by the afternoon of 9/10/18. He has been active throughout the week, with minimal coughing. His respiratory rate while sleeping is around 36-40 brpm. His owners have transitioned him to FROMM Gold Adult small breed dog food (contains grains). He has shown moderate interest in this food, but remains picky. He receives his medications in cooked chicken, which he eats readily. Current medications include: B6 B6 B6 B6

PHYSICAL EXAM FINDINGS:

B6

B6

RESULTS OF DIAGNOSTIC TESTS:

B6

2. CHEST RADIOGRAPHS - *final report pending*
a. Similar marked left-sided cardiomegaly and left atrial enlargement with perihilar and right caudal lung lobe unstructured interstitial pattern; consistent with dilated cardiomyopathy and recurrent left-sided congestive heart failure.

3. BRIEF ECHO - Progressive dilated cardiomyopathy with severe LV dilation and severely reduced systolic function, moderate to severe mitral regurgitation, severe left atrial enlargement

B6

ASSESSMENT:
Thank you for bringing B6 back to NCSU, he is such a sweet boy.

As you know, B6 has been previously diagnosed with diet induced dilated cardiomyopathy (DCM) and congestive heart failure. Today we performed chest radiographs, a brief cardiac ultrasound, and kidney bloodwork to evaluate his heart disease and response to treatment.

As we discussed B6 echocardiogram (heart ultrasound) showed evidence of disease progression. His heart has continued to enlarge over the past 5 months, and is more dilated today than it was in April. Additionally, his heart function remains severely decreased. These findings are not surprising, considering B6 continued to eat a grain free diet over the past 4 months, and we suspect the diet is causing his heart disease. B6 chest radiographs showed evidence of a small amount of fluid accumulation in his lungs today - indicating recurrent congestive heart failure. Given this finding, we would like to increase his heart failure medications further, in an attempt to clear the remaining fluid from his lungs. Please see below for the dosing instructions.

We are hopeful the new dose of medications will be adequate to resolve and control the fluid accumulation. As we have previously discussed, cases of diet induced dilated cardiomyopathy will typically improve with a diet change. However, it is possible B6 heart could continue to worsen, or fail to show improvement. We strongly recommend B6 continue to eat a diet containing grains. We are hopeful his heart size and function will show improvement in the coming months after this diet change. We will evaluate his heart structure and function in 3 months at his next recheck evaluation.

B6 kidney values showed a slight increase over the past week. This is not surprising given the increased dose of medications. The increase is mild, and overall not worrisome. However, we will continue to monitor these values going forward.

Please continue to monitor B6 for signs of worsening of heart failure such as increased exercise intolerance, labored breathing, increased coughing or fainting. Call NCSU Cardiology or your referring veterinarian if any of these signs occur. Also, please continue to take a respiratory (breathing) rate when he is resting. This can be done by counting the number of breaths he takes in 15 seconds and multiplying by 4 (to get the total breaths per minute). This number should remain less than 40 at rest.

INSTRUCTIONS FOR CARE

MEDICATIONS:

B6

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

DIET: Please continue B6 new diet (grain-based) and avoid highly salty treats. Given B6 picky appetite, you may need to offer him multiple varieties of food (grain based diets) to see what he likes. We can also discuss a personalized nutrition consult with our Nutrition Service if you are interested in a home cooked diet. If you would like to pursue this option, please let us know. A consultation

for homemade diets costs around B6

NEXT APPOINTMENT:

1. Ideally, we would like B6 o have his kidney values and chest radiographs rechecked in 1-2 weeks after increasing his heart failure medications (approximate cost of B6

B6

2. We would otherwise like B6 to have a recheck appointment in 3-4 months for a recheck exam, blood pressure, renal panel, chest radiographs and echocardiogram. If you notice signs of worsening heart disease as described above, please contact us or have him seen sooner.

COMMENTS:

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

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

B6 B6 Senior student

Clinicians:

B6

Residents:

B6

Clinical Technicians:

B6

Client Services:

B6

Research Technician

B6

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

NC State University
Veterinary Hospital
1052 William Moore Drive
Raleigh, NC 27607

Fax: Admin
Fax: Referral

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

Discharge Comments

Client	Patient		Attending DVM
B6	B6	Case # B6	Student
	YORKSHIRE TERRIER		Discharging DVM B6
	M	3.8 kg	Referring DVM
	MIX		
	CANINE		

Admission Date/Time: DEC 18, 2018 10:31 AM **Discharge Date/Time:** DEC 18, 2018 12:34 PM **Discharge Status:**

CASE SUMMARY
DIAGNOSES:
1. Dilated cardiomyopathy - suspect dietary induced - progressive
2. Congestive heart failure B6 recurrent 9/8/18)
3. Chronic intermittent diarrhea and varying appetite - improved

HISTORY:
B6 is a 1.5 year old male Yorkshire Terrier mix who was presented to the NCSU Cardiology Service on 12/18/18 for a recheck evaluation of suspected diet-induced DCM and recurrent heart failure.

B6 was first diagnosed with dilated cardiomyopathy and congestive heart failure in April 2018. Due to the severe degree of cardiac dilation, poor systolic function, signalment, and a history of a grain free diet - diet-induced cardiomyopathy was the primary differential. B6 responded well to medications in the hospital and was discharged on B6 B6 B6 His owners were also instructed to transition him to a balanced diet containing grains. A recheck evaluation 1 week later showed resolution of congestive heart failure, and B6 was doing well at home. A holter monitor showed no ventricular ectopy. His medications were continued at their prior doses, and the addition of B6 was recommended. From April through September 2018, B6 overall did well at home, and had a great energy level. He was taking his medications well (with the exception of B6 which was prescribed but not started).

B6 was initially eating a Royal Canin diet, however due to lack of interest his owners transitioned him to a raw/grain free diet called Primal (raw, freeze-dried, grain free), and continued to feed this diet from May-September 2018. On 9/7/18 B6 was noted to stop intermittently while walking, and was breathing heavily. That night, B6 was coughing, had increased respiratory effort, and had a few episodes of standing, swaying, and closing eyes, but no true collapse. B6 was presented to the NCSU SAES on the morning of 9/8/2018. He was diagnosed with progressive DCM, and recurrent congestive heart failure. He was managed overnight and responded well to treatment. He was discharged the following morning on B6 B6 B6 B6 B6

Since his last visit, B6 has been doing very well at home. He is noted to generally sleep while he is alone with his owner, but be very playful when around other dogs. He has has no recent coughing, vomiting, or changes to urination, though he does occasionally have loose stools. When counted, his respiratory rate while sleeping is around 25-35 brpm.

Since his episode of CHF in September 2018, B6 has been transitioned to a diet of Fromm Adult Gold Small Breed food (contains grains), supplemented with boiled chicken and brown rice. The owner reports that since his last visit, his appetite has been great, and she has not been concerned about his food intake. He receives his medications in cooked chicken, which he eats readily. B6 B6 B6 B6 B6 B6

PHYSICAL EXAM FINDINGS:

B6

RESULTS OF DIAGNOSTIC TESTS:

B6

2. ECHOCARDIOGRAM - Dilated cardiomyopathy with severe LV dilation and severely reduced systolic function, progressively decreased contractility, mild mitral regurgitation, severe left atrial enlargement

B6

ASSESSMENT:

Thank you for bringing B6 in to see us today! As always, he is completely adorable.

Today we saw B6 for a recheck evaluation of previously diagnosed DCM with episodes of heart failure that were suspected to be secondary to a grain-free diet. We performed an echocardiogram, to look inside his heart to evaluate its function. We saw today that B6 heart has not further enlarged from the last time he was seen in September 2018, and his mitral valve regurgitation is also relatively static to improved. Unfortunately, another measure of heart function, his contractility, is somewhat decreased from the last time he was seen. Although we have not seen improvements to his cardiac structure or function yet, we are still hopeful, as B6 has only been off of a grain free diet for 3 months, and he is doing very well clinically at home, with no episodes of labored breathing or weakness. Some patients take longer to recover. There is also a very real possibility that his heart will be permanently damaged since he was affected at such a young age while he was still growing. We elected to hold on chest x-rays today as they were unlikely to change our plan and B6 is doing so well clinically. They should be performed immediately if B6 has signs such as decreased activity, cough, or most importantly, increased resting respiratory rate.

Today we also ran some bloodwork to evaluate his renal function, which can often be impacted by heart medications. Although one value is slightly elevated (BUN), this has remained relatively unchanged since his last visit with us in September. Given the severity of his heart disease, we will continue him on his current dose of all his heart medications, but continue to monitor his renal function through regular blood work.

Ideally we would like to eventually see improvements in B6 heart size and function. Since we did not see this today, we are planning to start him on some supplements that all support cardiac function. These are listed below under "medications," and can all be purchased online or at most grocery stores and pharmacies. We hope that B6 continues to feel better, and that his heart may start to improve with more time on a grain diet.

INSTRUCTIONS FOR CARE

MEDICATIONS:

B6

ACTIVITY: B6 can continue to set his own activity level.

DIET: Please continue B6 on his current diet, Fromm Adult Gold Small Breed (with grains) with chicken and brown rice supplemented.

MONITORING: Please continue to monitor B6 at home for signs related to heart failure, including increased respiratory effort and rate, increased coughing, weakness, collapse, lethargy, and decreased appetite.

RECOMMENDATIONS FOR FURTHER EVALUATION:

We would like to see B6 back for a recheck echocardiogram, chest radiographs, and renal panel in 3-6 months. If B6 should develop signs of congestive heart failure or progressive disease prior to his next appointment, including exercise intolerance, weakness, lethargy, coughing, or increased respiratory rate or effort, please have him seen by a veterinarian immediately.

COMMENTS:

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

NOTE: If your pet is in need of emergency aid and you are not able to get to the NC State Veterinary Hospital quickly, please seek

care at the nearest veterinary emergency facility. Take these discharge instructions and current medications with you so that the treating veterinarian will know as much as possible regarding your pets' medical condition.

B6 Owner

B6 DVM

B6 Senior Student

Clinicians:

B6

Residents:

B6

Clinical Technicians:

B6

Client Services:

B6

Research Technician

B6

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

NC State University
Veterinary Hospital
1052 William Moore Drive
Raleigh, NC 27607

Fax: Admin
Fax: Referral

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

Discharge Comments

Client	Patient		Attending DVM	
B6	B6	Case # B6	Student	B6
	YORKSHIRE TERRIER		Discharging DVM	
	M	3.8 kg	Referring DVM	
	MIX			
	CANINE			

Admission Date/Time: B6 05:37 AM **Discharge Date/Time:** B6 07:15 AM **Discharge Status:** EUTHANIZED

*****NOTICE OF EUTHANASIA*****

CASE SUMMARY

Diagnoses/Problems:
1. Presumed dietary induced dilated cardiomyopathy
2. Suspected congestive heart failure
3. Cardiogenic shock

History:
B6 a 1.5-year-old male Yorkie who presented to the NCSU Small Animal Emergency Service in respiratory distress. B6 was previously diagnosed with dilated cardiomyopathy and congestive heart failure in April 2018. Due to the severe degree of cardiac dilation, poor systolic function, signalment, and history of a grain-free diet, dietary induced DCM was suspected. B6 was started on a Royal Canin diet after transition to a balanced diet containing grains was recommended; however, due to lack of interest he was switched to a raw/grain free diet called Primal, which he received from May-September 2018. B6 re-presented to NCSU on 9/7/18 for his second episode of congestive heart failure. He was treated and discharged.

About a week ago B6 began having an increased respiratory rate. B6 was instructed to give him an extra dose of his B6 and B6 improved. Last night B6 began breathing a little heavier again. Around 3 am this morning his respiratory rate worsened, so he was given B6. At 5 am B6 awoke to commotion under her bed and found B6 flailing and rolling. His respiratory rate and effort were significantly increased. She gave him an additional tab B6 and subsequently brought him to NCSU for further evaluation.

B6 has been eating a FROMM dry dog food that contains grains. He has not had any vomiting recently, but last week he experienced a couple of non-productive episodes where he looked like he wanted to cough something up.

Physical Exam Findings:

B6

B6 was laterally recumbent and dyspneic on initial presentation. His pulse quality was fair. Right-sided crackles were appreciated on pulmonary auscultation.

Results of Diagnostic Tests:

B6

Assessment:
B6 presented to the NCSU Small Animal Emergency Service in severe respiratory distress and cardiogenic shock. Hospitalization with mechanical ventilation was discussed; however, due to poor prognosis and quality of life considerations, humane euthanasia was elected. B6 received B6 followed by B6

B6

B6 DVM

B6

Faculty:

B6

Residents/Fellows:

B6

Interns:

B6

Supervisor:

B6

Technicians:

B6

Client Services:

B6

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

B6

NC STATE UNIVERSITY
CARDIOLOGY

1052 William Moore Drive
Raleigh, NC 27607
Phone: 919.513.6694 Fax: 919.513.6712

Canine Echocardiography Report

Patient Name:	B6	Date of Exam:	12/18/2018
Medical Rec #:		Breed:	Yorkshire
DOB:	B6	Weight:	4 kg
Age:	20 months	BSA:	0.23 m²
Sex:	Mc	HR:	
Sonographer:	B6	BP-sys:	

Report Status: READ
Ref. Clinician: B6
Diagnosis: Dilated cardiomyopathy
Study Details: 2D Echo/Doppler/Color Doppler. The images were of adequate diagnostic quality. The patient was awake.

2D

	Diastole	Systole				
IVS	B6		%FTivs	B6	LV EF,	B6
LV			%FS		LV CO,	
LVPW			%FTfw			

2D

LA Long Axis	B6		LAA Velocity
LA d			PDA Diam
Ao s			PDA ampulla
LA/Ao			PV Ann

M-mode

	Diastole	Systole					
		cm					
RV	B6		%FS	B6	LV EF	B6	
IVS			MRSIm		LV SV		
LV			MRSI		LV CO		
LVPW			EDVI				
LV normalized			ESVI				
LA			ESWS/ESV		EPSS		
Ao			wAo				
LA/Ao			TAPSE		LV-IVRT		

Normal Canine M-mode values (in cm) for 3 kg dogs.

LVIDd	LVPWd	IVSd	LA	AO	%FS
B6					

Normal Canine M-mode values (in cm) for 5 kg dogs.

LVIDd	LVPWd	IVSd	LA	AO	%FS
B6					

Tissue Doppler:

	Medial
E'	B6
A'	
E/E'	
E'/A'	

Final

FDA-CVM-FOIA-2019-1704-006196

Aortic Valve: AoV
VMax
Pk Grad B6

Mitral Valve:
Mn Grad E Vmax
P1/2T A Vmax
MV Area E/A B6

Mitral Regurgitation:
MR Vmax
MR Peak Gradient B6
Est SBP by MR

Tricuspid valve:
TV E Max TR Vmax
TV Mn Grad TR Pk Grad
P 1/2 T RA Pressure:
TV VTI RVSP B6

Pulmonic valve: PV
Vmax
Pk Grad B6

CLINICIAN INTERPRETATION:
Left Ventricle: The left ventricular cavity size is severely increased. LV ejection fraction is moderately decreased. LV basal fractional shortening is moderate to severely decreased. Spectral Doppler shows normal pattern of LV diastolic filling.
Left Atrium: The left atrium is severely dilated. The left atrial A/P dimension is 2.45 cm.
Right Atrium: The right atrium is mildly dilated.
Right Ventricle: The right ventricular size is mildly enlarged.
Mitral Valve: The E-point septal separation is increased. Mild mitral valve regurgitation. The MR jet is centrally-directed.
Tricuspid Valve: There is mild tricuspid regurgitation, with a jet that is directed centrally.
Pulmonic Valve: The pulmonic valve is normal.
Pericardium/Effusions: No pericardial effusion is seen.
Aorta: The aortic sinuses, arch, ascending and descending aorta appear all normal.
Pulmonary Artery: The pulmonary artery is of normal size and origin. The tricuspid regurgitant velocity is 1.63 m/s, and with an assumed right atrial pressure of 10 mmHg, the estimated right ventricular systolic pressure is normal at 20.6 mmHg.

ECHO SUMMARY:
1. Moderately decreased LV ejection fraction.
2. The left ventricular cavity size is severely increased.
3. Severely dilated left atrium.
4. Mildly dilated right atrium.
5. Mild mitral valve regurgitation.
6. Mild tricuspid regurgitation.

CV Exam:
Body condition was normal. Normal respirations. The mucous membranes appeared pink, with a normal capillary refill time. Femoral pulse quality was normal. Pulmonary auscultation revealed increased lung sounds.
ECG:
The ecg was either not available at the time of the report or was not done. The heart rate measured at 176 beats/minute. The ECG rhythm is sinus tachycardia. Single VPC and occasional supraventricular

Final

FDA-CVM-FOIA-2019-1704-006197

premature complexes was/were noted.

Recommendations: This study was performed 3 months after a transition to a grain containing diet. The patient has had 2 episodes of CHF (4/2018 and 9/2018) secondary to suspect diet-induced DCM. The patient is starting to have more activity and a much better appetite since his last recheck.

The left ventricle and left atrium are still severely dilated. There is mild mitral regurgitation (that is subjectively improved). While there is slight improvement in the dimensions of the LA and LV, there is significantly decreased systolic function of LV.

While there is minimal improvement in the chamber size, the decrease in systolic function is concerning. Diet induced DCM still remains the top differential. It could take longer for remodeling to occur, or the heart may be permanently dilated.

B6

B6

Electronically signed on 12/18/2018 on 6:16:07 PM

FDA-CVM-FOIA-2019-1704-006198

B6

NC STATE UNIVERSITY
CARDIOLOGY

1052 William Moore Drive
Raleigh, NC 27607
Phone: 919.513.6694 Fax: 919.513.6712

Canine Echocardiography Report

Patient Name:	B6	Date of Exam:	9/17/2018
Medical Rec #:		Breed:	Yorkshire
DOB:	B6	Weight:	4 kg
Age:		BSA:	0.24 m²
Sex:	Mc	HR:	
Sonographer:	B6	BP-sys:	

Report Status: READ
Ref. Clinician: B6
Diagnosis: Dilated cardiomyopathy - diet induced
Study Details: 2D Echo/Doppler/Color Doppler. The images were of adequate diagnostic quality. The patient was awake.

2D

	Diastole	Systole				
IVS	B6		%FTivs	B6	LV EF,	B6
LV			%FS		LV CO,	
LVPW			%FTfw			

2D

LA Long Axis	B6		LAA Velocity
LA d			PDA Diam
Ao s			PDA ampulla
LA/Ao			PV Ann

M-mode

	Diastole	Systole					
		cm				LV EF	B6
RV	B6	B6	%FS	B6	LV SV	
IVS			MRSIm		LV CO	
LV			MRSI			
LVPW			EDVI			
LV normalized			ESVI			
LA			ESWS/ESV		EPSS	B6
Ao			wAo			
LA/Ao			TAPSE		LV-IVRT	

Normal Canine M-mode values (in cm) for 3 kg dogs.

LVIDd	LVPWd	IVSd	LA	AO	%FS
B6					

Tricuspid valve:
P B6 RA Pressure: B6

CLINICIAN INTERPRETATION:
Left Ventricle: The left ventricular cavity size is severely increased. Ventricular wall thickness is decreased. LV basal fractional shortening is moderate to severely decreased.
Left Atrium: The left atrium is severely dilated. The left atrial A/P dimension is 2.81 cm.
Mitral Valve: The E-point septal separation is normal. Moderate to severe mitral valve regurgitation. The MR jet is centrally-directed.

Final

FDA-CVM-FOIA-2019-1704-006199

Pericardium/Effusions: No pericardial effusion is seen.

ECHO SUMMARY:

1. The left ventricular cavity size is severely increased.
2. Ventricular wall thickness is decreased.
3. Severely dilated left atrium.
4. Moderate to severe mitral valve regurgitation.

Recommendations: This is a brief echocardiogram - and is compared to the prior study dated B6 B6 was diagnosed with diet induced DCM and CHF in April 2018. His diet was initially changed to a Royal Canin formulation, but was then transitioned back to a grain-free diet in May 2018. He developed an additional episode of heart failure on 9/8/18. He was hospitalized and responded well. Today he is presenting for a 1 week recheck exam.

This study shows evidence of progressive heart disease. The LV has further increased in size, and continues to show poor systolic function. There is moderate centrally directed mitral regurgitation - secondary to annular dilation. The left atrium has increased in size and is severely dilated.

These changes are evidence of continued cardiac deterioration secondary to a grain-free diet. B6 has been transitioned to a diet containing grains, and his owners plan to continue this diet. Recommend a recheck echocardiogram in 3-4 months to evaluate for improvement.

B6

Electronically signed on 9/17/2018 on 2:43:08 PM

Final

FDA-CVM-FOIA-2019-1704-006200

B6

NC STATE UNIVERSITY
CARDIOLOGY

1052 William Moore Drive
Raleigh, NC 27607
Phone: 919.513.6694 Fax: 919.513.6712

Canine Echocardiography Report

Patient Name: B6
Medical Rec #:
DOB:
Age: B6
Sex: Mc
Sonographer: B6

Date of Exam: B6
Breed: Mixed breed
Weight: 4 kg
BSA: 0.23 m²
HR:
BP-sys:

Report Status: READ
Ref. Clinician: B6
Diagnosis: Dilated Cardiomyopathy - suspect dietary induced
Study Details: 2D Echo/Doppler/Color Doppler. The images were of adequate diagnostic quality. The patient was awake.

2D

	Diastole	Systole				
IVS	B6		%FTivs	B6	LV EF,	B6
LV			%FS		LV CO,	
LVPW			%FTfw			

2D

LA Long Axis	B6	LAA Velocity
LA d		PDA Diam
Ao s		PDA ampulla
LA/Ao		PV Ann

M-mode

	Diastole	Systole					
		cm				LV EF	
RV	B6		%FS	B6		LV SV	B6
IVS			MRSIm			LV CO	
LV			MRSI				
LVPW			EDVI				
LV normalized			ESVI			EPSS	
LA			ESWS/ESV				
Ao			wAo				
LA/Ao			TAPSE			LV-IVRT	

Normal Canine M-mode values (in cm) for 3 kg dogs.

LVIDd	LVPWd	IVSd	LA	AO	%FS
B6					

Aortic Valve: AoV

VMax	B6
Pk Grad	

Mitral Valve:

Mn Grad	E Vmax	B6
P1/2T	A Vmax	
MV Area	E/A	

Mitral Regurgitation:

Final

FDA-CVM-FOIA-2019-1704-006201

MR Vmax
MR Peak Gradient
Est SBP by MR

B6

Tricuspid valve:

TV E Max
TV Mn Grad
P 1/2 T
TV VTI

TR Vmax
TR Pk Grad
RA Pressure:
RVSP

B6

Pulmonic valve: PV
Vmax
Pk Grad

B6

CLINICIAN INTERPRETATION:

Left Ventricle: The left ventricular cavity size is severely increased. Ventricular wall thickness is decreased. LV basal fractional shortening is severely decreased. Spectral Doppler shows impaired relaxation pattern of LV diastolic filling.
Left Atrium: The left atrium is moderately dilated. The left atrial A/P dimension is 1.72 cm.
Right Atrium: The right atrium is mildly dilated.
Right Ventricle: The right ventricular size is moderately enlarged. RV wall thickness is normal. Global RV systolic function is moderately reduced.
Aortic Valve: No degree of aortic stenosis is present. Trivial aortic valve regurgitation.
Mitral Valve: The E-point septal separation is increased. Moderate mitral valve regurgitation. The MR jet is centrally-directed.
Pulmonic Valve: The pulmonic valve is normal. Trace pulmonary valve regurgitation.
Pericardium/Effusions: No pericardial effusion is seen.
Aorta: The aortic sinuses, arch, ascending and descending aorta appear all normal.
Pulmonary Artery: The pulmonary artery is of normal size and origin. The tricuspid regurgitant velocity is 2.79 m/s, and with an assumed right atrial pressure of 10 mmHg, the estimated right ventricular systolic pressure is mildly elevated at 41.2 mmHg.

ECHO SUMMARY:

1. Dilated cardiomyopathy
2. Impaired relaxation pattern of LV diastolic filling.
3. The left ventricular cavity size is severely increased.
4. Ventricular wall thickness is decreased.
5. Moderately enlarged right ventricle.
6. Moderately reduced RV systolic function.
7. Moderately dilated left atrium.
8. Mildly dilated right atrium.
9. Moderate mitral valve regurgitation.
10. Moderate tricuspid regurgitation.
11. Mildly elevated pulmonary artery systolic pressure.

CV Exam:

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

ECG:

The heart rate measured at 140 beats/minute. The ECG rhythm is regular sinus rhythm. Frequent supraventricular premature complexes was/were noted.

Recommendations: B6 was presented to the NCSU ER for evaluation of respiratory distress and

FDA-CVM-FOIA-2019-1704-006202

suspected CHF. He was given B6 orally prior to referral.

This echocardiogram shows evidence of dilated cardiomyopathy. The LV is severely dilated with thin walls and severely reduced systolic function. The mitral valve is structurally normal - however there is moderate centrally directed mitral regurgitation. The left atrium is moderately to severely dilated. The aorta and aortic outflow profile are normal.

The right heart is moderately dilated as well, with poor systolic function. There is moderate tricuspid regurgitation, and the right atrium is mildly to moderately dilated. The TR velocity is mildly elevated at 2.8m/sec - indicating mild pulmonary hypertension. The caudal cava compresses normally with respiration. The pulmonic valve and pulmonic outflow profile are normal.

There is no evidence of a patent ductus arteriosus or other congenital defects.

Thoracic radiographs show severe generalized cardiomegaly, and a mild diffuse unstructured interstitial pattern - consistent with CHF. The underlying ECG shows a sinus rhythm with frequent atrial premature beats.

In summary, B6 has been diagnosed with dilated cardiomyopathy and congestive heart failure. Given the young age and atypical breed - DCM secondary to diet, or secondary to prior myocarditis are the top differentials. B6 currently eats a grain free diet - and has since he was a puppy. Recommend obtaining a whole blood taurine level, supplementing taurine, and changing the diet. The prognosis is ultimately poor - however, if the changes seen today are dietary induced - a change in diet may result in improved cardiac function.

Recommendations

B6

B6

Electronically signed on 4/2/2018 on 3:07:23 AM

Final

FDA-CVM-FOIA-2019-1704-006203

NCSU, COLLEGE OF VETERINARY MEDICINE
ANATOMIC PATHOLOGY LABORATORY
http://www.cvm.ncsu.edu/dphp/labs/histologylab.htm
Room B104H 1060 William Moore Drive
RALEIGH, NC 27607
Phone #: 919-513-6390 Fax #: 919-513-6703

Owner: B6

Accession Number: B6
Reference Number:
Case Coordinator: B6
Received: B6 Finalized: 01/28/2019
Sampled:

To: B6

Final Report

ANATOMIC PATHOLOGY RESULTS

SMALLANIMAL NECROPSY

ANIMAL ID REF CASE NO	B6
SPECIES	Canine
BREED	Yorkshire Terrier
SEX	M
AGE	2y
SPECIMEN DESC	Body
GROSS	

B6

NCSU, COLLEGE OF VETERINARY MEDICINE
ANATOMIC PATHOLOGY LABORATORY
http://www.cvm.ncsu.edu/dphp/labs/histologylab.htm
Room B104H 1060 William Moore Drive
RALEIGH, NC 27607
Phone #: 919-513-6390 Fax #: 919-513-6703

Final Report

Accession Number: B6

ANATOMIC PATHOLOGY RESULTS

B6

GROSS DIAGNOSIS

Heart: Moderate cardiomegaly with biventricular dilation (see comment)
Lungs: Moderate, diffuse, pulmonary edema (presumptive)
Liver: Moderate hepatomegaly with an enhanced reticular pattern (consistent with chronic passive congestion)
Testicle: Unilateral inguinal cryptorchid

REPORT STATUS

PRELIMINARY REPORT-HISTOLOGY PENDING

COMMENTS

Evaluation of the heart is somewhat limited because post-mortem sampling by Cardiology has already been performed prior to the time of autopsy, but heart measurements support a diagnosis of dilated cardiomyopathy. Pulmonary edema is consistent with left-sided congestive heart failure, and evidence of chronic passive congestion in the liver is consistent with right-sided congestive heart failure. Unilateral cryptorchidism is considered an incidental finding. Histopathology is pending.

PATH RESIDENT
SENIOR PATH
DATE

B6

B6

B6

B6

Dear B6

This letter is regarding B6 male Yokie/chihuahua, owned by B6 seen by B6

B6

examined: B6 discharged: B6

Diagnosis: tachypnic with heart murmur and enlarged heart - suspect congestive heart failure

Histor

B6 08:51 PM

B6 and Examination

B6 presented for Labored breathing since this morning. Pt has had D+ for a few days. Today he has had faster breathing with a grunt at the end of the resps. O did report that he went on a long walk and was not as peppy as usual but did ok on the walk. O noted the breathing to be the same all day and not worsening much with activity or time. B6

B6

meds: none
preventions: yes
vaccines: UTD per O

Physical Exam:

B6

B6 09:31 PM Admitting Doctor: B6

B6

B6 9:03AM (GMT-04:00)

B6

Diagnostic Imaging - Radiographs & Ultrasounds:

B6 0:05 PM Radiology

Radiographs, Initial, 3-view
Area Radiographed:Whole Body
Views Taken:Right/Left lateral, V/D
Interpretation: The cardiac silhouette is severely enlarged with no left atrial enlargement. The cranial lobar artery is larger in diameter than the vein. There is moderate diffuse unstructured interstitial pattern perihilar and in the caudodorsal lung lobes.

Lab Work:

Chemistry Data (HSZ) B6 09:52 PM)

Test	Result	Flag	Normal Range	Indicator
WBC	B6		6-17 (10^3/uL)	B6
NEU			3.62-12.3 (10^3/uL)	
LYM			0.93-4.91 (10^3/uL)	
MONO			0.14-1.07 (10^3/uL)	
EOS			0.04-1.82 (10^3/uL)	
BAS			0-0.12 (10^3/uL)	
NEU %			62-81 (%)	
LYM %			12-33 (%)	
MONO %			2-13 (%)	
EOS %			0.5-10 (%)	
BAS %			0-1.3 (%)	
RBC			5.1-9.5 (10^6/uL)	
HGB			11-19 (g/dL)	
HCT			32-56 (%)	
MCV			60-76 (fL)	
MCH			20-27 (pg)	
MCHC			30-38 (g/dL)	
RDW %			12.5-17.2 (%)	
PLT		L	117-460 (10^3/uL)	
MPV			8-14.1 (fL)	

Thrombocytopenia

WBC DIFFERENTIAL (manual)
Total Leukocytes: (from HM5) B6
Neutrophils: B6 Absolute:
Bands: 0 % Absolute:
Lymphocytes: B6 Absolute: B6
Monocytes: B6 Absolute:
Eosinophils: B6 Absolute:

FDA-CVM-FOIA-2019-1704-006207

B6

Assessment: P is tachypnic with a heart murmur and an enlarged heart and caudal dorsal pulmonary edema on rads (no LAE). Suspect heart failure. Recommended that P be seen by a cardiologist ASAP and that transfer to NC State is the best option. B6

B6

Plan:

B6

Prescriptions: B6 11:25 PM

B6

Client Discharge Instructions:

B6

Normally blood flows in one direction. If the valves fail to close completely when the heart contracts, blood moves forward but some leaks backward. The clinical signs vary depending on whether the right and/or left side

FDA-CVM-FOIA-2019-1704-006208

of the heart is affected and whether heart enlargement presses on the windpipe (trachea). Fluid accumulates when the heart fails to pump enough blood is transmitted backward from the heart to the lung or body.

Thank you for allowing us to participate in the care of this patient. If you have any questions about his case or we can be of assistance in the future, please do not hesitate to contact us.

Same great team, brand new name & location. We are serving you from our new facility: B6
B6 The facility is located at B6, near the
B6 We are happy to host your veterinarians for a tour, or have the staff
come for a lunch n learn session - please email B6

B6

FDA-CVM-FOIA-2019-1704-006209

From: B6
To: Peloquin, Sarah
Sent: B6 5:41:39 PM
Subject: Re[4]: 800.267-FDA Case Investigation for B6 cc-297)

Great, Thanks.

B6

"I may not have gone where I intended to go, but I think I have ended up where I needed to be." Hey Douglas Adams, we feel you

------ Original Message ------
From: "Peloquin, Sarah" <Sarah.Peloquin@fda.hhs.gov>
To: B6
Cc: "Jones, Jennifer L" <Jennifer.Jones@fda.hhs.gov>
Sent: B6 1:31:26 PM
Subject: RE: Re[2]: 800.267-FDA Case Investigation for B6 (cc-297)

Hi B6

Not a dumb question—yes, our preference is to collect all of the samples listed in the document if possible. We examine all of the tissues (both gross and histo) to look for patterns.

However, we understand that in practice, taking the time to obtain the samples is not always feasible. Or sometimes all tissues aren't available. So even if we aren't able to collect all of the tissues, the intact heart is still very useful. As a reminder, FDA will reimburse your hospital for your time performing the necropsy/sample collection.

I hope this clears some things up. I'm sorry for any confusion.

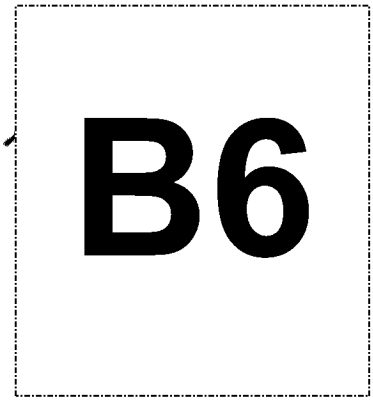
Thanks!
Sarah

Sarah Peloquin, DVM
Veterinary Medical Officer
tel: 240-402-1218

From B6
Sent: B6 1:22 PM
To: Peloquin, Sarah <Sarah.Peloquin@fda.hhs.gov>

Cc: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: Re[2]: 800.267-FDA Case Investigation for B6 (cc-297)

Sarah,
Thank you for sending the attachments. I had the first 2 however the rapid necropsy had been missing previously.
In looking through it, I realize that I had previously only sent the heart and liver in NBF.
I know this is a dumb question, but I need to be sure..... I assume that the FDA preference is to have all of the sampling listed under #6 and #7?
I want to be as helpful as possible and previously was told to only send the heart and liver.



"I may not have gone where I intended to go, but I think I have ended up where I needed to be." Hey Douglas Adams, we feel you

------ Original Message ------
From: "Peloquin, Sarah" <Sarah.Peloquin@fda.hhs.gov>
To: B6
Cc: "Jones, Jennifer L" <Jennifer.Jones@fda.hhs.gov>
Sent: B6 1:02:50 PM
Subject: RE: 800.267-FDA Case Investigation for B6 (cc-297)

Hi B6

I've attached the rapid necropsy document—my apologies, I thought that you already had it. Some additional information is below:

For the necropsy, please collect the heart, **intact**, and place directly in formalin. The rapid necropsy document provides additional instructions about what samples to take and how to store them.

- After you complete the necropsy, we will send you 2 boxes to collect the samples (1 for fixed tissue, 1 for frozen tissue). The boxes will have prepaid shipping labels.
  - I'll need to know *the final weight of each sample set (e.g. weight of all fixed tissue in formalin, weight of all frozen tissue)* before we can ship the boxes to you.
  - You may place multiple fixed samples in the same jar, but please label accordingly.
  - The frozen samples must be placed in sealable bags or containers.
- After you receive the boxes, you'll reuse the boxes, package the tissues according to the instructions, affix the prepaid labels to the boxes, and call UPS for the pick-up.
  - *Please return ship the samples to us on a Monday-Wednesday only.*
- After the necropsy is performed, **please send me a copy of the invoice for the necropsy charge**, and our business office will call back with our VISA information to reimburse the hospital directly.

I've cc'd Dr. Jones to these emails to keep her in the loop.

Thank you very much for your help with these cases!
Sarah

Sarah Peloquin, DVM
Veterinary Medical Officer
tel: 240-402-1218

From: B6
Sent: B6 12:50 PM
To: Peloquin, Sarah <Sarah.Peloquin@fda.hhs.gov>
Cc: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: Re: 800.267-FDA Case Investigation for B6 cc-297)

Sarah,
Thank you for the assistance.
I am able to preserve the tissue however you would like. Frozen or formalin or both. In rereading the emails from B6 I see that there was mention of both. I am not sure that I have the rapid necropsy document. Perhaps you could send that to me again?

Thanks

B6

"I may not have gone where I intended to go, but I think I have ended up where I needed to be." Hey Douglas Adams, we feel you

------ Original Message ------
From: "Peloquin, Sarah" <Sarah.Peloquin@fda.hhs.gov>
To: " B6
Cc: "Jones, Jennifer L" <Jennifer.Jones@fda.hhs.gov>
Sent: B6 11:59:32 AM
Subject: 800.267-FDA Case Investigation fo B6 (cc-297)

Good morning B6

I'm filling in on the DCM case investigation for Dr. Jennifer Jones this week. Dr. Lisa Freeman informed me that B6 will be euthanized—I'm sorry to hear this. If you are willing, please collect the same samples from B6 as you did for B6 (i.e. intact heart in formalin; and if possible, fixed/frozen tissues as described in the rapid necropsy document).

Dr. Jones will return at the end of next week, and we will send you boxes then for shipment.

Please send me the approximate weights of the samples, as you did for B6

Let me know if you have any additional questions.

Thank you!
Dr. Sarah Peloquin

Sarah K. Peloquin, DVM
Veterinary Medical Officer

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

This email has been checked for viruses by AVG antivirus software.
www.avg.com

From: Related PFR Event <pfrsignificantactivitycreation@fda.hhs.gov>

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

Sent: 6/11/2019 6:40:49 PM

Subject: Wellness Core grain-free ocean fish dry-Wellness core grain free turkey: Lisa Freeman - EON-390201

Attachments: 2068094-report.pdf; 2068094-attachments.zip

A PFR Report has been received and Related PFR Event [EON-390201] has been created in the EON System.

A "PDF" report by name "2068094-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 "2068094-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-390201
ICSR #: 2068094
EON Title: Related PFR Event created for Wellness Core grain-free ocean fish dry Wellness core grain free turkey chicken liver & turkey liver canned Wellness Hearty Cuts grain-free in gravy chicken and turkey recipe; 2068094

AE Date	01/15/2019	**Number Fed/Exposed**	6
Best By Date		**Number Reacted**	4
Animal Species	Dog	**Outcome to Date**	Died Euthanized
Breed	Bulldog		
Age	8.5 Years		
District Involved	PFR-New England DO		

Product information
Individual Case Safety Report Number: 2068094
Product Group: Pet Food
Product Name: Wellness Core grain-free ocean fish dry Wellness core grain free turkey, chicken liver & turkey liver canned Wellness Hearty Cuts grain-free in gravy chicken and turkey recipe
Description: DCM and CHF diagnosed 1/15/19 Eating BEG diet. 6 dogs being fed this diet - so far, 4 have been

diagnosed with DCM/ARVC. One other had a normal NT-proBNP and 2 others will be tested Diet has been changed to Royal Canin Early Cardiac and we will recheck in 3 months. I have sample of dry and canned food B6 - Owners elected humane euthanasia due to worsening heart failure. Samples of heart muscle were submitted to FDA from rDVM.
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 Euthanized
Number of Animals Treated With Product: 6
Number of Animals Reacted With Product: 4

Product Name	Lot Number or ID	Best By Date
Wellness Core grain-free ocean fish dry Wellness core grain free turkey, chicken liver & turkey liver canned Wellness Hearty Cuts grain-free in gravy chicken and turkey recipe		

This report is linked to:
Initial EON Event Key: EON-380742
Initial ICSR: 2063133

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

Owner information
B6
USA

To view this Related PFR Event, please click the link below:
https://eon.fda.gov/eon//browse/EON-390201

To view the Related PFR Event Report, please click the link below:
https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jspa?decorator=none&e=0&issueType=10100&issueId=407473&parentIssueTypeId=12

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{

Report Details - EON-390201

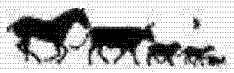
ICSR:	2068094		
Type Of Submission:	Followup		
Report Version:	FPSR.FDA.PETF.V.V1		
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)		
Reporting Type:	Voluntary		
Report Submission Date:	2019-06-11 14:32:32 EDT		
Initial Report Date:	02/25/2019		
Parent ICSR:	2063133		
Follow-up Report to FDA Request:	Yes		
Reported Problem:	**Problem Description:**	DCM and CHF diagnosed 1/15/19 Eating BEG diet. 6 dogs being fed this diet - so far, 4 have been diagnosed with DCM/ARVC. One other had a normal NT-proBNP and 2 others will be tested Diet has been changed to Royal Canin Early Cardiac and we will recheck in 3 months. I have sample of dry and canned food B6 B6 - Owners elected humane euthanasia due to worsening heart failure. Samples of heart muscle were submitted to FDA from rDVM.	
	Date Problem Started:	01/15/2019	
	Concurrent Medical Problem:	Yes	
	Pre Existing Conditions:	B6	
	Outcome to Date:	Died Euthanized	
	Date of Death:	B6	
Product Information:	**Product Name:**	Wellness Core grain-free ocean fish dry Wellness core grain free turkey, chicken liver & turkey liver canned Wellness Hearty Cuts grain-free in gravy chicken and turkey recipe	
	Product Type:	Pet Food	
	Lot Number:		
	Product Use Information:	**Description:**	Please see diet history
	Manufacturer /Distributor Information:		
	Purchase Location Information:		
Animal Information:	**Name:**	B6	
	Type Of Species:	Dog	
	Type Of Breed:	Bulldog	
	Gender:	Female	
	Reproductive Status:	Neutered	
	Weight:	19.8 Kilogram	
	Age:	8.5 Years	
	Assessment of Prior Health:	Excellent	
	Number of Animals Given the Product:	6	
	Number of Animals Reacted:	4	
	Owner Information:	**Owner Information provided:**	Yes
		Contact:	**Name:** B6
			Phone:
			Email:

FDA-CVM-FOIA-2019-1704-006217

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

Client:
Patient: **B6**

Chem 21 - 5/8/2019



Tufts Cummings School Of Veterinary Medicine

200 Westboro Road
North Grafton, MA 01536

DUPLICATE

Name/DOB: B6
Patient ID: B6
Phone number:
Collection Date: 5/8/2019 12:31 PM
Approval date: 5/8/2019 1:07 PM

Sex: SF
Age: 8
Species: Canine
Breed:

Provider: B6
Order Location: B6 Investigation into
Sample ID: 1905080053

Research Chemistry Profile - Small Animal (Cobas)

B6

DNOYES	Ref. Range/Females
Glucose	67-135 mg/dL
Urea	8-30 mg/dL
Creatinine	0.6-2.0 mg/dL
Phosphorus	2.6-7.2 mg/dL
Calcium 2	9.4-11.3 mg/dL
Magnesium 2+	1.8-3.0 mEq/L
Total Protein	5.5-7.8 g/dL
Albumin	2.8-4.0 g/dL
Globulins	2.3-4.2 g/dL
A/G Ratio	0.7-1.6
Sodium	140-150 mEq/L
Chloride	106-116 mEq/L
Potassium	3.7-5.4 mEq/L
tCO2(Bicarb)	14-28 mEq/L
AGAP	8.0-19.0
NA/K	29-40
Total Bilirubin	0.10-0.30 mg/dL
Alkaline Phosphatase	12-127 U/L
GGT	0-10 U/L
ALT	14-86 U/L
AST	9-54 U/L
Creatine Kinase	22-422 U/L
Cholesterol	82-355 mg/dL
Triglycerides	30-338 mg/dl
Amylase	409-1250 U/L
Osmolality (calculated)	291-315 mmol/L

Sample ID: 1905080053/1
END OF REPORT (Final)

Reviewed by: _____

FDA-CVM-FOIA-2019-1704-006219

Client: **B6**
Patient:

Diet hx 5/8/2019

B6

CARDIOLOGY DIET HISTORY FORM

Please answer the following questions about your pet

Pet's name: **B6** Owner's name: **B6** Today's date: 5/8/19

1. How would you assess your pet's appetite? (mark the point on the line below that best represents your pet's appetite)

Example: ***Poor*** _____ ***Excellent***

Poor _____ **Excellent**

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

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

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

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

Food (include specific product and flavor)	Form	Amount	How often?	Dates fed
Nutro Grain Free Chicken, Lentil, & Sweet Potato Adult	*dry*	*1 ½ cup*	*2x/day*	*Jan 2016-present*
85% lean hamburger	*microwaved*	*3 oz*	*1x/week*	*June -Aug 2016*
Pupperoni original beef flavor	*treat*	*½*	*1x/day*	*Sept 2016-present*
Rawhide	*treat*	*6 inch twist*	*1x/week*	*Dec 2018-present*
Royal Canin Early Cardiac	dry	1 1/2 cup	2x/day	FEB 2019 - PRES.

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

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

			Brand/Concentration	Amount per day
Taurine	☑Yes	☐No	Now / 500	2X
Carnitine	☐Yes	☐No		
Antioxidants	☐Yes	☐No		
Multivitamin	☐Yes	☐No		
Fish oil	☐Yes	☐No		
Coenzyme Q10	☐Yes	☐No		
Other (please list):				
Example: Vitamin C			*Nature's Bounty*	*500 mg tablets – 1 per day*

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

FDA-CVM-FOIA-2019-1704-006220

Client: B6
Patient:

Idexx NT-proBNP 5/8/2019

IDEXX Reference Laboratories

Client: B6 Patient: B6

IDEXX VetConnect 1-888-433-9987

Client: B6
Patient:
Species: CANINE
Breed: ENGLISH_BULLDOG
Gender: FEMALE SPAYED
Age: 0Y

Date: 05/08/2019
Requisition #: 437321
Accession #: B6
Ordered by: B6

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

Account: B6

CARDIOPET proBNP - CANINE

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

Comments
1. B6

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

Page 1 of 1

FDA-CVM-FOIA-2019-1704-006221

Client:
Patient: B6

Troponin 5/31/2019

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

Website User ID: B6 **@tufts.edu**

GI Lab Assigned Clinic ID: 23523

B6
Tufts Cummings School of Vet Med - Cardiology/Nutrition
200 Westboro Road
North Grafton, MA 01536
USA

Phone: 508 887 4696
Fax:
Animal Name: B6
Owner Name:
Species: Canine
Date Received: May 30, 2019

Tufts Cummings School of Vet Med - Cardiology/Nutrition Tracking Number: B6

GI Lab Accession: B6

Test	Result	Reference Interval	Assay Date
Ultra-Sensitive Troponin I Fasting	B6	≤0.06	05/31/19

Interpretation: B6

B6

Comments:

GI Lab Contact Information

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

FDA-CVM-FOIA-2019-1704-006222

Cummings
Veterinary Medical Center
AT TUFTS UNIVERSITY

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

Discharge Instructions

Patient
Name: B6
Species: Canine
Brown/White Female (Spayed) English Bulldog
Birthdate: B6

Owner
Name: B6
Address: B6

Patient ID: B6

Attending Cardiologist:
John E. Rush DVM, MS, DACVIM (Cardiology), DACVECC
B6

Cardiology Resident:
B6

Cardiology Technician:
B6

Student: B6

Date: 5/8/2019

Diagnoses: Dilated cardiomyopathy (DCM); history of active congestive heart failure

Clinical Findings:
Thank you for bringing B6 in today for a three month recheck as a part of the DCM study. B6 has been doing well at home and has had good energy, though she has been slightly stubborn about taking her medications.

During B6's appointment today, we performed a recheck echocardiogram (ultrasound of the heart). B6 still has significant structural and functional changes to her heart, but these changes do not appear to have worsened since her last echocardiogram in January. We also assessed B6 heart rhythm using electrocardiogram (EKG) and did not see any cardiac arrhythmias. We drew blood samples from B6 as part of the DCM study, and her kidney values are still perfect. We would therefore like to increase her enalapril to twice daily (see below). B6 is also on a relatively conservative dose of furosemide, so you should have no hesitation to give an extra dose if needed for increased breathing rate or effort.

Monitoring at Home:

- Please continue to monitor B6 breathing rate and effort at home, ideally during sleep or at a time of rest. The doses of drugs will be adjusted based on the breathing rate and effort.
- In general, most dogs with heart failure that is well controlled have a breathing rate at rest of less than 35 to 40 breaths per minute. In addition, the breathing effort, noted by the amount of belly wall motion used for each breath, is fairly minimal if heart failure is controlled.
- ***An increase in breathing rate or effort will usually mean that you should give an extra dose of*** B6
  If difficulty breathing is not improved by within 30-60 minutes after giving extra B6 then we recommend that a recheck exam be scheduled and/or that your dog be evaluated by an emergency clinic.

FDA-CVM-FOIA-2019-1704-006223

- We also want you to watch for weakness or collapse, a reduction in appetite, worsening cough, or distention of the belly as these findings indicate that we should do a recheck examination.
- If you have any concerns, please call or have your dog evaluated by a veterinarian. Our emergency clinic is open 24 hours/day.

Diet Suggestions:
Please continue to feed B6 the Royal Canin Cardiac diet.

Exercise Recommendations:
B6 may continue her normal exercise routine at home.

Recommended Medications:

B6

Recheck Visits: We would like to see B6 for a recheck appointment in 3 months. At this visit we will want to check breathing effort and heart function, do a blood test for the study, and recheck an echocardiogram. B6 will contact you to schedule this appointment.

Thank you for entrusting us with B6 care. She is such a sweet girl! Please contact our Cardiology liaison at (508)-887-4696 or email us at cardiovet@tufts.edu for scheduling and non-emergent questions or concerns.

Please visit our HeartSmart website for more information
http://vet.tufts.edu/heartsmart/

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

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

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

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Case: B6 Owner: B6 Discharge Instructions

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

B6

Patient ID: B6
B6 Canine
B6 Years Old Female (Spayed) English Bulldog
Brown/White

Cardiology Appointment Report
ENROLLED IN DCM DIET STUDY

Date: 5/8/2019

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

B6

Cardiology Resident:
B6

Cardiology Technician:

B6

Student: B6

Presenting Complaint: 3 month recheck DCM study, history of DCM and CHF

Concurrent Diseases:
None

General Medical History:
CHF diagnosed 1/16/19, BNP > B6 O reports good energy at home, but slightly decreased appetite. Can be difficult to medicate. Was previously on grain-free diet.

Diet and Supplements:
NOW Taurine 500mg BID
RC early cardiac diet

Cardiovascular History:
Prior CHF diagnosis? yes
Prior heart murmur? n
Prior ATE? n
Prior arrhythmia? n
Monitoring respiratory rate and effort at home? y- usually in the 30s
Cough? n
Shortness of breath or difficulty breathing? y (one day)

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

Current Medications Pertinent to CV System:

B6

Muscle condition:

- [x] Normal
- [ ] Mild muscle loss
- [ ] Moderate cachexia
- [ ] Marked cachexia

Cardiovascular Physical Exam:

Murmur Grade:

- [x] None/difficult to ausculT
- [ ] I/VI
- [ ] II/VI
- [ ] III/VI
- [ ] IV/VI
- [ ] V/VI
- [ ] VI/VI

Jugular vein:

- [x] Bottom 1/3 of the neck
- [ ] Middle 1/3 of the neck
- [ ] 1/2 way up the neck
- [ ] Top 2/3 of the neck

Arterial pulses:

- [ ] Weak
- [x] Fair
- [ ] Good
- [ ] Strong
- [ ] Bounding
- [ ] Pulse deficits
- [ ] Pulsus paradoxus
- [ ] Other:

Arrhythmia:

- [x] None
- [ ] Bradycardia

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- ☐ Sinus arrhythmia
- ☐ Premature beats
- ☐ Tachycardia

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

Pulmonary assessments:
- ☑ Eupneic
- ☐ Mild dyspnea
- ☐ Marked dyspnea
- ☑ Normal BV sounds
- ☐ Pulmonary crackles
- ☐ Wheezes
- ☑ Upper airway stridor

Abdominal exam:
- ☑ Normal
- ☐ Hepatomegaly
- ☐ Abdominal distension
- ☐ Mild ascites
- ☐ Marked ascites

Problems:
Suspected DCM based on previous echo findings

Differential Diagnoses:
DCM - diet-associated vs. primary

Diagnostic plan:
- ☑ Echocardiogram
- ☑ Chemistry profile
- ☐ EOG
- ☐ Renal profile
- ☐ Blood pressure
- ☐ Dialysis profile
- ☐ Thoracic radiographs
- ☐ NT-proBNP
- ☐ Troponin I
- ☑ Other tests: bloodwork for study

B6

Assessment and recommendations:
Patient has been doing well at home, but echocardiogram still reveals significant structural and functional changes to her heart. Measurements are stable overall. If renal values are stable then recommend

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B6

know. Recheck in 3 months for blood work/echo/DCM study, or sooner if clinical signs occur such as increased RR/RE, cough, collapse, or exercise intolerance.

Final Diagnosis:
DCM; history of L-CHF

Heart Failure Classification Score:
ISACHC Classification:

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

ACVIM Classification:

- ☐ A
- ☐ B1
- ☐ B2
- ☑ C
- ☐ D

B6

M-Mode		
IVSd		cm
LVIDd		cm
LVPWd		cm
IVSs		cm
LVIDs		cm
LVPWs		cm
EDV(Teich)		ml
ESV(Teich)		ml
EF(Teich)		%
%FS		%
SV(Teich)		ml
Max LA		cm
Ao Diam		cm
LA Diam		cm
LA/Ao		
TAPSE		cm
EPSS		cm

M-Mode Normalized		
IVSdN		(0.290 - 0.520)
LVIDdN		(1.350 - 1.730) !
LVPWdN		(0.330 - 0.530)
IVSsN		(0.430 - 0.710) !
LVIDsN		(0.790 - 1.140) !
LVPWsN		(0.530 - 0.780)

2D		
SA LA		cm
Ao Diam		cm

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SA LA / Ao Diam		
IVSd		cm
LVIDd		cm
LVPWd		cm
EDV(Teich)		ml
IVSs		cm
LVIDs		cm
LVPWs		cm
ESV(Teich)		ml
EF(Teich)		%
%FS		%
SV(Teich)		ml
Doppler	B6	
MR Vmax		m/s
MR maxPG		mmHg
MV E Vel		m/s
MV DecT		ms
MV Dec Slope		m/s
MV A Vel		m/s
MV E/A Ratio		
E'		m/s
E/E'		
A'		m/s
AV Vmax		m/s
AV maxPG		mmHg
PV Vmax		m/s
PV maxPG		mmHg

FDA-CVM-FOIA-2019-1704-006229

From: Jones, Jennifer L </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0F6CA12EAA9348959A4CBB1E829AF244-JENNIFER.JO>
To: B6
Sent: 6/14/2019 1:10:14 PM
Subject: RE: Re[2]: 800.267-cc-297-FDA Case Investigation for B6 (cc-297)

Absolutely. We will send a copy of the results as soon as they are read.

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

From: B6
Sent: Friday, June 14, 2019 8:55 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: Re[2]: 800.267-cc-297-FDA Case Investigation for B6 (cc-297)

Thank you Jennifer. I did receive an email from Jake.

Also, I believe that I read I should get a copy of the pathology results. Is this correct? I am interested in the results from B6

Thank you again.
I appreciate the work you all are doing for this.

B6

B6

"I may not have gone where I intended to go, but I think I have ended up where I needed to be." Hey Douglas Adams, we feel you

------ Original Message ------
From: "Jones, Jennifer L" <Jennifer.Jones@fda.hhs.gov>
To: B6
Cc: "Peloquin, Sarah" <Sarah.Peloquin@fda.hhs.gov>; "Guag, Jake" <Jake.Guag@fda.hhs.gov>

Sent: 6/13/2019 11:01:47 AM
Subject: RE: 800.267-cc-297-FDA Case Investigation for B6 (cc-297)

Thank you B6
We'll ship the box, and it should arrive before close of business Monday. Jake will send you a copy of the tracking when it ships.

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

From: B6
Sent: Tuesday, June 11, 2019 9:22 AM
To: Peloquin, Sarah <Sarah.Peloquin@fda.hhs.gov>
Cc: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: Re: 800.267-FDA Case Investigation for B6 (cc-297)

Good morning,
Weights for the samples from B6 are as follows:
Frozen tissue is 6ounces
Refrigerated samples (urine and small intestinal fluid) 2ounces
Formalin fixed samples 2 pounds 6 ounces

Thank you

B6

B6

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------ Original Message ------
From: "Peloquin, Sarah" <Sarah.Peloquin@fda.hhs.gov>
To: B6
Cc: "Jones, Jennifer L" <Jennifer.Jones@fda.hhs.gov>
Sent: B6 11:59:32 AM

Subject: 800.267-FDA Case Investigation for B6 (cc-297)

Good morning B6

I'm filling in on the DCM case investigation for Dr. Jennifer Jones this week. Dr. Lisa Freeman informed me that B6 –I'm sorry to hear this. If you are willing, please collect the same samples from B6 as you did for B6 (i.e. intact heart in formalin; and if possible, fixed/frozen tissues as described in the rapid necropsy document).

Dr. Jones will return at the end of next week, and we will send you boxes then for shipment.

Please send me the approximate weights of the samples, as you did for B6

Let me know if you have any additional questions.

Thank you!
Dr. Sarah Peloquin

Sarah K. Peloquin, DVM
Veterinary Medical Officer

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

U.S. FOOD & DRUG ADMINISTRATION

AVG This email has been checked for viruses by AVG antivirus software.
www.avg.com

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To: B6 Peloquin, Sarah
Sent: 8/27/2019 11:40:16 AM
Subject: RE: 800.267-cc-297-FDA Case Investigation for B6 (cc-297)

Thank you, B6 I'll submit this today, and someone from our business team should call your office in the next few business days with our VISA information.

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

From: B6
Sent: Monday, August 26, 2019 6:16 PM
To: Peloquin, Sarah <Sarah.Peloquin@fda.hhs.gov>
Cc: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: Re: 800.267-cc-297-FDA Case Investigation for B6 (cc-297)

Sarah,
I have attached the invoice for B6 necropsy. Thank you for the reminder.

Best
B6

B6

"I may not have gone where I intended to go, but I think I have ended up where I needed to be." Hey Douglas Adams, we feel you

------ Original Message ------
From: "Peloquin, Sarah" <Sarah.Peloquin@fda.hhs.gov>
To: B6
Cc: "Jones, Jennifer L" <Jennifer.Jones@fda.hhs.gov>
Sent: 8/15/2019 9:08:36 AM
Subject: 800.267-cc-297-FDA Case Investigation for B6 (cc-297)

Good morning B6

Please send us the invoices for B6 necropsies at your earliest convenience (by email or fax to 301-210-4685). We want to make sure we reimburse your hospital for these costs.

Thank you!
Sarah

Sarah Peloquin, DVM
Veterinary Medical Officer
tel: 240-402-1218

From: Jones, Jennifer L
Sent: Friday, June 14, 2019 9:10 AM
To: B6
Subject: RE: Re[2]: 800.267-cc-297-FDA Case Investigation for B6 (cc-297)

Absolutely. We will send a copy of the results as soon as they are read.

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

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

From: B6
Sent: Tuesday, June 11, 2019 9:22 AM
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To: B6
Cc: "Jones, Jennifer L" <Jennifer.Jones@fda.hhs.gov>
Sent B6 1:59:32 AM
Subject: 800.267-FDA Case Investigation for B6 (cc-297)

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Thank you!
Dr. Sarah Peloquin

Sarah K. Peloquin, DVM
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tel: 240-402-1218
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e-mail: sarah.peloquin@fda.hhs.gov

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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.

- Normal whole blood taurine: >250nmol/mL
- Normal plasma taurine: >70nmol/mL

- Marginal whole blood taurine: 200-250nmol/mL
- Marginal plasma taurine: 60-70nmol/mL

- Low whole Blood taurine: <200nmol/mL
- Low plasma taurine: <60nmol/mL

References:

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. 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.

FDA-CVM-FOIA-2019-1704-006237

Clinical Recommendations for Golden Retrievers based on taurine levels:

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

- 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 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.

<u>If taurine levels test 200 – 250nmol/mL in whole blood or 60-70nmol/mL in plasma</u>

- 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.

<u>If taurine levels test >250nmol/mL in whole blood or >70nmol/mL in plasma</u>

- 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.

FDA-CVM-FOIA-2019-1704-006238

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:
    - https://www.fda.gov/AnimalVeterinary/NewsEvents/CVMUpdates/ucm613305.htm

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)

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

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

The 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 ~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

FDA-CVM-FOIA-2019-1704-006239

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

Website User ID: clinpath@tufts.edu

GI Lab Assigned Clinic ID: 11405

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

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

Tufts University-Clinical Pathology Lab
Tracking Number: B6

GI Lab Accession: B6

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

B6

Comments:

GI Lab Contact Information

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

FDA-CVM-FOIA-2019-1704-006240

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

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

Tufts University-Clinical Pathology Lab Tracking Number:

GI Lab Accession: **B6**

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

B6

Comments:

GI Lab Contact Information

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

FDA-CVM-FOIA-2019-1704-006241

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: B6

Dr. Freeman
Tufts University-Clinical Pathology Lab
Attn: B6
200 Westboro Road
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USA

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

Tufts University-Clinical Pathology Lab Tracking Number:

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Ultra-Sensitive Troponin I Fasting	B6	≤0.06	03/06/19

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Website User ID: Cardiovet@tufts.edu OR clinpath@tufts.edu

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FDA-CVM-FOIA-2019-1704-006243

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Website User ID: Cardiovet@tufts.edu OR clinpath@tufts.edu

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Dr B6
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200 Westboro Road
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Animal Name: **B6**
Owner Name:
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GI Lab Accession: B6

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

B6

Comments:

GI Lab Contact Information

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

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: B6

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

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

Tufts University-Clinical Pathology Lab Tracking Number:

GI Lab Accession: B6

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

B6

Comments:

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USA

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

Tufts University-Clinical Pathology Lab Tracking Number:

GI Lab Accession: B6

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

B6

Comments:

GI Lab Contact Information

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

FDA-CVM-FOIA-2019-1704-006246

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: B6

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

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

Tufts University-Clinical Pathology Lab Tracking Number:

GI Lab Accession: B6

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

B6

Comments:

GI Lab Contact Information

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

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: B6

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

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

Tufts University-Clinical Pathology Lab Tracking Number:

GI Lab Accession B6

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

B6

Comments:

GI Lab Contact Information

Phone: (979) 862-2861
Fax: (979) 862-2864
Email: gilab@cvm.tamu.edu
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Gastrointestinal Laboratory
Dr. J.M. Steiner
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4474 TAMU
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Website User ID: clinpath@tufts.edu

GI Lab Assigned Clinic ID: B6

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

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

Tufts University-Clinical Pathology Lab Tracking Number:

GI Lab Accession: B6

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

B6

Comments:

GI Lab Contact Information

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

FDA-CVM-FOIA-2019-1704-006249

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:

Internal Medicine Conference

Join us for a unique continuing education event in Phuket, Thailand Oct 7th - 11th, 2019. For details see http://texasimconference.tamu.edu

Ongoing studies

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

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

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

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

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

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

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

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

GI Lab Contact Information

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

UCDAVIS
VETERINARY MEDICINE

CARDIOLOGY SERVICE UPDATES: DOG FOOD & DILATED CARDIOMYOPATHY

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

FDA Alerts found here:
https://www.fda.gov/AnimalVeterinary/NewsEvents/CVMUpdates/ucm613305.htm
https://www.fda.gov/AnimalVeterinary/ResourcesforYou/AnimalHealthLiteracy/ucm616279.htm

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

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

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

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

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

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

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

FDA reporting guidelines found here: https://www.fda.gov/AnimalVeterinary/SafetyHealth/ReportaProblem/ucm182403.htm

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

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

Report Details - EON-380742

ICSR:	2063133		
Type Of Submission:	Initial		
Report Version:	FPSR.FDA.PETF.V.V1		
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)		
Reporting Type:	Voluntary		
Report Submission Date:	2019-02-25 07:43:42 EST		
Reported Problem:	**Problem Description:**	DCM and CHF diagnosed 1/15/19 Eating BEG diet. 6 dogs being fed this diet - so far, 3 have been diagnosed with DCM/ARVC. One other had a normal NT-proBNP and 2 others will be tested Diet has been changed to Royal Canin Early Cardiac and we will recheck in 3 months. I have sample of dry and canned food	
	Date Problem Started:	01/15/2019	
	Concurrent Medical Problem:	Yes	
	Pre Existing Conditions:	B6	
	Outcome to Date:	Stable	
Product Information:	**Product Name:**	Wellness Core grain-free ocean fish dry Wellness core grain free turkey, chicken liver & turkey liver canned Wellness Hearty Cuts grain-free in gravy chicken and turkey recipe	
	Product Type:	Pet Food	
	Lot Number:		
	Product Use Information:	**Description:**	Please see diet history
	Manufacturer /Distributor Information:		
	Purchase Location Information:		
Animal Information:	**Name:**	B6	
	Type Of Species:	Dog	
	Type Of Breed:	Bulldog	
	Gender:	Female	
	Reproductive Status:	Neutered	
	Weight:	19.8 Kilogram	
	Age:	8.5 Years	
	Number of Animals Given the Product:	6	
	Number of Animals Reacted:	3	
	Owner Information:	**Owner Information provided:**	Yes
		Contact:	**Name:** B6
			Phone: B6
			Email: B6
		Address:	B6 United States
	Healthcare Professional Information:	**Practice Name:**	Tufts Cummings School of Veterinary Medicine
		Contact:	**Name:** Lisa Freeman
			Phone: (508) 887-4523
			Email: lisa.freeman@tufts.edu

FDA-CVM-FOIA-2019-1704-006252

		Address:	200 Westboro Rd North Grafton Massachusetts 01536 United States
Sender Information:	**Name:**	Lisa Freeman	
	Address:	200 Westboro Rd North Grafton Massachusetts 01536 United States	
	Contact:	**Phone:**	5088874523
		Email:	lisa.freeman@tufts.edu
	Permission To Contact Sender:	Yes	
	Preferred Method Of Contact:	Email	
Additional Documents:			
	Attachment:	rpt_medical_record_preview.pdf	
	Description:	Med records	
	Type:	Medical Records	

FDA-CVM-FOIA-2019-1704-006253

Report Details - EON-380743

ICSR:	2063134		
Type Of Submission:	Initial		
Report Version:	FPSR.FDA.PETF.V.V1		
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)		
Reporting Type:	Voluntary		
Report Submission Date:	2019-02-25 07:58:43 EST		
Reported Problem:	**Problem Description:**	Housemate (half sister; B6 (ICSR) of 2063133) diagnosed with DCM and CHF so screened by RDVM for BNP which was elevated. Evaluated at Tufts 2/1/19. ARVC/diet-induced DCM with ventricular arrhythmia. Diet changed to Royal Canin Early Cardiac and will re-evaluate in 3 months I have diet sample. 3 other dogs in household (1 had normal BNP, other 2 not yet evaluated)	
	Date Problem Started:	02/01/2019	
	Concurrent Medical Problem:	Yes	
	Pre Existing Conditions:	B6	
	Outcome to Date:	Stable	
Product Information:	**Product Name:**	Wellness CORE Grain-Free Ocean Whitefish dry Wellness Core grain free turkey, chicken liver, and turkey liver formula canned Wellness Core Hearty Cuts grain-free in gravy chicken and turkey recipe	
	Product Type:	Pet Food	
	Lot Number:		
	Product Use Information:	**Description:**	Please see diet history for more info (and refer to B6 B6 diet history for more complete info - all dogs eat same diets)
	Manufacturer /Distributor Information:		
	Purchase Location Information:		
Animal Information:	**Name:**	B6	
	Type Of Species:	Dog	
	Type Of Breed:	Bulldog	
	Gender:	Male	
	Reproductive Status:	Neutered	
	Weight:	22.1 Kilogram	
	Age:	8 Years	
	Assessment of Prior Health:	Good	
	Number of Animals Given the Product:	6	
	Number of Animals Reacted:	3	
	Owner Information:	**Owner Information provided:**	Yes
		Contact:	**Name:** B6 **Phone:** **Email:**
		Address:	B6 United States
	Healthcare Professional	**Practice Name:**	Tufts Cummings School of Veterinary Medicine

FDA-CVM-FOIA-2019-1704-006254

	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:	**Name:**	Lisa Freeman		
	Address:	200 Westboro Rd North Grafton Massachusetts 01536 United States		
	Contact:	**Phone:**	5088874523	
		Email:	lisa.freeman@tufts.edu	
	Permission To Contact Sender:	Yes		
	Preferred Method Of Contact:	Email		
Additional Documents:				
	Attachment:	rpt_medical_record_preview.pdf		
	Description:	Medical record		
	Type:	Medical Records		

Report Details - EON-380745

ICSR:	2063135	
Type Of Submission:	Initial	
Report Version:	FPSR.FDA.PETF.V.V1	
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)	
Reporting Type:	Voluntary	
Report Submission Date:	2019-02-25 08:12:41 EST	
Reported Problem:	**Problem Description:**	Eating BEG diet - 2 other dogs in household diagnosed with DCM B6 and B6 already reported) RDVM screened this dog with NT-proBNP which was elevated so we evaluated at Tufts 2/20/19 Probable ARVC/diet-associated DCM but no arrhythmia detected (enlarged right ventricle, reduced contractility) Changing diet to Royal Canin Early Cardiac and will re-evaluate in 3 months. Taurine and troponin pending
	Date Problem Started:	02/20/2019
	Concurrent Medical Problem:	Yes
	Pre Existing Conditions:	B6
	Outcome to Date:	Stable
Product Information:	**Product Name:**	Wellness CORE Grain-Free Ocean Whitefish dry Wellness Core grain free turkey, chicken liver, and turkey liver formula canned Wellness Core Hearty Cuts grain-free in gravy chicken and turkey recipe
	Product Type:	Pet Food
	Lot Number:	
	Product Use Information:	**Description:** Please see diet history for more info (and also see B6 B6 diet history for exact diets)
	Manufacturer /Distributor Information:	
	Purchase Location Information:	
Animal Information:	**Name:**	B6
	Type Of Species:	Dog
	Type Of Breed:	Bulldog
	Gender:	Female
	Reproductive Status:	Neutered
	Weight:	24.2 Kilogram
	Age:	B6 Years
	Assessment of Prior Health:	Good
	Number of Animals Given the Product:	6
	Number of Animals Reacted:	3
	Owner Information:	**Owner Information provided:** Yes
		Contact: **Name:** B6 **Phone:** **Email:**
		Address: B6 United States

FDA-CVM-FOIA-2019-1704-006256

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

FDA-CVM-FOIA-2019-1704-006257

Report Details - EON-390201

ICSR:	2068094		
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:	B6 14:32:32 EDT		
Initial Report Date:	02/25/2019		
Parent ICSR:	2063133		
Follow-up Report to FDA Request:	Yes		
Reported Problem:	**Problem Description:**	DCM and CHF diagnosed 1/15/19 Eating BEG diet. 6 dogs being fed this diet - so far, 4 have been diagnosed with DCM/ARVC. One other had a normal NT-proBNP and 2 others will be tested Diet has been changed to Royal Canin Early Cardiac and we will recheck in 3 months. I have sample of dry and canned food B6 B6 - Owners elected humane euthanasia due to worsening heart failure. Samples of heart muscle were submitted to FDA from rDVM.	
	Date Problem Started:	01/15/2019	
	Concurrent Medical Problem:	Yes	
	Pre Existing Conditions	B6	
	Outcome to Date:	Died Euthanized	
	Date of Death:	B6	
Product Information:	**Product Name:**	Wellness Core grain-free ocean fish dry Wellness core grain free turkey, chicken liver & turkey liver canned Wellness Hearty Cuts grain-free in gravy chicken and turkey recipe	
	Product Type:	Pet Food	
	Lot Number:		
	Product Use Information:	**Description:**	Please see diet history
	Manufacturer /Distributor Information:		
	Purchase Location Information:		
Animal Information:	**Name:**	B6	
	Type Of Species:	Dog	
	Type Of Breed:	Bulldog	
	Gender:	Female	
	Reproductive Status:	Neutered	
	Weight:	19.8 Kilogram	
	Age:	8.5 Years	
	Assessment of Prior Health:	Excellent	
	Number of Animals Given the Product:	6	
	Number of Animals Reacted:	4	
	Owner Information:	**Owner Information provided:**	Yes
		Contact:	**Name:** B6
			Phone:
			Email:

FDA-CVM-FOIA-2019-1704-006258

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

{

Report Details - EON-390205

ICSR:	2068096		
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:	2019-06-11 14:55:22 EDT		
Initial Report Date:	02/25/2019		
Parent ICSR:	2063134		
Follow-up Report to FDA Request:	Yes		
Reported Problem:	**Problem Description:**	Housemate (half sister; B6 - (ICSR) of 2063133) diagnosed with DCM and CHF so screened by RDVM for BNP which was elevated. Evaluated at Tufts 2/1/19. ARVC/diet-induced DCM with ventricular arrhythmia. Diet changed to Royal Canin Early Cardiac and will re-evaluate in 3 months I have diet sample. 3 other dogs in household (1 had normal BNP, other 2 not yet evaluated) Patient DOA when owners arrived home on: B6 . Suspected sudden death. Heart muscle samples were collected by rDVM and submitted to FDA for further evaluation.	
	Date Problem Started:	02/01/2019	
	Concurrent Medical Problem:	Yes	
	Pre Existing Conditions:	B6	
	Outcome to Date:	Died Other	
	Date of Death:	B6	
Product Information:	**Product Name:**	Wellness CORE Grain-Free Ocean Whitefish dry Wellness Core grain free turkey, chicken liver, and turkey liver formula canned Wellness Core Hearty Cuts grain-free in gravy chicken and turkey recipe	
	Product Type:	Pet Food	
	Lot Number:		
	Product Use Information:	**Description:**	Please see diet history for more info (and refer to B6 B6 diet history for more complete info - all dogs eat same diets)
	Manufacturer /Distributor Information:		
	Purchase Location Information:		
Animal Information:	**Name:**	B6	
	Type Of Species:	Dog	
	Type Of Breed:	Bulldog	
	Gender:	Male	
	Reproductive Status:	Neutered	
	Weight:	22.1 Kilogram	
	Age:	8 Years	
	Assessment of Prior Health:	Good	
	Number of Animals Given the Product:	6	
	Number of Animals Reacted:	4	
	Owner Information:	**Owner Information provided:**	Yes
		Contact:	**Name:** B6

FDA-CVM-FOIA-2019-1704-006260

		Phone:	B6
		Email:	
		Address:	B6 United States
	Healthcare Professional Information:	Practice Name:	Tufts Cummings School of Veterinary Medicine
		Contact:	Name: Lisa Freeman
			Phone: (508) 887-4523
			Email: lisa.freeman@tufts.edu
		Address:	200 Westboro Rd North Grafton Massachusetts 01536 United States
Sender Information:	Name:	Lisa Freeman	
	Address:	200 Westboro Rd North Grafton Massachusetts 01536 United States	
	Contact:	Phone:	5088874523
		Email:	lisa.freeman@tufts.edu
	Permission To Contact Sender:	Yes	
	Preferred Method Of Contact:	Email	
Additional Documents:			

FDA-CVM-FOIA-2019-1704-006261

Cummings Veterinary Medical Center
AT TUFTS UNIVERSITY

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

All Medical Records

Client: B6
Address:

Patient: B6
Breed: English Bulldog
DOB: B6

Species: Canine
Sex: Male (Neutered)

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

Referring Information

B6

Client: B6
Patient:

Initial Complaint:

Initial Complaint:

Initial Complaint:

FDA-CVM-FOIA-2019-1704-006262

Client:
Patient: B6

Initial Complaint:
Scanned Record

Initial Complaint:
Cardiology DCM study - will come fasted - u/f samples

SOAP Text Feb 1 2019 11:50AM - Rush, John

Disposition/Recommendations

FDA-CVM-FOIA-2019-1704-006263

FDA-CVM-FOIA-2019-1704-006264

Cummings Veterinary Medical Center AT TUFTS UNIVERSITY

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

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

Patient:	B6
Species:	Canine
Breed:	English Bulldog
Sex:	Male (Neutered)
Age:	B6 Years Old

Lab Results Report

Accession ID:

Test	Results	Reference Range	Units

FDA-CVM-FOIA-2019-1704-006265

Client:
Patient: **B6**

IDEXX Hematology 1/24/19

IDEXX

B6

PET OWNER: B6
SPECIES: Canine
BREED:
GENDER: Male
AGE: 8 Years
PATIENT ID: B6

B6

ACCOUNT #: B6
ATTENDING VET: B6

LAB ID: 2302815220
ORDER ID: 38459535
COLLECTION DATE: 1/23/19
DATE OF RECEIPT: 1/24/19
DATE OF RESULT: 1/24/19

IDEXX Services: **Senior Profile with Fecal Dx™ Profile, Giardia, Lab 4Dx® Plus and Reflex Quant C6® and UPC Select, SAMPLE/TEST INFO NEEDED, Cardiopet® proBNP-Canine Add-on***

Hematology

1/24/19 (Order Received)
1/24/19 11:05 AM (Last Updated)

3/2/17

TEST	RESULT	REFERENCE VALUE	3/2/17
RBC	B6	5.39 - 8.7 M/µL	B6
Hematocrit		38.3 - 56.5 %	
Hemoglobin		13.4 - 20.7 g/dL	
MCV		59 - 76 fL	
MCH		21.9 - 26.1 pg	
MCHC		32.6 - 39.2 g/dL	
% Reticulocyte		%	
Reticulocytes		10 - 110 K/µL	
Reticulocyte Hemoglobin		22.3 - 29.6 pg	
WBC		4.9 - 17.6 K/µL	
% Neutrophils		%	
% Lymphocytes		%	
% Monocytes		%	
% Eosinophils		%	
% Basophils		%	
Neutrophils		2.94 - 12.67 K/µL	
Lymphocytes		1.06 - 4.95 K/µL	
Monocytes		0.13 - 1.15 K/µL	
Eosinophils		0.07 - 1.49 K/µL	
Basophils		0 - 0.1 K/µL	
Platelets		143 - 448 K/µL	
Remarks	Slide reviewed microscopically. B6		SLIDE REV...

Generated by VetConnect® PLUS January 24, 2019 03:04 PM

Page 1 of 4

FDA-CVM-FOIA-2019-1704-006266

Client:
Patient: **B6**

IDEXX Hematology 1/24/19

IDEXX

PET: **B6** PET OWNER: **B6** DATE OF RESULT: **1/24/19** LAB ID: 2302815220

Chemistry

1/24/19 (Order Received)
1/24/19 11:05 AM (Last Updated)

3/2/17

TEST	RESULT	REFERENCE VALUE	RESULT
Glucose		63 - 114 mg/dL	
IDEXX SDMA		0 - 14 µg/dL	
Creatinine		0.5 - 1.5 mg/dL	
BUN		9 - 31 mg/dL	
BUN: Creatinine Ratio			
Phosphorus		2.5 - 6.1 mg/dL	
Calcium		8.4 - 11.8 mg/dL	
Sodium		142 - 152 mmol/L	
Potassium		4.0 - 5.4 mmol/L	
Na: K Ratio		28 - 37	
Chloride		108 - 119 mmol/L	
TCO2 (Bicarbonate)		13 - 27 mmol/L	
Anion Gap		11 - 26 mmol/L	
Total Protein		5.5 - 7.5 g/dL	
Albumin		2.7 - 3.9 g/dL	
Globulin		2.4 - 4.0 g/dL	
Albumin: Globulin Ratio		0.7 - 1.5	
ALT		18 - 121 U/L	
AST		16 - 55 U/L	
ALP		5 - 160 U/L	
GGT		0 - 13 U/L	
Bilirubin - Total		0.0 - 0.3 mg/dL	
Bilirubin - Unconjugated		0.0 - 0.2 mg/dL	
Bilirubin - Conjugated		0.0 - 0.1 mg/dL	
Cholesterol		131 - 345 mg/dL	
Amylase		337 - 1,469 U/L	
Lipase		138 - 755 U/L	
Creatine Kinase		10 - 200 U/L	

B6 **B6**

FDA-CVM-FOIA-2019-1704-006267

Client: B6
Patient:

IDEXX Hematology 1/24/19

IDEXX

B6 PET OWNER: B6 DATE OF RESULT: 1/24/19 LAB ID: 2302815220

Chemistry (continued)

TEST	RESULT	REFERENCE VALUE	
Hemolysis Index	B6		B6
Lipemia Index			
Cardiopet proBNP - Canine		0 - 900 pmol/L	B6

B6

Endocrinology

1/24/19 (Order Received)
1/24/19 11:05 AM (Last Updated)

3/2/17

TEST	RESULT	REFERENCE VALUE	
Total T4	B6	1 - 4 µg/dL	B6

B6

Serology

1/24/19 (Order Received)
1/24/19 11:05 AM (Last Updated)

TEST	RESULT
Heartworm Antigen	B6

FDA-CVM-FOIA-2019-1704-006268

IDEXX

B6 PET OWNER: B6 DATE OF RESULT: 1/24/19 LAB ID: 2302815220

Serology (continued)

TEST	RESULT
Ehrlichia canis / ewingii	B6
Lyme (Borrelia burgdorferi)	
Anaplasma phagocytophilum / platys	

B6

Other

1/24/19 (Order Received)
1/24/19 11:05 AM (Last Updated)

TEST	RESULT
More Information Needed	B6

FDA-CVM-FOIA-2019-1704-006269

Client:
Patient: B6

cbc and profile 2/1/19

Cummings School of Veterinary Medicine

Clinical Pathology Laboratory
200 Westboro Road
North Grafton, MA 01536

Name/DOB:
Patient ID: B6
Sex: CM
Provider: Dr. John Rush
Order Location: V320559: Investigation into
Phone number:
Age: 8
Sample ID: 1902010102
Collection Date: 2/1/2019 11:52 AM
Species: Canine
Approval date: 2/1/2019 12:57 PM
Breed:

TEST NAME	RESULT IN RANGE	RESULT OUT OF RANGE	RANGE	UNITS	REFERENCE RANGE
CBC, Comprehensive, Sm Animal (Research)					CSTCYR
WBC (ADVIA)	B6		B6	K/uL	4.40-15.10
RBC (Advia)				M/uL	5.80-8.50
Hemoglobin (ADVIA)				g/dL	13.3-20.5
Hematocrit (Advia)				%	39-55
MCV (ADVIA)				fL	64.5-77.5
MCH (ADVIA)				pg	21.3-25.9
CHCM				g/dl	
MCHC (ADVIA)				g/dL	31.9-34.3
RDW (ADVIA)					11.9-15.2
Platelet Count (Advia)		B6		K/uL	173-486
Mean Platelet Volume (Advia)				fl	8.29-13.20
02/01/19 12:12 PM	B6				
Platelet Crit		B6		%	0.129-0.403
02/01/19 12:12 PM		B6			
PDW				%	
Reticulocyte Count (Advia)		B6		%	0.20-1.60
Absolute Reticulocyte Count (Advia)				K/uL	14.7-113.7
CHr		B6		pg	
MCVr				fl	
Comments (Hematology)					
Microscopic Exam of Blood Smear (Advia)					CSTCYR
Seg Neuts (%)	B6		B6	%	43-86
Lymphocytes (%)				%	7-47
Monocytes (%)				%	1-15
Eosinophils (%)				%	0-16
Seg Neutrophils (Abs) Advia				K/ul	2.800-11.500
Lymphs (Abs) Advia				K/uL	1.00-4.80
Mono (Abs) Advia				K/uL	0.10-1.50
Eosinophils (Abs)				K/uL	0.00-1.40

Sample ID: 1902010102/1
This report continues... (Final)

Reviewed by: _____

FDA-CVM-FOIA-2019-1704-006270

Client:
Patient: B6

cbc and profile 2/1/19

Cummings School of Veterinary Medicine

Clinical Pathology Laboratory
200 Westboro Road
North Grafton, MA 01536

Name/DOB:
Patient ID: B6
Sex: CM
Phone number:
Age: 8
Collection Date: 2/1/2019 11:52 AM
Species: Canine
Approval date: 2/1/2019 12:57 PM
Breed:

Provider: Dr. John Rush
Order Location: V320559: Investigation into
Sample ID: 1902010102

TEST NAME	RESULT IN RANGE	RESULT OUT OF RANGE	RANGE	UNITS	REFERENCE RANGE
Microscopic Exam of Blood Smear (Advia) (cont'd)					CSTCYR
Advia WBC Morphology RBC Morphology	B6				
Research Chemistry Profile - Small Animal (Cobas)					SMACHUNSKI
Glucose	B6		B6	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
Magnesium 2+				mEq/L	1.8-3.0
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				mEq/L	140-150
Chloride				mEq/L	106-116
Potassium				mEq/L	3.7-5.4
tCO2(Bicarb)				mEq/L	14-28
AGAP					8.0-19.0
NA/K					29-40
Total Bilirubin				mg/dL	0.10-0.30
Alkaline Phosphatase				U/L	12-127
GGT				U/L	0-10
ALT				U/L	14-86
AST				U/L	9-54
Creatine Kinase				U/L	22-422
Cholesterol				mg/dL	82-355
Triglycerides				mg/dl	30-338
Amylase				U/L	409-1250
Osmolality (calculated)		B6		mmol/L	291-315

Sample ID: 1902010102/2
END OF REPORT (Final)

Reviewed by: _____
Page 2

FDA-CVM-FOIA-2019-1704-006271

Client: B6
Patient: B6

NT-proBNP 2/1/19

IDEXX Reference Laboratories

Client: B6 Patient: B6

IDEXX VetConnect 1-888-433-9987

Client: B6
Patient:
Species: CANINE
Breed: ENGLISH_BULLDOG
Gender: MALE NEUTERED
Age: 8Y

Date: 02/01/2019
Requisition #: 438225
Accession #: B6
Ordered by: RUSH

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

Account: B6

CARDIOPET proBNP - CANINE

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

Comments:

B6

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

FDA-CVM-FOIA-2019-1704-006272

Client:
Patient: B6

CBC/CHEM

Tufts Cummings School Of Veterinary Medicine

200 Westboro Road
North Grafton, MA 01536

DUPLICATE

Name/DOB:
Patient ID: B6
Phone number:
Collection Date: 2/1/2019 11:52 AM
Approval date: 2/1/2019 12:57 PM

Sex: CM
Age: 8
Species: Canine
Breed:

Provider: Dr. John Rush
Order Location: V320559: Investigation into
Sample ID: 1902010102

CBC, Comprehensive, Sm Animal (Research)

CSTCYR	B6	Ref. Range/Males
WBC (ADVIA)		4.40-15.10 K/uL
RBC (Advia)		5.80-8.50 M/uL
Hemoglobin (ADVIA)		13.3-20.5 g/dL
Hematocrit (Advia)		39-55 %
MCV (ADVIA)		64.5-77.5 fL
MCH (ADVIA)		21.3-25.9 pg
CHCM		
MCHC (ADVIA)		31.9-34.3 g/dL
RDW (ADVIA)		11.9-15.2
Platelet Count (Advia)		173-486 K/uL
Mean Platelet Volume (Advia)		8.29-13.20 fl
02/01/19 12:12 PM		
Platelet Crit		0.129-0.403 %
02/01/19 12:12 PM		
PDW		
Reticulocyte Count (Advia)		0.20-1.60 %
Absolute Reticulocyte Count (Advia)		14.7-113.7 K/uL
CHr		
MCVr		
Comments (Hematology)		

Microscopic Exam of Blood Smear (Advia)

CSTCYR	B6	Ref. Range/Males
Seg Neuts (%)		43-86 %
Lymphocytes (%)		7-47 %
Monocytes (%)		1-15 %
Eosinophils (%)		0-16 %
Seg Neutrophils (Abs) Advia		2.800-11.500 K/ul
Lymphs (Abs) Advia		1.00-4.80 K/uL
Mono (Abs) Advia		0.10-1.50 K/uL
Eosinophils (Abs) Advia		0.00-1.40 K/uL
WBC Morphology		
RBC Morphology		

Research Chemistry Profile - Small Animal (Cobas)

Sample ID: 1902010102/1
This report continues... (Final)

Reviewed by: _____

FDA-CVM-FOIA-2019-1704-006273

Client:
Patient: **B6**

CBC/CHEM

Tufts Cummings School Of Veterinary Medicine

200 Westboro Road
North Grafton, MA 01536

DUPLICATE

Name/DOB:
Patient ID: **B6**
Phone number:
Collection Date: 2/1/2019 11:52 AM
Approval date: 2/1/2019 12:57 PM

Sex: CM
Age: 8
Species: Canine
Breed:

Provider: Dr. John Rush
Order Location: V320559: Investigation into
Sample ID: 1902010102

Research Chemistry Profile - Small Animal (Cobas) (cont'd)

SMACHUNSKI **B6**

	Ref. Range/Males
Glucose	67-135 mg/dL
Urea	8-30 mg/dL
Creatinine	0.6-2.0 mg/dL
Phosphorus	2.6-7.2 mg/dL
Calcium 2	9.4-11.3 mg/dL
Magnesium 2+	1.8-3.0 mEq/L
Total Protein	5.5-7.8 g/dL
Albumin	2.8-4.0 g/dL
Globulins	2.3-4.2 g/dL
A/G Ratio	0.7-1.6
Sodium	140-150 mEq/L
Chloride	106-116 mEq/L
Potassium	3.7-5.4 mEq/L
tCO2(Bicarb)	14-28 mEq/L
AGAP	8.0-19.0
NA/K	29-40
Total Bilirubin	0.10-0.30 mg/dL
Alkaline Phosphatase	12-127 U/L
GGT	0-10 U/L
ALT	14-86 U/L
AST	9-54 U/L
Creatine Kinase	22-422 U/L
Cholesterol	82-355 mg/dL
Triglycerides	30-338 mg/dl
Amylase	409-1250 U/L
Osmolality (calculated)	291-315 mmol/L

Sample ID: 1902010102/2
REPRINT: Orig. printing on 2/1/2019 (Final)

Reviewed by: _____
Page 2

FDA-CVM-FOIA-2019-1704-006274

Client: B6
Patient:

Taurine level

B5

B6

Amino Acid Laboratory Sample Submission Form

2/1/2019 11:54 AM Pat Race
SHIP w ICE PACKS, TAURINE PANEL
Lithium Heparin
Rush

Amino Acid Laboratory, 1089 Veterinary Medicine Drive, Davis, Ca 95616
Telephone: 530-752-5058, Fax: 530-752-4698
Email: ucd.aminoacid.lab@ucdavis.edu
www.vetmed.ucdavis.edu/labs/amino-acid-laboratory

Veterinarian Contact: B6

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

Address: 200 Westboro Road, North Grafton, MA 015369

Email: Clinpath@tufts.edu cardiovet@tufts.edu

Telephone: 508-887-4669 **Fax:** 508-839-7936

Billing Contact: B6 **Email:** B6

Billing Contact Phone: 508-887-4267 **Tax ID:**

Patient Name: B6 **Species:** Canine

Breed: English Bulldog **Owner's Name:** B6

Current Diet : Wellness Core

Sample type: Plasma Whole Blood Urine Food Other

Test: Taurine Complete Amino Acids Other:

Taurine Results (lab use only)

Plasma: B6 Whole Blood: B6 Urine: Food:

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

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

FDA-CVM-FOIA-2019-1704-006275

Client:
Patient: **B6**

Diet history 2/1/19

CARDIOLOGY DIET HISTORY FORM

Please answer the following questions about your pet.

Pet's name: **B6** Owner's name: **B6** Today's date: 02-01-19

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

   Poor_____**Excellent**

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

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

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

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

Food (include specific product and flavor)	Form	Amount	How often?	Fed since
Nutro Grain Free Chicken, Lentil, & Sweet Potato Adult	*dry*	*1 ½ cup*	*2x/day*	*Jan 2018*
85% lean hamburger	*microwaved*	*3 oz*	*1x/week*	*Jan 2015*
Pupperoni original beef flavor	*treat*	*½*	*1x/day*	*Aug 2015*
Rawhide	*treat*	*6 inch twist*	*1x/week*	*Dec 2015*
Wellness Core Canned chicken	wet	4 oz	1x/day	Dec 2015
Wellness Core fish	dry	1/4 cup	2x/day	Dec 2015
Wellness Core	treat	3 pcs.	1x day	"
(SEE B6 FORM FOR EXACT BRANDS FORMULAS				

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

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

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

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

   CHANGING DIET TO ROYAL CANIN EARLY CARDIAC

FDA-CVM-FOIA-2019-1704-006276

Client:
Patient: B6

Troponin 2/1/19

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: B6

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

Phone: 508 887 4669
Fax: 9 508 839 7936
Animal Name: B6
Owner Name:
Species: Canine
Date Received: Feb 12, 2019

GI Lab Accession: B6

Test	Result	Control Range	Assay Date
Ultra-Sensitive Troponin I Fasting	B6	≤0.06	02/12/19

B6

Comments:

FDA-CVM-FOIA-2019-1704-006277

Client:
Patient: **B6**

Troponin 2/1/19

Important Notices:

Internal Medicine Conference

Join us for a unique continuing education event in Phuket, Thailand Oct 7th - 11th, 2019. For details see http://texasimconference.tamu.edu

Ongoing studies

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

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

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

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

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

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

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

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

GI Lab Contact Information

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

FDA-CVM-FOIA-2019-1704-006278

Client: B6
Patient:

Vitals Results

2/1/2019 11:00:04 AM	Weight (kg)

Patient History

01/28/2019 03:52 PM	Appointment
02/01/2019 08:05 AM	UserForm
02/01/2019 08:05 AM	UserForm
02/01/2019 10:37 AM	UserForm
02/01/2019 10:38 AM	UserForm
02/01/2019 10:44 AM	Purchase
02/01/2019 11:00 AM	Vitals
02/01/2019 12:03 PM	UserForm
02/01/2019 12:50 PM	Appointment
02/01/2019 12:58 PM	Prescription
02/20/2019 12:08 PM	Patient Merge
02/21/2019 04:32 PM	Purchase
02/21/2019 04:32 PM	Purchase

B6

FDA-CVM-FOIA-2019-1704-006279

FDA-CVM-FOIA-2019-1704-006280

Cummings
Veterinary Medical Center
AT TUFTS UNIVERSITY

B6

B6 Male (Neutered)
Canine English Bulldog Brown/White
Patient ID: B5

STANDARD CONSENT FORM

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

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

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

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

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

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

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

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

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

FDA-CVM-FOIA-2019-1704-006281

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

I do further agree that should any payment, or the full amount of the sum stated above, become overdue more than 20 days from the above agreed upon time of payment or payments, the entire balance shall be considered in default and become due and payable. I further agree to be responsible for any or all collection agency and/or attorney fees necessary to collect the full amount.

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

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

Owner's name: B6 Date: 2/1/2019

Owner's address: B6

B6

Date 01-02-19

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

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

Authorized Agent - Please Print

Agent's Signature

Street Address

Date

Town/City State Zip

Cummings
Veterinary Medical Center
AT TUFTS UNIVERSITY

B6

Patient ID: B6
B6 Canine
B6 Old Male (Neutered) English Bulldog
Body Weight: Weight (kg) 0.00

Brachycephalic Consent Form

Anesthesia, Sedation and Hospitalization

Brachycephalic is a term for "short-nosed". Several dog breeds may experience difficulty breathing due to the shape of their head, muzzle and throat. Shorter nosed dogs include English Bulldogs, French Bulldogs, Pugs, Boston Terriers and many other breeds. The shorter than average nose and face in proportion to their body size can cause problems for these breeds at times. Owners with brachycephalic breeds must pay extra attention to their animals during exercise, heat and while obtaining veterinary care.

Overview

The purpose of this form is to inform you of the risks associated with anesthesia/sedation and occasionally hospitalization, which are inherent for dogs with shorter noses (brachycephalic). Not all of these problems may apply to your dog, but these are part of the brachycephalic syndrome. Please discuss any specific concerns with your attending veterinarian.

Respiratory problems

Brachycephalic dogs have a shortened skull, resulting in a compressed nasal passage and abnormal throat anatomy. The abnormal upper airway anatomy causes increased negative pressure while taking a breath, leading to inflammation, deformation of throat tissues, and obstruction of breathing. We encourage corrective surgery in moderate to severely affected dogs.

Cooling problems

As dogs cool by panting, dogs with narrowed airways may have difficulty cooling themselves. This may be made worse by anxiety or stress.

Stomach and intestinal problems

Brachycephalic dogs may swallow a lot of air which can lead to increased vomiting or regurgitation, and this could lead to pneumonia. If possible, we pre-treat brachycephalic dogs with medications to reduce stomach acids, and to promote stomach emptying.

Restraint challenges

Due to their airway, and in some bulldogs, their intrinsic personality as "tough" dogs, it may be difficult to restrain them safely. This is a particularly significant problem with more aggressive dogs. We

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occasionally need to sedate them, or ask family members to help with some routine procedures to avoid unnecessary stress on the patient.

Sedation and anesthesia

While sedation and anesthesia are commonly performed in brachycephalic breeds, especially bulldogs, recovery from anesthesia may be more difficult for these patients due to a narrowed airway. We have our anesthesia team very closely involved in sedation and anesthesia of brachycephalic breeds especially bulldogs. They have found that careful monitoring is essential to a good outcome. In fact, many dog owners travel some distance in order to ensure that a Tufts board-certified anesthesiologist is present during anesthesia or sedation to minimize the risk of complications.

We consider brachycephalic dogs a high risk population. Please be sure you talk with your doctor about the following:

1. Any medical and/or surgical treatment alternatives for your pet
2. Sufficient details of this consent form and how they apply to your dog
3. How fully your pet might respond or recover and how long it could take
4. The most common complications and how serious they might be

I grant permission for my pet to undergo general anesthesia/sedation/hospitalization at Tufts Foster Hospital for Small Animals at the Cummings School of Veterinary Medicine.

I am aware that my pet has physical characteristics that make anesthesia and sedation more challenging and possibly more risky than for the average dog with a longer nose.

I am aware that brachycephalic breeds, such as the English and French bulldog, Boston Terrier, Pug, and Pekingese have a shortened skull, resulting in a compressed nasal passage and abnormal throat anatomy. The abnormal upper airway anatomy causes increased negative pressure while taking a breath, leading to inflammation, deformation of throat tissues, and obstruction of breathing.

I am aware that if my brachycephalic pet undergoes sedation or general anesthesia the potential complications include partial or complete airway obstruction during recovery and regurgitation/vomiting which could lead to aspiration pneumonia/respiratory distress. With airway surgery, death has been reported as a rare complication in <3% of cases.

I am aware that anesthetizing or sedating a brachycephalic animal for any reason can lead to the development of significant complications as described in this document.

Please answer YES or NO to the following questions:
My pet has demonstrated difficulty breathing, exercise intolerance, and/or collapse episodes.

☒ YES ☐ NO

My pet has demonstrated difficulty eating, such as gagging, vomiting, and regurgitation.

☐ YES ☒ NO

My pet is receiving or has recently received a non-steroidal anti-inflammatory drug (e.g., Rimadyl)

☐ YES ☒ NO

Your signature indicates that you have read and understand the above information and give your consent for treat

B6

Owner signature _____

Date: 2/1/2019

Cummings
Veterinary Medical Center
AT TUFTS UNIVERSITY

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

Cardiology Liaison: 508-887-4696

Discharge Instructions

Patient
Name: B6
Species: Canine
Brown/White Male (Neutered) English Bulldog
Birthdate: B6

Owner
Name: B6
Address: B6

Patient ID: B6

Attending Cardiologist:
☑ John E. Rush DVM, MS, DACVIM (Cardiology), DACVECC
B6

Cardiology Resident:
B6

Cardiology Technician:
B6

Veterinary Nutritionist : Dr. Lisa Freeman
Student: B6

Admit Date: 2/1/2019 10:36:11 AM
Discharge Date: 2/1/2019

Diagnoses: Arrhythmogenic right ventricular cardiomyopathy (ARVC) with marked right heart enlargement, ventricular premature depolarizations, and left ventricular dysfunction; possible component of diet-related cardiomyopathy

Clinical findings: B6 has been diagnosed with a primary heart muscle disease called arrhythmogenic right ventricular cardiomyopathy (ARVC). This disease is common in bulldogs and is characterized by replacement of the normal heart muscle by fat and/or scar tissue which may result in serious ventricular arrhythmias (abnormal heart rhythms originating from the lower chamber of the heart), cardiac enlargement and congestive heart failure, or both. Dogs with ARVC may experience syncope (fainting) or sudden death as the result of ventricular arrhythmia. Though we cannot reverse the changes in the heart muscle, we can control the heart disease with medical management.
The following diagnostic test results were obtained today:

ECG findings: The ECG shows a number of premature ventricular contractions (VPCS) orginating from the right ventricle.

Echocardiogram findings: The right ventricle is moderate to markedly enlarged. The left ventricle is mildly dilated with the left ventricular free wall thinned. There is reduced vigor of contraction of the left ventricle. The left atrium is mildly to oderately enlarged. The right atrium is moderately to markedly enlarged. There is some mitral and tricuspid valve regurgitation. The hepatic veins are markedly distended.

Monitoring at home: Please monitor for any signs of lethargy, weakness, pale gums, cough, shortness of breath, inappetence, or collapse. If a collapsing episode is noted, please check your dog's gum color and try to get a sense of whether the heart rate is slow or fast. If you have an iPhone or Android smartphone device, you may want to explore the

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option of purchasing the Kardia Mobile device which will allow you to monitor the heart rate and rhythm at home (www.alivecor.com). If you have any concerns, please call or have your dog evaluated by a veterinarian. Our emergency clinic is open 24-hours/day.

B6 may also benefit from wearing a Holter EKG, which is a harnessed EKG that he would wear for 24-hours. We can place that here, and send him home for the 24-hours duration. He would then return here the next day where we can remove the Holter and analyze his heart rythmn to fully assess his arrhythmia. Call if you decide to do this test.

Recommended Medications:

B6

Dry Food Options:
Royal Canin Early Cardiac (veterinary diet)
Royal Canin Boxer
Purina Pro Plan Adult Weight Management
Purina Pro Plan Bright Mind Adult Small Breed Formula
Canned Food Options:
Hill's Science Diet Adult Beef and Barley Entree
Hill's Science Diet Adult 1-6 Healthy Cuisine Roasted Chicken, Carrot, and Spinach Stew
Royal Canin Mature 8+

We recommend slowly introducing one of the diets on the above list as follows: 25% of the new diet mixed with 75% old diet for 2-3 days, then 50:50, etc.
Hopefully you can find a diet on the list that B6 will enjoy!

If your dog has special nutritional needs or requires a homecooked diet, we recommend you schedule an appointment with our nutritionists (508-887-4696).

Exercise recommendations: Generally we recommend limited activity for dogs with heart disease – Leash walk only is ideal. Repetitive or strenuous high energy activities (repetitive ball chasing, running fast off-leash, etc.) are not recommended as these activities may result in worsened arrhythmia or even sudden death.

Recheck visits: We would like to recheck B6 in 3 months, at which point we can discuss additional medications and

treatments as needed (such as antiarrhythmics). We will likely recommend recheck ECGs every 3 months, or you can purchase the AliveCor and send us an ECG about once a month.

Thank you for entrusting us with B6 's care. Please contact our Cardiology liaison at (508)-887-4696 or email us at cardiowet@tufts.edu for scheduling and non-emergent questions or concerns.
Please visit our HeartSmart website for more information

Please visit our HeartSmart website for more information
http://vet.tufts.edu/heartsmart/

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

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

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

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FDA-CVM-FOIA-2019-1704-006288

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

B6

Patient ID: B6
B6 Canine
B6 Years Old Male (Neutered) English Bulldog
Brown/White

Cardiology Appointment Report
Enrolled in DCM Study

Date: 2/1/2019

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

B6

Cardiology Resident:
B6

Cardiology Technician:
B6

Student: B6

Presenting Complaint: Here for possible entry to DCM study. Half-sister B6 came in last month for CHF. B6 had high proBNP on bloodwork B6 .

Concurrent Diseases:
B6

General Medical History:
B6 O says seen at Tufts.
Sedentary lifestyle, but healthy. Half- sister B6 here last month in CHF, which is what started concerns for DCM.
Fasted today.
Had reason for concern of DCM based on diet and sister, came in based on NTproBNP level.

Diet and Supplements:
Grain free diet- Wellness Core. Chicken and Turkey wet food 4oz BID. Fish dry food 1/4 cup BID.
No supplements or treats.

Cardiovascular History:
Prior CHF diagnosis? N
Prior heart murmur? N
Prior ATE? N

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Prior arrhythmia?N
Monitoring respiratory rate and effort at home? N, but taking notice more after sister's CHF. O thinks 20-30 at rest .
Cough? N
Shortness of breath or difficulty breathing? Sounds raspy when anxious.
Syncope or collapse? N
Sudden onset lameness? N
Exercise intolerance? N- Normally low energy.

Current Medications Pertinent to CV System:

B6

Muscle condition:

- [x] Normal
- [ ] Mild muscle loss
- [ ] Moderate cachexia
- [ ] Marked cachexia

Cardiovascular Physical Exam:

Murmur Grade:

- [x] None
- [ ] I/VI
- [ ] II/VI
- [ ] III/VI
- [ ] IV/VI
- [ ] V/VI
- [ ] VI/VI

Murmur location/description:

Jugular vein:

- [x] Bottom 1/3 of the neck
- [ ] Middle 1/3 of the neck
- [ ] 1/2 way up the neck
- [ ] Top 2/3 of the neck

Arterial pulses:

- [x] Weak - obese and difficult to palpate
- [ ] Fair
- [ ] Good
- [ ] Strong
- [ ] Bounding
- [ ] Pulse deficits
- [ ] Pulsus paradoxus
- [ ] Other:

Arrhythmia:

- [ ] None
- [x] Sinus arrhythmia
- [x] Premature beats infrequent
- [ ] Bradycardia
- [ ] Tachycardia

Gallop:

- [ ] Yes
- [ ] Pronounced

- [x] No
- [ ] Intermittent
- [ ] Other:

Pulmonary assessments:

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

Abdominal exam:

- [x] Normal
- [ ] Hepatomegaly
- [x] Abdominal distension mostly adipose tissue?
- [ ] Mild ascites
- [ ] Marked ascites

Problems:

Related dog with DCM

Has a high NT-proBNP

Differential Diagnoses: DCM vs other

Diagnostic plan:

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

Echocardiogram Findings:

B6

Assessment and recommendations:

Findings are consistent with ARVC with concurrent LV dysfunction which is either related to ARVC or could have a component of diet-related cardiomyopathy. There was not enough arrhythmia seen today to clearly trigger antiarrhythmic therapy, but a 24 hour Holter monitor could be performed for a better assessment of arrhythmia burden, or Alivecor tracings could be evaluated serially. B6

B6 Dog was enrolled in the DCM study, and troponin, NTproBNP, taurine levels, CBC/Chem were submitted via the study. Recheck echo, ECG, and blood work in

3, 6, and 9 months for the study. Disoussed pros and cons of starting B6 treatment today, or ACEi - owner leaning toward fewer drugs at this stage.

Final Diagnosis:
ARVC with LV dysfunction (possible component of diet associated cardiomyopathy)

Heart Failure Classification Score:
ISACHC Classification:

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

ACVIM Classification:

- ☐ A
- ☐ B1
- ☑ B2
- ☐ C
- ☐ D

M-Mode

B6

IVSd		cm
LVIDd		cm
LVPWd		cm
IVSs		cm
LVIDs		cm
LVPWs		cm
EDV(Teich)		ml
ESV(Teich)		ml
EF(Teich)		%
%FS		%
SV(Teich)		ml
Ao Diam		cm
LA Diam		cm
LA/Ao		
Max LA		cm
TAPSE		cm

M-Mode Normalized

B6

IVSdN		(0.290 - 0.520) !
LVIDdN		(1.350 - 1.730)
LVPWdN		(0.330 - 0.530)
IVSsN		(0.430 - 0.710)
LVIDsN		(0.790 - 1.140)
LVPWsN		(0.530 - 0.780) !
Ao Diam N		(0.680 - 0.890) !
LA Diam N		(0.640 - 0.900) !

2D

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SA LA	cm
Ao Diam	cm
SA LA / Ao Diam	
IVSd	cm
LVIDd	cm
LVPWd	cm
EDV(Teich)	ml
IVSs	cm
LVIDs	cm
LVPWs	cm
ESV(Teich)	ml
EF(Teich)	%
%FS	%
SV(Teich)	ml
LV Major	cm
LV Minor	cm
Sphericity Index	
LVLd LAX	cm
LVAd LAX	cm
LVEDV A-L LAX	ml
LVEDV MOD LAX	ml
LVLs LAX	cm
LVAs LAX	cm
LVESV A-L LAX	ml
LVESV MOD LAX	ml
HR	BPM
EF A-L LAX	%
LVEF MOD LAX	%
SV A-L LAX	ml
SV MOD LAX	ml
CO A-L LAX	l/min
CO MOD LAX	l/min
Doppler	
MR Vmax	m/s
MR maxPG	mmHg
MV E Vel	m/s
MV DecT	ms
MV Dec Slope	m/s
MV A Vel	m/s
MV E/A Ratio	
E'	m/s
E/E'	
A'	m/s
S'	m/s
AV Vmax	m/s
AV maxPG	mmHg
PV Vmax	m/s
PV maxPG	mmHg
TR Vmax	m/s

B6

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TR maxPG

B6

mmHg

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Cummings
Veterinary Medical Center
AT TUFTS UNIVERSITY

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

B6

B6 B6 Male (Neutered)
Canine English Bulldog
Brown/White
B6

2/12/2019

Dear B6

Thank you for referring B6 with their pet B6

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

Thank you,

John Rush DVM, DACVIM (Cardiology), DACVECC

Veterinary Laboratory Investigation and Response Network

Center for Veterinary Medicine
U.S. Food and Drug Administration
8401 Muirkirk Rd. Laurel, MD 20708
Tel: 240-402-0892 Fax: 301-210-4685

DIAGNOSTIC SAMPLE SUBMISSION FORM

Vet-LIRN use only:
Date received:
Study #: 800.267
Vet-LIRN #: cc-297

Date: 6/11/2019

Veterinarian: B6
Clinic:
Address:
City, Zip, State:
Phone:
Fax:
Email:

Owner: B6
Address:
City, Zip, State:
Phone:
Email:

Animal Information:

Clinic ID:
Animal Name/ID: B6
Species:

Breed:
Age:
Sex:

Body:

fresh ☐ frozen ☐

Organs:

thyroid ☐ thymus ☐ lung ☐ heart ☐ liver ☐ spleen ☐ adrenal ☐ kidney ☐ pancreas ☐
duodenum ☐ jejunum ☐ ileum ☐ colon ☐ urinary ☐ bladder ☐ skeletal muscle ☐ brain ☐
stomach ☐ other (list):

Clinical Samples:

serum ☐ blood ☐ urine ☐ feces ☐ biopsy samples ☐ cultures ☐
other (list):

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Name of the person preparing the package: _____

Note: please use a courier and follow their guidelines for shipping medical samples.

Additional Comments:

_____

_____

_____

_____

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_____

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_____

_____

_____

GENERAL INFORMATION FOR SAMPLE SUBMISSIONS

- Histological samples should NOT be frozen (please send in a separate package if also submitting frozen tissues)
- Samples other than histological samples should be placed on ice/cold packs
- Submit all tissues as individual samples (do not place liver/kidney/etc into the same bag)
- Please ship with tracking information
- Ship in the beginning of the week for weekday deliveries
- If advice is needed regarding sample collection or appropriate tests to request, please call:
    - Dr. Peloquin 240-402-1218
    - Dr. Jones 240-402-5421
    - Ms. Nemser 240-402-0892
    - Dr. Ceric 240-402-5419
    - Dr. Reimschuessel 240-402-5404

FDA-CVM-FOIA-2019-1704-006297

From: Guag, Jake </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E13AD3C7A7C5484C80E1D9CF9D1A15DE-JGUAG>
To: Rotstein, David; Jones, Jennifer L
CC: Peloquin, Sarah
Sent: 5/22/2019 2:54:09 PM
Subject: RE: Rapid necropsy for Vet-LIRN's Case Investigation into Canine Dilated Cardiomyopathy (DCM) 2018

Dave,
Do you have a report for B6 ? Jen B6

Jake

From: B6
Sent: Wednesday, May 22, 2019 10:47 AM
To: Guag, Jake <Jake.Guag@fda.hhs.gov>
Subject: Rapid necropsy for Vet-LIRN's Case Investigation into Canine Dilated Cardiomyopathy (DCM) 2018

Good morning,

I recently submitted a pet food report via the FDA Safety Reporting Portal on a deceased patient named B6 B6 was a 4yo CM Boxer with severe DCM who had been eating a grain-free dog food for the last two years. Dr. Lisa Freeman (PI for on-going DCM study here at Tufts) would like to submit collected samples (heart) to the FDA for further analysis. The sample was promptly placed in 10% NBF approximately 30 minutes post mortem on B6 Would it be possible to have boxes sent to us for sample submission?

Thank you,

B6
Department of Clinical Sciences
Cummings School of Veterinary Medicine at Tufts University
200 Westboro Road
North Grafton, MA 01536
B6
Fax: (508) 839-7922

From:	Rotstein, David </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0A3B17EBFCF14A6CB8E94F322906BADD-DROTSTEI>
To:	Guag, Jake; Jones, Jennifer L
CC:	Peloquin, Sarah
Sent:	5/22/2019 2:57:34 PM
Subject:	RE: Rapid necropsy for Vet-LIRN's Case Investigation into Canine Dilated Cardiomyopathy (DCM) 2018
Attachments:	Health Extension Grain Free Chicken and Turkey Dry Dog Food: B6 - EON-388261

I thought that I had forwarded this one on already-but here you go

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 david.rotstein@fda.hhs.gov.

From: Guag, Jake
Sent: Wednesday, May 22, 2019 10:54 AM
To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Peloquin, Sarah <Sarah.Peloquin@fda.hhs.gov>
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Thank you,

B6

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

To: Cleary, Michael *; HQ Pet Food Report Notification; usha.gulati@doveltech.com

Sent: 5/20/2019 4:09:00 PM

Subject: Health Extension Grain Free Chicken and Turkey Dry Dog Food B6 - EON-388261

Attachments: 2067185-report.pdf; 2067185-attachments.zip

A PFR Report has been received and PFR Event [EON-388261] has been created in the EON System.

A "PDF" report by name "2067185-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 "2067185-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-388261
ICSR #: 2067185
EON Title: PFR Event created for Health Extension Grain Free Chicken and Turkey Dry Dog Food; 2067185

AE Date	B6	**Number Fed/Exposed**	1
Best By Date		**Number Reacted**	1
Animal Species	Dog	**Outcome to Date**	Died Euthanized
Breed	Boxer (German Boxer)		
Age	B6 Years		
District Involved	PFR-New England DO		

Product information
Individual Case Safety Report Number: 2067185
Product Group: Pet Food
Product Name: Health Extension Grain Free Chicken and Turkey Dry Dog Food
Description: Patient was switched to a boutique grain-free diet in January 2017 B6 presented to local ER facility for lethargy, wheezing, coughing, polydipsia, and a distended abdomen. An echo was performed and patient was diagnosed with DCM, TVD, 3+ TR, 2+ MR, ventricular arrhythmias (isolated VPCs, ventricular bigeminy) , R-CHF (mild ascites w/ hepatic vein distension). Patient was referred to Tufts for further evaluation. Cardiac examination at Tufts revealed similar findings - during echo and ECG patient was having isolated VPCs

and one 8 beat run of ventricular tachycardia. A supraventricular arrhythmia was also observed which was believed to be atrial fibrillation d/t no clear P waves with some irregularity. Patient did very well during exam and owners were brought into treatment area to review findings with the cardiologist. Upon owners entering the room, B6 became very excited and about 2 minutes later he collapsed, paddling all four limbs and respiratory arrested. Suspected to have either sustained ventricular tachycardia or ventricular fibrillation but it was clear patient had resp arrested d/t pale white mucous membranes w/ no pulses. Patient was rushed to ER where CPR w/ chest compressions were started, ECG was attached to patient and IVC was placed. ROSC was achieved within minutes and patient was noted to be back in a normal sinus rhythm. Upon resuscitation patient was aware of surroundings. B6 was started as well as multiple B6 Owners elected humane euthanasia due to very poor prognosis. Owner's gave permission to obtain cardiac organs/tissues for research purposes.
Submission Type: Initial
Report Type: Adverse Event (a symptom, reaction or disease associated with the product)
Outcome of reaction/event at the time of last observation: Died Euthanized
Number of Animals Treated With Product: 1
Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Health Extension Grain Free Chicken and Turkey Dry Dog Food		

Sender information

B6

USA

Owner information

B6

USA

To view this PFR Event, please click the link below:
https://eon.fda.gov/eon//browse/EON-388261

To view the PFR Event Report, please click the link below:
https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jspa?decorator=none&e=0&issueType=12&issueId=405438

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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-388261

ICSR:	2067185	
Type Of Submission:	Initial	
Report Version:	FPSR.FDA.PETF.V.V1	
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)	
Reporting Type:	Voluntary	
Report Submission Date:	2019-05-20 11:59:16 EDT	
Reported Problem:	**Problem Description:**	Patient was switched to a boutique grain-free diet in January 2017. B6 B6 presented to local ER facility for lethargy, wheezing, coughing, polydipsia, and a distended abdomen. An echo was performed and patient was diagnosed with DCM, TVD, 3+ TR, 2+ MR, ventricular arrhythmias (isolated VPCs, ventricular bigeminy) , R-CHF (mild ascites w/ hepatic vein distension). Patient was referred to Tufts for further evaluation. Cardiac examination at Tufts revealed similar findings - during echo and ECG patient was having isolated VPCs and one 8 beat run of ventricular tachycardia. A supraventricular arrhythmia was also observed which was believed to be atrial fibrillation d/t no clear P waves with some irregularity. Patient did very well during exam and owners were brought into treatment area to review findings with the cardiologist. Upon owners entering the room, B6 became very excited and about 2 minutes later he collapsed, paddling all four limbs and respiratory arrested. Suspected to have either sustained ventricular tachycardia or ventricular fibrillation but it was clear patient had resp arrested d/t pale white mucous membranes w/ no pulses. Patient was rushed to ER where CPR w/ chest compressions were started, ECG was attached to patient and IVC was placed. ROSC was achieved within minutes and patient was noted to be back in a normal sinus rhythm. Upon resuscitation patient was aware of surroundings. B6 was started as well as multiple B6 Owners elected humane euthanasia due to very poor prognosis. Owner's gave permission to obtain cardiac organs/tissues for research purposes.
	Date Problem Started:	B6
	Concurrent Medical Problem:	Yes
	Pre Existing Conditions:	Feb 2017 - Patient was diagnosed with dietary hypersensitivity and mild-moderate IBD characterized by frequent regurgitation, low B12 and consistent w/ findings on surgical biopsies of the stomach and duodenum. Patient's diet was switched to a grain-free boutique diet, Health Extension turkey and chicken in January 2017. Patient has been otherwise very healthy with no other health issues or concerns.
	Outcome to Date:	Died Euthanized
	Date of Death:	**B6**
Product Information:	**Product Name:**	Health Extension Grain Free Chicken and Turkey Dry Dog Food
	Product Type:	Pet Food
	Lot Number:	
	Package Type:	BAG
	Package Size:	23.5 Pound
	Possess Unopened Product:	No
	Possess Opened Product:	Yes
	Product Use Information:	**First Exposure Date:** 01/01/2017
		Time Interval between Product Use and Adverse Event: 29 Months
		Product Use Stopped After the Onset of the Adverse Event: No
		Other Foods or Yes

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		Products Given to the Animal During This Time Period:	
	Manufacturer /Distributor Information:		
	Purchase Location Information:		
Animal Information:	Name:		
	Type Of Species:	Dog	
	Type Of Breed:	Boxer (German Boxer)	
	Gender:	Male	
	Reproductive Status:	Neutered	
	Weight:	32 Kilogram	
	Age:	B6 Years	
	Assessment of Prior Health:	Excellent	
	Number of Animals Given the Product:	1	
	Number of Animals Reacted:	1	
	Owner Information:	Owner Information provided:	Yes
		Contact:	Name: B6 Phone:
		Address:	B6 United States
	Healthcare Professional Information:	Practice Name:	Tufts Cummings School of Veterinary Medicine
		Contact:	Name: B6 Phone: Email:
		Address:	200 Westboro Road North Grafton Massachusetts 01536 United States
		Practice Name:	Tufts Univeristy - Cummings School of Veterinary Medicine
		Contact:	Name: Lisa Freeman Phone: 508 887 4523
		Type of Veterinarian:	Referred veterinarian
		Permission to Release Records to FDA:	Yes
Sender Information:	Name:		
	Address:	B6 United States	
	Contact:	Phone:	B6

FDA-CVM-FOIA-2019-1704-006305

	Email:	B6
	Permission To Contact Sender:	Yes
	Preferred Method Of Contact:	Email
	Reported to Other Parties:	None
Additional Documents:		
	Attachment:	med rec 1.pdf
	Description:	medical record pt 1
	Type:	Medical Records
	Attachment:	ECG B6 .pdf
	Description:	ECG
	Type:	Medical Records
	Attachment:	IDEXX Results B6
	Description:	lab results
	Type:	Laboratory Report
	Attachment:	med rec 2.pdf
	Description:	medical record pt 2
	Type:	Medical Records
	Attachment:	Diet Hx B6 .pdf
	Description:	diet history
	Type:	Medical Records

FDA-CVM-FOIA-2019-1704-006306

CARDIOLOGY DIET HISTORY FORM

Please answer the following questions about your pet

Pet's name B6 Owner's name B6 Today's date: 5/17/19

1. How would you assess your pet's appetite? (mark the point on the line below that best represents your pet's appetite)

Example: **Poor** ——|—— **Excellent**

Poor ——|—— **Excellent**

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

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

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

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

Food (include specific product and flavor)	Form	Amount	How often?	Dates fed
Nutro Grain Free Chicken, Lentil, & Sweet Potato Adult	*dry*	*1 ½ cup*	*2x/day*	*Jan 2016-present*
85% lean hamburger	*microwaved*	*3 oz*	*1x/week*	*June -Aug 2016*
Pupperoni original beef flavor	*treat*	*½*	*1x/day*	*Sept 2016-present*
Rawhide	*treat*	*6 inch twist*	*1x/week*	*Dec 2018-present*
Natural dog bones	treat	6inch	1 day	JAN – 2019 MAY
Health Extension Grain-free dogfood Chicken + Turkey	dry	3-4 Cup day	Every day	JAN 2018 - 2019 2017

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

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

		Brand/Concentration	Amount per day
Taurine	☐Yes ☑No		
Carnitine	☐Yes ☑No		
Antioxidants	☐Yes ☑No		
Multivitamin	☑Yes ☐No	probiotics 3 days ago	1 per day
Fish oil	☐Yes ☑No		
Coenzyme Q10	☐Yes ☑No		
Other (please list):			
Example: Vitamin C		*Nature's Bounty*	*500 mg tablets – 1 per day*

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

403 kcal/cup

1200-4600 kcal/d

B6

B6 10:40:46 AM

Tufts University
Tufts Cummings School of Vet Med
Cardiology

B6

B6 10:41:20 AM Page 1 of 2

Tufts University
Tufts Cummings School of Vet Med
Cardiology

B6

B6 10:41:20 AM Page 2 of 2

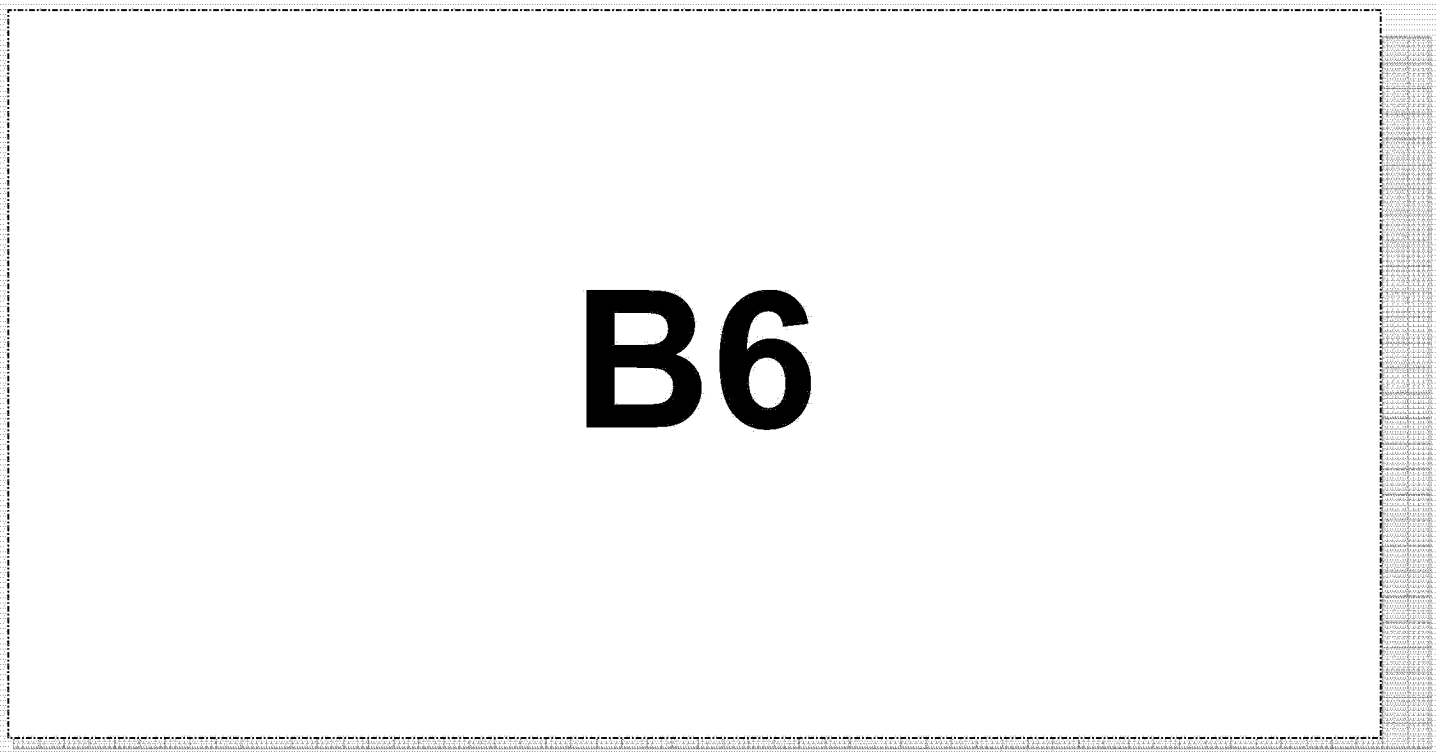
Tufts University
Tufts Cummings School of Vet Med
Cardiology

FDA-CVM-FOIA-2019-1704-006310

B6

B6 10:42:14 AM Page 1 of 2

Tufts University
Tufts Cummings School of Vet Med
Cardiology

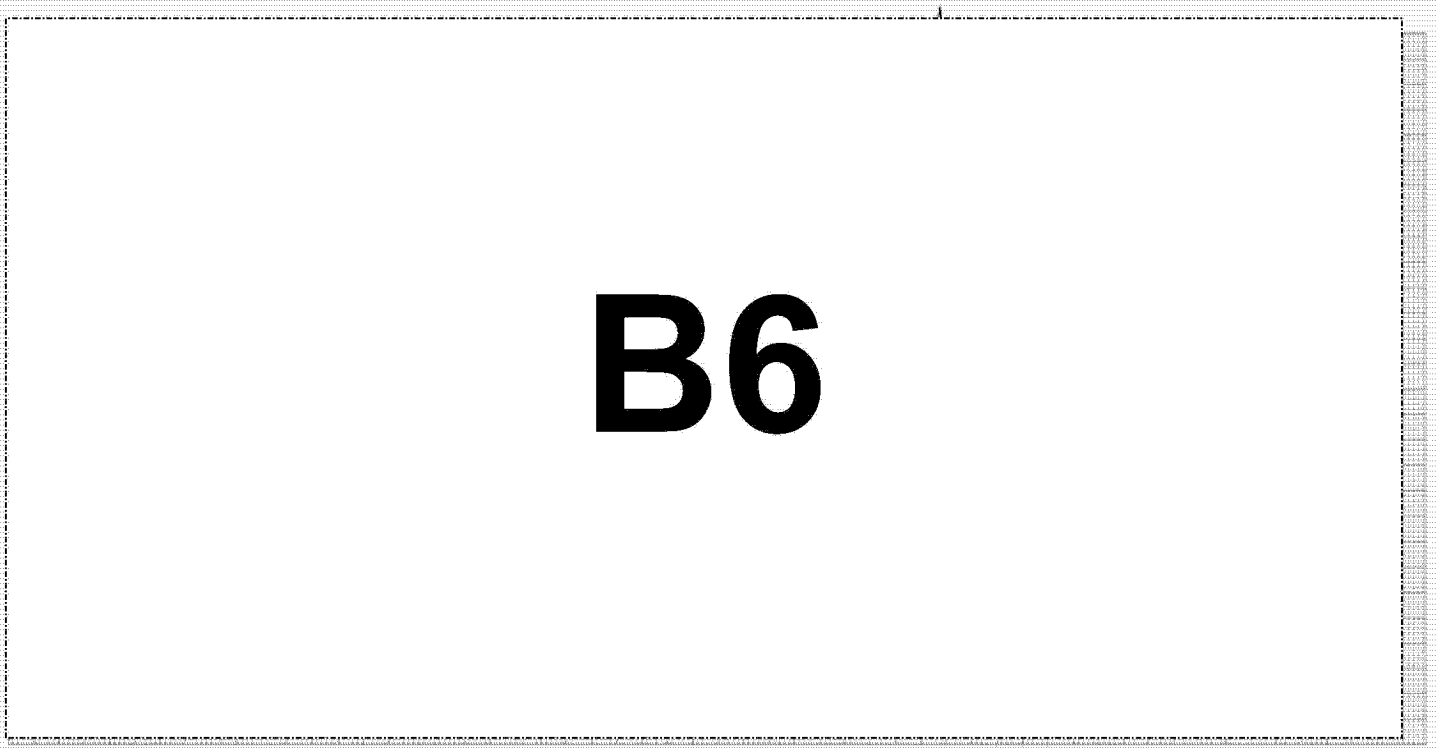


FDA-CVM-FOIA-2019-1704-006311

B6

B6 10:42:14 AM Page 2 of 2

Tufts University
Tufts Cummings School of Vet Med
Cardiology



FDA-CVM-FOIA-2019-1704-006312

IDEXX VetConnect 1-888-433-9987

Client: B6
Patient: B6
Species: CANINE
Breed: BOXER
Gender: MALE NEUTERED
Age: 4Y

Date: B6
Requisition #: 1A
Accession # B6
Ordered by: RUSH

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

Account # B6

CARDIOPET proBNP - CANINE

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

Comments:

B6

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

B6

FDA-CVM-FOIA-2019-1704-006313

B6

Patient Chart

Printed: B6 at 5:44p

CLIENT INFORMATION

Name B6
Address

PATIENT INFORMATION

Name	B6	Species	Canine
Sex		Breed	Boxer
Birthday		Age	4y
ID		Rabies	
Color	Fawn	Weight	72.50 lbs
Reminded	(none)	Codes	

MEDICAL HISTORY

Date	By	Code	Description	Qty (Variance)
B6				

Drug Name
Quantity
Instruction
Pharmacy
Pharm. Loc
Refills

B6

Age: 4y **Weight:** 72.50

History

B6

Presenting complaint: lethargic, drinking water and vomiting it up

Significant medical conditions: Sensitive stomach (vomiting)

NO S/V/D/PU coughs, wheezing last night, polydipsic
Appetite: good
Current Diet: Healthy extension dry food (grain free)
Current Medications: no
Current supplements: probiotic
Heartworm preventative: yes
Up to date on vaccinations? yes
Cardiac Exam
BAR/anxious, BCS 4/9, apparently adequate hydration

FDA-CVM-FOIA-2019-1704-006314

B6

Patient Chart for B6
Da B6 ime: 5:44p

Client: B6
Page: 2

Date	By	Code	Description	Qty (Variance)

B6

M-Mode

B6

Xray Findings
Single lateral reveals mild to moderate cardiomegaly without any evidence of pulmonary edema.
ECG Findings
Rhythm strip reveals ventricular bigeminy (VPCs conducted with left bundle brought branch block morphology consistent with right-sided focus).
Final Diagnosis
1. Tricuspid valve dysplasia: Moderate TR, marked RAE, moderate to severe RVE.
2. Aortic stenosis: Mild LVOT obstruction without any visible obstructive lesion (likely noncontributory).
3. Dilated cardiomyopathy: Rule out nutritional cardiomyopathy versus AVRC related

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B6

Date	By	Code	Description	Qty (Variance)

4. Ventricular bigeminy (right-sided ventricular focus). Rule out arrhythmogenic right ventricular cardiomyopathy.
5. Right-sided congestive heart failure.

Diagnostic Plan

B6

–Submit whole blood taurine level (UC Davis) if patient is not admitted for the nutritional cardiomyopathy study.

Therapeutic rec

B6

Prognosis
–The prognosis is fairly guarded given the combination of problems facing this patient but if the cardiomyopathy is nutritional and a diet change free results in significant improvement the prognosis may be more favorable than it currently seems.
–The significance of the ventricular arrhythmias is currently unknown but on 2 separate occasions patient had ventricular bigeminy which appears to be a relatively stable rhythm

Follow-up
–5-7 days (renal panel, fluid check, EKG)

Performed by: B6

B6 B6 CHECKIN Patient check-in

Age: 4y

SUBJECTIVE SECTION

consult/Echo

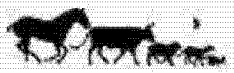
FNOTES
FNOTES
IM154
FNOTES

B6

FDA-CVM-FOIA-2019-1704-006316

Client: B6
Patient:

Research CBC/Chem B6



Tufts Cummings School Of Veterinary Medicine

200 Westboro Road
North Grafton, MA 01536

Name/DOB: B6
Patient ID: 358549
Phone number:
Collection Date: B6 :51 PM
Approval date: :43 PM

Sex: CM
Age: 4
Species: Canine
Breed: Boxer

Provider: Dr. John Rush
Order Location: V320559: Investigation into
Sample ID: 1905170090

CBC, Comprehensive, Sm Animal (Research)

ABLASOTTO		Ref. Range/Males
WBC (ADVIA)		4.40-15.10 K/uL
RBC (Advia)		5.80-8.50 M/uL
Hemoglobin (ADVIA)		13.3-20.5 g/dL
Hematocrit (Advia)		39-55 %
MCV (ADVIA)		64.5-77.5 fL
MCH (ADVIA)		21.3-25.9 pg
CHCM		
MCHC (ADVIA)		31.9-34.3 g/dL
RDW (ADVIA)		11.9-15.2
Platelet Count (Advia)		173-486 K/uL
B6 2:43 PM	B6	
Mean Platelet Volume (Advia)		8.29-13.20 fl
B6 2:13 PM		
Platelet Crit		0.129-0.403 %
05/17/19 2:13 PM		
PDW		
Reticulocyte Count (Advia)		0.20-1.60 %
Absolute Reticulocyte Count (Advia)		14.7-113.7 K/uL
CHr		
MCVr		

Microscopic Exam of Blood Smear (Advia)

ABLASOTTO		Ref. Range/Males
Seg Neuts (%)		43-86 %
Lymphocytes (%)		7-47 %
Monocytes (%)		1-15 %
Eosinophils (%)		0-16 %
Nucleated RBC		0-1 /100 WBC
B6 2:13 PM	B6	
Seg Neutrophils (Abs) Advia		2.800-11.500 K/ul
Lymphs (Abs) Advia		1.00-4.80 K/uL
Mono (Abs) Advia		0.10-1.50 K/uL
Eosinophils (Abs) Advia		0.00-1.40 K/uL
WBC Morphology		

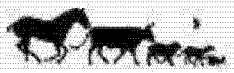
Sample ID: 1905170090/1
This report continues... (Final)

Reviewed by: _____

FDA-CVM-FOIA-2019-1704-006317

Client: B6
Patient:

Research CBC/Chem B6



Tufts Cummings School Of Veterinary Medicine

200 Westboro Road
North Grafton, MA 01536

Name/DOB: B6
Patient ID: 3588349
Phone number:
Collection Date: B6 1:51 PM
Approval date: 2:43 PM

Sex: CM
Age: 4
Species: Canine
Breed: Boxer

Provider: Dr. John Rush
Order Location: V320559: Investigation into
Sample ID: 1905170090

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

		Ref. Range/Males
ABLASOTTO	B6	
Poikilocytosis		

Research Chemistry Profile - Small Animal (Cobas)

		Ref. Range/Males
CSTCYR	B6	
Glucose		67-135 mg/dL
Urea		8-30 mg/dL
Creatinine		0.6-2.0 mg/dL
Phosphorus		2.6-7.2 mg/dL
Calcium 2		9.4-11.3 mg/dL
Magnesium 2+		1.8-3.0 mEq/L
Total Protein		5.5-7.8 g/dL
Albumin		2.8-4.0 g/dL
Globulins		2.3-4.2 g/dL
A/G Ratio		0.7-1.6
Sodium		140-150 mEq/L
Chloride		106-116 mEq/L
Potassium		3.7-5.4 mEq/L
tCO2(Bicarb)		14-28 mEq/L
AGAP		8.0-19.0
NA/K		29-40
Total Bilirubin		0.10-0.30 mg/dL
Alkaline Phosphatase		12-127 U/L
GGT		0-10 U/L
ALT		14-86 U/L
AST		9-54 U/L
Creatine Kinase		22-422 U/L
Cholesterol		82-355 mg/dL
Triglycerides		30-338 mg/dl
Amylase		409-1250 U/L
Osmolality (calculated)		291-315 mmol/L

Sample ID: 1905170090/2
END OF REPORT (Final)

Reviewed by: _____
Page 2

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Cummings
Veterinary Medical Center
AT TUFTS UNIVERSITY

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

Discharge Instructions

Patient
Name: B6
Species: Canine
Fawn Male (Neutered) Boxer
Birthdate: B6

Owner
Name:
Addres B6

Patient ID: B6

Attending Cardiologist:
☑ John E. Rush DVM, MS, DACVIM (Cardiology), DACVECC
B6

Cardiology Resident:
B6

Cardiology Technician:
B6

Student: B6

Admit Date: B6 9:39:22 AM

Diagnoses: Dilated cardiomyopathy R/O ARVC vs diet-related, tricuspid valve dysplasia, active right-sided CHF with ascites, ventricular and supraventricular arrhythmias, cardiopulmonary arrest with cardiopulmonary resuscitation

Clinical Findings:

B6 presented for evaluation and possible enrollment in the diet DCM study, with prior diagnoses of DCM, tricuspid valve dysplasia, right heart failure, and some transient arrhythmias. We found similar findings to Dr. B6 except the dog might have developed atrial fibrillation nd had one approximately 8-10 beat run of ventricular tachycardia during the echocardiogram. The dog was enrolled in the study. After Echo, ECG and blood draw, we started to talk to the owners abou B6 heart disease. Within 2-3 minutes of the owners entering the cardiology room to discuss th findings, B6 ell over, did a short bit of limb paddling, and and then respiratory arrested with no palpable pulses and white mucous membranes. The dog was suspected to have either sustained ventricular tachycardia or ventricular fibrillation but it was clear the dog had respiratory arrest with no pulses before the leads of the ECG could be attached. B6 was rushed to ER where CPR with chest compressions were started, ECG hooked up, and IV cath was placed. ROSC was achieved within minutes, and now there were clear P waves noted. Patient must have had run of pulseless VT or Vfib and once chest compressions begun, was able to convert back to normal rhythm. During CPR B6 was given IV. Started ar B6 Additiona B6 were given until owners elected humane euthanasia. Dog was awake and responsive and visual by the time of euthanasia. The owners did not want to risk that he would collapse and arrest again at home and so they elected euthanasia. Gave permission to get a piece of the heart for

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research purposes. Cremation with return of ashes elected.

Please contact our Cardiology liaison at (508)-887-4696 or email us at cardiovet@tufts.edu for non-emergent questions or concerns.

Please visit our HeartSmart website for more information
http://vet.tufts.edu/heartsmart/

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

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

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

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Case B6 **Owner** B6 **Discharge Instructions**

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

B6

Patient ID: B6
B6 Canine
Years Old Male (Neutered) Boxer
Fawn

Cardiology Appointment Report
ENROLLED IN DCM DIET STUDY

Date: B6

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

B6

Cardiology Resident:
B6

Cardiology Technician:
B6

Student: B6

Presenting Complaint: lethargic and wheezing, polydipsic, bloated stomach, some coughing, referred from B6

Prior echo demonstrated tricuspid valve dysplasia, mild SAS, DCM, R-CHF, and ventricular arrhythmias

Concurrent Diseases: hypersensitive stomach (vomiting, r/o food sensitivity)

General Medical History: Sensitive stomach, otherwise healthy

Diet and Supplements: Health Extension Grain free Chicken and Turkey with whole vegetables and berries, no other supplements

Cardiovascular History:
Prior CHF diagnosis? Y
Prior heart murmur? Y
Prior ATE? N
Prior arrhythmia? Y
Monitoring respiratory rate and effort at home? Not that has been noticed
Cough? Y
Shortness of breath or difficulty breathing? N
Syncope or collapse? N

Sudden onset lameness? N
Exercise intolerance? Y, pants when runs

Current Medications Pertinent to CV System:

B6

Muscle condition:

- ☐ Normal
- ☑ Mild muscle loss to
- ☑ Moderate cachexia over ribs
- ☐ Marked cachexia

Cardiovascular Physical Exam:

Murmur Grade:

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

B6

Jugular vein:

- ☑ Bottom 1/3 of the neck but with strong pulsations
- ☐ Middle 1/3 of the neck
- ☐ 1/2 way up the neck
- ☐ Top 2/3 of the neck

Arterial pulses:

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

Arrhythmia:

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

Gallop:

- ☑ Yes Faint
- ☐ Pronounced

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- ☐ No
- ☐ Intermittent
- ☐ Other:

Pulmonary assessments:

- ☑ Eupneic
- ☐ Mild dyspnea
- ☐ Marked dyspnea
- ☐ Normal BV sounds
- ☐ Pulmonary crackles
- ☐ Wheezes
- ☐ Upper airway stridor

Abdominal exam:

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

Problems:

DCM, TVD, arrhythmias, R-CHF. Possible diet study candidate

Diagnostic plan:

- ☑ Echocardiogram
- ☐ Chemistry profile
- ☑ ECG
- ☑ Renal profile
- ☐ Blood pressure
- ☐ Dialysis profile
- ☐ Thoracic radiographs
- ☑ NT-proBNP
- ☑ Troponin I
- ☐ Other tests: Diet study workup

Echocardiogram Findings:

B6

B6

Radiographic findings:

None taken

Assessment and recommendations:

Dilated cardiomyopathy: r/o nutritional vs AVRC
Discussed diet change and beginning antiarrhythmics, but dog collapsed and owners decided to euthanize.

After echocardiogram was done, owner was brought into cardiology to go over findings. B6 was excited to see owner then, about 2 minutes later, all of a sudden went down, paddling, and respiratory arrested. Suspected to have either sustained ventricular tachycardia or ventricular fibrillation but it was clear the dog had respiratory arrest and was pale white with no pulses before the leads of the ECG could be attached. Rushed to ER where CPR with chest compressions were started, ECG hooked up, and IV cath was placed. ROSC was achieved within minutes, and now there were clear P waves noted. Patient must have had run of pulseless VT or Vfib and once chest compressions begun, was able to convert back to normal rhythm. B6 was given IV. Started B6 Additional B6 were given until owners elected humane euthanasia. Dog was awake and responsive and visual by the time of euthanasia. The owners did not want to risk that he would collapse and arrest again at home and so they elected euthanasia. Gave permission to get a piece of the heart for research purposes. Cremation with return of ashes elected.

Final Diagnosis:
Dilated cardiomyopathy: r/o nutritional vs ARVC vs other cause of DCM
Ventricular arrhythmias and supraventricular arrhythmias, likely atrial fibrillation
Tricuspid valve dysplasia
Cardiopulmonary arrest and CPR during appointment with ROSC and subsequent euthanasia.

Heart Failure Classification Score:
ISACHC Classification:

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

ACVIM Classification:

- ☐ A
- ☐ B1
- ☐ B2
- ☑ C
- ☐ D

M-Mode		
IVSd	B6	cm
LVIDd		cm
LVPWd		cm
IVSs		cm
LVIDs		cm
LVPWs		cm
EDV(Teich)		ml
ESV(Teich)		ml
EF(Teich)		%
%FS		%
SV(Teich)		ml
Ao Diam		cm
LA Diam		cm

FDA-CVM-FOIA-2019-1704-006324

LA/Ao		
Max LA		cm
TAPSE		cm
EPSS		cm
M-Mode Normalized		
IVSdN		(0.290 - 0.520)
LVIDdN		(1.350 - 1.730)
LVPWdN		(0.330 - 0.530)
IVSsN		(0.430 - 0.710) !
LVIDsN		(0.790 - 1.140) !
LVPWsN		(0.530 - 0.780)
Ao Diam N		(0.680 - 0.890) !
LA Diam N		(0.640 - 0.900) !
2D		
SA LA		cm
Ao Diam		cm
SA LA / Ao Diam		
IVSd		cm
LVIDd		cm
LVPWd		cm
EDV(Teich)		ml
IVSs		cm
LVIDs		cm
LVPWs		cm
ESV(Teich)		ml
EF(Teich)		%
%FS		%
SV(Teich)		ml
LV Majpr		cm
LV Minor		cm
Sphericity Index		
LVLd A4C		cm
LVEDV MOD A4C		ml
LVLs A4C		cm
LVESV MOD A4C		ml
LVEF MOD A4C		%
SV MOD A4C		ml
R-R		ms
HR		BPM
Doppler		
MR Vmax		m/s
MR maxPG		mmHg
E'		m/s
S'		m/s
AV Vmax		m/s
AV maxPG		mmHg
PV Vmax		m/s

B6

FDA-CVM-FOIA-2019-1704-006325

PV maxPG
TR Vmax
TR maxPG

B6

mmHg
m/s
mmHg

FDA-CVM-FOIA-2019-1704-006326

From: Guag, Jake </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E13AD3C7A7C5484C80E1D9CF9D1A15DE-JGUAG>
To: Rotstein, David; Peloquin, Sarah; Jones, Jennifer L
Sent: 5/22/2019 3:47:38 PM
Subject: RE: Rapid necropsy for Vet-LIRN's Case Investigation into Canine Dilated Cardiomyopathy (DCM) 2018

Thanks!
FYI. I emailed Jen will contact when she returns.
Jake

From: Rotstein, David
Sent: Wednesday, May 22, 2019 11:46 AM
To: Peloquin, Sarah <Sarah.Peloquin@fda.hhs.gov>; Guag, Jake <Jake.Guag@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: RE: Rapid necropsy for Vet-LIRN's Case Investigation into Canine Dilated Cardiomyopathy (DCM) 2018

Fantastic!!!

From: Peloquin, Sarah <Sarah.Peloquin@fda.hhs.gov>
Date: May 22, 2019 at 11:07:09 AM EDT
To: Rotstein, David <David.Rotstein@fda.hhs.gov>, Guag, Jake <Jake.Guag@fda.hhs.gov>, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: RE: Rapid necropsy for Vet-LIRN's Case Investigation into Canine Dilated Cardiomyopathy (DCM) 2018

Found it—I was looking for the owner's last name. Thanks!

Sarah Peloquin, DVM
Veterinary Medical Officer
tel: 240-402-1218

From: Rotstein, David
Sent: Wednesday, May 22, 2019 10:58 AM
To: Guag, Jake <Jake.Guag@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Peloquin, Sarah <Sarah.Peloquin@fda.hhs.gov>
Subject: RE: Rapid necropsy for Vet-LIRN's Case Investigation into Canine Dilated Cardiomyopathy (DCM) 2018

I thought that I had forwarded this one on already-but here you go

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

U.S. FOOD & DRUG ADMINISTRATION

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From: Guag, Jake
Sent: Wednesday, May 22, 2019 10:54 AM
To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Peloquin, Sarah <Sarah.Peloquin@fda.hhs.gov>
Subject: RE: Rapid necropsy for Vet-LIRN's Case Investigation into Canine Dilated Cardiomyopathy (DCM) 2018

Dave,
Do you have a report for B6 ? Jen is B6

Jake

From: B6
Sent: Wednesday, May 22, 2019 10:47 AM
To: Guag, Jake <Jake.Guag@fda.hhs.gov>
Subject: Rapid necropsy for Vet-LIRN's Case Investigation into Canine Dilated Cardiomyopathy (DCM) 2018

Good morning,

I recently submitted a pet food report via the FDA Safety Reporting Portal on a deceased patient named B6 B6 was a 4yo CM Boxer with severe DCM who had been eating a grain-free dog food for the last two years. Dr. Lisa Freeman (PI for on-going DCM study here at Tufts) would like to submit collected samples (heart) to the FDA for further analysis. The sample was promptly placed in 10% NBF approximately 30 minutes post mortem on B6 Would it be possible to have boxes sent to us for sample submission?

Thank you,

B6

From: B6
To: Jones, Jennifer L
Sent: 5/30/2019 4:57:23 PM
Subject: RE: Rapid necropsy for Vet-LIRN's Case Investigation into Canine Dilated Cardiomyopathy (DCM) 2018

Hi Jen,

I apologize for the delay in getting back to you. The container is a larger formalin container that is 6 inches tall and about 5.5 inches wide. The container is not a screw top so we were wondering if a more secure container could be sent as well. The weight of the container w/ with the sample and formalin is 1.23kg.

We also recently collected a heart sample from a feline who died of DCM (2yo CM DSH). I will be submitting the report shortly. We can send a portion of heart as well if you'd like. That container is a screw top and weighs 0.77kg and measures about 5 inches tall and 4.5 inches wide.

Thank you,
B6

From: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Sent: Thursday, May 23, 2019 12:34 PM
To: B6
Cc: Guag, Jake <Jake.Guag@fda.hhs.gov>; Peloquin, Sarah <Sarah.Peloquin@fda.hhs.gov>
Subject: RE: Rapid necropsy for Vet-LIRN's Case Investigation into Canine Dilated Cardiomyopathy (DCM) 2018

Hi B6
Thank you for the updates and collecting the samples. How large is the container and how much does it weigh? We will send you a box with a prepaid shipping label.
Thank you kindly,
Jen

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

From: B6
Sent: Wednesday, May 22, 2019 11:31 AM
To: Guag, Jake <Jake.Guag@fda.hhs.gov>
Cc: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: RE: Rapid necropsy for Vet-LIRN's Case Investigation into Canine Dilated Cardiomyopathy (DCM) 2018

Hi Jake,

Yes, we can hold onto the samples until instructed otherwise.

Thank you,

B6

From: Guag, Jake <Jake.Guag@fda.hhs.gov>
Sent: Wednesday, May 22, 2019 11:16 AM
To: B6
Cc: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: RE: Rapid necropsy for Vet-LIRN's Case Investigation into Canine Dilated Cardiomyopathy (DCM) 2018

Dear B6
Thank you for the contacting us. Could you please hold the samples?
Dr. Jones is a person in charge for the case and B6 She will contact you when she returns.

Thanks
Jake

From: B6
Sent: Wednesday, May 22, 2019 10:47 AM
To: Guag, Jake <Jake.Guag@fda.hhs.gov>
Subject: Rapid necropsy for Vet-LIRN's Case Investigation into Canine Dilated Cardiomyopathy (DCM) 2018

Good morning,

I recently submitted a pet food report via the FDA Safety Reporting Portal on a deceased patient named B6 B6 was a 4yo CM Boxer with severe DCM who had been eating a grain-free dog food for the last two years. Dr. Lisa Freeman (PI for on-going DCM study here at Tufts) would like to submit collected samples (heart) to the FDA for further analysis. The sample was promptly placed in 10% NBF approximately 30 minutes post mortem on B6 Would it be possible to have boxes sent to us for sample submission?

Thank you,

B6

Cummings
Veterinary Medical Center
AT TUFTS UNIVERSITY

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

Discharge Instructions

Patient
Name: B6
Species: Canine
Gold Male (Neutered) Golden Retriever
Birthdate: B6

Owner
Name: B6
Address: B6

Patient ID: B6

Attending Cardiologist:
John E. Rush DVM, MS, DACVIM (Cardiology), DACVECC
B6

Cardiology Resident:
B6

Cardiology Technician:
B6

Student: B6 V'19

Admit Date: B6 10:05:33 AM
Discharge Date: B6

Diagnoses:
1. Decreased contractile function and mildly enlarged heart
2. Low normal whole blood taurine levels

Clinical Findings:
Thank you for bringing B6 to Tufts to screen him for heart disease related to being on a grain free diet. Labwork from your referring veterinarian showed that B6 taurine levels were lower than we would like. On physical exam there were no abnormalities while listening to his heart, and he had nice strong pulses.

B6 echocardiogram today showed that his heart is not normal for a 3 year old golden retriever. His contractile function is decreased and his heart is mildly enlarged. He also has a small leak at his mitral and tricuspid valves. His EKG showed a normal heart rhythm.

We have enrolled B6 in our DCM study that is looking at heart disease associated with grain free, boutique and exotic diets. We have submitted bloodwork for the study and will inform you of the results. At this time we would like to start B6 on taurine supplementation, but do not need to start him on any heart medications.

Monitoring at Home:
B6 is very stable today and is not close to heart failure. However, please monitor for him for any weakness or collapse, a reduction in appetite, cough or distension of the belly. If you notice any abnormalities we would like to see him for a recheck exam.

If you ever have any concerns, please call or have B6 evaluated by a veterinarian. Our emergency clinic is open 24 hours

a day.

Diet Suggestions:
Please continue feeding B6 the Purina Pro Plan diet.

Recommended Medications:
1. Taurine Supplement - Give 1000mg by mouth every 12 hours.
(brands we recommend include TwinLab, Swanson, NOW and GNC brands)
Taurine is an amino acid that is shown to be necessary for appropriate heart health. Supplemening Taurine, in some cases, has lead to reduction in heart enlargement and an increase in heart health in dogs with DCM.
NEXT DOSE DUE: tonight or tomorrow morning

Recheck Visits: We would like to see B6 back for a recheck appointment in **3 months.** At this visit we will want to recheck an echocardiogram and bloodwork.

Thank you for entrusting us with B6 care, he was a wonderful patient! Please contact our Cardiology liaison at (508)-887-4696 or email us at **cardiovet@tufts.edu** for scheduling and non-emergent questions or concerns.

Please visit our HeartSmart website for more information
http://vet.tufts.edu/heartsmart/

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

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

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

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FDA-CVM-FOIA-2019-1704-006332

Amino Acid Laboratory Sample Submission Form

Amino Acid Laboratory
1089 Veterinary Medicine Drive
Davis, Ca 95616
Telephone: 530-752-5058, **Fax:** 530-752-4698
Email: ucd.aminoacid.lab@ucdavis.edu
www.vetmed.ucdavis.edu/labs/amino-acid-laboratory

Veterinarian Contact: B6

Clinic/Company Name: B6

Address: B6

Email:

Telephone: B6 **Fax:** B6

Billing Contact: B6 **Email:** B6

Patient Name: B6 **Species:** CANINE

Breed: GOLDEN RETRIEVER **Owner's Name:** B6

Current Diet : B6 - 10/1/18 - ZIGNATURE TROUT + SALMON
10/1/18 - 10/12/18 NATURES VARIETY INSTINCT RAW BEEF + BARLEY
10/12/18 - NOW - PURINA PRO PLAN SPORT 30/20

Sample type: Plasma Whole Blood Urine Food Other

Test: Taurine Complete Amino Acids Other:

Taurine Results (lab use only)

Plasma: **Whole Blood:** **Urine:** **Food:**

B6 nmol/mL

FDA-CVM-FOIA-2019-1704-006333

From: Rotstein, David
To: Carey, Lauren; Ceric, Olgica; Glover, Mark; Jones, Jennifer L; Nemser, Sarah; Palmer, Lee Anne; Peloquin, Sarah; Queen, Jackie L; Rotstein, David
Subject: couple more related DCM- PFRs-FW: Zignature trout & salmon dry: Lisa Freeman - EON-390034 + Pure VitaVenison and Red Lentisl
Date: Monday, June 10, 2019 12:39:19 PM
Attachments: 2067994-report.pdf
2067994-attachments.zip
PureVita Venison Red Lentils Grain-Free Dry Dog Food [B6] - EON-390031.msg
PureVita Venison Red Lentils Grain-Free Dry Dog Food [B6] EON-386301.msg
Zignature trout salmon dry Lisa Freeman - EON-370715.msg
image001.png

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

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From: Related PFR Event <pfrsignificantactivitycreation@fda.hhs.gov>
Sent: Monday, June 10, 2019 11:13 AM
To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Cleary, Michael * <Michael.Cleary@fda.hhs.gov>; HQ Pet Food Report Notification <HQPetFoodReportNotification@fda.hhs.gov>; [B6]
Subject: Zignature trout & salmon dry: Lisa Freeman - EON-390034

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

A "PDF" report by name "2067994-report.pdf" is attached to this email notification for your reference. Please note that all documents received in the report are compressed into a zip file by name "2067994-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-390034
ICSR #: 2067994
EON Title: Related PFR Event created for Zignature trout & salmon dry; 2067994

AE Date	11/07/2018	**Number Fed/Exposed**	3
Best By Date		**Number Reacted**	2
Animal Species	Dog	**Outcome to Date**	Better/Improved/Recovering
Breed	Retriever - Labrador		
Age	3 Years		
District Involved	PFR-New England DO		

Product information
Individual Case Safety Report Number: 2067994
Product Group: Pet Food
Product Name: Zignature trout & salmon dry

Description: Older housemate diagnosed with DCM and CHF. Screening B6 because he has been eating the same diet. Does not have clearcut DCM on echo but has reduced cardiac contractility. Taurine pending and owner has changed diet and started taurine supplementation
Submission Type: Followup
Report Type: Adverse Event (a symptom, reaction or disease associated with the product)
Outcome of reaction/event at the time of last observation: Better/Improved/Recovering
Number of Animals Treated With Product: 3
Number of Animals Reacted With Product: 2

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

This report is linked to:
Initial EON Event Key: EON-370715
Initial ICSR: 2058683

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

Owner information
B6
B6 USA

To view this Related PFR Event, please click the link below:
https://eon.fda.gov/eon//browse/EON-390034

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

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

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

Sent: 4/29/2019 8:12:57 PM

Subject: PureVita Venison & Red Lentils Grain-Free Dry Dog Food: B6 - EON-386301

Attachments: 2066404-report.pdf; 2066404-attachments.zip

A PFR Report has been received and PFR Event [EON-386301] has been created in the EON System.

A "PDF" report by name "2066404-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 "2066404-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-386301
ICSR #: 2066404
EON Title: PFR Event created for PureVita Venison & Red Lentils Grain-Free Dry Dog Food, NutriSource Adult Chicken and Rice formula; 2066404

AE Date	03/01/2019	**Number Fed/Exposed**	1
Best By Date		**Number Reacted**	1
Animal Species	Dog	**Outcome to Date**	Stable
Breed	American Pit Bull Terrier		
Age	B6 Years		
District Involved	PFR-New England DO		

Product information
Individual Case Safety Report Number: 2066404
Product Group: Pet Food
Product Name: PureVita Venison & Red Lentils Grain-Free Dry Dog Food, NutriSource Adult Chicken and Rice formula
Description: Patient presented to rDVM in March of 2019 for acute onset of a non-productive cough, exercise intolerance and decreased appetite. Patient was diagnosed in CHF secondary to DCM - suspect diet-related. Patient was placed on B6 taurine. Taurine levels prior to supplementation was WNL.

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

Product Name	Lot Number or ID	Best By Date
NutriSource Adult Chicken and Rice formula		
PureVita Venison & Red Lentils Grain-Free Dry Dog Food		

Sender information

B6

USA

Owner information

B6 USA

To view this PFR Event, please click the link below:
https://eon.fda.gov/eon//browse/EON-386301

To view the PFR Event Report, please click the link below:
https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jspa?decorator=none&e=0&issueType=12&issueId=403429

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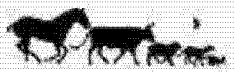
Report Details - EON-386301		
ICSR:	2066404	
Type Of Submission:	Initial	
Report Version:	FPSR.FDA.PETF.V.V1	
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)	
Reporting Type:	Voluntary	
Report Submission Date:	2019-04-29 16:02:28 EDT	
Reported Problem:	**Problem Description:**	Patient presented to rDVM in March of 2019 for acute onset of a non-productive cough, exercise intolerance and decreased appetite. Patient was diagnosed in CHF secondary to DCM - suspect diet-related. Patient was placed on B6 B6 and taurine. Taurine levels prior to supplementation was WNL.
	Date Problem Started:	03/01/2019
	Concurrent Medical Problem:	No
	Outcome to Date:	Stable
Product Information:	**Product Name:**	NutriSource Adult Chicken and Rice formula
	Product Type:	Pet Food
	Lot Number:	
	UPC:	9B15P 18581
	Package Type:	BAG
	Package Size:	30 Pound
	Possess Opened Product:	Yes
	Product Use Information:	
	Manufacturer /Distributor Information:	
	Purchase Location Information:	
	Product Name:	PureVita Venison & Red Lentils Grain-Free Dry Dog Food
	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:	American Pit Bull Terrier
	Gender:	Male
	Reproductive Status:	Neutered
	Weight:	32 Kilogram
	Age:	B6 Years
	Assessment of Prior Health:	Excellent
	Number of Animals Given the Product:	1
	Number of Animals Reacted:	1
	Owner Information:	**Owner** Yes

FDA-CVM-FOIA-2019-1704-006339

		Information provided:	
		Contact:	Name: B6
			Phone: B6
			Email: B6
		Address:	B6 United States
	Healthcare Professional Information:	Practice Name:	Tufts Cummings School of Veterinary Medicine
		Contact:	Name: B6
			Phone: B6
			Email: B6
		Address:	200 Westboro Road North Grafton Massachusetts 01536 United States
		Practice Name:	Tufts University
		Contact:	Name: Lisa Freeman
			Phone: (508) 887-4523
			Email: lisa.freeman@tufts.edu
		Type of Veterinarian:	Referred veterinarian
		Permission to Release Records to FDA:	Yes
Sender Information:	Name: B6		
	Address:		200 Westboro Road North Grafton Massachusetts 01536 United States
	Contact:	Phone:	B6
		Email:	B6
	Permission To Contact Sender:		Yes
	Preferred Method Of Contact:		Email
	Reported to Other Parties:		None
Additional Documents:			
	Attachment:		Med records pt 2.pdf
	Description:		Medical Records
	Type:		Medical Records
	Attachment:		Med records pt 1 4-29-2019.pdf
	Description:		Medical Records
	Type:		Medical Records

Client: B6
Patient:

Research cbc/chem 4/26/2019



Tufts Cummings School Of Veterinary Medicine

200 Westboro Road
North Grafton, MA 01536

Name/DOB: B6
Patient ID: B6
Phone number:
Collection Date: 4/26/2019 4:57 PM
Approval date: 4/26/2019 5:57 PM

Sex: CM
Age: 2
Species: Canine
Breed: Pit Bull

Provider: Dr. Lisa Freeman
Order Location: Foster Hospital for Small Animals
Sample ID: B6

CBC, Comprehensive, Sm Animal (Research)

SMACHUNSKI

			Ref. Range/Males
WBC (ADVIA)		B6	4.40-15.10 K/uL
RBC (Advia)			5.80-8.50 M/uL
Hemoglobin (ADVIA)			13.3-20.5 g/dL
Hematocrit (Advia)			39-55 %
MCV (ADVIA)			64.5-77.5 fL
MCH (ADVIA)			21.3-25.9 pg
CHCM			
MCHC (ADVIA)			31.9-34.3 g/dL
RDW (ADVIA)	L		11.9-15.2
Platelet Count (Advia)			173-486 K/uL
04/26/19 5:54 PM		B6	
Mean Platelet Volume (Advia)		B6	8.29-13.20 fl
04/26/19 5:30 PM		B6	
Platelet Crit		B6	0.129-0.403 %
04/26/19 5:30 PM		B6	
PDW		B6	
Reticulocyte Count (Advia)			0.20-1.60 %
Absolute Reticulocyte Count (Advia)			14.7-113.7 K/uL
CHr		B6	
MCVr			

Microscopic Exam of Blood Smear (Advia)

SMACHUNSKI

			Ref. Range/Males
Seg Neuts (%)		B6	43-86 %
Lymphocytes (%)	L		7-47 %
Monocytes (%)			1-15 %
Eosinophils (%)			0-16 %
Seg Neutrophils (Abs) Advia			2.800-11.500 K/ul
Lymphs (Abs) Advia	L	B6	1.00-4.80 K/uL
Mono (Abs) Advia			0.10-1.50 K/uL
Eosinophils (Abs) Advia			0.00-1.40 K/uL
WBC Morphology		B6	
RBC Morphology			

Research Chemistry Profile - Small Animal (Cobas)

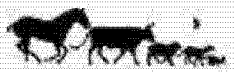
Sample ID: 1904260155/1
This report continues... (Final)

Reviewed by: _____

FDA-CVM-FOIA-2019-1704-006341

Client:
Patient: **B6**

Research cbc/chem 4/26/2019



Tufts Cummings School Of Veterinary Medicine

200 Westboro Road
North Grafton, MA 01536

Name/DOB: B6
Patient ID: B6
Phone number:
Collection Date: 4/26/2019 4:57 PM
Approval date: 4/26/2019 5:57 PM

Sex: CM
Age: 2
Species: Canine
Breed: Pit Bull

Provider: Dr. Lisa Freeman
Order Location: Foster Hospital for Small Animals
Sample ID: B6

Research Chemistry Profile - Small Animal (Cobas) (cont'd)

SMACHUNSKI	B6	Ref. Range/Males
Glucose		67-135 mg/dL
Urea		8-30 mg/dL
Creatinine		0.6-2.0 mg/dL
Phosphorus		2.6-7.2 mg/dL
Calcium 2		9.4-11.3 mg/dL
Magnesium 2+		1.8-3.0 mEq/L
Total Protein		5.5-7.8 g/dL
Albumin		2.8-4.0 g/dL
Globulins		2.3-4.2 g/dL
A/G Ratio		0.7-1.6
Sodium		140-150 mEq/L
Chloride		106-116 mEq/L
Potassium		3.7-5.4 mEq/L
tCO2(Bicarb)		14-28 mEq/L
AGAP		8.0-19.0
NA/K		29-40
Total Bilirubin		0.10-0.30 mg/dL
Alkaline Phosphatase		12-127 U/L
GGT		0-10 U/L
ALT		14-86 U/L
AST		9-54 U/L
Creatine Kinase		22-422 U/L
Cholesterol		82-355 mg/dL
Triglycerides		30-338 mg/dl
Amylase		409-1250 U/L
Osmolality (calculated)		291-315 mmol/L

Sample ID: 19042601552
END OF REPORT (Final)

Reviewed by: _____
Page 2

FDA-CVM-FOIA-2019-1704-006342

Client: B6
Patient:

Idexx NT-proBNP 4/26/2019

IDEXX Reference Laboratories

Client: B6 Patient: B6

IDEXX VetConnect 1-888-433-9987

Client: B6
Patient: B6
Species: CANINE
Breed: AMERICAN_PIT_BU
Gender: MALE NEUTERED
Age: 2Y

Date: 04/26/2019
Requisition #: N/A
Accession: B6
Ordered by: B6

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

Account: B6

CARDIOPET proBNP - CANINE

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

Comments

B6

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

Page 1 of 1

FDA-CVM-FOIA-2019-1704-006343

Client: B6
Patient:

Diet Hx 4/26/2019

B6

CARDIOLOGY DIET HISTORY FORM

Please answer the following questions about your pet

Pet's name: B6 Owner's name: B6 Today's date: B6

1. How would you assess your pet's appetite? (mark the point on the line below that best represents your pet's appetite)

Example: Poor ——— | ——— Excellent

Poor ——— | ——— Excellent

2. Have you noticed a change in your pet's appetite over the last 1-2 weeks? (check all that apply)
☐Eats about the same amount as usual ☐Eats less than usual ☐Eats more than usual
☐Seems to prefer different foods than usual ☒Other I have reduced his intake because of switching to grain foods

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

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

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

Food (include specific product and flavor)	Form	Amount	How often?	Dates fed
Nutro Grain Free Chicken, Lentil, & Sweet Potato Adult	*dry*	*1 ½ cup*	*2x/day*	*Jan 2016-present*
85% lean hamburger	*microwaved*	*3 oz*	*1x/week*	*June -Aug 2016*
Pupperoni original beef flavor	*treat*	*½*	*1x/day*	*Sept 2016-present*
Rawhide	*treat*	*6 inch twist*	*1x/week*	*Dec 2018-present*
Nutro Source Purevita Venison + Red Lentils	Dry	2 cups	2 x day	Aug 2018 - Mar 2019
Natural Balance Venison + Sweet Potato	Can	3 tbls	2 x day	Aug 2018 - Mar 2019
Natural Balance venison + Sweet Potato	Treat	6 treats/day	6 a day	Aug 2018 - Mar 2019
Natural Balance Sweet Potato + Fish	Treat	11 same	6 a day	Aug 2018 - Mar 2019
Nutro Source Chicken + Rice Formula	Dry	1.5 cups	2 x day	Mar 2019 - present
" "	Can	1.5 tbls	2 x day	Mar 2019 - present
Pupperoni 2oz Treats	treat	1/2	1 x day	Mar 2019 - present
Milk Bone Small Marrco	Treat	4	1 x day	Mar 2019 - present
Pig ears	Treat	1	1 x week	Mar 2019 - present
Femur & Knuckle Bone	Treat	1	1 x month	Mar 2019 - present

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

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

		Brand/Concentration	Amount per day
Taurine	☒Yes ☐No	CNC	2000 mg
Carnitine	☐Yes ☐No		
Antioxidants	☐Yes ☐No		
Multivitamin	☐Yes ☐No		
Fish oil	☐Yes ☐No		
Coenzyme Q10	☐Yes ☐No		
Other (please list):			
Example: Vitamin C		*Nature's Bounty*	*500 mg tablets – 1 per day*

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

FDA-CVM-FOIA-2019-1704-006344

Dear Doctors,

Please see the accompanying cardiology report for our mutual patient. Thank you for the referral and your continued support of B6. Please contact me if you need any more information regarding this patient. As I am only at B6 once to twice per month, email (see below) is the best mode of communication for me.

B6 DVM, DACVIM (Cardiology)
Cardiologist, B6

B6

Email: B6
Website: B6

Consulting Cardiologist: B6 DVM, DACVIM (Cardiology)

FDA-CVM-FOIA-2019-1704-006345

Client: B6
Patient: B6 (2yo MN pit bull)

Examination Date: B6

CARDIOLOGY EXAMINATION

HISTORY: Cough x 2 weeks, decreased appetite. Admitted yesterday for monitoring/echo. Started on B6 (rDVM) B6 aurine drawn/not yet submitted. ECG 100 bpm NSF. TFAST suspect DCM. rDVM rads in record.

MEDICATIONS:

DIET: grain free pork and pea

WEIGHT: 27 kg

Consulting Cardiologist: B6 DVM, DACVIM (Cardiology)

FDA-CVM-FOIA-2019-1704-006346

rDVM Cardiology report B6

B6

ECHOCARDIOGRAPHIC DIAGNOSIS:
1. Dilated cardiomyopathy (severe left atrial and left ventricular enlargement; moderate right atrial and right ventricular enlargement; severely reduced left ventricular wall motion)
2. Mild mitral and trace tricuspid regurgitations – likely from annular stretch secondary to #1

RADIOGRAPHIC FINDINGS: 2 view thorax, rDVM: The cardiac silhouette is severely and globally enlarged. The pulmonary vasculature is moderately dilated. There is a moderate to severe bilateral caudodorsal interstitial pattern consistent with congestive heart failure.

**** FINAL REPORT ******
FINAL DIAGNOSIS:
1. Dilated cardiomyopathy (severe left atrial and left ventricular enlargement; moderate right atrial and right ventricular enlargement; severely reduced left ventricular wall motion) – R/O nutritional (taurine deficiency or secondary to grain free/pork based diet) vs familial vs hypothyroidism
2. Mild mitral and trace tricuspid regurgitations – likely from annular stretch secondary to #1
3. Congestive heart failure (pulmonary edema) B6

B6

FOLLOW UP SCHEDULE:
10-14 days for recheck exam, renal panel, CXR.
3 months for echocardiogram

*There is a chance that some of B6 cardiac disease may be reversible if this is secondary to nutritional cause. However, even some patients with diet-induced DCM can have irreversible cardiac changes. Thus, prognosis is variable and will be determined based on followup testing.

Consulting Cardiologist: B6 DVM, DACVIM (Cardiology)

Consulting Cardiologist: B6 DVM, DACVIM (Cardiology)

FDA-CVM-FOIA-2019-1704-006347

Consulting Cardiologist: B6 , DVM, DACVIM (Cardiology)

FDA-CVM-FOIA-2019-1704-006348

Client: B6
Patient:

B4 **thyroid panel 3/14/2019**

B4

B6
B6

Accession No: B6
Received 03/14/2019
Reported 03/16/2019 04:32 AM

Doctor: B6 DVM

Owner	Pet Name	Species	Breed	Sex	Pet Age	Chart#
B6	B6	Canine	Other	CM	3Y	B4

Test Requested	Results	Reference Range	Units
T4			
T4	B6	0.8-3.5	µg/dL
FREE T4 BY EQUILIBRIUM DIALYSIS			
Free T4 (Dialysis)		8-40	pmol/L
TSH			
TSH		0 - 0.60	ng/mL

While many dogs with primary hypothyroidism have elevated cTSH concentrations, up to one third of affected dogs have normal or low cTSH concentrations, for reasons that are unclear. In those cases where TSH concentrations are normal and hypothyroidism is still strongly suspected, consider performing a free T4 and/or thyroglobulin autoantibodies.

FDA-CVM-FOIA-2019-1704-006349

Client:
Patient: **B6**

Vitals Results

4/26/2019 2:52:48 PM	Weight (kg)	32.0000

FDA-CVM-FOIA-2019-1704-006350

Medical Record Image

FDA-CVM-FOIA-2019-1704-006351

B6

FDA-CVM-FOIA-2019-1704-006352

FDA-CVM-FOIA-2019-1704-006353

Client: B6
Patient:

ECG from Cardio

B6 B6 4:27:10 PM

Tufts University
Tufts Cummings School of Vet Med
Cardiology

FDA-CVM-FOIA-2019-1704-006354

Client: B6
Patient:

ECG from Cardio

B6 B6 4:27:45 PM

Tufts University
Tufts Cummings School of Vet Med
Cardiology

FDA-CVM-FOIA-2019-1704-006355

Client: B6
Patient:

ECG from Cardio

B6 B6 4:28:13 PM

Tufts University
Tufts Cummings School of Vet Med
Cardiology

FDA-CVM-FOIA-2019-1704-006356

Cummings
Veterinary Medical Center
AT TUFTS UNIVERSITY

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

Discharge Instructions

Patient
Name: B6
Species: Canine
Mahogany Male (Neutered) Pit Bull
Birthdate: B6

Owner
Name: B6
Address: B6

Patient ID: B6

Attending Cardiologist:
☐ John E. Rush DVM, MS, DACVIM (Cardiology), DACVECC
B6

Cardiology Resident:
B6

Cardiology Technician:
B6

Student: B6 V'19

Admit Date: 4/26/2019 2:17:55 PM
Discharge Date: 4/26/2019

Diagnoses: Dilated cardiomyopathy (DCM) with history of congestive heart failure

Case summary:
B6 was diagnosed with a heart muscle disease called dilated cardiomyopathy (DCM) in March. He was started on several cardiac medications at that time as well as a change in diet since he had been on a grain-free diet. Since then, he has shown improvement in his appetite and weight; however, he is still coughing and experiencing some exercise intolerance. On physical examination today, he is very bright and alert. We could hear a small Grade II/VI heart murmur that was noted previously.

We performed an echocardiogram (ultrasound of the heart) which confirmed B6 still has DCM. This disease is characterized by thinning of the walls of the heart, reduced cardiac pump function, and enlargement of the upper chambers of the heart. B6 has a leak at his mitral valve (valve between his left atrium and ventricle) which is the cause of his murmur. His mitral valve is slightly thickened as well so he could also have a component of a congenital mitral valve disease. The medications he is currently on are the same medications we would be using to treat any mitral valve disease. An ECG was performed to evaluate his heart rhythym which showed normal rhythym today. We also took chest x-rays to determine if he still has evidence of fluid in his lungs that could be contributing to his cough. His x-rays are improved compared to those taken previously by his primary care veterinarian but his lungs still have residual fluid. Because of this, we made adjustments to his medications as detailed below. Finally, we also collected blood to ensure his kidneys are tolerating his cardiac medications and for cardiac biomarkers useful for monitoring his disease progression and for the research study. We will call you with the results of this bloodwork.

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Monitoring at home:

- We would like you to monitor your dog's breathing rate and effort at home, ideally during sleep or at a time of rest. The doses of drugs will be adjusted based on the breathing rate and effort.
- In general, most dogs with heart failure that is well controlled have a breathing rate at rest of less than 35 to 40 breaths per minute. In addition, the breathing effort, noted by the amount of belly wall motion used for each breath, is fairly minimal if heart failure is controlled.
- An increase in breathing rate or effort will usually mean that you should give an extra dose of B4 If difficulty breathing is not improved by within 30-60 minutes after giving extra B4 then we recommend that a recheck exam be scheduled and/or that your dog be evaluated by an emergency clinic.
- There are instructions for monitoring breathing, and a form to help keep track of breathing rate and drug doses, on the Tufts HeartSmart web site (http://vet.tufts.edu/heartsmart/at-home-monitoring/).
- We also want you to watch for weakness or collapse, a reduction in appetite, worsening cough, or distention of the belly as these findings indicate that we should do a recheck examination.
- If you have any concerns, please call or have your dog evaluated by a veterinarian. Our emergency clinic is open 24 hours/day.

Recommended Medications:

B6

Diet suggestions:

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

Your dog's usual diet may also have more sodium than recommended – we want him/her to continue to eat his/her normal diet for the first 7 to 14 days so we can make sure he is tolerating medications well, but after that time we would recommend slowly introducing one of the lower sodium diets on the HeartSmart list (25% of the new diet and 75% old diet for 2-3 days, then 50:50, etc.). Hopefully you can find a diet on the list that your dog likes to eat. Alternatively, if you are attached to the current diet you can research the amount of sodium in the diet to ensure that the sodium content is similar to those on the list.

- The FDA is currently investigating an apparent association between diet and a type of heart disease called dilated cardiomyopathy. The exact cause is still unclear, but it appears to be associated with boutique diets and those

containing exotic ingredient or are grain-free. Therefore, we are currently recommending that dogs do not eat these types of diets.

- We recommend switching B6 to commercial diet made by a well-established company that is not grain-free and does not contain any exotic ingredients, such as kangaroo, duck, lamb, venison, lentils, peas, beans, buffalo, tapioca, barley, and chickpeas.
- The FDA issued a statement regarding this issue (https://www.fda.gov/AnimalVeterinary/NewsEvents/CVMUpdates/ucm613305.htm) and a recent article published by Dr. Lisa Freeman on the Cummings School's Petfoodology blog can further explain these findings (http://vetnutrition.tufts.edu/2018/06/a-broken-heart-risk-of-heart-disease-in-boutique-or-grain-free-diets-and-exotic-ingredients/).
- Our nutritionists have compiled a list of dog foods that are good options for dogs with heart disease.

Dry Food Options:
Royal Canin Early Cardiac (veterinary diet)
Royal Canin Boxer
Purina Pro Plan Adult Weight Management
Purina Pro Plan Bright Mind Adult Small Breed Formula
Canned Food Options:
Hill's Science Diet Adult 1-6 Healthy Cuisine Roasted Chicken, Carrot, and Spinach Stew
Royal Canin Mature 8+

We think Royal Canin Boxer or the Royal Canin Early Cardiac diets would be good choices for B6 We have sent you home with a sample of the Royal Canin Boxer diet. If your dog has special nutritional needs or requires a homecooked diet, we recommend you schedule an appointment with our nutritionists (508-887-4696).

Exercise Recommendations:
For the first 7 to 10 days after starting medications for heart failure we recommend very limited activity. Leash walking only is ideal, and short walks to start. Once the heart failure is better controlled, then slightly longer walks are acceptable. However, if you find tha B6 lagging behind or needs to stop on a walk then this was too long a walk and shorter walks are advised in the future. Repetitive or strenuous high energy activities (repetitive ball chasing, running fast off-leash, etc.) are generally not advised at this stage of heart failure.

Recheck Visits:
A recheck visit is scheduled for **Friday, May 3rd at 11:00 AM** to recheck his bloodwork to see if he is tolerating the changes to his medicatoins. Additionally, recheck visits at 3 months and 6 months are needed for monitoring and would be covered by the DOM study.

Thank you for entrusting us with B6 care; he is a very sweet boy! Please contact our Cardiology liaison at (508)-887-4696 or email us at cardiowt@tufts.edu for scheduling and non-emergent questions or concerns.

Please visit our HeartSmart website for more information
http://vet.tufts.edu/heartsmart/

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

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

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

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FDA-CVM-FOIA-2019-1704-006359

Cummings
Veterinary Medical Center
AT TUFTS UNIVERSITY

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

Nutritional Tips for Pets with Heart Disease

Low sodium, high quality pet treats

Notes:

1. Most other dog treats are high in sodium.
2. If your pet has other medical conditions, these treats may not be appropriate. Talk to your veterinarian if you have questions or make an appointment with the Nutrition Service.

Product	Calories per treat
Dogs	
Hill's Science Diet Baked Light Biscuits with Real Chicken Small Dog Treat	8
Hill's Science Diet Baked Light Biscuits with Real Chicken Medium Dog Treat	34
Hill's Science Diet Soft Savories Peanut Butter & Banana, Beef & Cheddar, or Chicken & Yogurt Dog Treat	25-27, depending on flavor
Hill's Ideal Balance Soft-Baked Naturals with Chicken & Carrots, Duck & Pumpkin, or Beef & Sweet Potato Dog Treat	12-13, depending on flavor
Purina Beyond Natural Salmon Dog Biscuit Treat with Oats or Chicken & Barley	27-29, depending on flavor
Purina Alpo Variety Snaps Little Bites (beef, chicken, liver, lamb or beef, bacon, cheese, peanut butter)	16
Purina Alpo Variety Snaps Big Bites (beef, chicken, liver, lamb)	58
Royal Canin Original Canine treat	5
Cats	
Royal Canin Original Feline treat	2
Fancy Feast Duos Natural Rotisserie Chicken Cat treat	2
Fancy Feast Duos Tuna with Accents of Parsley Cat treat	2

Taste enhancers to can make your pet's food tastier to increase food intake

Safe and effective appetite stimulants are now available for dogs and cats. Please talk to your veterinarian if your pet is not eating well, not eating ideal foods, or is losing weight.

Notes:

1. All foods in this list should be prepared without salt
2. These taste enhancers should be added in small amounts. If your pet eats too much of them, they will unbalance the diet and increase your pet's risk for nutritional deficiencies

Dogs

- Honey or maple syrup
- Homemade chicken, beef, or fish broth (made without salt; avoid all deli meats and rotisserie chicken). Avoid store bought broths because even the low sodium brands are too high in sodium.
- Sugar (brown or white) – Domino pourable light brown sugar is a good option
- Vanilla or fruit yogurt – One option that dogs seem to like is Yoplait Custard Yogurt (caramel or vanilla flavors). If you try other brands, just be sure the sodium is less than 100 mg per 100 calories (the Yoplait is 95 mg per 170 calories which comes out to 56 mg sodium per 100 calories). Also avoid yogurts with artificial sweeteners.
- Maple syrup. Low salt brands include Log Cabin All Natural, Maple Grove Farm 100% pure maple syrup, or Stop and Shop Original Syrup
- Applesauce (be sure they have less than 50 mg sodium per serving)
- Ketchup (no salt added). Examples include Hunts or Heinz no salt added
- Pasta sauce (no salt added). Examples: Francesco Rinaldi no salt added or Enrico's no salt added)
- Frosted Mini Wheats Original – these can be crumbled on his food
- Lean meats, cooked (chicken, turkey, beef, or fish) – not deli/sandwich meats/cold cuts, rotisserie chicken, and any canned fish or meat
- Eggs, cooked

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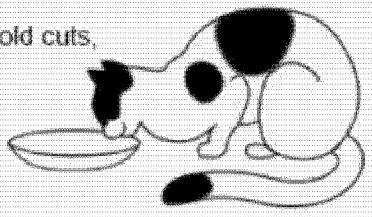
Dogs (continued)

- Homemade chicken, beef, or fish broth (even low sodium store-bought broths are too high in sodium). Avoid all canned soups unless labeled as no salt added
- Low-salt breakfast cereal - the label should read, "very low sodium food" or contain less than 20 mg sodium per serving. A good option is Frosted Mini Wheats Original or Little Bites Original
- Fresh vegetables/fruit. Examples include carrots, green beans, apple, orange, banana (avoid grapes, raisins, onions, garlic)
- Low sodium canned dog foods

Cats

- Lean meats, cooked (chicken, turkey, beef, or fish) – not sandwich meats/cold cuts, canned tuna, or rotisserie chicken
- Eggs, cooked
- Homemade chicken, beef, or fish broth (even low sodium store-bought broths are too high in sodium)
- Low sodium canned cat foods



Foods to avoid

- Fatty foods (meat trimmings, cream, ice cream)
- Baby food
- Pickled foods
- Bread
- Pizza
- Condiments (ketchup, soy sauce, barbecue sauce, etc – unless they are unsalted or no salt added)
- Sandwich meats/cold cuts (ham, corned beef, salami, sausages, bacon, hot dogs)
- Rotisserie chicken
- Most cheeses, including "squirtable" cheeses
- Processed foods (such as, potato mixes, rice mixes, macaroni and cheese)
- Canned vegetables (unless "no salt added")
- Potato chips, packaged popcorn, crackers, and other snack foods
- Soups (unless homemade without salt)
- Most commercial pet treats

Tips for administering medications

Foods commonly used to administer your pet's pills can provide a large amount of additional salt to your pet's diet. Preferable ways to give medications include:

- Have one of our staff show you how to give medications without using food
- Insert medications into one of the following foods:

  Dogs or cats

  - Low-sodium canned pet food
  - Home-cooked meat such as chicken or hamburger (made without salt); not lunch meats
  - Whipped cream (Reddi Wip)
  - Marshmallows
  - Greenies Pill Pockets
    - Dog chicken, hickory smoke, or peanut butter flavors; cat chicken or salmon flavor
    - Avoid grain-free duck and pea which is high in sodium
    - Try to use the smallest size possible (ideally, the cat sized Pill Pockets, even for dogs) and as few as possible to avoid excessive salt.
      - Caution: Not all similar products from other companies are low in sodium .

  Dogs

  - Soft fruit, such as banana, orange, melon, or strawberries (avoid grapes)
  - Peanut butter (only if labeled as "no salt added") – examples include Smucker's Natural Creamy Peanut Butter with No Salt Added or Teddie All Natural Smooth Unsalted Butter
  - Frosting (should be less than 75 mg/serving and contain no artificial sweeteners or xylitol). Examples include Duncan Hines whipped vanilla frosting, Betty Crocker whipped vanilla frosting)

You may find our Petfoodology post called, "Pill-popping pets" helpful for additional ideas: http://vetnutrition.tufts.edu/2018/09/foods_for_giving_pills/

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

B6

Patient ID: B6
B6 Canine
B6 Years Old Male (Neutered) Pit Bull
Mahogany

Cardiology Appointment Report
DCM STUDY

Date: 4/26/2019

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

B6

Cardiology Resident:
B6

Cardiology Technician:
B6

Student: B6 V'19

Presenting Complaint: DCM

Concurrent Diseases:
None

General Medical History:
Diagnosed with DCM in March.

In March, owners noticed he was coughing alot and had labored breathing. rDVM did x-ray and showed enlarged heart. Also treated for potential kennel cough at that time. Referred to CAVES (emergency room) where they did cardiac workup which showed DCM. He was immediately started on cardiac medications and diet change. Since starting meds and changing diet, still coughing but gaining weight. Coughing in the middle of the night, after exercise/excitement; roughly 10 times per day. Owner trying to limit exercise, but B6 has always had good energy. After exercise sometimes seems to have trouble catching his breath. Owner has not been counting RR at home. Appetite has been decreased prior to DCM diagnosis but has improved since starting meds.

Diet and Supplements:
Previous diet: Venison and red lentils (Pure Vida), canned food- natural balance venice and sweet potatoe; treats- natural balance venison and fish

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Current Diet: Nutri Source Chicken and Rice (dry and canned), treats, cooked chicken.

Cardiovascular History:

Prior CHF diagnosis? Yes
Prior heart murmur? Y Grade II/VI left sided
Prior ATE? N
Prior arrhythmia?
Monitoring respiratory rate and effort at home? Effort increased during exercise, not monitoring rate
Cough? Yes
Shortness of breath or difficulty breathing? After exercise
Syncope or collapse? No
Sudden onset lameness? No
Exercise intolerance? Tires easier because of cough

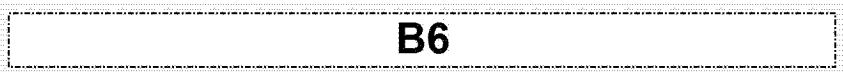
Muscle condition:

- [x] Normal
- [ ] Mild muscle loss
- [ ] Moderate cachexia
- [ ] Marked cachexia

Cardiovascular Physical Exam:

Murmur Grade:

- [ ] None
- [ ] I/VI
- [x] II/VI
- [ ] III/VI
- [ ] IV/VI
- [ ] V/VI
- [ ] VI/VI



Jugular vein:

- [x] Bottom 1/3 of the neck
- [ ] 1/2 way up the neck
- [ ] Middle 1/3 of the neck
- [ ] Top 2/3 of the neck

Arterial pulses:
- [ ] Weak
- [ ] Bounding
- [x] Fair
- [ ] Pulse deficits
- [ ] Good
- [ ] Pulsus paradoxus
- [ ] Strong
- [ ] Other:

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

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

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

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

Problems and Differential Diagnoses:

History of DCM: R/O- diet-associated vs. taurine vs. primary

Cough: R/O- secondary to DCM vs. less likely infectious

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

B6

Mitral inflow:
- [ ] Summated
- [ ] Pseudonormal
- [x] Normal
- [ ] Restrictive

FDA-CVM-FOIA-2019-1704-006364

☐ Delayed relaxation

B6

Assessment and recommendations:

The patient is still in mild CHF based on radiographs. We are therefore going to increase his B6 B6 Recheck renal values in 1-2 weeks. If renal values are normal at that time, we will increase B6 Recheck echocardiogram in 3 months. Patient enrolled in the DCM diet study. We recommend switching the patient to the RC Boxer diet.

Final Diagnosis:

DCM with LCHF. R/O diet-induced, primary, toxin
+/- mitral valve dysplasia

Heart Failure Classification Score:

ISACHC Classification:

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

ACVIM Classification:

- ☐ A
- ☐ B1
- ☐ B2
- ☑ C
- ☐ D

M-Mode	B6	
IVSd		cm
LVIDd		cm
LVPWd		cm
IVSs		cm
LVIDs		cm
LVPWs		cm
EDV(Teich)		ml
ESV(Teich)		ml
EF(Teich)		%
%FS		%
SV(Teich)		ml
Ao Diam		cm
LA Diam		cm
LA/Ao		
Max LA		cm
TAPSE		cm
EPSS		cm

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M-Mode Normalized		
IVSdN	B6	(0.290 - 0.520)
LVIDdN		(1.350 - 1.730) !
LVPWdN		(0.330 - 0.530)
IVSsN		(0.430 - 0.710)
LVIDsN		(0.790 - 1.140) !
LVPWsN		(0.530 - 0.780)
Ao Diam N		(0.680 - 0.890) !
LA Diam N		(0.640 - 0.900) !

2D		
SA LA	B6	cm
Ao Diam		cm
SA LA / Ao Diam		
IVSd		cm
LVIDd		cm
LVPWd		cm
EDV(Teich)		ml
IVSs		cm
LVIDs		cm
LVPWs		cm
ESV(Teich)		ml
EF(Teich)		%
%FS		%
SV(Teich)		ml
LVLd A4C		cm
LVEDV MOD A4C		ml
LVLs A4C		cm
LVESV MOD A4C		ml
LVEF MOD A4C		%
SV MOD A4C		ml

Doppler		
MR Vmax	B6	m/s
MR maxPG		mmHg
MV E Vel		m/s
MV DecT		ms
MV Dec Slope		m/s
MV A Vel		m/s
MV E/A Ratio		
E'		m/s
E/E'		
A'		m/s
S'		m/s
AV Vmax		m/s
AV maxPG		mmHg
PV Vmax		m/s
PV maxPG		mmHg

FDA-CVM-FOIA-2019-1704-006366

FDA-CVM-FOIA-2019-1704-006367

Cummings
Veterinary Medical Center
AT TUFTS UNIVERSITY

B6

B6 Male (Neutered)
Canine Pit Bull Mahogany
Patient ID: B6

Outside Prescription Log

1. Date: B6
   Clinician: B6
   Prescription: RC vet diet original dog treats, unlimited
   Pharmacy sent to: chewy 800-994-4358 (order B6
   Completed by: B6
   Origin of request: chewy

2. Date:
   Clinician:
   Prescription:
   Pharmacy sent to:
   Completed by:
   Origin of request:

3. Date:
   Clinician:
   Prescription:
   Pharmacy sent to:
   Completed by:
   Origin of request:

4. Date:
   Clinician:
   Prescription:
   Pharmacy sent to:
   Completed by:
   Origin of request:

5. Date:
   Clinician:
   Prescription:
   Pharmacy sent to:
   Completed by:
   Origin of request:

6. Date:
   Clinician:
   Prescription:
   Pharmacy sent to:
   Completed by:
   Origin of request:

7. Date:

FDA-CVM-FOIA-2019-1704-006368

Clinician:
Prescription:
Pharmacy sent to:
Completed by:
Origin of request:

8. Date:
Clinician:
Prescription:
Pharmacy sent to:
Completed by:
Origin of request:

9. Date:
Clinician:
Prescription:
Pharmacy sent to:
Completed by:
Origin of request:

10. Date:
Clinician:
Prescription:
Pharmacy sent to:
Completed by:
Origin of request:

FDA-CVM-FOIA-2019-1704-006369

Cummings
Veterinary Medical Center
AT TUFTS UNIVERSITY

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

B6

B6 Male (Neutered)
Canine Pit Bull Mahogany
B6

B6

Dear B6

Thank you for referring B6 with their pet B6.

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

Thank you,

B6 DVM, DACVIM (Cardiology), PhD

{

Report Details - EON-390034

ICSR:	2067994			
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 11:03:47 EDT			
Initial Report Date:	11/09/2018			
Parent ICSR:	2058683			
Follow-up Report to FDA Request:	Yes			
Reported Problem:	**Problem Description:**	Older housemate diagnosed with DCM and CHF. Screening B6 because he has been eating the same diet. Does not have clearcut DCM on echo but has reduced cardiac contractility. Taurine pending and owner has changed diet and started taurine supplementation		
	Date Problem Started:	11/07/2018		
	Concurrent Medical Problem:	No		
	Outcome to Date:	Better/Improved/Recovering		
Product Information:	**Product Name:**	Zignature trout & salmon dry		
	Product Type:	Pet Food		
	Lot Number:			
	Package Type:	BAG		
	Product Use Information:	**Description:**	B6, is four and was born on B6. He ate Zignature trout & salmon from 09/30/15-10/01/18. 1.25 cups twice daily of Zignature. The primary cookies he ate was Earthborn Holistic Grain-Free, all varieties, and he might have had 3-4 cookies per day. The only other cookies he would have eaten were misc. varieties brought by misc. delivery people (propane, UPS, etc.) and not regularly. If we ever had to give medication, we always used the Greenies Pill Pockets.	
	Manufacturer /Distributor Information:			
	Purchase Location Information:			
Animal Information:	**Name:**	B6		
	Type Of Species:	Dog		
	Type Of Breed:	Retriever - Labrador		
	Gender:	Male		
	Reproductive Status:	Neutered		
	Weight:	25.9 Kilogram		
	Age:	3 Years		
	Assessment of Prior Health:	Excellent		
	Number of Animals Given the Product:	3		
	Number of Animals Reacted:	2		
	Owner Information:	**Owner Information provided:**	Yes	
		Contact:	**Name:**	B6
			Phone:	B6

FDA-CVM-FOIA-2019-1704-006371

		Email:	B6
		Address:	B6 United States
	Healthcare Professional Information:	Practice Name:	Tufts Cummings School of Veterinary Medicine
		Contact:	Name: Lisa Freeman
			Phone: (508) 887-4523
			Email: lisa.freeman@tufts.edu
		Address:	200 Westboro Rd North Grafton Massachusetts 01536 United States
Sender Information:	Name:	Lisa Freeman	
	Address:	200 Westboro Rd North Grafton Massachusetts 01536 United States	
	Contact:	Phone:	5088874523
		Email:	lisa.freeman@tufts.edu
	Permission To Contact Sender:	Yes	
	Preferred Method Of Contact:	Email	
	Reported to Other Parties:	None	
Additional Documents:			
	Attachment:	Med Records pt 2.pdf	
	Description:	Medical Records	
	Type:	Medical Records	
	Attachment:	Med Records pt 1.pdf	
	Description:	Medical Records	
	Type:	Medical Records	

FDA-CVM-FOIA-2019-1704-006372

Cummings Veterinary Medical Center at Tufts University

Foster Hospital for Small Animals

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

All Medical Records

Client:
Address: B6

Patient: B6
Breed: Golden Retriever
DOB: B6

Species: Canine
Sex: Male (Neutered)

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

Referring Information

B6

Client:
Patient: B6

Initial Complaint:
Scanned Record

Initial Complaint:
New - B6 - DCM study

SOAP Text B6 **12:08PM** - B6

Disposition/Recommendations

FDA-CVM-FOIA-2019-1704-006373

FDA-CVM-FOIA-2019-1704-006374

Cummings Veterinary Medical Center
AT TUFTS UNIVERSITY

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

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

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

Lab Results Report

B6 1:29:30 PM **Accession ID:** B6

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

stringsoft

Printed Friday, November 09, 2018

FDA-CVM-FOIA-2019-1704-006375

B6

B6

B6

FDA-CVM-FOIA-2019-1704-006376

B6

B6

B6

FDA-CVM-FOIA-2019-1704-006377

B6

B6

B6

FDA-CVM-FOIA-2019-1704-006378

B6

B6

B6

FDA-CVM-FOIA-2019-1704-006379

B6

B6

B6

FDA-CVM-FOIA-2019-1704-006380

Client: B6
Patient:

RDVM B6 records

B6

B6

B6

B6

B6

B6

B6

FDA-CVM-FOIA-2019-1704-006381

B6

B6

B6

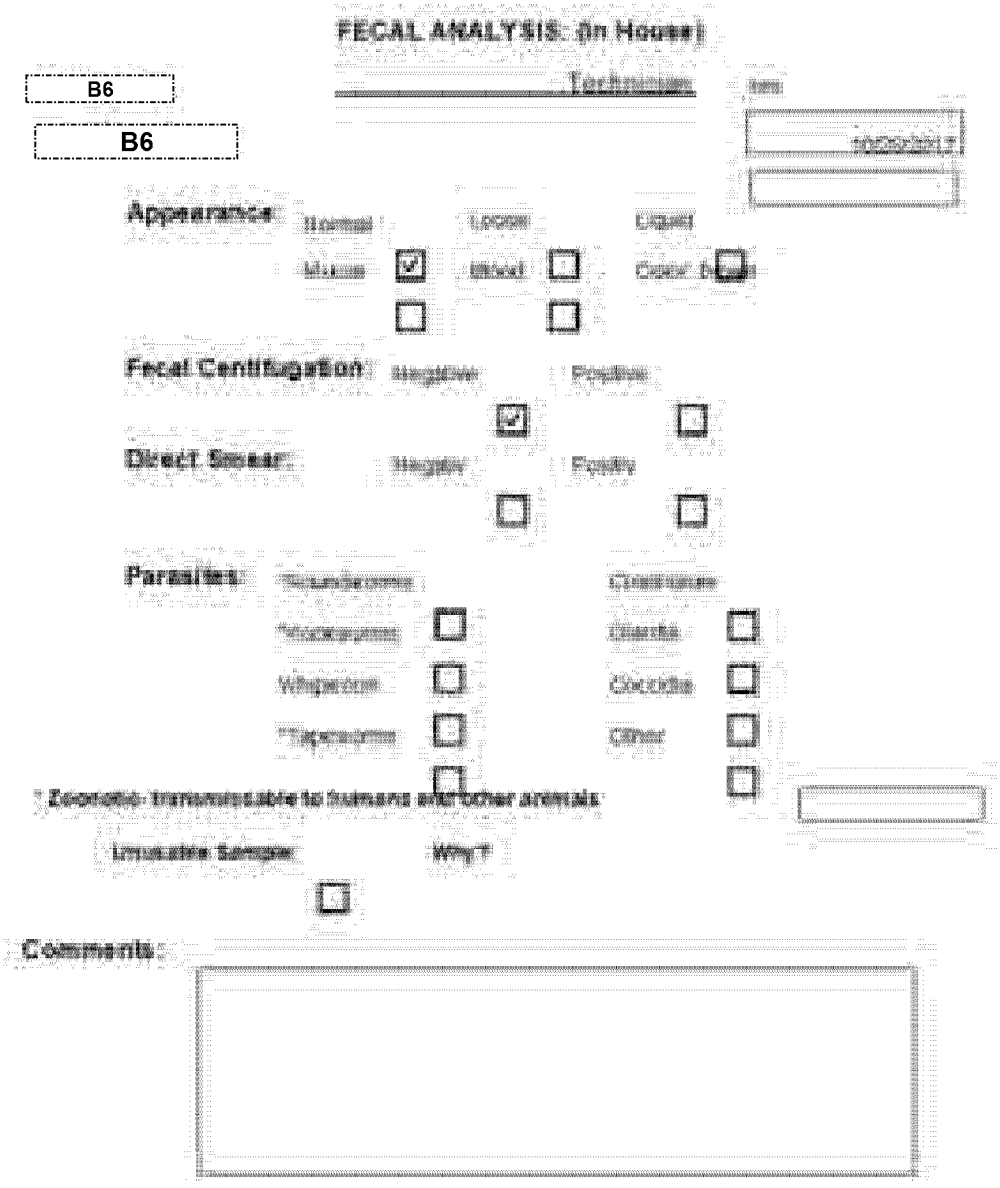
B6

B6

B6

B6

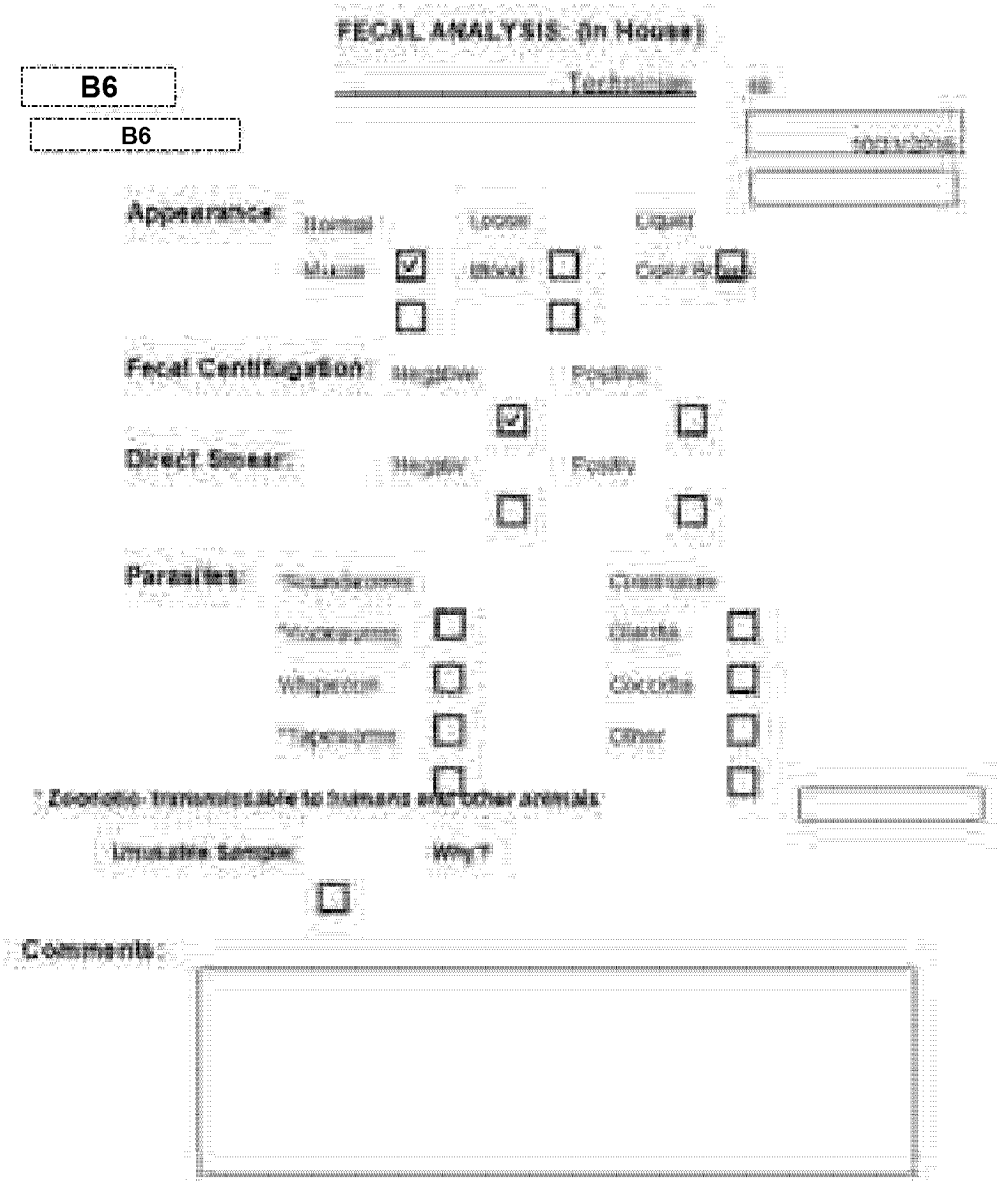
FDA-CVM-FOIA-2019-1704-006382



FDA-CVM-FOIA-2019-1704-006383

Client: B6
Patient:

RDVM B6 **records**



FDA-CVM-FOIA-2019-1704-006384

Client: B6
Patient:

RDVM p B6 **records**

B6

B6

B6

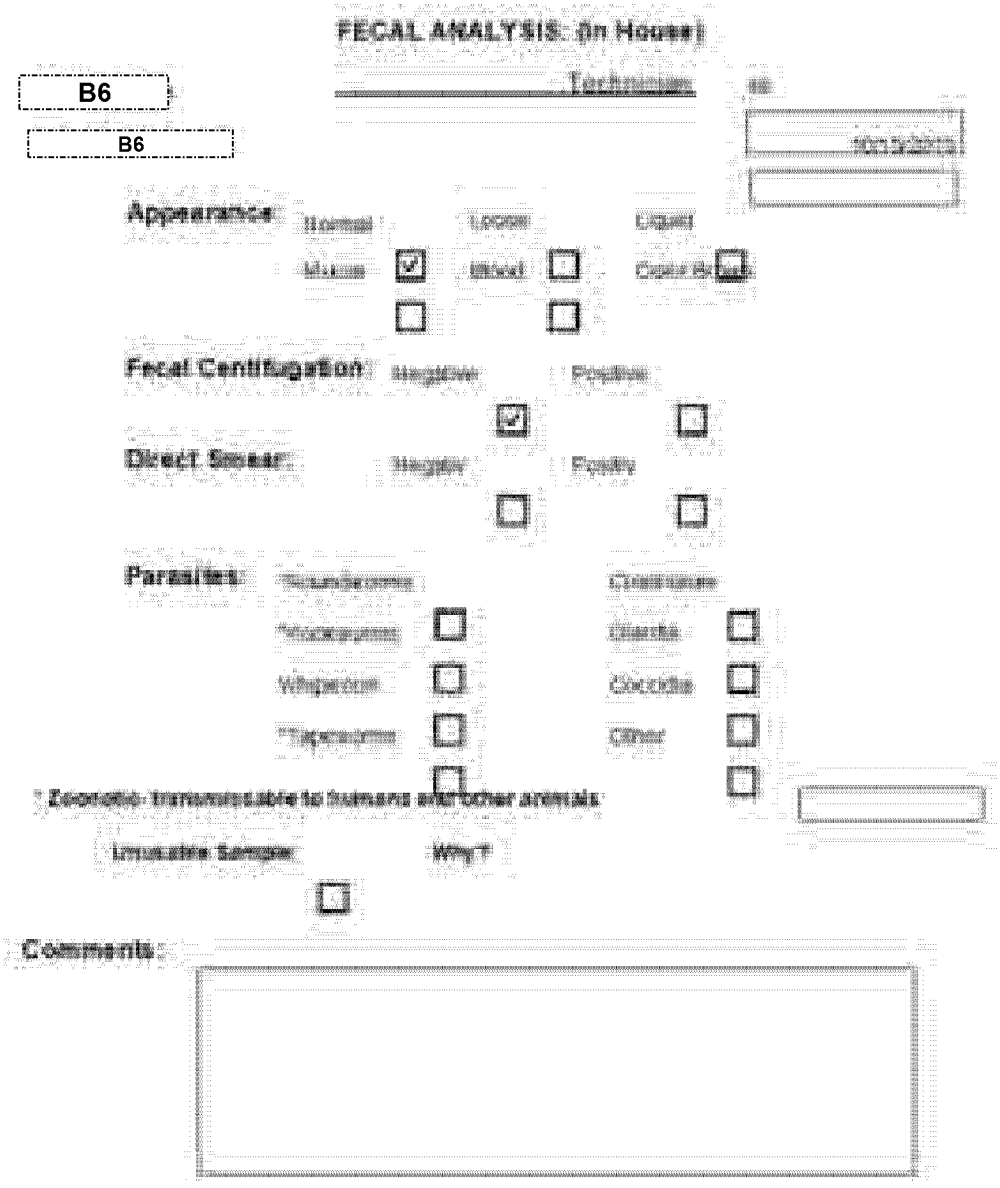
B6

B6

FDA-CVM-FOIA-2019-1704-006385

Client: B6
Patient:

RDVM B6 **records**



FDA-CVM-FOIA-2019-1704-006386

Client: B6
Patient:

IDEXX BNP - 11/8/2018

B6

B6
B6

B6
B6

B6

B6

FDA-CVM-FOIA-2019-1704-006387

Client: **B6**
Patient:

CBC/Chem - 11/7/2018

Tufts Cummings School Of Veterinary Medicine

[illegible]

DUPLICATE

Name [illegible] **B6**
Patient ID **B6**
Client [illegible]
Collection Date: [illegible]
Approval Date: [illegible]

Sex: [illegible]
Age: 3
Species: Canine
Breed: Guinea Pig

Provider **B6**
Order Location: [illegible]
Sample ID **B6**

CBC (Research) (Advia)

[illegible]		Ref Range/Units
WBC (ADVIA)	**B6**	[illegible]
RBC (ADVIA)		[illegible]
Hemoglobin (ADVIA)		[illegible]
Hematocrit (Advia)		[illegible]
MCV (ADVIA)		[illegible]
MCH (ADVIA)		[illegible]
MCHC (ADVIA)		[illegible]
RDW (ADVIA)		[illegible]
Comment (Hematology)	[illegible]	

Microscopic Exam of Blood Smear (Advia)

[illegible]		Ref Range/Units
Seg Neuts (%)	**B6**	[illegible]
Lymphocytes (%)		[illegible]
Monocytes (%)		[illegible]
Eosinophils (%)		[illegible]
Seg Neutrophils (Abs)		[illegible]
Absolute		
Lymphs (Abs) Advia	L	[illegible]
Monos (Abs) Advia		[illegible]
Eosinophils (Abs) Advia		[illegible]
WBC Morphology	[illegible]	
Platelets		

Research Chemistry Profile - Small Animal (Cobas)

[illegible]		Ref Range/Units
Glucose	**B6**	[illegible]
Urea		[illegible]
Creatinine		[illegible]
Phosphorus		[illegible]
Calcium T		[illegible]
Magnesium		[illegible]
Total Protein		[illegible]
Albumin		[illegible]
Globulin	L	[illegible]
A:G Ratio	L	[illegible]
Sodium	H	[illegible]
Chloride		[illegible]
Potassium		[illegible]
tCO2 (bicarb)		[illegible]
ALT/ALP		[illegible]
ALP/ALT		[illegible]
GGT		[illegible]
Total Bilirubin		[illegible]

Sample ID: [illegible]
Received: [illegible]

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FDA-CVM-FOIA-2019-1704-006388

Client: B6
Patient: B6

CBC/Chem - 11/7/2018

Tufts Cummings School Of Veterinary Medicine

[redacted]

DUPLICATE

Name DOB: B6
Patient ID: B6
Species: [redacted]
Collection Date: [redacted]
Approval Date: [redacted]

Sex: CM
Age: 3
Species: Canine
Breed: Guinea Pig

Provider: B6
Order Location: [redacted]
Sample ID: B6

Research Chemistry Profile - Small Animal (Cobas) (cont'd)

ANALYTE		Ref. Range/Status
Bilirubin, Direct	B6	[redacted]
Bilirubin, Indirect		
Alkaline Phosphatase		
GGT		
ALT		
AST		
Creatine Kinase		
Cholesterol		
Triglycerides		
Amylase		
Osmolality (calculated)		

Sample ID: B6
[redacted]

Reviewed By: _____
Page 2

FDA-CVM-FOIA-2019-1704-006389

Client:
Patient: B6

Vitals Results

11/7/2018 11:32:13 AM	Weight (kg)	25.9000

FDA-CVM-FOIA-2019-1704-006390

ECG from cardio

B6

B6

B6

FDA-CVM-FOIA-2019-1704-006391

ECG from cardio

B6

B6

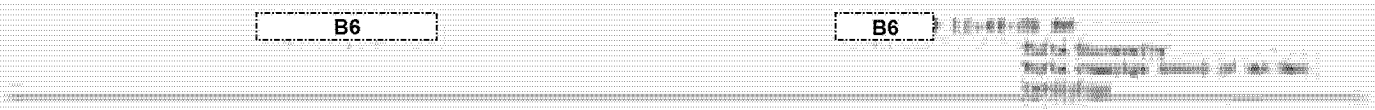
B6

FDA-CVM-FOIA-2019-1704-006392

Client: B6
Patient:

ECG from cardio

B6 B6



B6

FDA-CVM-FOIA-2019-1704-006393

Client: B6
Patient:

Patient History

11/05/2018 10:46 AM	Appointment
11/05/2018 12:36 PM	Appointment
11/07/2018 10:07 AM	UserForm
11/07/2018 10:48 AM	UserForm
11/07/2018 10:53 AM	Treatment
11/07/2018 11:32 AM	Vitals
11/07/2018 12:08 PM	Purchase
11/07/2018 12:18 PM	UserForm
11/07/2018 01:29 PM	Labwork
11/07/2018 01:30 PM	Purchase
11/07/2018 01:30 PM	Purchase
11/07/2018 01:30 PM	Purchase

B6

FDA-CVM-FOIA-2019-1704-006394

Cummings Veterinary Medical Center
AT TUFTS UNIVERSITY

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

Discharge Instructions

Patient
Name: B6
Species: Canine
Gold Male (Neutered) Golden Retriever
Birthdate: B6

Owner
Name: B6
Address: B6

Patient ID: B6

Attending Cardiologist:
John E. Rush DVM, MS, DACVIM (Cardiology), DACVECC
B6

Cardiology Resident:
B6

Cardiology Technician:
B6

Student:
B6 V19, B6 V19

Admit Date: 1/24/2019 10:26:41 AM
Discharge Date: 1/24/2019

Diagnoses: Decreased contractile function and mildly enlarged heart (stable).

Clinical Findings:
Thank you for bringing B6 in today for his recheck echocardiogram. You report that B6 is doing well at home, although he sometimes has a dry cough after eating. On physical exam there were no abnormalities while listening to his heart, and he had nice strong pulses.

Today on echocardiogram (ultrasound of the heart), B6 heart looks similar to how it did previously. He still has a slight reduced contractile function and his heart is mildly enlarged which is abnormal for a dog of his age. This is not yet severe enough that B6 requires any additional medications, however, we recommend continuing him on his taurine supplement and we will continue to monitor his heart closely in the future.

Monitoring at Home:
B6 is very stable today and is not close to heart failure. However, please monitor for him for any signs of weakness or collapse, a reduction in appetite, cough, or distension of the belly. If you notice any abnormalities, we would like to see him for a recheck exam.

If you ever have any concerns, please call or have B6 evaluated by a veterinarian. Our emergency clinic is open 24 hours a day.

FDA-CVM-FOIA-2019-1704-006395

Diet Suggestions:
Please continue feeding B6 the Purina Pro Plan diet.

Exercise Recommendations: B6 may continue his normal activity and exercise regime

Recommended Medications:
1. Taurine Supplement - Give 1000mg by mouth every 12 hours.
(brands we recommend include TwinLab, Swanson, NOW and GNC brands)
Taurine is an amino acid that is shown to be necessary for appropriate heart health. Supplemening Taurine, in some cases, has lead to reduction in heart enlargement and an increase in heart health in dogs with DCM.

Recheck Visits: We would like to see B6 back for a recheck echocardiogram in 6 months.

Thank you for entrusting us with B6 care- he is such a good boy!. Please contact our Cardiology liaison at (508)-887-4696 or email us at cardiovet@tufts.edu for scheduling and non-emergent questions or concerns.

Please visit our HeartSmart website for more information
http://vet.tufts.edu/heartsmart/

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

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

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

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FDA-CVM-FOIA-2019-1704-006396

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

B6

Patient ID: B6
B6 Canine
B6 Years Old Male (Neutered) Golden Retriever
Gold

Cardiology Appointment Report

Date: 1/24/2019

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

B6

Cardiology Resident:
B6

Cardiology Technician:
B6

Student: B6 V19, B6 V19

Presenting Complaint: DCM Study, last echocardiogram performed 11/2018 revealing decreased contractile function - r/o DCM vs. diet induce cardiomyopathy. Did not require medical intervention
B6 at that time, but initiated Taurine supplementation and diet change.

Concurrent Diseases: Apparently healthy pet

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

Diet and Supplements: Eats purina proplan sport, taurine supplement

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

Sudden onset lameness? No
Exercise intolerance? No

Current Medications Pertinent to CV System:

B6

Medication:
Formulation/Tab Size:
Administration Frequency:
Need refills?

Cardiac Physical Examination:

B6

Muscle condition:

- [x] Normal
- [ ] Mild muscle loss
- [ ] Moderate cachexia
- [ ] Marked cachexia

Cardiovascular Physical Exam:

Murmur Grade:

- [x] None
- [ ] I/VI
- [ ] II/VI
- [ ] III/VI
- [ ] IV/VI
- [ ] V/VI
- [ ] VI/VI

Murmur location/description:

Jugular vein:

- [x] Bottom 1/3 of the neck
- [ ] Middle 1/3 of the neck
- [ ] 1/2 way up the neck
- [ ] Top 2/3 of the neck

Arterial pulses:

- [ ] Weak
- [ ] Fair
- [ ] Good
- [x] Strong
- [ ] Bounding
- [ ] Pulse deficits
- [ ] Pulsus paradoxus
- [ ] Other:

Arrhythmia:

- [x] None
- [ ] Sinus arrhythmia
- [ ] Bradycardia
- [ ] Tachycardia

FDA-CVM-FOIA-2019-1704-006398

☐ Premature beats

Gallop:

☐ Yes
☑ No
☐ Intermittent
☐ Pronounced
☐ Other:

Pulmonary assessments:

☑ Eupneic
☐ Mild dyspnea
☐ Marked dyspnea
☐ Normal BV sounds
☐ Pulmonary crackles
☐ Wheezes
☐ Upper airway stridor

Abdominal exam:

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

Problems:

Differential Diagnoses:

Diagnostic plan:

☑ Echocardiogram
☐ Chemistry profile
☐ EOG
☐ Renal profile
☐ Blood pressure
☐ Dialysis profile
☐ Thoracic radiographs
☐ NT-proBNP
☐ Troponin I
☐ Other tests:

B6

Mitral inflow:

☐ Summated
☑ Normal
☐ Delayed relaxation
☐ Pseudonormal
☐ Restrictive

B6

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

Final Diagnosis:

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

Heart Failure Classification Score:

ISACHC Classification:

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

ACVIM Classification:

- ☐ A
- ☐ B1
- ☑ B2
- ☐ C
- ☐ D

B6

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

FDA-CVM-FOIA-2019-1704-006400

EPSS	B6	cm
M-Mode Normalized		
IVSdN	B6	(0.290 - 0.520) !
LVIDdN		(1.350 - 1.730) !
LVPWdN		(0.330 - 0.530)
IVSsN		(0.430 - 0.710) !
LVIDsN		(0.790 - 1.140) !
LVPWsN		(0.530 - 0.780)
2D		
SA LA	B6	cm
Ao Diam		cm
SA LA / Ao Diam		
IVSd		cm
LVIDd		cm
LVPWd		cm
EDV(Teich)		ml
IVSs		cm
LVIDs		cm
LVPWs		cm
ESV(Teich)		ml
EF(Teich)		%
%FS		%
SV(Teich)		ml
Doppler		
MV E Vel	B6	m/s
MV DecT		ms
MV Dec Slope		m/s
MV A Vel		m/s
MV E/A Ratio		
E'		m/s
E/E'		
A'		m/s
S'		m/s
IVRT		ms
AV Vmax		m/s
AV maxPG		mmHg
PV Vmax		m/s
PV maxPG		mmHg
TR Vmax		m/s
TR maxPG		mmHg

FDA-CVM-FOIA-2019-1704-006401

Cummings Veterinary Medical Center
AT TUFTS UNIVERSITY

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

Discharge Instructions

Patient
Name: B6
Species: Canine
Gold Male (Neutered) Golden Retriever
Birthdate: B6

Owner
Name: B6
Address: B6

Patient ID: B6

Attending Cardiologist:
John E. Bush DVM, MS, DACVIM (Cardiology), DACVECC
B6

Cardiology Resident:
B6

Cardiology Technician:
B6

Student: B6 V20

Admit Date: 5/1/2019 12:00:53 PM
Discharge Date: 5/1/2019

Diagnoses: Decreased contractile function and mildly enlarged heart.

Clinical Findings:
Thank you for bringing B6 in today for his recheck echocardiogram. You report that B6 is doing well at home and has not had any coughing or exercise intolerance. On physical exam there were no abnormalities while listening to his heart, and he had nice strong pulses.

Today on echocardiogram (ultrasound of the heart), B6 heart looks similar to how it did previously. His heart is has decreased contractile function and is mildly enlarged which is abnormal for a dog of his age. B6 does not require any additional medications at this time, however, we recommend continuing him on his taurine supplement and we will continue to monitor his heart closely in the future.

Monitoring at Home:
B6 is very stable today and is not close to heart failure. However, please monitor for him for any signs of weakness or collapse, a reduction in appetite, cough, or distension of the belly. If you notice any abnormalities, we would like to see him for a recheck exam.

If you ever have any concerns, please call or have B6 evaluated by a veterinarian. Our emergency clinic is open 24 hours a day.

Diet Suggestions:

Please continue feeding B6 the Purina Pro Plan diet.

Exercise Recommendations: B6 may continue his normal activity and exercise regime

Recommended Medications:
1. Taurine Supplement - Give 1000mg by mouth every 12 hours.
(brands we recommend include TwinLab, Swanson, NOW and GNC brands)
Taurine is an amino acid that is shown to be necessary for appropriate heart health. Supplementing Taurine, in some cases, has lead to reduction in heart enlargement and an increase in heart health in dogs with DCM.

Recheck Visits: We would like to see B6 back for a recheck echocardiogram in 2-3 months. B6 will call you to schedule this appointment.

Thank you for entrusting us with B6 care- he is such a sweet boy! Please contact our Cardiology liaison at (508)-887-4696 or email us at cardiovet@tufts.edu for scheduling and non-emergent questions or concerns.

Please visit our HeartSmart website for more information
http://vet.tufts.edu/heartsmart/

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

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

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

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FDA-CVM-FOIA-2019-1704-006403

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

B6

Patient ID: B6
B6 Canine
B6 Years Old Male (Neutered) Golden Retriever
Gold

Cardiology Appointment Report

Date: 5/1/2019

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

B6

Cardiology Resident:
B6

Cardiology Technician:
B6

Student: B6, V20; B6 V20

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

Concurrent Diseases:
none

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

Diet and Supplements:
Taurine 1000mg BID

Cardiovascular History:
Prior CHF diagnosis? n
Prior heart murmur? n
Prior ATE? n
Prior arrhythmia? n
Monitoring respiratory rate and effort at home? n
Cough? very rarely -o cannot remember the last time he coughed
Shortness of breath or difficulty breathing? n
Syncope or collapse? n
Sudden onset lameness? n

Exercise intolerance? n

Current Medications Pertinent to CV System:

None

Cardiac Physical Examination:

B6

Muscle condition:

- [x] Normal
- [ ] Mild muscle loss
- [ ] Moderate cachexia
- [ ] Marked cachexia

Cardiovascular Physical Exam:

Murmur Grade:

- [x] None
- [ ] I/VI
- [ ] II/VI
- [ ] III/VI
- [ ] IV/VI
- [ ] V/VI
- [ ] VI/VI

Murmur location/description:

Jugular vein:

- [x] Bottom 1/3 of the neck
- [ ] Middle 1/3 of the neck
- [ ] 1/2 way up the neck
- [ ] Top 2/3 of the neck

Arterial pulses:

- [ ] Weak
- [ ] Fair
- [x] Good
- [ ] Strong
- [ ] Bounding
- [ ] Pulse deficits
- [ ] Pulsus paradoxus
- [ ] Other:

Arrhythmia:

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

Gallop:

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

Pulmonary assessments:

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

Abdominal exam:

- [x] Normal
- [ ] Hepatomegaly
- [ ] Mild ascites
- [ ] Marked ascites

FDA-CVM-FOIA-2019-1704-006405

☐ Abdominal distension

Problems:
DCM with mildly decreased contractile function

Differential Diagnoses:
Diet-associated DCM vs primary DCM

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

B6

Mitral inflow:
- ☐ Summated
- ☑ Normal
- ☐ Delayed relaxation
- ☐ Pseudonormal
- ☐ Restrictive

ECG findings:

B6

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

Final Diagnosis:
- Decreased contractile function - r/o mild DCM vs. diet induced cardiomyopathy.

Heart Failure Classification Score:
ISACHC Classification:
- ☐ Ia
- ☑ Ib
- ☐ II
- ☐ IIIa
- ☐ IIIb

ACVIM Classification:
- ☐ A
- ☐ C

FDA-CVM-FOIA-2019-1704-006406

☐ B1
☑ B2

☐ D

M-Mode

IVSd	B6	cm
LVIDd		cm
LVPWd		cm
IVSs		cm
LVIDs		cm
LVPWs		cm
EDV(Teich)		ml
ESV(Teich)		ml
EF(Teich)		%
%FS		%
SV(Teich)		ml
Max LA		cm
Ao Diam		cm
LA Diam		cm
LA/Ao		
TAPSE		cm
EPSS		cm

M-Mode Normalized

IVSdN	B6	(0.290 - 0.520)
LVIDdN		(1.350 - 1.730) !
LVPWdN		(0.330 - 0.530)
IVSsN		(0.430 - 0.710)
LVIDsN		(0.790 - 1.140) !
LVPWsN		(0.530 - 0.780)

2D

SA LA	B6	cm
Ao Diam		cm
SA LA / Ao Diam		
IVSd		cm
LVIDd		cm
LVPWd		cm
EDV(Teich)		ml
IVSs		cm
LVIDs		cm
LVPWs		cm
ESV(Teich)		ml
EF(Teich)		%
%FS		%
SV(Teich)		ml
LV Major		cm
LV Minor		cm

FDA-CVM-FOIA-2019-1704-006407

Sphericity Index		
LVLd A4C		cm
LVEDV MOD A4C		ml
LVLs A4C	B6	cm
LVESV MOD A4C		ml
LVEF MOD A4C		%
SV MOD A4C		ml
Doppler		
MR Vmax		m/s
MR maxPG		mmHg
MV E Vel		m/s
MV DecT		ms
MV Dec Slope		m/s
MV A Vel		m/s
MV E/A Ratio		
E'		m/s
E/E'		
A'	B6	m/s
S'		m/s
IVRT		ms
AV Vmax		m/s
AV maxPG		mmHg
PV Vmax		m/s
PV maxPG		mmHg
TR Vmax		m/s
TR maxPG		mmHg

FDA-CVM-FOIA-2019-1704-006408

CARDIOLOGY DIET HISTORY FORM

Please answer the following questions about your pet

Pet's name: B6 Owner's name : B6 Today's date: 3/27/2019

1. How would you assess your pet's appetite? (mark the point on the line below that best represents your pet's appetite)

Example: **Poor**_____**Excellent**

Poor_____**Excellent**

2. Have you noticed a change in your pet's appetite over the last 1-2 weeks? (check all that apply)

☒ Eats about the same amount as usual ☐ Eats less than usual ☐ Eats more than usual
☐ Seems to prefer different foods than usual ☐ Other_____

3. Over the last few weeks, has your pet (check one)

☐ Lost weight ☐ Gained weight ☒ Stayed about the same weight ☐ Don't know

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

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

Food (include specific product and flavor)	Form	Amount	How often?	Fed since
Nutro Grain Free Chicken, Lentil, & Sweet Potato Adult	*dry*	*1 ½ cup*	*2x/day*	*Jan 2018*
85% lean hamburger	*microwaved*	*3 oz*	*1x/week*	*Jan 2015*
Pupperoni original beef flavor	*treat*	*½*	*1x/day*	*Aug 2015*
Rawhide	*treat*	*6 inch twist*	*1x/week*	*Dec 2015*
Royal Canine	dry	1 ½ cup	1x day	Oct 2018
Hills Science Diet – Chicken stew	wet	½ can	1x day	Oct 2018

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

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

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

6. How do you administer pills to your pet?

☐ I do not give any medications
☐ I put them directly in my pet's mouth without food
☐ I put them in my pet's dog/cat food
☐ I put them in a Pill Pocket or similar product
☐ I put them in foods (list foods):_____

Cummings Veterinary Medical Center AT TUFTS UNIVERSITY

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

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

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

Lab Results Report

Nova Full Panel-ICU B6 **1:30:25 AM** **Accession ID:** B6

Test	Results	Reference Range	Units
SO2%	B6	94 - 100	%
HCT (POC)		38 - 48	%
HB (POC)		12.6 - 16	g/dL
NA (POC)		140 - 154	mmol/L
K (POC)		3.6 - 4.8	mmol/L
CL(POC)		109 - 120	mmol/L
CA (ionized)		1.17 - 1.38	mmol/L
MG (POC)		0.1 - 0.4	mmol/L
GLUCOSE (POC)		80 - 120	mg/dL
LACTATE		0 - 2	mmol/L
BUN (POC)		12 - 28	mg/dL
CREAT (POC)		0.2 - 2.1	mg/dL
TCO2 (POC)		0 - 0	mmol/L
nCA		0 - 0	mmol/L
nMG		0 - 0	mmol/L
GAP		0 - 0	mmol/L
CA/MG		0 - 0	mol/mol
BEecf		0 - 0	mmol/L
BEb		0 - 0	mmol/L
A		0 - 0	mmHg
NOVA SAMPLE		0 - 0	

FDA-CVM-FOIA-2019-1704-006410

FiO2	B6	0 - 0	%
PCO2		36 - 44	mmHg
PO2		80 - 100	mmHg
PH		7.337 - 7.467	
PCO2		36 - 44	mmHg
PO2		80 - 100	mmHg
HCO3		18 - 24	mmol/L

Nova Full Panel-ICU B6 **1:52:25 AM** **Accession ID:** B6

Test	Results	Reference Range	Units
TS (FHSA)	B6	0 - 0	g/dL
Lactate (FHSA) *		0 - 0	mmol/L
BG (FHSA)		0 - 0	g/dL
TS (FHSA)		0 - 0	g/dL
PCV		0 - 0	%

Nova Full Panel-ICU B6 **2:06:14 AM** **Accession ID:** B6

Test	Results	Reference Range	Units
PT (ER)-Citrate	B6	0 - 0	sec

Nova Full Panel-ICU B6 **3:50:25 AM** **Accession ID:** B6

Test	Results	Reference Range	Units
SO2%	B6	94 - 100	%
HCT (POC)		38 - 48	%
HB (POC)		12.6 - 16	g/dL
NA (POC)		140 - 154	mmol/L
K (POC)		3.6 - 4.8	mmol/L
CL(POC)		109 - 120	mmol/L
CA (ionized)		1.17 - 1.38	mmol/L
MG (POC)		0.1 - 0.4	mmol/L
GLUCOSE (POC)		80 - 120	mg/dL
LACTATE		0 - 2	mmol/L
BUN (POC)		12 - 28	mg/dL
CREAT (POC)	uncalibrated	0.2 - 2.1	mg/dL
TCO2 (POC)	uncalibrated	0 - 0	mmol/L
nCA	B6	0 - 0	mmol/L
nMG		0 - 0	mmol/L
GAP	uncalibrated	0 - 0	mmol/L
CA/MG	B6	0 - 0	mol/mol
BEecf	uncalibrated	0 - 0	mmol/L
BEb	uncalibrated	0 - 0	mmol/L
Λ	uncalibrated	0 - 0	mmHg
NOVA SAMPLE	Venous	0 - 0	

FDA-CVM-FOIA-2019-1704-006411

Client:
Patient: B6

FiO2	B6 (room air)	0 - 0	%
PCO2	uncalibrated	36 - 44	mmHg
PO2	B6	80 - 100	mmHg
PH		7.337 - 7.467	
PCO2	uncalibrated	36 - 44	mmHg
PO2	B6	80 - 100	mmHg
HCO3	uncalibrated	18 - 24	mmol/L

Nova Full Panel-ICU B6 **1:30:17 PM** **Accession ID:** B6

Test	Results	Reference Range	Units
TS (FHSA)	B6	0 - 0	g/dl
PCV **		0 - 0	%
TS (FHSA)		0 - 0	g/dl

Nova Full Panel-ICU B6 **7:54:25 AM** **Accession ID:** B6

Test	Results	Reference Range	Units
SO2%	B6	94 - 100	%
HCT (POC)		38 - 48	%
HB (POC)		12.6 - 16	g/dL
NA (POC)		140 - 154	mmol/L
K (POC)		3.6 - 4.8	mmol/L
CL(POC)		109 - 120	mmol/L
CA (ionized)		1.17 - 1.38	mmol/L
MG (POC)		0.1 - 0.4	mmol/L
GLUCOSE (POC)		80 - 120	mg/dL
LACTATE		0 - 2	mmol/L
BUN (POC)		12 - 28	mg/dL
CREAT (POC)		0.2 - 2.1	mg/dL
TCO2 (POC)		0 - 0	mmol/L
nCA		0 - 0	mmol/L
nMG		0 - 0	mmol/L
GAP		0 - 0	mmol/L
CA/MG		0 - 0	mol/mol
BEecf		0 - 0	mmol/L
BEb		0 - 0	mmol/L
A		0 - 0	mmHg
NOVA SAMPLE		0 - 0	
FiO2	B6 (room air)	0 - 0	%
PCO2	B6	36 - 44	mmHg
PO2		80 - 100	mmHg
PH		7.337 - 7.467	
PCO2		36 - 44	mmHg

FDA-CVM-FOIA-2019-1704-006412

PO2	B6	80 - 100	mmHg
HCO3		18 - 24	mmol/L

Nova Full Panel-ICU B6 **8:25:41 AM** **Accession ID:** B6

Test	Results	Reference Range	Units
TS (FHSA)		0 - 0	g/dl
PCV **	B6	0 - 0	%
TS (FHSA)		0 - 0	g/dl

Nova Full Panel-ICU B6 **10:31:12 AM** **Accession ID:** B6

Test	Results	Reference Range	Units
WBC (ADVIA)		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)	B6	31.9 - 34.3	g/dL
RDW (ADVIA)		11.9 - 15.2	
PLT(ADVIA)		173 - 486	K/uL
MPV (ADVIA)		8.29 - 13.2	fl
PLTCRT		0.129 - 0.403	%
RETIC(ADVIA)		0.2 - 1.6	%
RETICS (ABS) ADVIA		14.7 - 113.7	K/uL

Nova Full Panel-ICU **10/7/2018 10:31:27 AM** **Accession ID:** B6

Test	Results	Reference Range	Units
GLUCOSE		67 - 135	mg/dL
UREA		8 - 30	mg/dL
CREATININE		0.6 - 2	mg/dL
PHOSPHORUS		2.6 - 7.2	mg/dL
CALCIUM2		9.4 - 11.3	mg/dL
MAGNESIUM 2+		1.8 - 3	mEq/L
T. PROTEIN		5.5 - 7.8	g/dL
ALBUMIN	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
CHLORIDE		106 - 116	mEq/L
POTASSIUM		3.7 - 5.4	mEq/L
tCO2 (BICARB)		14 - 28	mEq/L
AGAP		8 - 19	
NA/K		29 - 40	

FDA-CVM-FOIA-2019-1704-006413

T BILIRUBIN	B6	0.1 - 0.3	mg/dL
D.BILIRUBIN		0 - 0.1	mg/dL
I BILIRUBIN		0 - 0.2	mg/dL
ALK PHOS		12 - 127	U/L
GGT		0 - 10	U/L
ALT		14 - 86	U/L
4309 Result(s) verified			
AST		9 - 54	U/L
2648 Result(s) verified			
CK		22 - 422	U/L
16084 Result(s) verified			
CHOLESTEROL	B6	82 - 355	mg/dL
TRIGLYCERIDES		30 - 338	mg/dl
AMYLASE		409 - 1250	U/L
OSMOLALITY (CALCULATED)		291 - 315	mmol/L

Nova Full Panel-ICU **10/7/2018 10:31:11 AM** **Accession ID:** B6

Test	Results	Reference Range	Units
SEGS%	B6	43 - 86	%
LYMPHS%		7 - 47	%
MONOS%		1 - 15	%
EOS%		0 - 16	%
SEGS (AB)ADVIA		2.8 - 11.5	K/ul
LYMPHS (ABS)ADVIA		1 - 4.8	K/uL
MONOS (ABS)ADVIA		0.1 - 1.5	K/uL
EOS (ABS)ADVIA		0 - 1.4	K/uL
TOXIC CHANGE		0 - 0	
Occasional Occasional neutrophil appears slightly toxic			
ACANTHOCYTES	Occasional	0 - 0	
KERATOCYTES/BLISTER CELLS	Occasional	0 - 0	
POIKILOCYTOSIS	B6	0 - 0	

Nova Full Panel-ICU **10/31/2018 3:19:40 PM** **Accession ID:** B6

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

FDA-CVM-FOIA-2019-1704-006414

Client: B6
Patient:

Anesthesia Record

Tufts Cummings School of Veterinary Medicine SA Anesthesia Surgical Checklist

App

Patient: B6
Client: B6

Species: Canine
Breed: Boxer
Sex: Male
Weight kg: 0.00
Date of Birth: B6
Color: White
Check-in Date: B6 2:54:23 AM

Patient ID: B6
City: B6
Home Phone:
Cell Phone: B6
Ref Facility
Ref Phone B6

Additional notes:

Before Premedication of Patient	*After Induction in Prep Area*	*Prior to Leaving OR*
Confirmed by Anesthesia Team	**Initiated by Anesthesia Team**	**Initiated by Anesthesia Team**
☑ Patient ID, procedure,& procedure site	Radiology work-up completed o Yes ☑ N/A	Phone call to radiology o Yes ☑ N/A
☑ Blood work and SOAP complete	Cefazolin (or other antibiotic) requested and available ☑ Yes o Hold o N/A	**Anesthesia Service States** ☑ Any concerns for patient recovery?
☑ Body weight matches patient size	Number of catheters placed is appropriate for patient needs ☑ Yes o No, additional catheters placed	**Surgeon States** ☑ Any concerns for patient recovery?
☑ Work-up sheet reviewed & signed by anesthesiologist	Does patient need T-set? o Yes (place T set in induction) ☑ No	☑ Ward where patient will spend the evening ICU
Before Induction of Patient	*Before Skin Incision*	If patient can receive NSAIDs o Yes ☑ No Which NSAID?
Confirmed by Anesthesia Team	**Initiated by Anesthesia Team**	Additional analgesics surgery will use ☑ Yes rescue fentanyl o No Which analgesic?
Met check cleared o Yes ☑ N/A	☑ Patient's ID, procedure, & procedure site confirmed	Bladder o Express o U cath
Red line cleared by accounting ☑ Yes o N/A	Cefazolin (or other a/b) requested & given within the prev. 60 min ☑ Yes o Hold o N/A	Surgeon/ Resident: B6
☑ Anesthesia machine checked and pop-off valve open	**Anesthetist States** ☑ Any specific anesthetic concerns	Anesthetist Tech/Studer B6
Difficult airway or aspiration risk? ☑ No o Yes, nec. equipment available o Yes, Surgeon must be present	**Surgeon States** ☑ Critical or non-routine steps ☑ Anticipated blood loss	Surgery Tech B6
Risk of significant blood loss o No o Yes, blood type (+/- crossmatch) and appropriate blood available	**Surgery Technician States** ☑ Sterilization indicators confirmed	Date: B6
This form remains with the patient through recovery.		

FDA-CVM-FOIA-2019-1704-006415

Client: B6
Patient:

Anesthesia Record

Emergency Anesthesia/Surgery Checklist

Faculty: _____ **Resident/Intern:** B6

Surgical Procedure: B6

Patient Code: Green X **Yellow** ___ **Red** ___

Weight(kg): 30.8 Temp: 96.9 ASA Status: I II III (IV) V

IVC placed? Y X N ___ Gauge/Location: 18G Sheath Rt cephalic & R lateral saphenous

Met Check completed? Y ___ N X N/A X Results: _____

NOVA Completed? Y X N ___ Reviewed? Y X N ___

Analgesia? Y X N ___ Drug/Dose: B6 Time: 1:20 AM

Fluids? Y X N ___ Type/Amount: 1L bolus Time: 1:20 AM

Repeat AXR prior to surgery? Y ___ N X

Surgical(surgeon/tech/student)/Anesthesia(anesthetist/student) Called? Time: _____

If ASA status ≥ III consider (check if done):

Blood Type _____ Coags _____ 2nd IVC (hind leg) ✓

Lumen catheter _____ Doppler BP _____ Heat support _____

Other Considerations (check if applicable):

Brachycephalic? _____ vWD protocol _____ Sepsis protocol _____

NOTES: _____

SOAP COMPLETE? Y ___ N ___ SX DEPOSIT COLLECTED? Y ___ N ___

Place B6

Species: Canine
Breed: Boxer
Sex: Male
Weight kg: 0.00
Date of Birth B6
Color: White
Check-in Date: B6 12:54:23 AM

Patient ID: B6
City: B6
Home Phone:
Cell Phone: B6
Ref Facility
Ref Phone

FDA-CVM-FOIA-2019-1704-006416

Anesthesia Record

Tufts University Cummings School of Veterinary Medicine
ANESTHESIA RECORD

B6

Weight: # B6

Cage/Stall: TCU Run 2

Anesthetist/Student/Anesthesiologist: B6

Procedure: B6

PRE-ANESTHESIA DISPOSITION
☐ Alert ☒ Recumbent
☐ Excited ☐ Caution
☒ Depressed ☐ Painful
☐ Anxious ☐

B6

Species: Canine
Breed: Boxer
Sex: Male
Weight kg: 0.00
Date of Birth: B6
Color: White
Check-in Da: B6 12:54:23 AM

Patient ID: B6
City: B6
Home Phone:
Cell Phone:
Ref Facility
Ref Phone

B6

Page 1 of 1

Discarded Drugs: 230m B6

PRE-ANESTHETIC DRUGS:

Drug	Dose	Route	Time
B6	B6	IV	2:26 A
		IV	2:26 A

PRE-MED. RESULTS
Sedation / Resistance
☐ None ☒
☐ Slight ☐
☒ Moderate ☐
☐ Marked ☐
Vomited: ☐ Yes ☒ No

ANESTHETIC INDUCTION:

Drug	Dose	Route	Time
B6	50.0mg	IV	2:29 AM

B6

TU-V0031 Rev. 01-2015 Reorder Copy Center 617-636-5373 (Form #240)

FDA-CVM-FOIA-2019-1704-006417

Client: B6
Patient:

Rx B6 10mg B6

B6 07:22 PM B6 via B6 FAX Page 1 of 1 B6

B6

B6

B6

Employee # B6

Date B6

Dear Doctor, 5243234

Please review and complete the following prescription authorization and fax the form back to our pharmacy at B6. If you need to speak with our pharmacists, or prefer to call us with this prescription, please call B6 Thank you.

FAXED 11-1-18

Pet Owner Information

Pet Owner's Name (First) B6 (Last) B6 C# B6

Address B6 City B6

State B6 Zip B6 Phone B6 Ord # B6

Pet & Prescription Information

Attn Veterinarian: Please enter all of the following Rx information.

	Pet Name	Weight	Medication	Strength	Qty	Additional Refills
B6 1	B6		B6	10mg	100	11
	Species: DOG	Directions for Use: Give 1 tablet by mouth twice daily				
	Denied:	Reason:				
2						
	Species	Directions for Use:				
	Denied:	Reason:				

Additional Comments: **Client is requesting additional refills, thank you.**

Veterinarian Information

In compliance with pharmacy law, we are only able to accept prescriptions faxed from a licensed veterinarian. Please fax the completed form to B6 Thank You

Veterinarian Name B6 State License B6 DEA # (if applicable)

Clinic Name Cummings Medical Center Phone 508-839-5395 Fax 508-839-7951

Address City State Zip

Email ID # (Pharmacy use only)

Patient Information ** To be completed by Veterinarian **

Please indicate any known significant allergies/medical conditions:

Veterinarian's Signature **Per Pharmacy Law we are unable to accept stamped signatures.** Date B6

B6 Generic Equivalent Permissible Medically Necessary B6 Printed Name

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FDA-CVM-FOIA-2019-1704-006418

Client: B6
Patient:

BNP 10/31/18

B4 Laboratories

Clie B6 Patie B6

IDEXX VetConnect 1-888-433-9987

Client: B6
Patient: B6
Species: CANINE
Breed:
Gender:
Age: 0Y

Date: 10/31/2018
Requisition #: B6
Accession #: B6
Ordered by: NOT SPECIFIED

TUFTS UNIVERSITY
200 WESTBORO RD
NORTH GRAFTON, Massachusetts 01536-1828
508-839-5395

Account: B6

CARDIOPET proBNP - CANINE

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

Comments:

B6

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

FDA-CVM-FOIA-2019-1704-006419

Client: B6
Patient:

UCDavis Taurine Panel

PL 2 B6

Amino Acid Laboratory Sample Submission Form

Amino Acid Laboratory, 1089 Veterinary Medicine Drive, Davis, Ca 95616
Telephone: 530-752-5058, Fax: 530-752-4698
Email: ucd.aminoacid.lab@ucdavis.edu
www.vetmed.ucdavis.edu/labs/amino-acid-laboratory

B6
B6
B6 Canine 10:45 AM
TAURINE PANEL
Lithium Heparin

Veterinarian Contact: B6

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

Address: 200 Westboro Road, North Grafton MA 015369

Email: Clinpath@tufts.edu / cardiovet@tufts.edu

Telephone: 508-887-4669 Fax: 508-839-7936

Billing Contact: B6 Email: B6

Billing Contact Phone: B6 Tax ID:

Patient Name: B6 Species: Canine

Breed: Boxer Owner's Name: B6

Current Diet: Rachel Ray super premium dry chicken/veggies dry, Purina One chicken/rice canned, Newman's own chicken/rice

Sample type: (Plasma) (Whole Blood) Urine Food Other

Test: (Taurine) Complete Amino Acids Other:

Taurine Results (lab use only)

Plasma: B6 Whole Blood: B6 Urine: Food:

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

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

FDA-CVM-FOIA-2019-1704-006420

From: Related PFR Event <pfrsignificantactivitycreation@fda.hhs.gov>

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

Sent: 3/21/2019 4:00:51 PM

Subject: Acana Lamb and Apple singles: Lisa Freeman - EON-382951

Attachments: 2064360-report.pdf; 2064360-attachments.zip

A PFR Report has been received and Related PFR Event [EON-382951] has been created in the EON System.

A "PDF" report by name "2064360-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 "2064360-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-382951
ICSR #: 2064360
EON Title: Related PFR Event created for Acana Lamb and Apple singles; 2064360

AE Date	11/08/2018	**Number Fed/Exposed**	1
Best By Date		**Number Reacted**	1
Animal Species	Dog	**Outcome to Date**	Stable
Breed	Irish Wolfhound		
Age	3 Years		
District Involved	PFR-New England DO		

Product information
Individual Case Safety Report Number: 2064360
Product Group: Pet Food
Product Name: Acana Lamb and Apple singles
Description: Littermate diagnosed with DCM. Initial taurine level (plasma only) was B6 WB taurine submitted = B6 Eats BEG diet Mildly reduced contractile function on echo NT-proBNP = B6 troponin mildly elevated at B6 istat) and B6 t Texas A&M Will recheck in 3-4 months Follow-up - NT-proBNP, troponin, echo and ECG
Submission Type: Followup

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

Product Name	Lot Number or ID	Best By Date
Acana Lamb and Apple singles		

This report is linked to:
Initial EON Event Key: EON-372606
Initial ICSR: 2059540

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

Owner information
B6 USA

To view this Related PFR Event, please click the link below:
https://eon.fda.gov/eon//browse/EON-382951

To view the Related PFR Event Report, please click the link below:
https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jspa?decorator=none&e=0&issueType=10100&issueId=400049&parentIssueTypeId=12

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{

Report Details - EON-382951

ICSR:	2064360		
Type Of Submission:	Followup		
Report Version:	FPSR.FDA.PETF.V.V1		
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)		
Reporting Type:	Voluntary		
Report Submission Date:	2019-03-21 11:55:12 EDT		
Initial Report Date:	12/03/2018		
Parent ICSR:	2059540		
Follow-up Report to FDA Request:	Yes		
Reported Problem:	**Problem Description:**	Littermate diagnosed with DCM. Initial taurine level (plasma only) was B6 WB taurine submitted = B6 Eats BEG diet Mildly reduced contractile function on echo NT-proBNP = B6 troponin mildly elevated at B6 (istat) and B6 at Texas A&M Will recheck in 3-4 months Follow-up - NT-proBNP, troponin, echo and ECG	
	Date Problem Started:	11/08/2018	
	Concurrent Medical Problem:	Yes	
	Pre Existing Conditions:	B6	
	Outcome to Date:	Stable	
Product Information:	**Product Name:**	Acana Lamb and Apple singles	
	Product Type:	Pet Food	
	Lot Number:		
	Package Type:	BAG	
	Product Use Information:	**Description:**	Fed since 2016
	Manufacturer /Distributor Information:		
	Purchase Location Information:		
Animal Information:	**Name:**	B6	
	Type Of Species:	Dog	
	Type Of Breed:	Irish Wolfhound	
	Gender:	Male	
	Reproductive Status:	Intact	
	Weight:	82.7 Kilogram	
	Age:	3 Years	
	Assessment of Prior Health:	Good	
	Number of Animals Given the Product:	1	
	Number of Animals Reacted:	1	
	Owner Information:	**Owner Information provided:**	Yes
		Contact:	**Name:** B6
			Phone: B6
			Email: B6
		Address:	B6

FDA-CVM-FOIA-2019-1704-006424

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

Client: B6
Patient:

IDEXX BNP - 3/5/2019

IDEXX Reference Laboratories

Client B6 Patient B6

IDEXX VetConnect 1-888-433-9987

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

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

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

Account B6

CARDIOPET proBNP - CANINE

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

Comments:
1. B6

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

Page 1 of 1

FDA-CVM-FOIA-2019-1704-006426

Client: B6
Patient:

Texas A and M Troponin

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

Website User ID: clinpath@tufts.edu

GI Lab Assigned Clinic ID: 11405

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

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

Tufts University-Clinical Pathology Lab
Tracking Number: 337144

GI Lab Accession: B6

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

B6

Comments:

GI Lab Contact Information

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

FDA-CVM-FOIA-2019-1704-006427

Client: B6
Patient:

Diet Hx 3/5/19

CARDIOLOGY DIET HISTORY FORM

Please answer the following questions about your pet

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

1. How would you assess your pet's appetite? (mark the point on the line below that best represents your pet's appetite)

Example: *Poor* _____|_____ *Excellent*

Poor _____|_____ **Excellent**

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

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

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

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

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

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

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

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

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

FDA-CVM-FOIA-2019-1704-006428

Client: B6
Patient:

Vitals Results

B6	3:47:44 PM	Nursing note	B6
	4:41:36 PM	Heart Rate (/min)	
	4:41:37 PM	Respiratory Rate	
	4:41:38 PM	Temperature (F)	
11/8/2018 10:04:53 AM		Weight (kg)	
3/5/2019 10:04:41 AM		Weight (kg)	

FDA-CVM-FOIA-2019-1704-006429

Client: B6
Patient:

ECG from Cardio

B6

11/8/2018 12:00:47 PM

Tufts University
Tufts Cummings School of Vet Med
Cardiology

12 Lead; Standard Placement

FDA-CVM-FOIA-2019-1704-006430

ECG from Cardio

B6

Tufts University
Tufts Cummings School of Vet Med
Cardiology

FDA-CVM-FOIA-2019-1704-006431

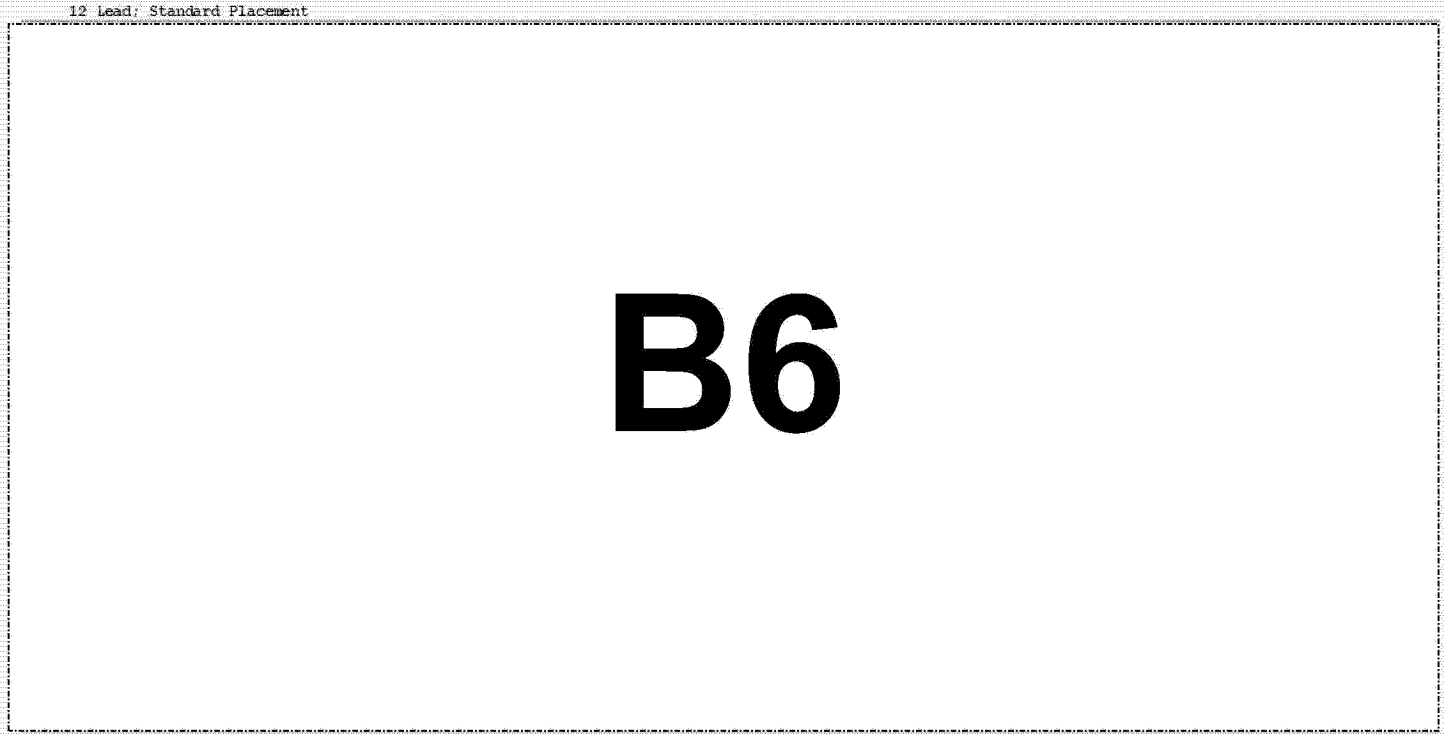
Client: B6
Patient:

ECG from Cardio

B6

11/8/2018 12:00:59 PM
Tufts University
Tufts Cummings School of Vet Med
Cardiology

12 Lead; Standard Placement



FDA-CVM-FOIA-2019-1704-006432

Patient History

03/28/2016 08:35 PM	UserForm
03/28/2016 08:36 PM	Purchase
03/28/2016 10:53 PM	Treatment
03/28/2016 10:55 PM	Prescription
03/28/2016 11:03 PM	UserForm
03/28/2016 11:04 PM	Purchase
06/07/2017 10:45 PM	Prescription
06/07/2017 10:48 PM	Purchase
06/07/2017 10:48 PM	Purchase
06/08/2017 06:01 AM	UserForm
06/08/2017 06:01 AM	Email
06/08/2017 01:12 PM	Purchase
06/08/2017 02:15 PM	UserForm
06/08/2017 03:18 PM	Purchase
06/08/2017 03:18 PM	Treatment
06/08/2017 03:30 PM	UserForm
06/08/2017 03:45 PM	Treatment
06/08/2017 03:45 PM	Deleted Reason
06/08/2017 03:47 PM	Treatment
06/08/2017 03:47 PM	Vitals
06/08/2017 04:41 PM	Vitals
06/08/2017 04:41 PM	Vitals
06/08/2017 04:41 PM	Vitals
06/09/2017 02:38 AM	UserForm
06/09/2017 02:38 AM	Email
10/05/2018 10:40 AM	Appointment
11/08/2018 10:04 AM	UserForm
11/08/2018 10:04 AM	Vitals
11/08/2018 11:07 AM	Treatment
11/08/2018 11:14 AM	UserForm
11/08/2018 11:30 AM	Purchase
11/08/2018 03:31 PM	Labwork
11/08/2018 03:34 PM	Purchase
11/08/2018 03:34 PM	Purchase
11/08/2018 03:34 PM	Purchase
01/15/2019 01:04 PM	Appointment
02/19/2019 06:07 PM	Appointment

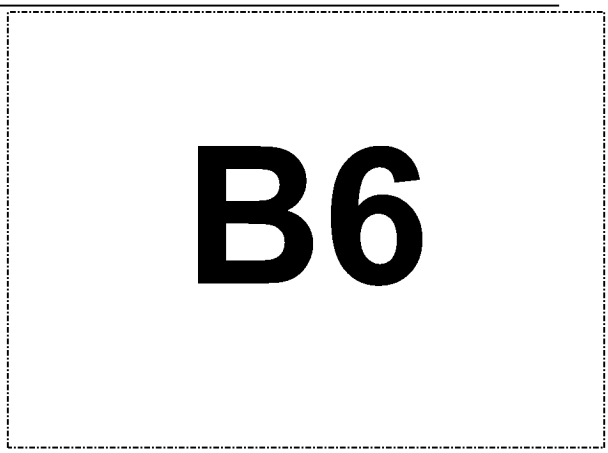
B6

FDA-CVM-FOIA-2019-1704-006433

Client:
Patient: B6

Patient History

03/05/2019 09:51 AM	Purchase
03/05/2019 09:55 AM	UserForm
03/05/2019 09:59 AM	Treatment
03/05/2019 10:04 AM	Vitals
03/05/2019 10:28 AM	UserForm
03/05/2019 11:12 AM	Appointment
03/05/2019 11:12 AM	Email
03/05/2019 03:03 PM	Purchase



Patient Account History	Description	Qty	price	Extended	Disc	Pmt

FDA-CVM-FOIA-2019-1704-006434

From:	Rotstein, David </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0A3B17EBFCF14A6CB8E94F322906BADD-DROTSTEI>
To:	Carey, Lauren; Ceric, Olgica; Glover, Mark; Jones, Jennifer L; Nemser, Sarah; Palmer, Lee Anne; Peloquin, Sarah; Queen, Jackie L; Rotstein, David
Sent:	4/11/2019 9:22:54 PM
Subject:	forwarding in case this was a case that was being follow-up-FW: Purina One Smart Blend Lamb and Rice dry: Lisa Freeman - EON-384837
Attachments:	2065714-report.pdf; Purina One Smart Blend Lamb and Rice dry: Lisa Freeman - EON-380707

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

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From: Related PFR Event <pfrsignificantactivitycreation@fda.hhs.gov>
Sent: Thursday, April 11, 2019 5:21 PM
To: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Cleary, Michael * <Michael.Cleary@fda.hhs.gov>; HQ Pet Food Report Notification <HQPetFoodReportNotification@fda.hhs.gov>; B6
Subject: Purina One Smart Blend Lamb and Rice dry: Lisa Freeman - EON-384837

A PFR Report has been received and Related PFR Event [EON-384837] has been created in the EON System.

A "PDF" report by name "2065714-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report:

EON Key: EON-384837
ICSR #: 2065714
EON Title: Related PFR Event created for Purina One Smart Blend Lamb and Rice dry; 2065714

AE Date	08/01/2018	**Number Fed/Exposed**	3
Best By Date		**Number Reacted**	1
Animal Species	Dog	**Outcome to Date**	Died Other
Breed	Doberman Pinscher		

Age	B6 Years		
District Involved	PFR-New England DO		

Product information
Individual Case Safety Report Number: 2065714
Product Group: Pet Food
Product Name: Purina One Smart Blend Lamb and Rice dry
Description: DCM and CHF diagnosed Aug 2018 We saw 1/11/19 - CHF still not well controlled Eating Purina Lamb and Rice - unlikely to be associated with DCM but reporting just in case Owner is now changing to different diet and will recheck in 3 months 2 other dogs eating same diet - we have not screened them yet. BNP = B6 troponin B6, but taurine normal (B6 plasma, B6 whole blood)
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 Other
Number of Animals Treated With Product: 3
Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Purina One Smart Blend Lamb and Rice dry		

This report is linked to:
Initial EON Event Key: EON-380707
Initial ICSR: 2063114

Sender information

B6

USA

Owner information

B6

B6 USA

To view this Related PFR Event, please click the link below:
https://eon.fda.gov/eon//browse/EON-384837

To view the Related PFR Event Report, please click the link below:
https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jspa?decorator=none&e=0&issueType=10100&issueId=401965&parentIssueTypeId=12

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{

Report Details - EON-384837

ICSR:	2065714
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:	2019-04-11 17:17:15 EDT
Initial Report Date:	02/24/2019
Parent ICSR:	2063114
Follow-up Report to FDA Request:	Yes

Reported Problem:

Problem Description:	DCM and CHF diagnosed Aug 2018 We saw 1/11/19 - CHF still not well controlled Eating Purina Lamb and Rice - unlikely to be associated with DCM but reporting just in case Owner is now changing to different diet and will recheck in 3 months 2 other dogs eating same diet - we have not screened them yet. BNP = B6 troponin B6 but taurine normal (B6 plasma B6 whole blood)
Date Problem Started:	08/01/2018
Concurrent Medical Problem:	No
Outcome to Date:	Died Other
Date of Death:	B6

Product Information:

Product Name:	Purina One Smart Blend Lamb and Rice dry	
Product Type:	Pet Food	
Lot Number:		
Product Use Information:	**Description:**	1/2 cup twice daily since a puppy See diet history for additional details
Manufacturer /Distributor Information:		
Purchase Location Information:		

Animal Information:

Name:	B6
Type Of Species:	Dog
Type Of Breed:	Doberman Pinscher
Gender:	Male
Reproductive Status:	Neutered
Weight:	29.9 Kilogram
Age:	B6 Years
Assessment of Prior Health:	Excellent
Number of Animals Given the Product:	3
Number of Animals Reacted:	1

Owner Information:

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

FDA-CVM-FOIA-2019-1704-006438

			B6 United States
	Healthcare Professional Information:	Practice Name:	Tufts Cummings School of Veterinary Medicine
		Contact:	Name: Lisa Freeman
			Phone: (508) 887-4523
			Email: lisa.freeman@tufts.edu
		Address:	200 Westboro Rd North Grafton Massachusetts 01536 United States
Sender Information:	Name:	Lisa Freeman	
	Address:	200 Westboro Rd North Grafton Massachusetts 01536 United States	
	Contact:	Phone:	5088874523
		Email:	lisa.freeman@tufts.edu
	Permission To Contact Sender:	Yes	
	Preferred Method Of Contact:	Email	
Additional Documents:			

FDA-CVM-FOIA-2019-1704-006439

Cummings Veterinary Medical Center
AT TUFTS UNIVERSITY

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

All Medical Records

Client:
Address: B6

Patient: B6
Breed: Doberman
DOB: B6

Species: Canine
Sex: Male (Neutered)

Home Phone:
Work Phone:
Cell Phone: B6

Referring Information

B6

Client:
Patient: B6

Initial Complaint:
Scanned Record

Initial Complaint:
New - B6 - CHF

SOAP Text Jan 11 2019 5:37PM - B6

Initial Complaint:
Chem 21 - B6 5856

SOAP Text Jan 18 2019 3:04PM - B6

Disposition/Recommendations

FDA-CVM-FOIA-2019-1704-006440

FDA-CVM-FOIA-2019-1704-006441

Cummings Veterinary Medical Center AT TUFTS UNIVERSITY

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

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

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

Lab Results Report

Accession ID:

Test	Results	Reference Range	Units

stringsoft

Printed Sunday, February 24, 2019

Vitals Results

1/11/2019 4:07:45 PM	Weight (kg)	B6
1/11/2019 4:43:10 PM	Nursing note	
1/18/2019 3:12:02 PM	Weight (kg)	

FDA-CVM-FOIA-2019-1704-006442

Cummings Veterinary Medical Center
AT TUFTS UNIVERSITY

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

Medical Record for B6

Client:
Address: B6

Patient: B6
Breed: English Cocker Spaniel
DOB: B6

Species: Canine
Sex: Male (Neutered)

Home Phone:
Work Phone:
Cell Phone: B6

Referring Information

B6

Client:
Patient: B6

Initial Complaint:

B6

SOAP Text B6 11:31AM - B6

Disposition/Recommendations

FDA-CVM-FOIA-2019-1704-006443

FDA-CVM-FOIA-2019-1704-006444

Cummings Veterinary Medical Center AT TUFTS UNIVERSITY

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

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

Patient:	B6
Species:	Canine
Breed:	English Cocker Spaniel
Sex:	Male (Neutered)
Age:	B6 Years Old

Lab Results Report

Phenobarbital B6 11:31:00 AM **Accession ID:** B6

Test	Results	Reference Range	Units
PHENOBARB	B6	10 - 40	ug/mL

3/19 B6

stringsoft

Printed Monday, February 25, 2019

FDA-CVM-FOIA-2019-1704-006445

Client: B6
Patient: B6

IDEXX BNP - 1/23/2019

IDEXX Reference Laboratories

Client: B6 Patient: B6

IDEXX VetConnect 1-888-433-9987

Client: B6
Patient:
Species: CANINE
Breed: COCKER_SPANIEL
Gender: MALE
Age: 5Y

Date: B6
Requisition #: 1
Accession #: B6
Ordered by: B6

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

Account: B6

CARDIOPET proBNP - CANINE

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

Comments:

1. B6

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

Page 1 of 1

FDA-CVM-FOIA-2019-1704-006446

DISCHARGE CHECKLIST FOR SURGERY

Patient's Full Name B6 Case # B6

Owner's Town B6 Sx performed B6

Location of patient: B ward Date of surgery B6

Dr. of record: B6 Date of discharg

- ☑ Pet is clean and dry
- ☑ Catheter is removed and green bandage placed
- ☑ Green bandage removed OR in rare instances owner instructed to remove
- ☒ Biogard/Tegaderm is removed
- ☒ Urinary catheter AND stay sutures are removed
- ☒ Telemetry pads are removed
- ☒ Orthopedic bandage removed, if applicable, otherwise instructions given to owner for bandage care.
- ☑ d/c meds given to owner with instructions
- ☑ owner informed when to start medications
- ☒ owners meds returned
- ☑ owner informed last time pet ate
- ☑ collar/leash/personal belongings returned
- ☑ e-collar given to owner, if necessary
- ☐ recheck appointments not needed

Or: ☐ Suture removal on _____

☑ Recheck x-rays on in 8 wks 3/26 10:00

☐ bandage change on _____

This form MUST be placed on Leslie's desk after discharge. Thank you!

Date: B6 **Time:** 5 **Student's name** B6

FDA-CVM-FOIA-2019-1704-006447

Client: B6
Patient:

Taurine B6

Cummings School of Veterinary Medicine

Clinical Pathology Laboratory
200 Westboro Road
North Grafton, MA 01536

Name/DOB: B6
Patient ID: 343384
Phone number:
Collection Date: B6 2:37 PM
Approval date: 1/31/2019 7:55 AM

Sex: CM
Age: 5
Species: Canine
Breed: English Cocker Spaniel

Provider: B6
Order Location: V320559: Investigation into
Sample ID: 1901220112

TEST NAME	RESULT IN RANGE	RESULT OUT OF RANGE	RANGE	UNITS	REFERENCE RANGE
Taurine Panel					B6
Plasma Taurine B6 2:51 PM		B6 >40 nmol/mL=no risk for tautine deficiency	* [_____]	nmol/mL	60-120
Whole Blood Taurine B6 2:51 PM		B6 >200 nmol/ml=no risk for taurine deficiency	[*_____]	nmol/mL	200-350

Sample ID: 1901220112/1
END OF REPORT (Final)

Reviewed by: _____

FDA-CVM-FOIA-2019-1704-006448

B6

Saturday, February 02, 2019

Dr. B6
Tufts Cummings Vet Medical Center
55 Willard St
North Grafton, MA 01536
FAX: (508) 839-7951

Re: B6
Spaniel, English Cocker, Neutered Male, 5 Yrs. 2 Mos.
B6

Dear Dr. B6

B6

B6

B6

Sincerely,

B6

FDA-CVM-FOIA-2019-1704-006449

RDVM 2/2/19

FDA-CVM-FOIA-2019-1704-006450

Client: B6
Patient:

Amino Acid Labs Taurine Panel B6

B6

B6 2:37 PM

SHIP w ICE PACKS, TAURINE PANEL

Lithium Heparin

B6

Amino Acid Laboratory Sample Submission Form

Amino Acid Laboratory, 1089 Veterinary Medicine Drive, Davis, Ca 9561
Telephone: 530-752-5058, Fax: 530-752-4698
Email: ucd.aminoacid.lab@ucdavis.edu
www.vetmed.ucdavis.edu/labs/amino-acid-laboratory

Veterinarian Contact: Dr. B6

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

Address: 200 Westboro Road, North Grafton, MA, 015369

Email: Clinpath@tufts.edu cardiovet@tufts.edu

Telephone: 508-887-4669 **Fax:** 508-839-7936

Billing Contact: B6 **Email:** B6

Billing Contact Phone: B6 **Tax ID:**

Patient Name: B6 **Species:** Canine

Breed: Cocker **Owner's Name:** B6

Current Diet : A Can'o

Sample type: Plasma Whole Blood Urine Food Other

Test: Taurine Complete Amino Acids Other:

Taurine Results (lab use only)

Plasma: B6 Whole Blood: B6 Urine: Food:

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

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

FDA-CVM-FOIA-2019-1704-006451

Client:
Patient: **B6**

Amino Acid Labs Taurine Panel **B6**

UNIVERSITY OF CALIFORNIA, DAVIS

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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.

- Normal whole blood taurine: >250nmol/mL
- Normal plasma taurine: >70nmol/mL

- Marginal whole blood taurine: 200-250nmol/mL
- Marginal plasma taurine: 60-70nmol/mL

- Low whole Blood taurine: <200nmol/mL
- Low plasma taurine: <60nmol/mL

References:

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. 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.

FDA-CVM-FOIA-2019-1704-006452

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 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 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.
  - 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 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.

FDA-CVM-FOIA-2019-1704-006453

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:
  - https://www.fda.gov/AnimalVeterinary/NewsEvents/CVMUpdates/ucm613305.htm

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)

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

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

The 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 ~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

FDA-CVM-FOIA-2019-1704-006454

UCDAVIS VETERINARY MEDICINE

CARDIOLOGY SERVICE UPDATES: DOG FOOD & DILATED CARDIOMYOPATHY

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

FDA Alerts found here:
https://www.fda.gov/AnimalVeterinary/NewsEvents/CVMUpdates/ucm613305.htm
https://www.fda.gov/AnimalVeterinary/ResourcesforYou/AnimalHealthLiteracy/ucm616279.htm

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

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

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

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

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

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

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

FDA reporting guidelines found here: https://www.fda.gov/AnimalVeterinary/SafetyHealth/ReportaProblem/ucm182403.htm

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

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

FDA-CVM-FOIA-2019-1704-006455

Client: B6
Patient:

Diet history 2/13/19

2.2CARDIOLOGY DIET HISTORY FORM
Please answer the following questions about your pet

Pet's name: B6 Owner's name: B6 Today's date: 2/13/2019

1. How would you assess your pet's appetite? (mark the point on the line below that best represents your pet's appetite)

Example: ***Poor*** _____ ***Excellent***

Poor _____ **Excellent**

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

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

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

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

Food (include specific product and flavor)	Form	Amount	How often?	Dates fed
Nutro Grain Free Chicken, Lentil, & Sweet Potato Adult	*dry*	*1 ½ cup*	*2x/day*	*Jan 2016-present*
85% lean hamburger	*microwaved*	*3 oz*	*1x/week*	*June -Aug 2016*
Pupperoni original beef flavor	*treat*	*½*	*1x/day*	*Sept 2016-present*
Rawhide	*treat*	*6 inch twist*	*1x/week*	*Dec 2018-present*
Acana Lamb & Apple	dry	¾ cup	daily	2013 – JAN 2019
Carrot slices, broccoli crown pieces	treat	1 – 2 pieces	3x/week	
Raw beef rib bones	treat	1 - 2	weekly	

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

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

Brand/Concentration
Amount per day

Taurine ☐Yes X No _____

Carnitine ☐Yes X No _____

Antioxidants ☐Yes X No _____

Multivitamin ☐Yes X No _____

Fish oil ☐Yes X No _____

Coenzyme Q10 ☐Yes X No _____

Other (please list):
Example: Vitamin C *Nature's Bounty*
500 mg tablets – 1 per day

_____ _____

FDA-CVM-FOIA-2019-1704-006456

_____ _____
_____
_____ _____
_____
_____ _____
_____

3. How do you administer pills to your pet?
   - ☐ I do not give any medications
   - ☐ I put them directly in my pet's mouth without food
   - ☐ I put them in my pet's dog/cat food
   - ☐ I put them in a Pill Pocket or similar product
   - X I put them in foods (list foods):__Mostly banana slices or pure peanut butter.

FDA-CVM-FOIA-2019-1704-006457

Client: B6
Patient:

Vitals Results

B6	3:10:53 PM	Nursing note	B6
	4:15:34 PM	Nursing note	

FDA-CVM-FOIA-2019-1704-006458

Client: B6
Patient:

ECG from Cardio

B6 B6 2:59:42 PM

Tufts University
Tufts Cummings School of Vet Med
Cardiology

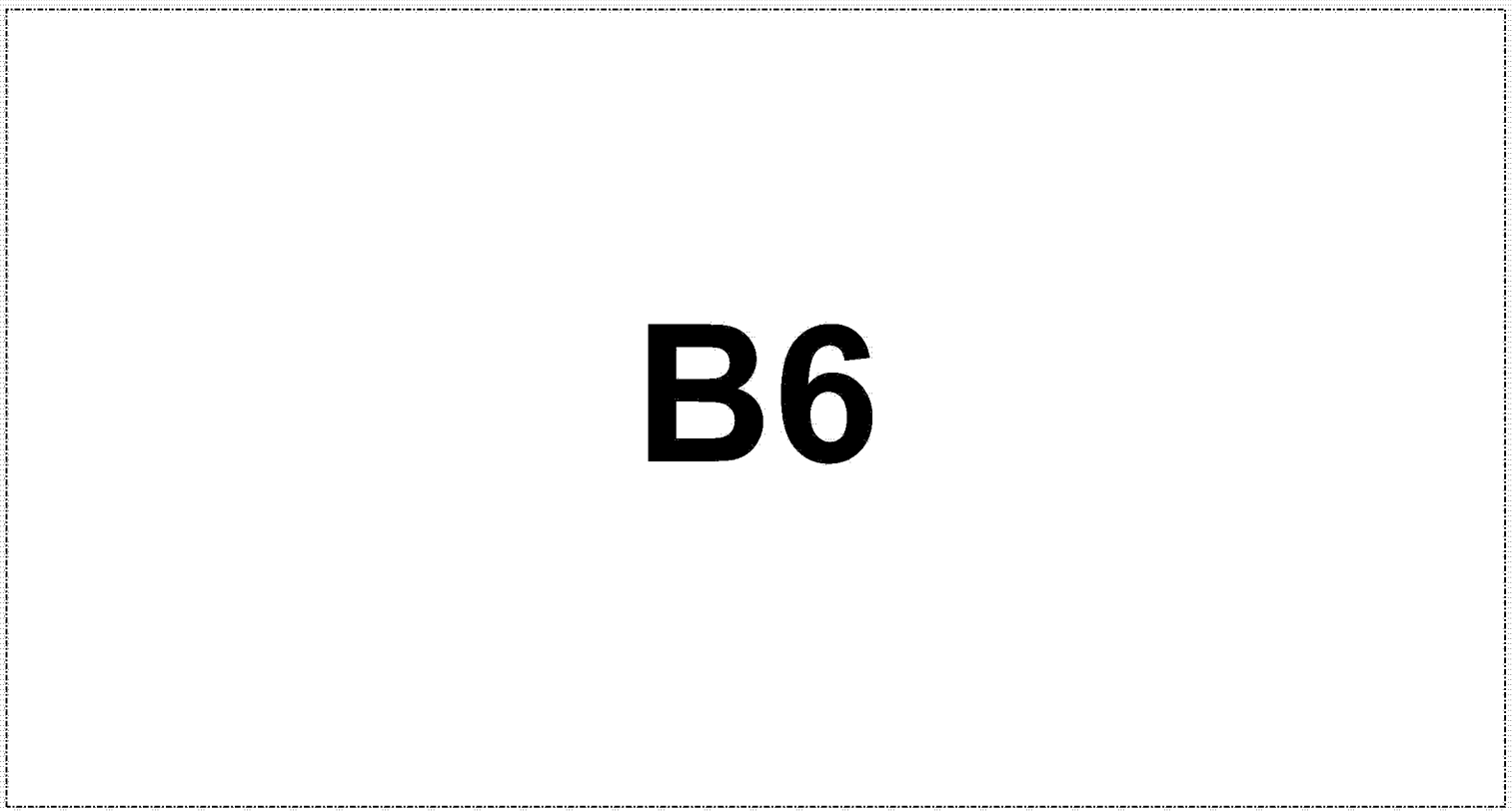
FDA-CVM-FOIA-2019-1704-006459

Client B6
Patien

ECG from Cardio

B6

B6 3:00:04 PM
Tufts University
Tufts Cummings School of Vet Med
Cardiology



FDA-CVM-FOIA-2019-1704-006460

Client: B6
Patient

Patient History

B6

11:28 AM	UserForm
11:31 AM	Purchase
11:36 AM	UserForm
11:41 AM	UserForm
01:46 PM	Treatment
01:47 PM	Purchase
02:08 PM	Prescription
02:10 PM	Prescription
02:13 PM	Prescription
02:28 PM	Deleted Reason
03:10 PM	Treatment
03:10 PM	Purchase
03:10 PM	Vitals
04:15 PM	Treatment
04:15 PM	Vitals
04:27 PM	Purchase
04:27 PM	Deleted Reason
04:27 PM	Deleted Reason
05:24 PM	Purchase
05:24 PM	Purchase
05:24 PM	Purchase
05:24 PM	Purchase
06:02 PM	Purchase
04:45 PM	Email
09:35 AM	Purchase
11:08 AM	Purchase

B6

FDA-CVM-FOIA-2019-1704-006461

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

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

Sent: 2/26/2019 12:21:16 AM

Subject: Wellness Complete Health Fish and Sweet Potato dry: Lisa Freeman - EON-380848

Attachments: 2063189-report.pdf; 2063189-attachments.zip

A PFR Report has been received and PFR Event [EON-380848] has been created in the EON System.

A "PDF" report by name "2063189-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 "2063189-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-380848
ICSR #: 2063189
EON Title: PFR Event created for Wellness Complete Health Fish and Sweet Potato dry; 2063189

AE Date	02/22/2019	**Number Fed/Exposed**	2
Best By Date		**Number Reacted**	1
Animal Species	Dog	**Outcome to Date**	Stable
Breed	Boxer (German Boxer)		
Age	B6 Years		
District Involved	PFR-New England DO		

Product information
Individual Case Safety Report Number: 2063189
Product Group: Pet Food
Product Name: Wellness Complete Health Fish and Sweet Potato dry
Description: Arrhythmia dx at RDVM July 2018 (had been "wheezing") Started wheezing again 1 week before admission. Diagnosed with DCM, CHF, and ventricular tachycardia 2/22/19 Was fed Wellness diet until 6/2018 then changed to Royal Canin Boxer (current diet). Taurine and troponin pending. Owner has another Boxer eating same diets - has not been screened Enrolled in DCM study. Changing to different diet (although Boxer diet is probably fine) and will recheck in 7 days and 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: 2
Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Wellness Complete Health Fish and Sweet Potato dry		

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

Owner information
B6
USA

To view this PFR Event, please click the link below:
https://eon.fda.gov/eon//browse/EON-380848

To view the PFR Event Report, please click the link below:
https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jspa?decorator=none&e=0&issueType=12&issueId=397857

==========

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-380848

ICSR:	2063189		
Type Of Submission:	Initial		
Report Version:	FPSR.FDA.PETF.V.V1		
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)		
Reporting Type:	Voluntary		
Report Submission Date:	2019-02-25 19:07:14 EST		
Reported Problem:	**Problem Description:**	Arrhythmia dx at RDVM July 2018 (had been "wheezing") Started wheezing again 1 week before admission. Diagnosed with DCM, CHF, and ventricular tachycardia 2/22/19 Was fed Wellness diet until 6/2018 then changed to Royal Canin Boxer (current diet). Taurine and troponin pending. Owner has another Boxer eating same diets - has not been screened Enrolled in DCM study. Changing to different diet (although Boxer diet is probably fine) and will recheck in 7 days and 3 months.	
	Date Problem Started:	02/22/2019	
	Concurrent Medical Problem:	No	
	Outcome to Date:	Stable	
Product Information:	**Product Name:**	Wellness Complete Health Fish and Sweet Potato dry	
	Product Type:	Pet Food	
	Lot Number:		
	Product Use Information:	**Description:**	Fed this diet 2012 - June, 2018 Currently, fed Royal Canin Boxer See diet history
	Manufacturer /Distributor Information:		
	Purchase Location Information:		
Animal Information:	**Name:**	B6	
	Type Of Species:	Dog	
	Type Of Breed:	Boxer (German Boxer)	
	Gender:	Male	
	Reproductive Status:	Neutered	
	Weight:	23.3 Kilogram	
	Age:	B6 Years	
	Number of Animals Given the Product:	2	
	Number of Animals Reacted:	1	
	Owner Information:	**Owner Information provided:**	Yes
		Contact:	**Name:** B6
			Phone:
			Email:
		Address:	B6 United States
	Healthcare Professional Information:	**Practice Name:**	Tufts Cummings School of Veterinary Medicine
		Contact:	**Name:** Lisa Freeman
			Phone: (508) 887-4523
			Email: lisa.freeman@tufts.edu
		Address:	

FDA-CVM-FOIA-2019-1704-006465

			200 Westboro Rd North Grafton Massachusetts 01536 United States
Sender Information:	**Name:**	Lisa Freeman	
	Address:	200 Westboro Rd North Grafton Massachusetts 01536 United States	
	Contact:	**Phone:**	5088874523
		Email:	lisa.freeman@tufts.edu
	Permission To Contact Sender:	Yes	
	Preferred Method Of Contact:	Email	
Additional Documents:			
	Attachment:	rpt_medical_record_preview small.pdf	
	Description:	Med records	
	Type:	Medical Records	

Cummings Veterinary Medical Center
AT TUFTS UNIVERSITY

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

All Medical Records

Client: B6
Address:

Patient: B6
Breed: Boxer
DOB: B6

Species: Canine
Sex: Male (Neutered)

Home Phone:
Work Phone:
Cell Phone: B6

Referring Information

B6

Client: B6
Patient:

Initial Complaint:
ARVC vs. DCM with active CHF and uncontrolled Vtach.

SOAP Text Feb 22 2019 9:34AM - Clinician, Unassigned FHSA

Subjective
NEW VISIT (ER)

Doctor: Dr. B6
Student: B6 r V'19
Presenting complaint: wheezing
Referral visit? B6
Diagnostics completed prior to visit - saw this morning but referred straight here
rDVM records in email

HISTORY:

Signalment: B6 y/o MN Boxer
Current history:
In July primary vet noticed heart arrythmia during appointment, was seen then due to symptom of wheezing. rDVM Started on B6, owners gave that for a couple of weeks and wheezing resolved, owners then stopped B6 1 week ago started wheezing again (sporadic), became clingy and lethargic. Owner had been out of town for a week, B6 was at home with husband and owner is unsure what other symptoms B6 has. Owner's husband did restart B6 on Tuesday. No vomting/heaving. Owner reports that he is drinking water normally, but didn't finish his food this morning which is abnormal for him. Unknown diarrhea, appetite status while owner was gone.
Prior medical history: none, B6

FDA-CVM-FOIA-2019-1704-006467

Client:
Patient: B6

Current medications: B6

B6.

Diet: royal canin boxer, dry , unknown length of time (last 1.5-2 yrs)
Vaccination status/flea & tick preventative use: UTD
Travel history: none

EXAM:

B6

ASSESSMENT:

A1: Severe cardiomegaly with poor contractile function - r/o primary DCM, diet-induced cardiomyopathy, ARVC, tachycardiac induced cardiomyopathy.
A2: Malignant ventricular arrhythmia - non-sustained VTach and frequent polymorphic VPCs
A3: Left sided congestive heart failure.

PLAN:

- B6

Treatments:

B6

Diagnostics completed:

- Thoracic radiographs:
    - Cardiopulmonary changes are consistent with left-sided congestive heart failure. Given moderate generalized cardiomegaly and moderate left atrial enlargement, consider DCM given breed. Echocardiography is

FDA-CVM-FOIA-2019-1704-006468

recommended and repeat thoracic radiographs to monitor response to therapy.
- Impression of faint rounded soft tissue opacities mixed in with the intersitital pattern may represent peribronchial cuffing and end on vessels, pulmonary nodules are thought less likely. Follow-up radiographs to reassess the lungs are recommended after resolution of cardiogenic pulmonary edema.
- Concurrent mild diffuse bronchial pattern likely represents a component of lower airway disease.

- Echocardiogram:

Findings consistent with DCM with active CHF and frequent ventricular arrhythmia. Patient has enough malignant arrhythmia that hospitalization and B6 B6 B6 Patient has historically been on grain free diet for years before been switched to current diet. It is unclear whether this is a primary DCM, ARVC with DCM phenotype, or diet-induced cardiomyopathy, but B6 B6 B6 B6 Thus, recommend bloodwork and if liver values are normal, B6 should be started. Fish oil may also be effective helping decrease ventricular arrhythmia density. B6 B6 Recommend repeat echocardiogram in 3 months or sooner in case patient develops clinical signs consistent with progression of the disease (shortness breath, collapse, syncope, exercise intolerance, pale mucous membrane). Client can be instructed on how to use AliveCor and assess heart rate and rhythm from home if patient at rest and calm at home.

PLAN (cardio consult):

B6

B6

FDA-CVM-FOIA-2019-1704-006469

Client: B6
Patient:

Current history:
In July primary vet noticed heart arrythmia during appointment, when he was seen then due to symptom of wheezing. rDVM started B6, and owners gave that for a couple of weeks and wheezing resolved, owners then stopped B6 (they didn't know they were supposed to continue). About 1 week ago started wheezing again (sporadic), becaming more clingy and lethargic. Owner had been out of town for a week, B6 was at home with husband and owner is unsure what other symptoms B6 has. Owner's husband did restart B6 on Tuesday. No vomiting/heaving. Owner reports that he is drinking water normally, but didn't finish his food this morning which is abnormal for him. Unknown diarrhea, appetite status while owner was gone.

Prior medical history: none, B6
Current medications: 1/2 tablet BID (owner unsure strength), did start it on Tuesday. Took months long break of B6 due to symptoms resolving.
Diet: royal canin boxer, dry , unknown length of time (last 1.5-2 yrs); was on grain free diet before this
Vaccination status/flea & tick preventative use: UTD on vaccines
Travel history: none

Overnight update: AIVR and occasional VPCs. Not interested in food. Nauseaus last night, was given one dose of B6 that helped a little bit. Also had 2 episodes of vtach around 7am, resolved on own.

EXAM:

ASSESSMENT:
A1: Severe cardiomegaly with poor contractile function - r/o primary DCM, diet-induced cardiomyopathy, ARVC, tachycardiac induced cardiomyopathy
A2: Malignant ventricular arrhythmia - non-sustained VTach and frequent polymorphic VPCs
A3: Left sided congestive heart failure

PLAN:

Treatment Plan (2/22):
B6

FDA-CVM-FOIA-2019-1704-006470

Client: B6
Patient:

B6

B6

Diagnostics completed:

- Thoracic radiographs (2/22):
  - Cardiopulmonary changes are consistent with left-sided congestive heart failure. Given moderate generalized cardiomegaly and moderate left atrial enlargement, consider DCM given breed. Echocardiography is recommended and repeat thoracic radiographs to monitor response to therapy.
  - Impression of faint rounded soft tissue opacities mixed in with the intersitital pattern may represent peribronchial cuffing and end on vessels, pulmonary nodules are thought less likely. Follow-up radiographs to reassess the lungs are recommended after resolution of cardiogenic pulmonary edema.
  - Concurrent mild diffuse bronchial pattern likely represents a component of lower airway disease.
- Echocardiogram/ Cardio recommendations (2/22):

  Findings consistent with DCM with active CHF and frequent ventricular arrhythmia. Patient has enough malignant arrhythmia that hospitalization and B6 B6 is recommended for the day and depending how well he responds, maybe we can decrease to q6-8h overnight. Patient has historically been on grain free diet for years before been switched to current diet. It is unclear whether this is a primary DCM, ARVC with DCM phenotype, or diet-induced cardiomyopathy, but B6 B6 but at this point this medication should ideally be avoided at this point due to potential beta-blocker effects that may worsen systolic function. Thus, recommend bloodwork and if liver values are normal, B6 (decreasing to SID after 5 days) should be started. Fish oil may also be effective helping decrease ventricular arrhythmia density. Recommend addition of an ACE inhibitor when patient is eating and not azotemic. Recommend repeat echocardiogram in 3 months or sooner in case patient develops clinical signs consistent with progression of the disease (shortness breath, collapse, syncope, exercise intolerance, pale mucous membrane). Client can be instructed on how to use AliveCor and assess heart rate and rhythm from home if patient at rest and calm at home.

  PLAN:

B6

- NOVA B6
- PCV/T B6
- CBC B6
- Chemistry
- Chemistry B6

Plan (2/23):

- Re-check chemistry

FDA-CVM-FOIA-2019-1704-006471

Client: B6
Patient:

B6

B6 DVM

SOAP Text Feb 24 2019 9:19AM - Clinician, Unassigned FHSA

B6

B6 yo MN Boxer

HISTORY:

Current history:

In July primary vet noticed heart arrythmia during appointment, when he was seen then due to symptom of wheezing. rDVM B6, and owners gave that for a couple of weeks and wheezing resolved, B6 (they didn't know they were supposed to continue). About 1 week ago started wheezing again (sporadic), becaming more clingy and lethargic. Owner had been out of town for a week, B6 was at home with husband and owner is unsure what other symptoms B6 has. Owner's husband did B6 on Tuesday. No vomiting/heaving. Owner reports that he is drinking water normally, but didn't finish his food this morning which is abnormal for him. Unknown diarrhea, appetite status while owner was gone.

Prior medical history: none, B6

Current medications: B6, did start it on Tuesday. Took months long break of B6 due to symptoms resolving.

Diet: royal canin boxer, dry , unknown length of time (last 1.5-2 yrs); was on grain free diet before this

Vaccination status/flea & tick preventative use: UTD on vaccines

Travel history: none

Overnight update:

Patient starting to be a little interested in food. Arrhythmia still not well under control -- HR B6 with intermittent R on T, pauses and AIVR, multiforme VPCs.

EXAM:

B6

FDA-CVM-FOIA-2019-1704-006472

B6

ASSESSMENT:

A1: Severe cardiomegaly with poor contractile function - r/o primary DCM, diet-induced cardiomyopathy, ARVC, tachycardiac induced cardiomyopathy
A2: Malignant ventricular arrhythmia - non-sustained VTach and frequent polymorphic VPCs
A3: Left sided congestive heart failure

PLAN:

Diagnostics completed:

- Thoracic radiographs (2/22):
  - Cardiopulmonary changes are consistent with left-sided congestive heart failure. Given moderate generalized cardiomegaly and moderate left atrial enlargement, consider DCM given breed. Echocardiography is recommended and repeat thoracic radiographs to monitor response to therapy.
  - Impression of faint rounded soft tissue opacities mixed in with the intersitital pattern may represent peribronchial cuffing and end on vessels, pulmonary nodules are thought less likely. Follow-up radiographs to reassess the lungs are recommended after resolution of cardiogenic pulmonary edema.
  - Concurrent mild diffuse bronchial pattern likely represents a component of lower airway disease.
- Echocardiogram/ Cardio recommendations (2/22):

  Findings consistent with DCM with active CHF and frequent ventricular arrhythmia. Patient has enough malignant arrhythmia that hospitalization and B6 B6 q 4-6h is recommended for the day and depending how well he responds, maybe we can decrease to q6-8h overnight. Patient has historically been on grain free diet for years before been switched to current diet. It is unclear whether this is a primary DCM, ARVC with DCM phenotype, or diet-induced cardiomyopathy, but B6 B6 B6 Thus, recommend bloodwork and if liver values are normal, B6 B6 . Recommend addition of an ACE inhibitor when patient is eating and not azotemic. Recommend repeat echocardiogram in 3 months or sooner in case patient develops clinical signs consistent with progression of the disease (shortness breath, collapse, syncope, exercise intolerance, pale mucous membrane). Client can be instructed on how to use AliveCor and assess heart rate and rhythm from home if patient at rest and calm at home.
- BNP (2/22): B6
- NOVA (2/22): B6
- PCV/TS (2/22): B6
- CBC (2/22): B6
- Chemistry B6
- Chemistry
- Chemistry

	BUN	creat	Na	K	Cl	ALT
2/22	B6					

FDA-CVM-FOIA-2019-1704-006473

Client:
Patient: B6

2/23	B6
2/24	

Treatment Plan (2/22):

B6

Plan (2/23):
- Re-check chemistry

B6

Plan (2/24)
- Re-check chemistry this am

B6

B6 DVM

SOAP Text Feb 25 2019 7:17AM - Clinician, Unassigned FHSA

History:

B6 y.o MN Boxer presented to rDVM 2/22/19 for wheezing and decreased appetite at home for 1 week. rDVM referred to Tufts ER. O were on vacation and are unclear on exact symptoms and duration. Pt was previously seen at rDVM for wheezing in July where arrhythmia was noted and pt B6 (O unclear on dose). B6 when wheezing resolved. Was on grain-free diet until ~1.5 years ago.

Subjective:

T: n/a
HR:
RR: B6
W: with telemetry pack

Mentation: QAR, friendly

Hydration: Euhydrated, mucous membrane pink and moist. CRT <2sec.

FDA-CVM-FOIA-2019-1704-006474

Client: B6
Patient:

Overall impression since arrival or since last exam:Improved since admission to ER o B6 The RR are back to normal and his has no RE. Ate for us a small amount this morning which is good. Seems slightly brighter. Telemetry revealed persistent multiform ventricular tachycardia with fast rate with no obvious improvement compared to previously.
Appetite:No immediate interest in food, ate when stimulated and hand fed.

Objective:

BCS(1-9): B6
MCS(normal, mild, moderate, severe): B6
EENT:
PLN: B6
Heart: Grade II-II/VI left apical systolic murmur. Multiple premature beats with short runs of sustained tachycardia. Jugular veins bottom 1/3 of the neck. Femoral pulses fair with pulses deficits.

B6

Treatments in hospital

B6

Diagnostics

- Thoracic rads 2/22: Moderate generalized cardiomegaly and moderate left atrial enlargement onsistent with left-sided congestive heart failure/DCM. Cardiogenic pulmonary edema. Concurrent mild diffuse bronchial pattern likely represents a component of lower airway disease.
- Echo (Abridged due to dyspnea)2/22: Findings consistent with DCM with active CHF and frequent ventricular arrhythmia. Severe cardiomegaly with poor contractile function.
- NOVA (2/22): B6
- BNP (2/22): B6
- PCV/TS (2/22): B6
- CBC (2/22): B6
- Chemistry
- Chemistry
- Chemistry

B6

Assessments

A1: DCM vs. ARVC with DCM phenotype with history of active LCHF
A2: Malignant ventricular arrhythmia - non-sustained VTach and frequent polymorphic VPCs

Plan

1.
2.
3.

B6

FDA-CVM-FOIA-2019-1704-006475

Client: B6
Patient:

4. B6
5.
6.

SOAP completed by: B6 V19
SOAP reviewed by: B6 DVM

Disposition/Recommendations

FDA-CVM-FOIA-2019-1704-006476

FDA-CVM-FOIA-2019-1704-006477

Cummings Veterinary Medical Center AT TUFTS UNIVERSITY

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

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

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

Lab Results Report

Nova Full Panel-ICU **2/22/2019 9:30:25 AM** **Accession ID:** B6

Test	Results	Reference Range	Units
SO2%	B6	94 - 100	%
HCT (POC)		38 - 48	%
HB (POC)		12.6 - 16	g/dL
NA (POC)		140 - 154	mmol/L
K (POC)		3.6 - 4.8	mmol/L
CL(POC)		109 - 120	mmol/L
CA (ionized)		1.17 - 1.38	mmol/L
MG (POC)		0.1 - 0.4	mmol/L
GLUCOSE (POC)		80 - 120	mg/dL
LACTATE		0 - 2	mmol/L
BUN (POC)		12 - 28	mg/dL
CREAT (POC)		0.2 - 2.1	mg/dL
TCO2 (POC)		0 - 0	mmol/L
nCA		0 - 0	mmol/L
nMG		0 - 0	mmol/L
GAP		0 - 0	mmol/L
CA/MG		0 - 0	mol/mol
BEecf		0 - 0	mmol/L
BEb		0 - 0	mmol/L
A		0 - 0	mmHg
NOVA SAMPLE		0 - 0	

FDA-CVM-FOIA-2019-1704-006478

FiO2	B6	0 - 0	%
PCO2		36 - 44	mmHg
PO2		80 - 100	mmHg
PH		7.337 - 7.467	
PCO2		36 - 44	mmHg
PO2		80 - 100	mmHg
HCO3		18 - 24	mmol/L

Nova Full Panel-ICU **2/22/2019 9:36:12 AM** **Accession ID:** B6

Test	Results	Reference Range	Units
TS (FHSA)	B6	0 - 0	g/dl
PCV **		0 - 0	%
TS (FHSA)		0 - 0	g/dl

Nova Full Panel-ICU **2/23/2019 9:56:25 AM** **Accession ID:** B6

Test	Results	Reference Range	Units
GLUCOSE	B6	67 - 135	mg/dL
UREA		8 - 30	mg/dL
CREATININE		0.6 - 2	mg/dL
PHOSPHORUS		2.6 - 7.2	mg/dL
CALCIUM2		9.4 - 11.3	mg/dL
MAGNESIUM 2+		1.8 - 3	mEq/L
T. PROTEIN		5.5 - 7.8	g/dL
ALBUMIN		2.8 - 4	g/dL
GLOBULINS		2.3 - 4.2	g/dL
A/G RATIO		0.7 - 1.6	
SODIUM		140 - 150	mEq/L
CHLORIDE		106 - 116	mEq/L
POTASSIUM		3.7 - 5.4	mEq/L
tCO2 (BICARB)		14 - 28	mEq/L
AGAP		8 - 19	
NA/K		29 - 40	
T BILIRUBIN		0.1 - 0.3	mg/dL
ALK PHOS		12 - 127	U/L
GGT		0 - 10	U/L
ALT		14 - 86	U/L
AST		9 - 54	U/L
CK		22 - 422	U/L
CHOLESTEROL		82 - 355	mg/dL
TRIGLYCERIDES		30 - 338	mg/dl
AMYLASE		409 - 1250	U/L

1930 Result(s) verified

FDA-CVM-FOIA-2019-1704-006479

Client:
Patient: B6

OSMOLALITY (CALCULATED)	B6	291 - 315	mmol/L

Nova Full Panel-ICU **2/24/2019 12:18:25 PM** **Accession ID:** B6

Test	Results	Reference Range	Units
GLUCOSE		67 - 135	mg/dL
UREA		8 - 30	mg/dL
CREATININE		0.6 - 2	mg/dL
PHOSPHORUS		2.6 - 7.2	mg/dL
CALCIUM2		9.4 - 11.3	mg/dL
MAGNESIUM 2+		1.8 - 3	mEq/L
T. PROTEIN		5.5 - 7.8	g/dL
ALBUMIN		2.8 - 4	g/dL
GLOBULINS		2.3 - 4.2	g/dL
A/G RATIO		0.7 - 1.6	
SODIUM		140 - 150	mEq/L
CHLORIDE		106 - 116	mEq/L
POTASSIUM		3.7 - 5.4	mEq/L
tCO2 (BICARB)	B6	14 - 28	mEq/L
AGAP		8 - 19	
NA/K		29 - 40	
T BILIRUBIN		0.1 - 0.3	mg/dL
ALK PHOS		12 - 127	U/L
GGT		0 - 10	U/L
ALT		14 - 86	U/L
AST		9 - 54	U/L
CK		22 - 422	U/L
CHOLESTEROL		82 - 355	mg/dL
TRIGLYCERIDES		30 - 338	mg/dl
AMYLASE		409 - 1250	U/L
2888 Result(s) verified			
OSMOLALITY (CALCULATED)		291 - 315	mmol/L

FDA-CVM-FOIA-2019-1704-006480

B6

FAX COVER SHEET

Date: 2/22/19

To: DFIS ER

Comments: B6 Pages:

If you have received this fax in error, please contact

B6

Thank you, and have a nice day!

FDA-CVM-FOIA-2019-1704-006481

B6

Patient Chart

Printed: 02-22-19 at 8:51a

CLIENT INFORMATION

Name B6
Address

PATIENT INFORMATION

Name	B6	Species	Canine
Sex	Male, Neutered	Breed	Boxer
Birthday	B6	Age	10y
ID		Rabies	1959-16
Color	Brown	Weight	57.40 Lbs
Reminded	02-18-19	Codes	

Reminders for B6 Last done

06-12-20	B6
07-24-19	
07-24-19	
07-24-19	
05-26-19	
02-23-19	
08-14-18	
07-07-17	

Charlie's weight history

02-22-19	B6
12-26-17	
09-08-17	
06-13-17	
11-07-16	
07-07-16	
05-26-16	
07-17-15	
05-30-14	
10-28-13	
10-28-13	
05-06-13	
01-06-11	

MEDICAL HISTORY - S.O.A.P. View

Date	By	Code	Description	Qty (Variance)	Photo
02-22-19	B6				

B6

SUBJECTIVE SECTION

01 /2 # B6 B6 :01 02-22-19;09:58AM;From:

FDA-CVM-FOIA-2019-1704-006482

B6

Patient Chart for B6 Client: Ms. B6
Date: 02-22-19, Time: 8:51a Page: 2

Date	By	Code	Description	Qty (Variance)	Photo

B6 (female owner) brought B6 in today... she just got home from a business trip and her husband told her that B6 has been coughing at night and generally not doing well. There are notes of collapsing episodes in 2014 in our records (owner doesn't remember these) and we have ausculted an arrhythmia at visits since 2015. ARVC and cardiologist intervention has been discussed on numerous occasions but has always been declined. Dr B6 started B6 on B6 in July 2018 due to a profound arrhythmia, but the owners were unaware that this was something they should have continued long-term and stopped it a long time ago because B6 had been doing well at home. His condition at home has declined in the last week or two and now they are seeing:
- a light wheeze-like outward coughing/chuffing intermittently throughout the day, but mostly at night
- generalized lethargy and exercise intolerance on walks
- appetite is decreased

OBJECTIVE SECTION

Quiet, nervous

Examination Results:

Heart
irregular cardiac arrhythmia with variable pulse quality and dropped beats, grade I-II murmur, slightly pale mm for a nervous dog

Oral / Nasal
B6 d

Lungs
subjectively mild increased RE at rest (also nervous), audible crackles bilaterally

Musculoskeletal
B6)

Normal Systems: Coat & Skin, Eyes, Ears, Abdominal Palpation, Gastrointestinal, Lymph Nodes, Urogenital, Neurologic

ASSESSMENT SECTION

NOTES

10yo CM Boxer
- hx cardiac arrhythmia (not worked up): suspect ARVC
- new heart murmur, pulmonary crackles: suspect CHF... r/o primary pulmonary pathology

PLAN SECTION

NOTES

Discussed with B6 certainly has ARVC which has never been worked up with a cardiologist and I fear that he is currently in heart failure. He needs to be evaluated by a cardiologist ASAP to get him started on medication which may help improve heart function and lessen frequency of arrhythmia. Things are now an emergency B6 will bring him to Tufts. Discussed that if he seems "stable" (understanding dogs with ARVC are ALWAYS at risk of sudden death) and/or owner has financial constraints he may be able to be evaluated as a day-case (admit through the ER for the day to facilitate

02-22-19 09:58AM From: B6 To: # 3/ 10

FDA-CVM-FOIA-2019-1704-006483

B6

Patient Chart for B6 Client: Ms. B6
Date: 02-22-19, Time: 8:51a Page: 3

Date	By	Code	Description	Qty (Variance)	Photo

cardiac workup and home on oral meds). If he seems unstable they may recommend admission for monitoring overnight. Did not take CXR or perform diagnostics since Tufts will repeat these anyway.

07-24-18 B6

Age: 9y

SUBJECTIVE SECTION

Annual exam. O does not take dog on long walks or runs anymore after the collapsing episode. Hx of arrhythmia, not seen a cardiologist. Lump on left shoulder growing. B6

B6 s

OBJECTIVE SECTION

BAR, nice, nervous, shaking

B6

ASSESSMENT SECTION

NOTES

1. Ventricular tachycardia
2. mass

PLAN SECTION

NOTES

EKG: many runs of V-tach mixed with normal QRS complex. More than 1/2 of complexes are VPCs
FNA mass: monomorphic population. multiple nucleoli, sometimes in acini but sometimes the cells look stellate. Sample appears neoplastic. Need pathologist interpretation. Want to know is this something we should ignore or does it need surgery. If so, needs to see cardiologist ASAP to see if anesthesia possible.
Recommend see cardiologist for consultation and further work up. Going to start o B6 oday. Dog at risk for sudden death.
lepto, lyme #1, 4dx

0: /? # B6 :01 02-22-19:09:58AM:E/OM

FDA-CVM-FOIA-2019-1704-006484

B6

Patient Chart for B6
Date: 02-22-19, Time: 8:51a

Client: Ms. B6 s
Page: 4

Date	By	Code	Description	Qty (Variance)	Photo

12-26-17 rc B6

B6

SUBJECTIVE SECTION

B6

OBJECTIVE SECTION

Examination Results:

B6 t

PLAN SECTION

NOTES

Disp 1.
2.
3.
4.
5.
6.

B6

NONWELL Non-Wellness Medical Record

Age: 9y

SUBJECTIVE SECTION

See 2nd EMR above

09-08-17 B6 PRO Recheck /cr Brief Medical Record

Age: 9y Weight: 55.40

06-13-17 B6 WELL Wellness Annual Medical Record

Age: 8y Weight: 53.30

B6 5.00 / 9.00

SUBJECTIVE SECTION

Annual exam. Doing well for an older dog. History of B6 no recent signs of weakness or collapse. He does tremble sometimes but o thinks that is due to nervousness. A couple new skin bumps.

B6

B6

FDA-CVM-FOIA-2019-1704-006485

B6

Patient Chart for B6 Client: Ms. B6
Date: 02-22-19, Time: 8:51a Page: 5

Date	By	Code	Description	Qty (Variance)	Photo

they intentionally reduced the food

OBJECTIVE SECTION

BAR

Examination Results:

Coat & Skin

B6

Heart
sinus arrhythmia and some ectopic beats. PSS. NMA

Oral / Nasal
B6

Normal Systems: Eyes, Ears, Lungs, Abdominal Palpation, Gastrointestinal, Lymph Nodes, Urogenital, Neurologic, Musculoskeletal

ASSESSMENT SECTION

NOTES

arrhythmia r/o ARVC vs DCM
gingival hyperplasia

PLAN SECTION

NOTES

Since B6 is not experiencing anything that sounds like heart disease, o elects to hold off on diagnostics and medication.
DAPPL, lyme, 4dx
cysts, ok to just leave alone.

11-08-16 CJC NONWELL Non-Wellness Medical Record
Client Instructions - Please keep B6 rested for the next week (on a leash for short bathroom breaks then back inside). Avoid running/jumping/stairs if possible.
Give the B6 l as directed for discomfort.
He may need to wear an E-collar if he continues licking at his foot.
Please call if he doesn't improve over the next week. *we can dispense gentaspray which is a topical that will help with inflammation or consider x-rays

Age: 8y Temp: B6 Pulse: B6
BCS: B6

SUBJECTIVE SECTION

B6

02-22-19 08:56AM From: B6 To: # 6/ 10

FDA-CVM-FOIA-2019-1704-006486

B6

Patient Chart for: B6
Date: 02-22-19, Time: 8:51a

Client: B6
Page: 6

Date	By	Code	Description	Qty (Variance)	Photo

O applying B6

OBJECTIVE SECTION

BAR

B6

Heart
Arrhythmia (chronic hx).

B6

ASSESSMENT SECTION

NOTES

B6

PLAN SECTION

NOTES

Exercise restriction for the next week
B6
Discussed Gentaspray but O to hold for now
Call if doesn't improve, can consider x-rays for further workup (would recommend bloodwork first ideally for further evaluation of weight loss)

11-07-16 B6 PRO Recheck /or Brief Medical Record

Age: 8y Weight: 64.00

SUBJECTIVE SECTION

B6

OBJECTIVE SECTION

BAR

Examination Results:
Coat & Skin

02-22-19 08:58AM From: B6 To: # 7/ 10

FDA-CVM-FOIA-2019-1704-006487

B6

Patient Chart for B6 Client: B6
Date: 02-22-19, Time: 8:51a Page: 7

Date	By	Code	Description	Qty (Variance)	Photo

B6

PLAN SECTION

NOTES

B6

07-07-16 CJC WELL Wellness Annual Medical Record
Client Instructions - We will call tomorrow if there are any issues with his B6 testing results (no call means clear).
Please call if you would like to further discuss or schedule and echocardiogram and EKG to check his heart.

B6

SUBJECTIVE SECTION

B6

OBJECTIVE SECTION

B6

Examination Results:
Heart
Arrhythmia auscultated with occasional dropped pulses.

Oral / Nasal

B6

B6

ASSESSMENT SECTION

NOTES

7yo CM Boxer. Arrhythmia, history of collapsing episodes (none recently) r/o ARVC. B6
B6 Suspect neurogenic tremor in hind.

PLAN SECTION

NOTES

02-22-19,08:58AM;From: B6 To: # 8/ 10

FDA-CVM-FOIA-2019-1704-006488

B6

Patient Chart for B6 Client: B6
Date: 02-22-19, Time: 8:51a Page: 8

Date	By	Code	Description	Qty (Variance)	Photo

4dx, fecal

B6

05-26-16 B6 WELL Wellness Annual Medical Record

B6

SUBJECTIVE SECTION

Presenting for rabies. Doing well. They are getting a puppy

PLAN SECTION

B6

ASSESSMENT SECTION

01 /6 # B6 :01 02-22-19:09:58AM:From:

FDA-CVM-FOIA-2019-1704-006489

B6

Patient Chart for B6 Client: B6
Date: 02-22-19, Time: 8:51a

Date	By	Code	Description	Qty (Variance)	Photo

NOTES

6yo CM Boxer. Hx collapsing episodes during exercise r/o ARVC.

PLAN SECTION

NOTES

4dx, fecal
Lepto, Lyme
Recommend echo with EKG, gave handout on ARVC in boxers. Recommend call with questions or to schedule.

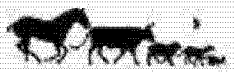
05-30-14		CONVW	Converted Weight	0	
Age: 5y	Weight: 60.80				
10-28-13		CONVW	Converted Weight	0	
Age: 5y	Weight: 58.70				
		CONVW	Converted Weight	0	
Age: 5y	Weight: 58.70				
05-06-13		CONVW	Converted Weight	0	
Age: 4y	Weight: 59.30				
01-06-11		CONVW	Converted Weight	0	
Age: 2y	Weight: 55.00				

02-22-19;09:58AM;From: B6 ;To: B6 ; # 10/ 10

FDA-CVM-FOIA-2019-1704-006490

Client: B6
Patient:

CBC/Chem - 2/22/2019



Tufts Cummings School Of Veterinary Medicine

200 Westboro Road
North Grafton, MA 01536

DUPLICATE

Name/DOB: B6
Patient ID:
Phone number:
Collection Date: 2/22/2019 12:37 PM
Approval date: 2/22/2019 1:35 PM

Sex: CM
Age: 10
Species: Canine
Breed: Boxer

Provider: B6
Order Location: V320559: Investigation into
Sample ID: 1902220072

CBC, Comprehensive, Sm Animal (Research)

			Ref. Range/Males
SMACHUNSKI			
WBC (ADVIA)			4.40-15.10 K/uL
RBC (Advia)			5.80-8.50 M/uL
Hemoglobin (ADVIA)			13.3-20.5 g/dL
Hematocrit (Advia)	H		39-55 %
MCV (ADVIA)			64.5-77.5 fL
MCH (ADVIA)			21.3-25.9 pg
CHCM			
MCHC (ADVIA)			31.9-34.3 g/dL
RDW (ADVIA)			11.9-15.2
Platelet Count (Advia)			173-486 K/uL
02/22/19 1:35 PM			
Mean Platelet Volume (Advia)			8.29-13.20 fl
02/22/19 1:13 PM			
Platelet Crit			0.129-0.403 %
02/22/19 1:13 PM			
PDW			
Reticulocyte Count (Advia)			0.20-1.60 %
Absolute Reticulocyte Count (Advia)			14.7-113.7 K/uL
CHr			
MCVr			

Microscopic Exam of Blood Smear (Advia)

			Ref. Range/Males
SMACHUNSKI			
Seg Neuts (%)			43-86 %
Lymphocytes (%)			7-47 %
Monocytes (%)			1-15 %
Nucleated RBC	H		0-1 /100 WBC
02/22/19 1:13 PM			
Seg Neutrophils (Abs) Advia			2.800-11.500 K/ul
Lymphs (Abs) Advia	L		1.00-4.80 K/uL
Mono (Abs) Advia			0.10-1.50 K/uL
WBC Morphology			

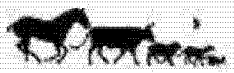
Sample ID: 1902220072/1
This report continues... (Final)

Reviewed by: _____

FDA-CVM-FOIA-2019-1704-006491

Client: B6
Patient:

CBC/Chem - 2/22/2019



Tufts Cummings School Of Veterinary Medicine

200 Westboro Road
North Grafton, MA 01536

DUPLICATE

Name/DOB:
Patient ID: B6
Phone number:
Collection Date: 2/22/2019 12:37 PM
Approval date: 2/22/2019 1:35 PM

Sex: CM
Age: 10
Species: Canine
Breed: Boxer

Provider: B6
Order Location: V320559: Investigation into
Sample ID: 1902220072

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

		Ref. Range/Males
SMACHUNSKI		
Echinocytes	B6	

Research Chemistry Profile - Small Animal (Cobas)

			Ref. Range/Males
CSTCYR			
Glucose			67-135 mg/dL
Urea			8-30 mg/dL
Creatinine			0.6-2.0 mg/dL
Phosphorus			2.6-7.2 mg/dL
Calcium 2			9.4-11.3 mg/dL
Magnesium 2+			1.8-3.0 mEq/L
Total Protein			5.5-7.8 g/dL
Albumin	H		2.8-4.0 g/dL
Globulins			2.3-4.2 g/dL
A/G Ratio			0.7-1.6
Sodium	H		140-150 mEq/L
Chloride	L		106-116 mEq/L
Potassium		B6	3.7-5.4 mEq/L
tCO2(Bicarb)			14-28 mEq/L
AGAP			8.0-19.0
NA/K			29-40
Total Bilirubin			0.10-0.30 mg/dL
Alkaline Phosphatase			12-127 U/L
GGT			0-10 U/L
ALT	H		14-86 U/L
AST			9-54 U/L
Creatine Kinase			22-422 U/L
Cholesterol			82-355 mg/dL
Triglycerides			30-338 mg/dl
Amylase			409-1250 U/L
Osmolality (calculated)			291-315 mmol/L

Sample ID: 19022200722
REPRINT: Orig. printing on 2/22/2019 (Final)

Reviewed by: _____
Page 2

FDA-CVM-FOIA-2019-1704-006492

Client: B6
Patient: B6

IDEXX BNP - 2/22/2019

IDEXX Reference Laboratories

Client: B6 Patient: B6

IDEXX VetConnect 1-888-433-9987

Client: B6
Patient: B6
Species: CANINE
Breed: BOXER
Gender: MALE NEUTERED
Age: 11Y

Date: 02/22/2019
Requisition #: [illegible]
Accession #: B6
Ordered by: B6

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

Account: B6

CARDIOPET proBNP - CANINE

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

Comments:
1 B6

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

B6

Page 1 of 1

FDA-CVM-FOIA-2019-1704-006493

Client: B6
Patient:

Diet history 2/22/19

CARDIOLOGY DIET HISTORY FORM B6
Please answer the following questions about your pet

Pet's name: B6 Owner's name: B6 Today's date: 2/22/19

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

   Poor_____**Excellent**

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

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

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

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

Food (include specific product and flavor)	Form	Amount	How often?	Dates fed
Nutro Grain Free Chicken, Lentil, & Sweet Potato Adult	*dry*	*1 ½ cup*	*2x/day*	*Jan 2016-present*
85% lean hamburger	*microwaved*	*3 oz*	*1x/week*	*June -Aug 2016*
Pupperoni original beef flavor	*treat*	*½*	*1x/day*	*Sept 2016-present*
Rawhide	*treat*	*6 inch twist*	*1x/week*	*Dec 2018-present*
Wellness Complete Health - Sweet Potato & Fish	dry	1 cup	2x/day	2012-2018
Mother Hubbards Grainfree	dry	1 cup	2x/day	2008-2012
Milkbone brushing Chews	Treat		1/day	2018-2019
Milkbone treat	Treats		2-3x/day	Long-time
Royal Canine Boxer	Dry	1 cup	2x/day	6/2018-present
Wellness Soft Bites Lamb+Salmon grainfree	Treats		1x/day	Long time

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

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

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

3. How do you administer pills to your pet? Will switch to RC Canine
   ☐ 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): Cheese, Pepperoni

FDA-CVM-FOIA-2019-1704-006494

Client: B6
Patient:

Vitals Results

2/22/2019 10:25:01 AM	Lasix treatment note
2/22/2019 10:36:48 AM	Weight (kg)
2/22/2019 10:58:00 AM	Lasix treatment note
2/22/2019 12:43:21 PM	Eliminations
2/22/2019 12:43:37 PM	Nursing note
2/22/2019 12:44:22 PM	Quantify IV Fluids (CRI) in mls
2/22/2019 12:50:46 PM	Cardiac rhythm
2/22/2019 12:50:47 PM	Heart Rate (/min)
2/22/2019 12:52:26 PM	Respiratory Rate
2/22/2019 1:00:33 PM	Eliminations
2/22/2019 1:10:19 PM	Quantify IV Fluids (CRI) in mls
2/22/2019 1:10:20 PM	Catheter Assessment
2/22/2019 2:03:55 PM	Cardiac rhythm
2/22/2019 2:03:56 PM	Heart Rate (/min)
2/22/2019 2:04:50 PM	Respiratory Rate
2/22/2019 2:25:32 PM	Lasix treatment note
2/22/2019 2:40:57 PM	Eliminations
2/22/2019 3:00:23 PM	Cardiac rhythm
2/22/2019 3:00:24 PM	Heart Rate (/min)
2/22/2019 3:01:00 PM	Respiratory Rate
2/22/2019 3:49:48 PM	Cardiac rhythm
2/22/2019 3:49:49 PM	Heart Rate (/min)
2/22/2019 3:50:33 PM	Respiratory Rate
2/22/2019 4:05:52 PM	Eliminations
2/22/2019 4:07:29 PM	Eliminations
2/22/2019 4:07:44 PM	Nursing note
2/22/2019 4:31:46 PM	Nursing note
2/22/2019 5:00:16 PM	Cardiac rhythm
2/22/2019 5:00:17 PM	Heart Rate (/min)
2/22/2019 5:05:10 PM	Respiratory Rate
2/22/2019 5:38:29 PM	Eliminations
2/22/2019 5:38:44 PM	Amount eaten
2/22/2019 5:55:28 PM	Nursing note
2/22/2019 6:03:19 PM	Cardiac rhythm
2/22/2019 6:03:20 PM	Heart Rate (/min)
2/22/2019 6:04:06 PM	Respiratory Rate
2/22/2019 6:24:06 PM	Quantify IV Fluids (CRI) in mls

B6

FDA-CVM-FOIA-2019-1704-006495

Vitals Results

2/22/2019 6:24:07 PM	Catheter Assessment
2/22/2019 6:51:37 PM	Cardiac rhythm
2/22/2019 6:51:38 PM	Heart Rate (/min)
2/22/2019 6:51:49 PM	Respiratory Rate
2/22/2019 7:51:32 PM	Respiratory Rate
2/22/2019 7:52:03 PM	Cardiac rhythm
2/22/2019 7:52:04 PM	Heart Rate (/min)
2/22/2019 7:53:44 PM	Lasix treatment note
2/22/2019 8:45:01 PM	Eliminations
2/22/2019 8:52:50 PM	Cardiac rhythm
2/22/2019 8:52:51 PM	Heart Rate (/min)
2/22/2019 8:59:02 PM	Respiratory Rate
2/22/2019 9:25:37 PM	Quantify IV Fluids (CRI) in mls
2/22/2019 9:25:38 PM	Catheter Assessment
2/22/2019 9:49:17 PM	Cardiac rhythm
2/22/2019 9:49:18 PM	Heart Rate (/min)
2/22/2019 9:56:13 PM	Respiratory Rate
2/22/2019 10:51:19 PM	Cardiac rhythm
2/22/2019 10:51:20 PM	Heart Rate (/min)
2/22/2019 10:52:28 PM	Respiratory Rate
2/22/2019 11:34:01 PM	Amount eaten
2/22/2019 11:55:25 PM	Respiratory Rate
2/22/2019 11:55:36 PM	Eliminations
2/22/2019 11:55:46 PM	Cardiac rhythm
2/22/2019 11:55:47 PM	Heart Rate (/min)
2/23/2019 1:00:00 AM	Cardiac rhythm
2/23/2019 1:00:01 AM	Heart Rate (/min)
2/23/2019 1:00:21 AM	Respiratory Rate
2/23/2019 1:52:25 AM	Lasix treatment note
2/23/2019 1:52:38 AM	Eliminations
2/23/2019 1:53:31 AM	Respiratory Rate
2/23/2019 1:53:43 AM	Quantify IV Fluids (CRI) in mls
2/23/2019 1:53:44 AM	Catheter Assessment
2/23/2019 1:54:09 AM	Cardiac rhythm
2/23/2019 1:54:10 AM	Heart Rate (/min)
2/23/2019 2:16:55 AM	Eliminations
2/23/2019 2:33:32 AM	Eliminations
2/23/2019 2:39:52 AM	Cardiac rhythm
2/23/2019 2:39:53 AM	Heart Rate (/min)
2/23/2019 3:36:15 AM	Cardiac rhythm
2/23/2019 3:36:16 AM	Heart Rate (/min)

B6

FDA-CVM-FOIA-2019-1704-006496

Client:
Patient: B6

Vitals Results

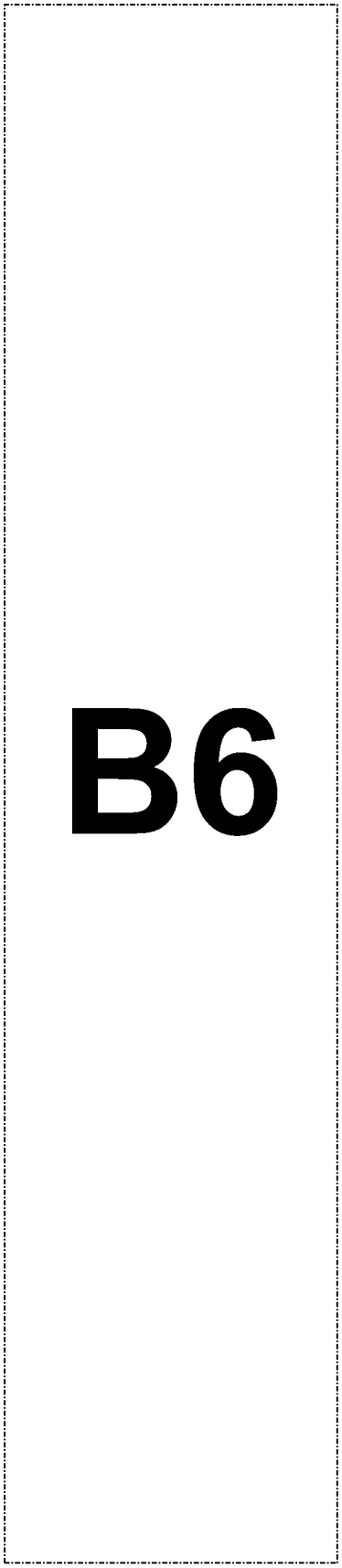
2/23/2019 3:41:17 AM	Respiratory Rate
2/23/2019 3:41:27 AM	Eliminations
2/23/2019 4:49:07 AM	Cardiac rhythm
2/23/2019 4:49:08 AM	Heart Rate (/min)
2/23/2019 4:49:51 AM	Respiratory Rate
2/23/2019 5:28:53 AM	Respiratory Rate
2/23/2019 5:29:07 AM	Quantify IV Fluids (CRI) in mls
2/23/2019 5:29:08 AM	Catheter Assessment
2/23/2019 5:36:36 AM	Temperature (F)
2/23/2019 5:56:48 AM	Cardiac rhythm
2/23/2019 5:56:49 AM	Heart Rate (/min)
2/23/2019 6:56:08 AM	Cardiac rhythm
2/23/2019 6:56:09 AM	Heart Rate (/min)
2/23/2019 6:56:56 AM	Respiratory Rate
2/23/2019 7:37:07 AM	Weight (kg)
2/23/2019 7:37:52 AM	Eliminations
2/23/2019 7:58:21 AM	Cardiac rhythm
2/23/2019 7:58:22 AM	Heart Rate (/min)
2/23/2019 7:59:12 AM	Respiratory Rate
2/23/2019 9:09:20 AM	Cardiac rhythm
2/23/2019 9:09:21 AM	Heart Rate (/min)
2/23/2019 9:33:45 AM	Respiratory Rate
2/23/2019 10:02:14 AM	Cardiac rhythm
2/23/2019 10:02:15 AM	Heart Rate (/min)
2/23/2019 10:05:31 AM	Respiratory Rate
2/23/2019 10:05:43 AM	Catheter Assessment
2/23/2019 10:05:50 AM	Lasix treatment note
2/23/2019 11:06:13 AM	Cardiac rhythm
2/23/2019 11:06:14 AM	Heart Rate (/min)
2/23/2019 11:07:32 AM	Respiratory Rate
2/23/2019 11:27:21 AM	Eliminations
2/23/2019 11:27:43 AM	Amount eaten
2/23/2019 12:23:03 PM	Cardiac rhythm
2/23/2019 12:23:04 PM	Heart Rate (/min)
2/23/2019 12:26:12 PM	Respiratory Rate
2/23/2019 1:04:31 PM	Cardiac rhythm
2/23/2019 1:04:32 PM	Heart Rate (/min)
2/23/2019 1:05:24 PM	Respiratory Rate
2/23/2019 1:20:37 PM	Catheter Assessment

B6

FDA-CVM-FOIA-2019-1704-006497

Vitals Results

2/23/2019 1:55:09 PM	Cardiac rhythm
2/23/2019 1:55:10 PM	Heart Rate (/min)
2/23/2019 1:55:50 PM	Respiratory Rate
2/23/2019 2:52:23 PM	Cardiac rhythm
2/23/2019 2:52:24 PM	Heart Rate (/min)
2/23/2019 2:53:23 PM	Respiratory Rate
2/23/2019 3:12:08 PM	Eliminations
2/23/2019 3:50:24 PM	Respiratory Rate
2/23/2019 3:50:40 PM	Cardiac rhythm
2/23/2019 3:50:41 PM	Heart Rate (/min)
2/23/2019 4:49:31 PM	Respiratory Rate
2/23/2019 4:54:01 PM	Cardiac rhythm
2/23/2019 4:54:02 PM	Heart Rate (/min)
2/23/2019 5:22:43 PM	Catheter Assessment
2/23/2019 5:33:09 PM	Amount eaten
2/23/2019 5:46:40 PM	Respiratory Rate
2/23/2019 5:46:52 PM	Cardiac rhythm
2/23/2019 5:46:53 PM	Heart Rate (/min)
2/23/2019 6:00:15 PM	Amount eaten
2/23/2019 6:20:32 PM	Lasix treatment note
2/23/2019 6:30:51 PM	Eliminations
2/23/2019 7:00:21 PM	Cardiac rhythm
2/23/2019 7:00:22 PM	Heart Rate (/min)
2/23/2019 7:08:36 PM	Respiratory Rate
2/23/2019 8:00:49 PM	Eliminations
2/23/2019 8:07:32 PM	Cardiac rhythm
2/23/2019 8:07:33 PM	Heart Rate (/min)
2/23/2019 8:08:32 PM	Respiratory Rate
2/23/2019 9:00:28 PM	Cardiac rhythm
2/23/2019 9:00:29 PM	Heart Rate (/min)
2/23/2019 9:06:37 PM	Respiratory Rate
2/23/2019 9:17:59 PM	Catheter Assessment
2/23/2019 9:36:52 PM	Eliminations
2/23/2019 9:40:20 PM	Respiratory Rate
2/23/2019 9:41:25 PM	Cardiac rhythm
2/23/2019 9:41:26 PM	Heart Rate (/min)
2/23/2019 11:21:33 PM	Cardiac rhythm
2/23/2019 11:21:34 PM	Heart Rate (/min)
2/23/2019 11:22:05 PM	Respiratory Rate
2/23/2019 11:24:38 PM	Amount eaten
2/23/2019 11:27:39 PM	Weight (kg)



FDA-CVM-FOIA-2019-1704-006498

Vitals Results

2/24/2019 12:10:14 AM	Cardiac rhythm
2/24/2019 12:10:15 AM	Heart Rate (/min)
2/24/2019 12:10:41 AM	Respiratory Rate
2/24/2019 1:02:51 AM	Catheter Assessment
2/24/2019 1:03:53 AM	Cardiac rhythm
2/24/2019 1:03:54 AM	Heart Rate (/min)
2/24/2019 1:04:19 AM	Respiratory Rate
2/24/2019 1:05:57 AM	Eliminations
2/24/2019 1:22:13 AM	Respiratory Rate
2/24/2019 1:22:23 AM	Eliminations
2/24/2019 1:22:32 AM	Nursing note
2/24/2019 1:57:47 AM	Lasix treatment note
2/24/2019 2:00:09 AM	Cardiac rhythm
2/24/2019 2:00:10 AM	Heart Rate (/min)
2/24/2019 2:59:53 AM	Cardiac rhythm
2/24/2019 2:59:54 AM	Heart Rate (/min)
2/24/2019 3:03:46 AM	Respiratory Rate
2/24/2019 3:04:41 AM	Eliminations
2/24/2019 3:51:27 AM	Respiratory Rate
2/24/2019 3:58:14 AM	Cardiac rhythm
2/24/2019 3:58:15 AM	Heart Rate (/min)
2/24/2019 4:58:50 AM	Catheter Assessment
2/24/2019 5:06:40 AM	Weight (kg)
2/24/2019 5:06:48 AM	Eliminations
2/24/2019 5:06:59 AM	Temperature (F)
2/24/2019 5:08:17 AM	Cardiac rhythm
2/24/2019 5:08:18 AM	Heart Rate (/min)
2/24/2019 5:08:31 AM	Respiratory Rate
2/24/2019 5:14:08 AM	Amount eaten
2/24/2019 5:48:40 AM	Cardiac rhythm
2/24/2019 5:48:41 AM	Heart Rate (/min)
2/24/2019 5:48:58 AM	Respiratory Rate
2/24/2019 6:48:56 AM	Cardiac rhythm
2/24/2019 6:48:57 AM	Heart Rate (/min)
2/24/2019 6:49:50 AM	Respiratory Rate
2/24/2019 7:40:17 AM	Eliminations
2/24/2019 8:00:06 AM	Cardiac rhythm
2/24/2019 8:00:07 AM	Heart Rate (/min)
2/24/2019 8:01:08 AM	Respiratory Rate
2/24/2019 9:04:42 AM	Respiratory Rate
2/24/2019 9:10:17 AM	Cardiac rhythm

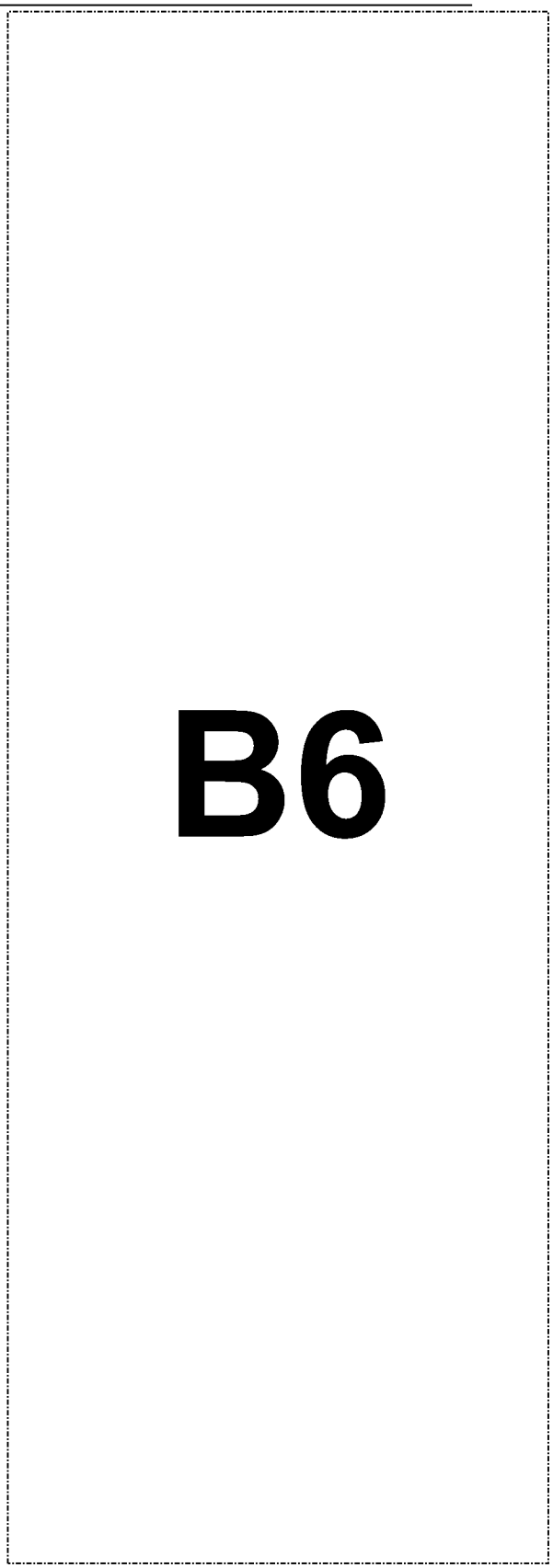
B6

FDA-CVM-FOIA-2019-1704-006499

Client: B6
Patient:

Vitals Results

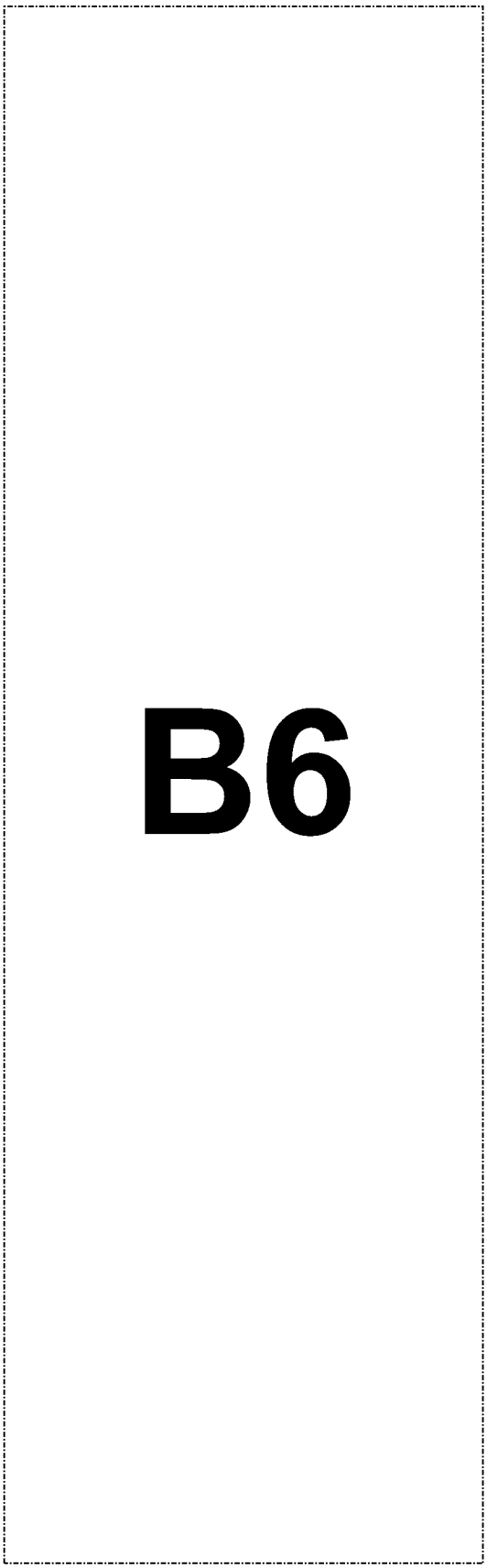
2/24/2019 9:10:18 AM	Heart Rate (/min)
2/24/2019 9:53:51 AM	Cardiac rhythm
2/24/2019 9:53:52 AM	Heart Rate (/min)
2/24/2019 10:00:19 AM	Respiratory Rate
2/24/2019 10:01:02 AM	Lasix treatment note
2/24/2019 10:01:17 AM	Catheter Assessment
2/24/2019 10:02:17 AM	Eliminations
2/24/2019 11:05:02 AM	Respiratory Rate
2/24/2019 11:06:36 AM	Cardiac rhythm
2/24/2019 11:06:37 AM	Heart Rate (/min)
2/24/2019 11:31:26 AM	Amount eaten
2/24/2019 12:11:21 PM	Cardiac rhythm
2/24/2019 12:11:22 PM	Heart Rate (/min)
2/24/2019 12:13:06 PM	Respiratory Rate
2/24/2019 12:55:17 PM	Respiratory Rate
2/24/2019 12:55:33 PM	Cardiac rhythm
2/24/2019 12:55:34 PM	Heart Rate (/min)
2/24/2019 12:59:07 PM	Eliminations
2/24/2019 12:59:18 PM	Catheter Assessment
2/24/2019 1:49:53 PM	Respiratory Rate
2/24/2019 1:50:09 PM	Cardiac rhythm
2/24/2019 1:50:10 PM	Heart Rate (/min)
2/24/2019 3:10:31 PM	Respiratory Rate
2/24/2019 3:11:24 PM	Cardiac rhythm
2/24/2019 3:11:25 PM	Heart Rate (/min)
2/24/2019 4:04:23 PM	Cardiac rhythm
2/24/2019 4:04:24 PM	Heart Rate (/min)
2/24/2019 4:04:40 PM	Respiratory Rate
2/24/2019 5:04:41 PM	Cardiac rhythm
2/24/2019 5:04:42 PM	Heart Rate (/min)
2/24/2019 5:04:55 PM	Respiratory Rate
2/24/2019 5:11:38 PM	Eliminations
2/24/2019 5:19:41 PM	Amount eaten
2/24/2019 5:31:53 PM	Amount eaten
2/24/2019 5:35:31 PM	Catheter Assessment
2/24/2019 5:57:20 PM	Cardiac rhythm
2/24/2019 5:57:21 PM	Heart Rate (/min)
2/24/2019 5:57:37 PM	Respiratory Rate



FDA-CVM-FOIA-2019-1704-006500

Vitals Results

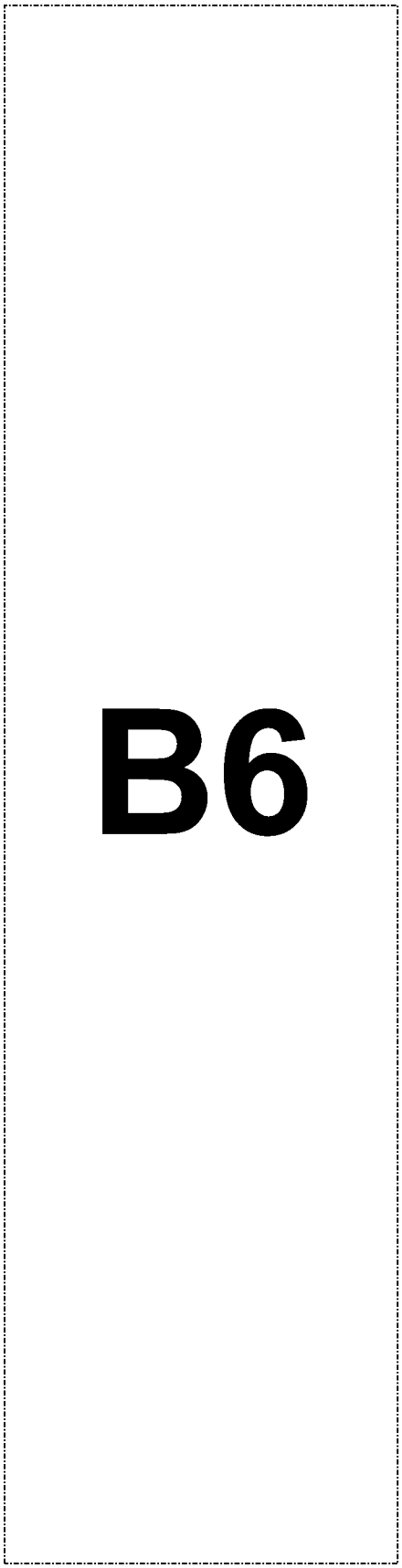
2/24/2019 7:23:42 PM	Cardiac rhythm
2/24/2019 7:23:43 PM	Heart Rate (/min)
2/24/2019 7:24:28 PM	Respiratory Rate
2/24/2019 7:56:19 PM	Cardiac rhythm
2/24/2019 7:56:20 PM	Heart Rate (/min)
2/24/2019 7:56:35 PM	Respiratory Rate
2/24/2019 8:11:41 PM	Eliminations
2/24/2019 8:11:50 PM	Weight (kg)
2/24/2019 8:46:12 PM	Cardiac rhythm
2/24/2019 9:17:13 PM	Catheter Assessment
2/24/2019 9:17:21 PM	Lasix treatment note
2/24/2019 9:18:03 PM	Cardiac rhythm
2/24/2019 9:18:04 PM	Heart Rate (/min)
2/24/2019 9:19:25 PM	Respiratory Rate
2/24/2019 9:23:52 PM	Weight (kg)
2/24/2019 9:24:05 PM	Eliminations
2/24/2019 9:53:36 PM	Cardiac rhythm
2/24/2019 9:53:37 PM	Heart Rate (/min)
2/24/2019 9:53:49 PM	Respiratory Rate
2/24/2019 11:08:13 PM	Cardiac rhythm
2/24/2019 11:08:14 PM	Heart Rate (/min)
2/24/2019 11:08:51 PM	Respiratory Rate
2/24/2019 11:09:13 PM	Amount eaten
2/25/2019 12:11:22 AM	Cardiac rhythm
2/25/2019 12:11:23 AM	Heart Rate (/min)
2/25/2019 12:12:14 AM	Respiratory Rate
2/25/2019 12:50:11 AM	Cardiac rhythm
2/25/2019 12:50:12 AM	Heart Rate (/min)
2/25/2019 12:50:28 AM	Respiratory Rate
2/25/2019 12:50:56 AM	Catheter Assessment
2/25/2019 2:11:35 AM	Cardiac rhythm
2/25/2019 2:11:36 AM	Heart Rate (/min)
2/25/2019 2:12:04 AM	Eliminations
2/25/2019 2:15:50 AM	Respiratory Rate
2/25/2019 3:09:06 AM	Cardiac rhythm
2/25/2019 3:09:07 AM	Heart Rate (/min)
2/25/2019 3:09:21 AM	Respiratory Rate
2/25/2019 4:42:38 AM	Cardiac rhythm
2/25/2019 4:42:39 AM	Heart Rate (/min)
2/25/2019 4:42:59 AM	Respiratory Rate
2/25/2019 5:32:29 AM	Catheter Assessment



FDA-CVM-FOIA-2019-1704-006501

Vitals Results

2/25/2019 5:32:40 AM	Respiratory Rate
2/25/2019 5:32:49 AM	Cardiac rhythm
2/25/2019 5:32:50 AM	Heart Rate (/min)
2/25/2019 5:41:15 AM	Eliminations
2/25/2019 5:41:26 AM	Weight (kg)
2/25/2019 5:45:16 AM	Temperature (F)
2/25/2019 5:45:27 AM	Amount eaten
2/25/2019 5:58:53 AM	Cardiac rhythm
2/25/2019 5:58:54 AM	Heart Rate (/min)
2/25/2019 5:59:10 AM	Respiratory Rate
2/25/2019 7:26:07 AM	Respiratory Rate
2/25/2019 7:28:28 AM	Cardiac rhythm
2/25/2019 7:28:29 AM	Heart Rate (/min)
2/25/2019 7:52:07 AM	Cardiac rhythm
2/25/2019 7:52:08 AM	Heart Rate (/min)
2/25/2019 7:54:41 AM	Respiratory Rate
2/25/2019 9:01:52 AM	Cardiac rhythm
2/25/2019 9:01:53 AM	Heart Rate (/min)
2/25/2019 9:09:06 AM	Respiratory Rate
2/25/2019 9:22:41 AM	Eliminations
2/25/2019 10:03:30 AM	Cardiac rhythm
2/25/2019 10:03:31 AM	Heart Rate (/min)
2/25/2019 10:21:53 AM	Catheter Assessment
2/25/2019 10:22:05 AM	Respiratory Rate
2/25/2019 10:25:31 AM	Lasix treatment note
2/25/2019 10:51:49 AM	Cardiac rhythm
2/25/2019 10:51:50 AM	Heart Rate (/min)
2/25/2019 10:57:46 AM	Respiratory Rate
2/25/2019 12:03:00 PM	Cardiac rhythm
2/25/2019 12:03:01 PM	Heart Rate (/min)
2/25/2019 12:03:41 PM	Respiratory Rate
2/25/2019 12:59:10 PM	Cardiac rhythm
2/25/2019 12:59:11 PM	Heart Rate (/min)
2/25/2019 1:00:11 PM	Respiratory Rate
2/25/2019 1:06:35 PM	Eliminations
2/25/2019 1:07:04 PM	Catheter Assessment
2/25/2019 1:58:26 PM	Cardiac rhythm
2/25/2019 1:58:27 PM	Heart Rate (/min)
2/25/2019 1:59:52 PM	Respiratory Rate
2/25/2019 2:49:26 PM	Cardiac rhythm



FDA-CVM-FOIA-2019-1704-006502

Client: B6
Patient:

Vitals Results

2/25/2019 2:49:27 PM	Heart Rate (/min)	B6
2/25/2019 2:49:40 PM	Respiratory Rate	
2/25/2019 3:47:30 PM	Cardiac rhythm	
2/25/2019 3:47:31 PM	Heart Rate (/min)	
2/25/2019 3:47:42 PM	Respiratory Rate	

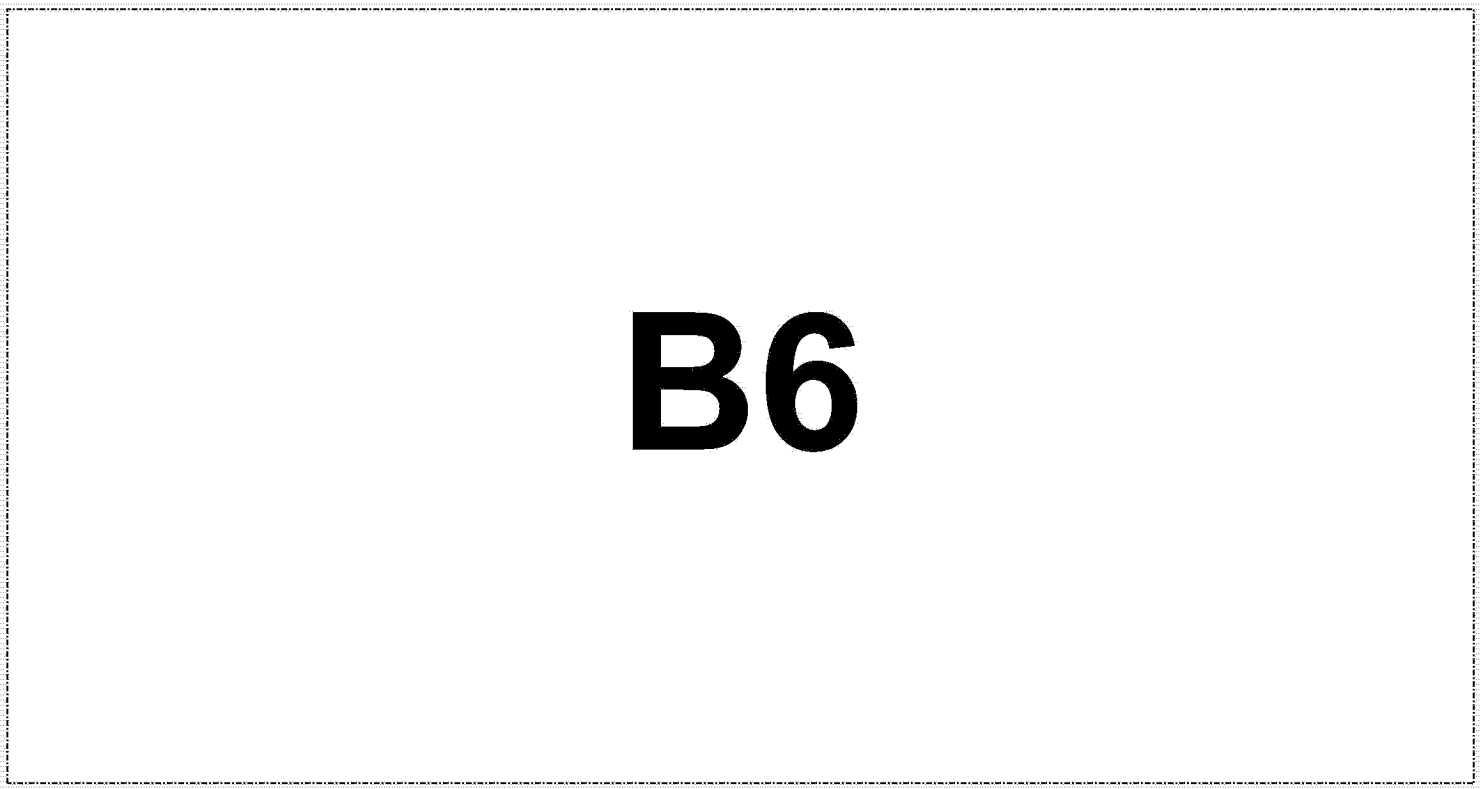
FDA-CVM-FOIA-2019-1704-006503

Client: B6
Patient:

ECG from Cardio

B6

2/22/2019 11:43:38 AM
Tufts University
Tufts Cummings School of Vet Med
Cardiology



FDA-CVM-FOIA-2019-1704-006504

Client: B6
Patient:

ECG from Cardio

B6

2/22/2019 11:45:45 AM Page 1 of 2
Tufts University
Tufts Cummings School of Vet Med
Cardiology

FDA-CVM-FOIA-2019-1704-006505

Client: B6
Patient:

ECG from Cardio

B6 2/22/2019 11:45:45 AM Page 2 of 2

Tufts University
Tufts Cummings School of Vet Med
Cardiology

FDA-CVM-FOIA-2019-1704-006506

Client: B6
Patient:

ECG from Cardio

B6

2/22/2019 11:46:06 AM
Tufts University
Tufts Cummings School of Vet Med
Cardiology

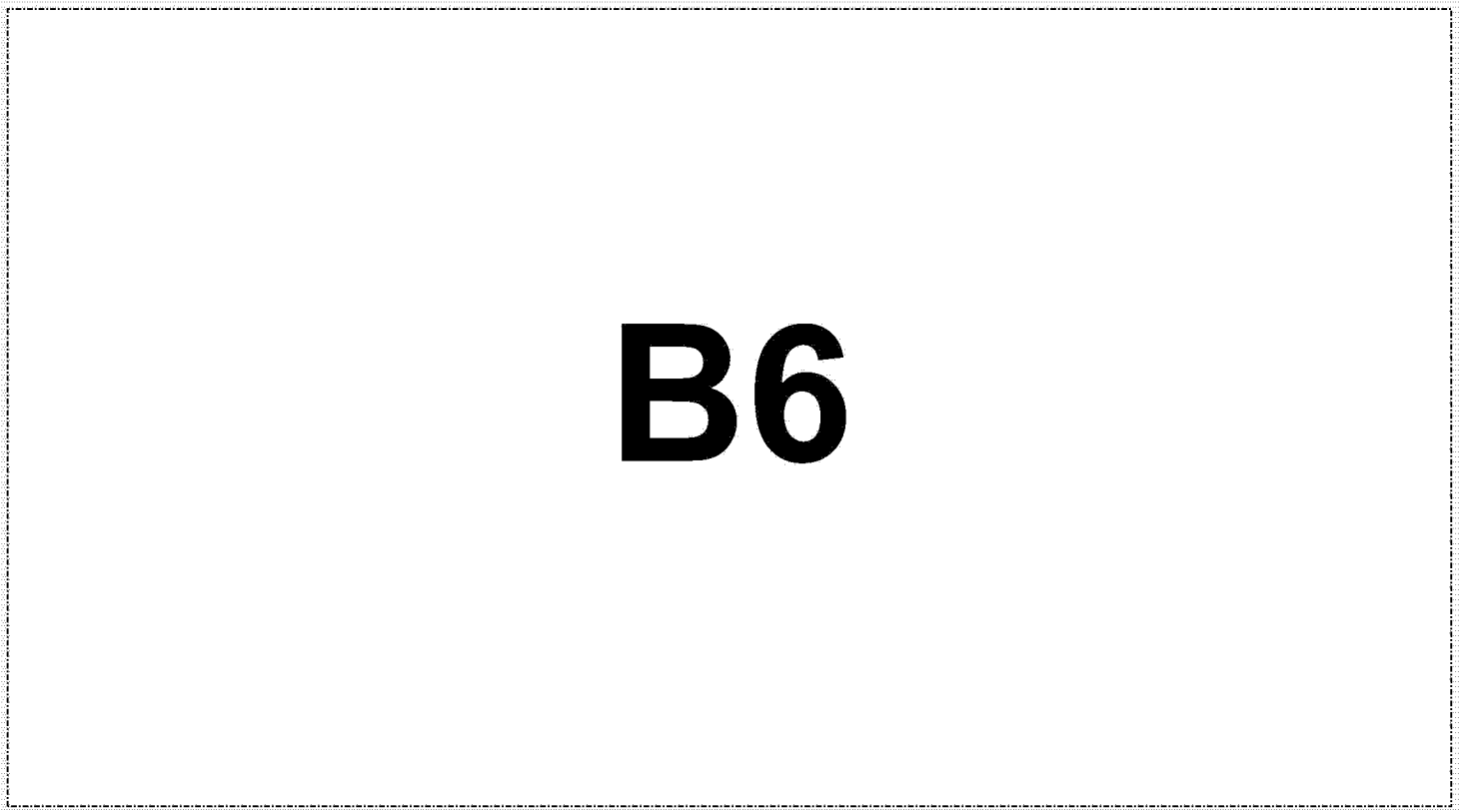
FDA-CVM-FOIA-2019-1704-006507

Client: B6
Patient:

ECG from Cardio

B6

2/22/2019 11:46:06 AM
Tufts University
Tufts Cummings School of Vet Med
Cardiology



FDA-CVM-FOIA-2019-1704-006508

Client: B6
Patient:

ECG from Cardio

B6

2/22/2019 11:48:08 AM
Tufts University
Tufts Cummings School of Vet Med
Cardiology

FDA-CVM-FOIA-2019-1704-006509

Client: B6
Patient:

ECG from Cardio

B6

2/22/2019 11:50:34 AM
Tufts University
Tufts Cummings School of Vet Med
Cardiology

FDA-CVM-FOIA-2019-1704-006510

Patient History

02/22/2019 09:15 AM	UserForm
02/22/2019 09:30 AM	Purchase
02/22/2019 09:36 AM	Labwork
02/22/2019 09:36 AM	Purchase
02/22/2019 10:10 AM	UserForm
02/22/2019 10:16 AM	Purchase
02/22/2019 10:16 AM	Treatment
02/22/2019 10:25 AM	Vitals
02/22/2019 10:34 AM	UserForm
02/22/2019 10:36 AM	Vitals
02/22/2019 10:46 AM	UserForm
02/22/2019 10:52 AM	Deleted Reason
02/22/2019 10:52 AM	Deleted Reason
02/22/2019 10:52 AM	Treatment
02/22/2019 10:58 AM	Vitals
02/22/2019 11:36 AM	Treatment
02/22/2019 11:47 AM	Purchase
02/22/2019 12:01 PM	Prescription
02/22/2019 12:02 PM	Prescription
02/22/2019 12:43 PM	Vitals
02/22/2019 12:43 PM	Vitals
02/22/2019 12:44 PM	Vitals
02/22/2019 12:50 PM	Purchase
02/22/2019 12:50 PM	Purchase
02/22/2019 12:50 PM	Treatment
02/22/2019 12:50 PM	Vitals
02/22/2019 12:50 PM	Vitals
02/22/2019 12:52 PM	Treatment
02/22/2019 12:52 PM	Vitals
02/22/2019 01:00 PM	Treatment
02/22/2019 01:00 PM	Vitals
02/22/2019 01:00 PM	Treatment
02/22/2019 01:10 PM	Treatment
02/22/2019 01:10 PM	Vitals

B6

FDA-CVM-FOIA-2019-1704-006511

Patient History

02/22/2019 01:10 PM	Vitals
02/22/2019 01:26 PM	Purchase
02/22/2019 01:26 PM	Purchase
02/22/2019 01:26 PM	Purchase
02/22/2019 01:42 PM	Purchase
02/22/2019 01:42 PM	Purchase
02/22/2019 02:03 PM	Treatment
02/22/2019 02:03 PM	Vitals
02/22/2019 02:03 PM	Vitals
02/22/2019 02:04 PM	Treatment
02/22/2019 02:04 PM	Vitals
02/22/2019 02:11 PM	Purchase
02/22/2019 02:11 PM	Purchase
02/22/2019 02:25 PM	Vitals
02/22/2019 02:40 PM	Treatment
02/22/2019 02:40 PM	Vitals
02/22/2019 03:00 PM	Treatment
02/22/2019 03:00 PM	Vitals
02/22/2019 03:00 PM	Vitals
02/22/2019 03:01 PM	Treatment
02/22/2019 03:01 PM	Vitals
02/22/2019 03:49 PM	Treatment
02/22/2019 03:49 PM	Vitals
02/22/2019 03:49 PM	Vitals
02/22/2019 03:50 PM	Treatment
02/22/2019 03:50 PM	Vitals
02/22/2019 04:05 PM	Vitals
02/22/2019 04:07 PM	Vitals
02/22/2019 04:07 PM	Vitals
02/22/2019 04:24 PM	Deleted Reason
02/22/2019 04:30 PM	Deleted Reason
02/22/2019 04:31 PM	Vitals
02/22/2019 04:32 PM	Prescription
02/22/2019 05:00 PM	Treatment
02/22/2019 05:00 PM	Vitals
02/22/2019 05:00 PM	Vitals
02/22/2019 05:05 PM	Treatment
02/22/2019 05:05 PM	Vitals

B6

FDA-CVM-FOIA-2019-1704-006512

Patient History

02/22/2019 05:16 PM	Treatment
02/22/2019 05:38 PM	Treatment
02/22/2019 05:38 PM	Vitals
02/22/2019 05:38 PM	Treatment
02/22/2019 05:38 PM	Vitals
02/22/2019 05:39 PM	Treatment
02/22/2019 05:55 PM	Vitals
02/22/2019 06:03 PM	Treatment
02/22/2019 06:03 PM	Vitals
02/22/2019 06:03 PM	Vitals
02/22/2019 06:04 PM	Treatment
02/22/2019 06:04 PM	Vitals
02/22/2019 06:24 PM	Treatment
02/22/2019 06:24 PM	Vitals
02/22/2019 06:24 PM	Vitals
02/22/2019 06:49 PM	Prescription
02/22/2019 06:51 PM	Treatment
02/22/2019 06:51 PM	Vitals
02/22/2019 06:51 PM	Vitals
02/22/2019 06:51 PM	Treatment
02/22/2019 06:51 PM	Vitals
02/22/2019 07:51 PM	Treatment
02/22/2019 07:51 PM	Treatment
02/22/2019 07:51 PM	Vitals
02/22/2019 07:52 PM	Treatment
02/22/2019 07:52 PM	Vitals
02/22/2019 07:52 PM	Vitals
02/22/2019 07:53 PM	Vitals
02/22/2019 07:53 PM	Treatment
02/22/2019 08:45 PM	Vitals
02/22/2019 08:52 PM	Treatment
02/22/2019 08:52 PM	Treatment
02/22/2019 08:52 PM	Vitals
02/22/2019 08:52 PM	Vitals
02/22/2019 08:59 PM	Treatment
02/22/2019 08:59 PM	Vitals
02/22/2019 09:09 PM	Treatment
02/22/2019 09:09 PM	Treatment
02/22/2019 09:25 PM	Treatment
02/22/2019 09:25 PM	Vitals
02/22/2019 09:25 PM	Vitals

B6

FDA-CVM-FOIA-2019-1704-006513

Patient History

02/22/2019 09:49 PM	Treatment
02/22/2019 09:49 PM	Vitals
02/22/2019 09:49 PM	Vitals
02/22/2019 09:56 PM	Treatment
02/22/2019 09:56 PM	Vitals
02/22/2019 10:51 PM	Treatment
02/22/2019 10:51 PM	Vitals
02/22/2019 10:51 PM	Vitals
02/22/2019 10:52 PM	Treatment
02/22/2019 10:52 PM	Vitals
02/22/2019 11:34 PM	Treatment
02/22/2019 11:34 PM	Vitals
02/22/2019 11:55 PM	Treatment
02/22/2019 11:55 PM	Vitals
02/22/2019 11:55 PM	Treatment
02/22/2019 11:55 PM	Vitals
02/22/2019 11:55 PM	Treatment
02/22/2019 11:55 PM	Vitals
02/22/2019 11:55 PM	Vitals
02/23/2019 12:00 AM	Purchase
02/23/2019 01:00 AM	Treatment
02/23/2019 01:00 AM	Vitals
02/23/2019 01:00 AM	Vitals
02/23/2019 01:00 AM	Treatment
02/23/2019 01:00 AM	Vitals
02/23/2019 01:00 AM	Treatment
02/23/2019 01:52 AM	Vitals
02/23/2019 01:52 AM	Treatment
02/23/2019 01:52 AM	Vitals
02/23/2019 01:53 AM	Treatment
02/23/2019 01:53 AM	Vitals
02/23/2019 01:53 AM	Treatment
02/23/2019 01:53 AM	Vitals
02/23/2019 01:53 AM	Vitals
02/23/2019 01:54 AM	Treatment
02/23/2019 01:54 AM	Vitals
02/23/2019 01:54 AM	Vitals
02/23/2019 02:16 AM	Vitals
02/23/2019 02:33 AM	Vitals
02/23/2019 02:39 AM	Treatment
02/23/2019 02:39 AM	Vitals

B6

FDA-CVM-FOIA-2019-1704-006514

Patient History

02/23/2019 02:39 AM	Vitals
02/23/2019 03:36 AM	Treatment
02/23/2019 03:36 AM	Vitals
02/23/2019 03:36 AM	Vitals
02/23/2019 03:41 AM	Treatment
02/23/2019 03:41 AM	Vitals
02/23/2019 03:41 AM	Treatment
02/23/2019 03:41 AM	Vitals
02/23/2019 04:49 AM	Treatment
02/23/2019 04:49 AM	Vitals
02/23/2019 04:49 AM	Vitals
02/23/2019 04:49 AM	Treatment
02/23/2019 04:49 AM	Vitals
02/23/2019 05:25 AM	Treatment
02/23/2019 05:28 AM	Treatment
02/23/2019 05:28 AM	Vitals
02/23/2019 05:29 AM	Treatment
02/23/2019 05:29 AM	Vitals
02/23/2019 05:29 AM	Vitals
02/23/2019 05:29 AM	Treatment
02/23/2019 05:36 AM	Treatment
02/23/2019 05:36 AM	Vitals
02/23/2019 05:36 AM	Treatment
02/23/2019 05:56 AM	Treatment
02/23/2019 05:56 AM	Vitals
02/23/2019 05:56 AM	Vitals
02/23/2019 06:56 AM	Treatment
02/23/2019 06:56 AM	Vitals
02/23/2019 06:56 AM	Vitals
02/23/2019 06:56 AM	Treatment
02/23/2019 06:56 AM	Vitals
02/23/2019 07:37 AM	Treatment
02/23/2019 07:37 AM	Vitals
02/23/2019 07:37 AM	Treatment
02/23/2019 07:37 AM	Vitals
02/23/2019 07:38 AM	Treatment
02/23/2019 07:58 AM	Treatment
02/23/2019 07:58 AM	Vitals
02/23/2019 07:58 AM	Vitals
02/23/2019 07:59 AM	Treatment

B6

FDA-CVM-FOIA-2019-1704-006515

Patient History

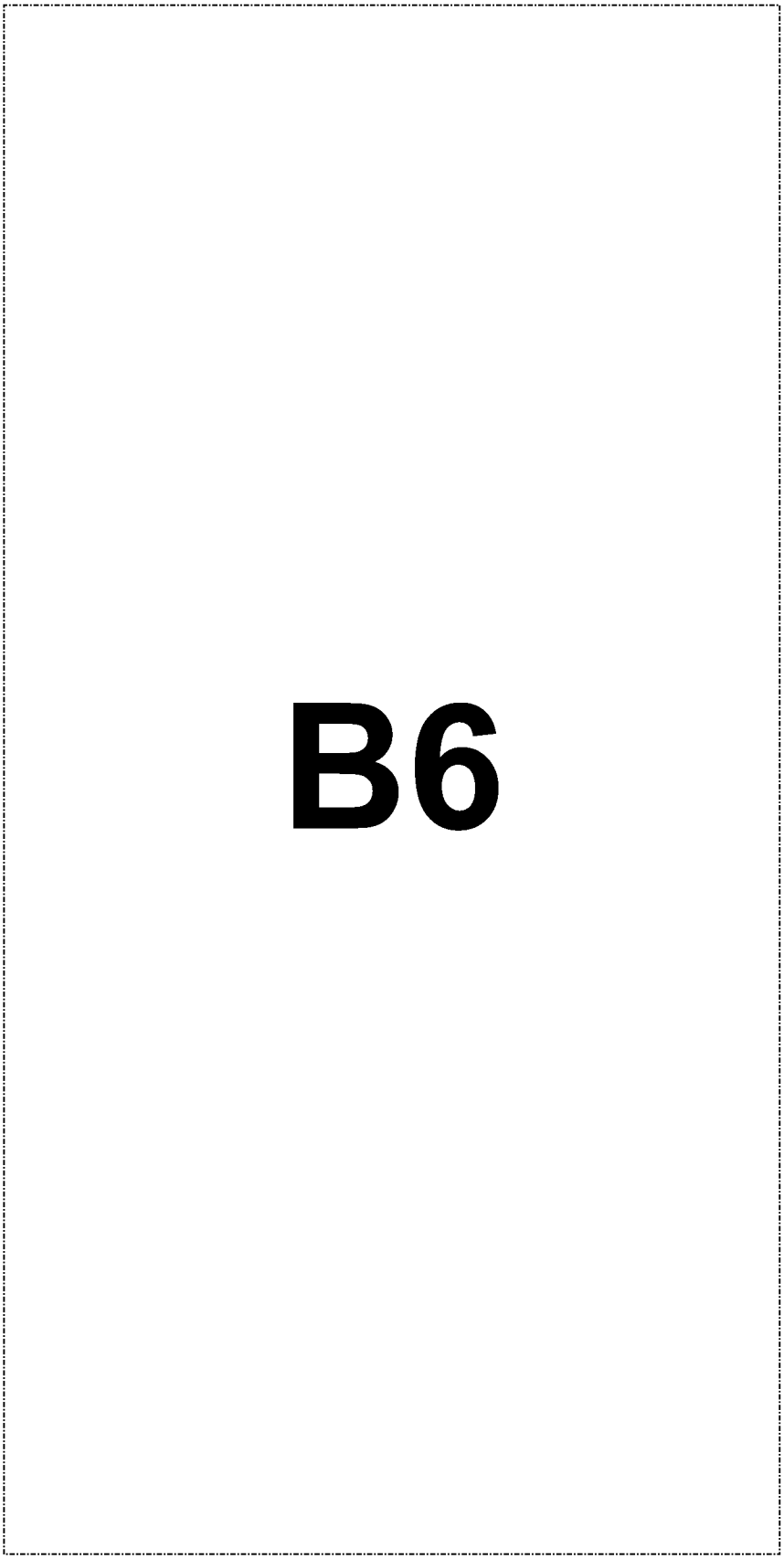
02/23/2019 07:59 AM	Vitals
02/23/2019 09:02 AM	Treatment
02/23/2019 09:05 AM	Prescription
02/23/2019 09:09 AM	Treatment
02/23/2019 09:09 AM	Vitals
02/23/2019 09:09 AM	Vitals
02/23/2019 09:12 AM	Treatment
02/23/2019 09:27 AM	Deleted Reason
02/23/2019 09:29 AM	Purchase
02/23/2019 09:29 AM	Treatment
02/23/2019 09:33 AM	Treatment
02/23/2019 09:33 AM	Vitals
02/23/2019 09:46 AM	Treatment
02/23/2019 09:56 AM	Purchase
02/23/2019 10:02 AM	Treatment
02/23/2019 10:02 AM	Vitals
02/23/2019 10:02 AM	Vitals
02/23/2019 10:05 AM	Treatment
02/23/2019 10:05 AM	Vitals
02/23/2019 10:05 AM	Treatment
02/23/2019 10:05 AM	Vitals
02/23/2019 10:05 AM	Vitals
02/23/2019 10:06 AM	Treatment
02/23/2019 11:06 AM	Treatment
02/23/2019 11:06 AM	Vitals
02/23/2019 11:06 AM	Vitals
02/23/2019 11:07 AM	Treatment
02/23/2019 11:07 AM	Vitals
02/23/2019 11:27 AM	Treatment
02/23/2019 11:27 AM	Vitals
02/23/2019 11:27 AM	Treatment
02/23/2019 11:27 AM	Vitals
02/23/2019 11:53 AM	UserForm
02/23/2019 12:02 PM	Purchase
02/23/2019 12:02 PM	Purchase
02/23/2019 12:23 PM	Treatment
02/23/2019 12:23 PM	Vitals
02/23/2019 12:23 PM	Vitals
02/23/2019 12:26 PM	Treatment

B6

FDA-CVM-FOIA-2019-1704-006516

Patient History

02/23/2019 12:26 PM	Vitals
02/23/2019 01:04 PM	Treatment
02/23/2019 01:04 PM	Vitals
02/23/2019 01:04 PM	Vitals
02/23/2019 01:05 PM	Treatment
02/23/2019 01:05 PM	Vitals
02/23/2019 01:05 PM	Treatment
02/23/2019 01:20 PM	Treatment
02/23/2019 01:20 PM	Vitals
02/23/2019 01:55 PM	Treatment
02/23/2019 01:55 PM	Vitals
02/23/2019 01:55 PM	Vitals
02/23/2019 01:55 PM	Vitals
02/23/2019 01:55 PM	Vitals
02/23/2019 01:55 PM	Treatment
02/23/2019 01:55 PM	Vitals
02/23/2019 02:52 PM	Treatment
02/23/2019 02:52 PM	Vitals
02/23/2019 02:52 PM	Vitals
02/23/2019 02:53 PM	Treatment
02/23/2019 02:53 PM	Vitals
02/23/2019 03:12 PM	Treatment
02/23/2019 03:12 PM	Vitals
02/23/2019 03:50 PM	Treatment
02/23/2019 03:50 PM	Vitals
02/23/2019 03:50 PM	Treatment
02/23/2019 03:50 PM	Vitals
02/23/2019 03:50 PM	Vitals
02/23/2019 04:49 PM	Treatment
02/23/2019 04:49 PM	Vitals
02/23/2019 04:54 PM	Treatment
02/23/2019 04:54 PM	Vitals
02/23/2019 04:54 PM	Vitals
02/23/2019 05:16 PM	Treatment
02/23/2019 05:22 PM	Treatment
02/23/2019 05:22 PM	Treatment
02/23/2019 05:22 PM	Vitals
02/23/2019 05:28 PM	Treatment
02/23/2019 05:29 PM	Treatment
02/23/2019 05:33 PM	Treatment
02/23/2019 05:33 PM	Vitals
02/23/2019 05:46 PM	Treatment



FDA-CVM-FOIA-2019-1704-006517

Patient History

02/23/2019 05:46 PM	Vitals
02/23/2019 05:46 PM	Treatment
02/23/2019 05:46 PM	Vitals
02/23/2019 05:46 PM	Vitals
02/23/2019 06:00 PM	Vitals
02/23/2019 06:20 PM	Vitals
02/23/2019 06:21 PM	Treatment
02/23/2019 06:21 PM	Treatment
02/23/2019 06:30 PM	Vitals
02/23/2019 06:45 PM	Treatment
02/23/2019 06:51 PM	Treatment
02/23/2019 07:00 PM	Vitals
02/23/2019 07:00 PM	Vitals
02/23/2019 07:08 PM	Treatment
02/23/2019 07:08 PM	Treatment
02/23/2019 07:08 PM	Vitals
02/23/2019 08:00 PM	Vitals
02/23/2019 08:07 PM	Treatment
02/23/2019 08:07 PM	Vitals
02/23/2019 08:07 PM	Vitals
02/23/2019 08:08 PM	Treatment
02/23/2019 08:08 PM	Vitals
02/23/2019 09:00 PM	Vitals
02/23/2019 09:00 PM	Vitals
02/23/2019 09:06 PM	Treatment
02/23/2019 09:06 PM	Vitals
02/23/2019 09:14 PM	Treatment
02/23/2019 09:17 PM	Treatment
02/23/2019 09:17 PM	Vitals
02/23/2019 09:18 PM	Treatment
02/23/2019 09:36 PM	Treatment
02/23/2019 09:36 PM	Treatment
02/23/2019 09:36 PM	Vitals
02/23/2019 09:40 PM	Treatment
02/23/2019 09:40 PM	Vitals
02/23/2019 09:41 PM	Treatment
02/23/2019 09:41 PM	Vitals
02/23/2019 09:41 PM	Vitals
02/23/2019 11:21 PM	Treatment
02/23/2019 11:21 PM	Vitals
02/23/2019 11:21 PM	Vitals

B6

FDA-CVM-FOIA-2019-1704-006518

Patient History

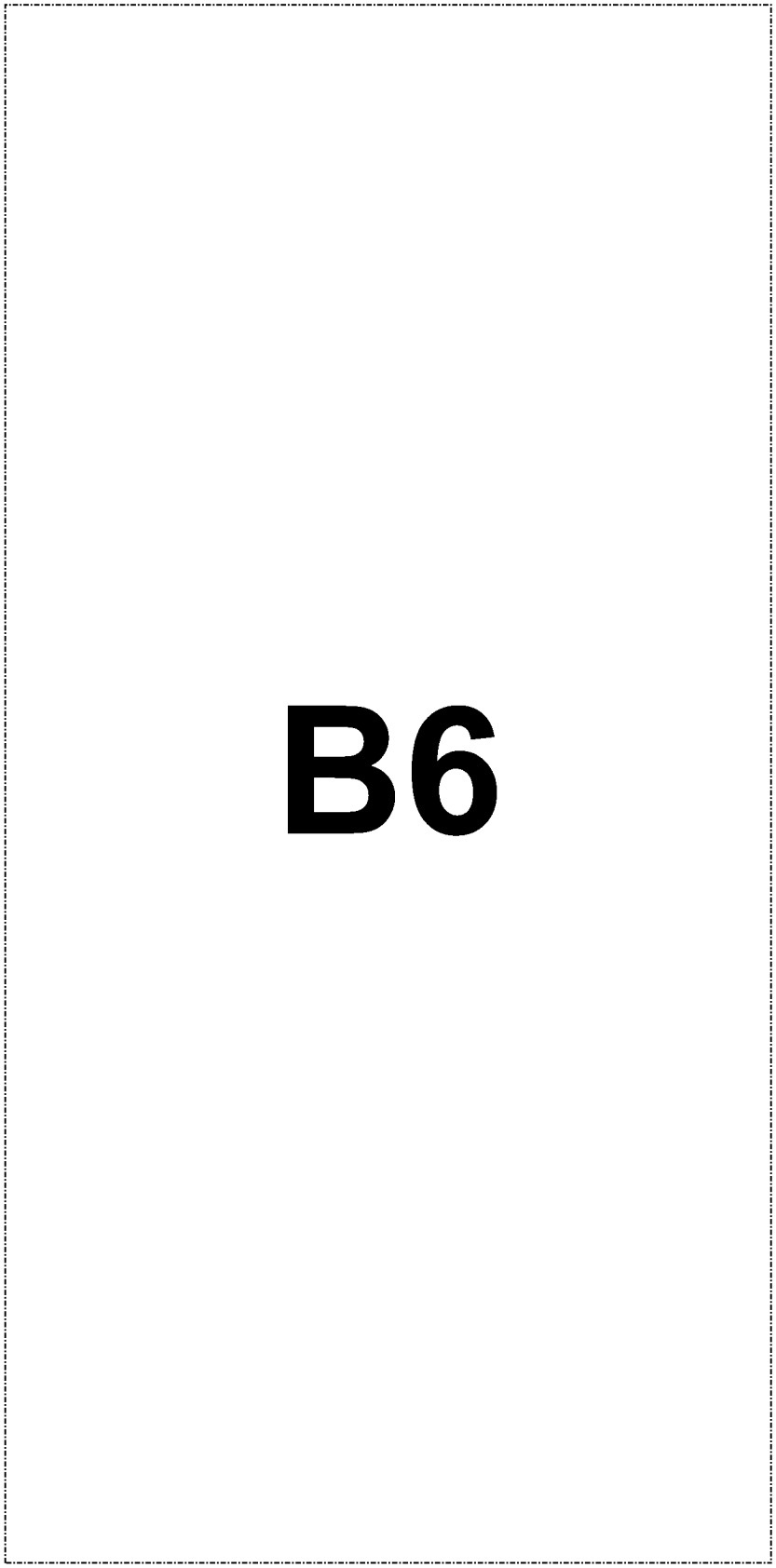
02/23/2019 11:22 PM	Treatment
02/23/2019 11:22 PM	Vitals
02/23/2019 11:24 PM	Treatment
02/23/2019 11:24 PM	Vitals
02/23/2019 11:27 PM	Vitals
02/24/2019 12:00 AM	Purchase
02/24/2019 12:10 AM	Treatment
02/24/2019 12:10 AM	Vitals
02/24/2019 12:10 AM	Vitals
02/24/2019 12:10 AM	Treatment
02/24/2019 12:10 AM	Vitals
02/24/2019 01:02 AM	Treatment
02/24/2019 01:02 AM	Treatment
02/24/2019 01:02 AM	Vitals
02/24/2019 01:03 AM	Treatment
02/24/2019 01:03 AM	Vitals
02/24/2019 01:03 AM	Vitals
02/24/2019 01:04 AM	Treatment
02/24/2019 01:04 AM	Vitals
02/24/2019 01:05 AM	Vitals
02/24/2019 01:22 AM	Treatment
02/24/2019 01:22 AM	Vitals
02/24/2019 01:22 AM	Treatment
02/24/2019 01:22 AM	Vitals
02/24/2019 01:22 AM	Vitals
02/24/2019 01:57 AM	Vitals
02/24/2019 01:58 AM	Treatment
02/24/2019 02:00 AM	Treatment
02/24/2019 02:00 AM	Vitals
02/24/2019 02:00 AM	Vitals
02/24/2019 02:59 AM	Treatment
02/24/2019 02:59 AM	Vitals
02/24/2019 02:59 AM	Vitals
02/24/2019 03:03 AM	Treatment
02/24/2019 03:03 AM	Vitals
02/24/2019 03:04 AM	Vitals
02/24/2019 03:51 AM	Treatment
02/24/2019 03:51 AM	Vitals
02/24/2019 03:58 AM	Treatment
02/24/2019 03:58 AM	Vitals
02/24/2019 03:58 AM	Vitals
02/24/2019 03:58 AM	Vitals
02/24/2019 04:58 AM	Treatment

B6

FDA-CVM-FOIA-2019-1704-006519

Patient History

02/24/2019 04:58 AM	Treatment
02/24/2019 04:58 AM	Treatment
02/24/2019 04:58 AM	Vitals
02/24/2019 04:59 AM	Treatment
02/24/2019 04:59 AM	Treatment
02/24/2019 05:06 AM	Treatment
02/24/2019 05:06 AM	Vitals
02/24/2019 05:06 AM	Treatment
02/24/2019 05:06 AM	Vitals
02/24/2019 05:06 AM	Treatment
02/24/2019 05:06 AM	Vitals
02/24/2019 05:08 AM	Treatment
02/24/2019 05:08 AM	Vitals
02/24/2019 05:08 AM	Vitals
02/24/2019 05:08 AM	Treatment
02/24/2019 05:08 AM	Vitals
02/24/2019 05:14 AM	Treatment
02/24/2019 05:14 AM	Vitals
02/24/2019 05:48 AM	Treatment
02/24/2019 05:48 AM	Vitals
02/24/2019 05:48 AM	Vitals
02/24/2019 05:48 AM	Treatment
02/24/2019 05:48 AM	Vitals
02/24/2019 06:48 AM	Treatment
02/24/2019 06:48 AM	Vitals
02/24/2019 06:48 AM	Vitals
02/24/2019 06:49 AM	Treatment
02/24/2019 06:49 AM	Vitals
02/24/2019 07:40 AM	Vitals
02/24/2019 08:00 AM	Treatment
02/24/2019 08:00 AM	Vitals
02/24/2019 08:00 AM	Vitals
02/24/2019 08:01 AM	Treatment
02/24/2019 08:01 AM	Vitals
02/24/2019 09:04 AM	Treatment
02/24/2019 09:04 AM	Vitals
02/24/2019 09:05 AM	Treatment
02/24/2019 09:10 AM	Treatment
02/24/2019 09:10 AM	Vitals
02/24/2019 09:10 AM	Vitals
02/24/2019 09:53 AM	Treatment



FDA-CVM-FOIA-2019-1704-006520

Patient History

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02/24/2019 09:53 AM	Vitals
02/24/2019 10:00 AM	Treatment
02/24/2019 10:00 AM	Vitals
02/24/2019 10:00 AM	Treatment
02/24/2019 10:01 AM	Vitals
02/24/2019 10:01 AM	Treatment
02/24/2019 10:01 AM	Treatment
02/24/2019 10:01 AM	Vitals
02/24/2019 10:02 AM	Vitals
02/24/2019 10:24 AM	Purchase
02/24/2019 11:05 AM	Treatment
02/24/2019 11:05 AM	Vitals
02/24/2019 11:06 AM	Treatment
02/24/2019 11:06 AM	Vitals
02/24/2019 11:06 AM	Vitals
02/24/2019 11:31 AM	Treatment
02/24/2019 11:31 AM	Vitals
02/24/2019 12:02 PM	Purchase
02/24/2019 12:02 PM	Purchase
02/24/2019 12:11 PM	Treatment
02/24/2019 12:11 PM	Vitals
02/24/2019 12:11 PM	Vitals
02/24/2019 12:13 PM	Treatment
02/24/2019 12:13 PM	Vitals
02/24/2019 12:17 PM	Treatment
02/24/2019 12:18 PM	Purchase
02/24/2019 12:54 PM	Treatment
02/24/2019 12:55 PM	Treatment
02/24/2019 12:55 PM	Vitals
02/24/2019 12:55 PM	Treatment
02/24/2019 12:55 PM	Vitals
02/24/2019 12:55 PM	Vitals
02/24/2019 12:59 PM	Treatment
02/24/2019 12:59 PM	Vitals
02/24/2019 12:59 PM	Treatment
02/24/2019 12:59 PM	Vitals
02/24/2019 01:49 PM	Treatment
02/24/2019 01:49 PM	Vitals
02/24/2019 01:50 PM	Treatment
02/24/2019 01:50 PM	Vitals

B6

FDA-CVM-FOIA-2019-1704-006521

Patient History

02/24/2019 01:50 PM	Vitals
02/24/2019 03:10 PM	Treatment
02/24/2019 03:10 PM	Vitals
02/24/2019 03:11 PM	Treatment
02/24/2019 03:11 PM	Vitals
02/24/2019 03:11 PM	Vitals
02/24/2019 04:04 PM	Treatment
02/24/2019 04:04 PM	Vitals
02/24/2019 04:04 PM	Vitals
02/24/2019 04:04 PM	Treatment
02/24/2019 04:04 PM	Vitals
02/24/2019 05:04 PM	Treatment
02/24/2019 05:04 PM	Vitals
02/24/2019 05:04 PM	Vitals
02/24/2019 05:04 PM	Treatment
02/24/2019 05:04 PM	Vitals
02/24/2019 05:07 PM	Treatment
02/24/2019 05:11 PM	Treatment
02/24/2019 05:11 PM	Vitals
02/24/2019 05:19 PM	Treatment
02/24/2019 05:19 PM	Vitals
02/24/2019 05:24 PM	Prescription
02/24/2019 05:24 PM	Prescription
02/24/2019 05:31 PM	Treatment
02/24/2019 05:31 PM	Treatment
02/24/2019 05:31 PM	Vitals
02/24/2019 05:35 PM	Treatment
02/24/2019 05:35 PM	Vitals
02/24/2019 05:57 PM	Treatment
02/24/2019 05:57 PM	Vitals
02/24/2019 05:57 PM	Vitals
02/24/2019 05:57 PM	Treatment
02/24/2019 05:57 PM	Vitals
02/24/2019 07:23 PM	Treatment
02/24/2019 07:23 PM	Vitals
02/24/2019 07:23 PM	Vitals
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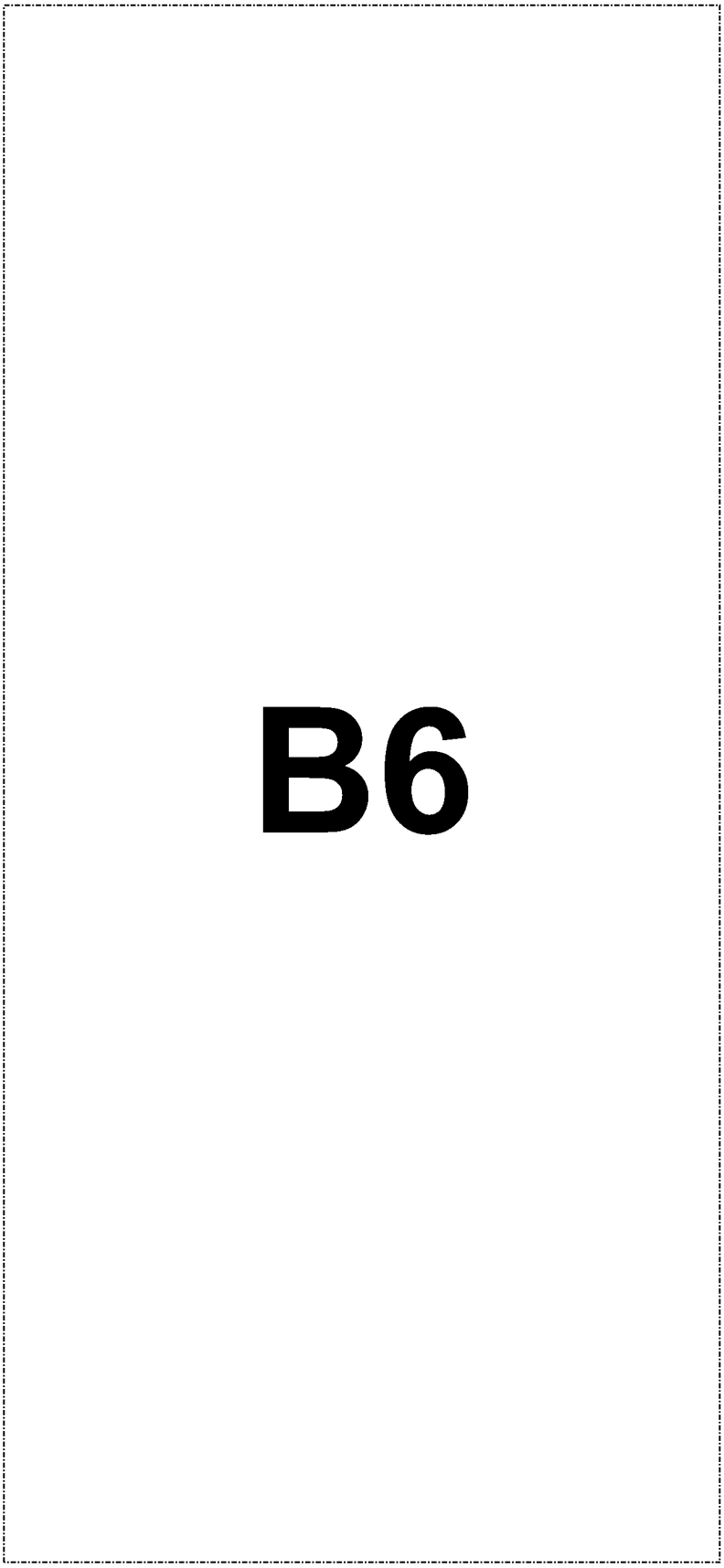

FDA-CVM-FOIA-2019-1704-006522

Patient History

02/24/2019 07:56 PM	Vitals
02/24/2019 07:56 PM	Treatment
02/24/2019 07:56 PM	Vitals
02/24/2019 08:11 PM	Vitals
02/24/2019 08:11 PM	Vitals
02/24/2019 08:46 PM	Treatment
02/24/2019 08:46 PM	Vitals
02/24/2019 09:17 PM	Treatment
02/24/2019 09:17 PM	Treatment
02/24/2019 09:17 PM	Vitals
02/24/2019 09:17 PM	Vitals
02/24/2019 09:17 PM	Treatment
02/24/2019 09:18 PM	Treatment
02/24/2019 09:18 PM	Vitals
02/24/2019 09:18 PM	Vitals
02/24/2019 09:19 PM	Treatment
02/24/2019 09:19 PM	Vitals
02/24/2019 09:23 PM	Vitals
02/24/2019 09:24 PM	Treatment
02/24/2019 09:24 PM	Vitals
02/24/2019 09:53 PM	Treatment
02/24/2019 09:53 PM	Vitals
02/24/2019 09:53 PM	Vitals
02/24/2019 09:53 PM	Treatment
02/24/2019 09:53 PM	Vitals
02/24/2019 11:08 PM	Treatment
02/24/2019 11:08 PM	Vitals
02/24/2019 11:08 PM	Vitals
02/24/2019 11:08 PM	Treatment
02/24/2019 11:08 PM	Vitals
02/24/2019 11:09 PM	Treatment
02/24/2019 11:09 PM	Vitals
02/25/2019 12:00 AM	Purchase
02/25/2019 12:11 AM	Treatment
02/25/2019 12:11 AM	Vitals
02/25/2019 12:11 AM	Vitals
02/25/2019 12:12 AM	Treatment
02/25/2019 12:12 AM	Vitals
02/25/2019 12:50 AM	Treatment
02/25/2019 12:50 AM	Vitals
02/25/2019 12:50 AM	Vitals
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02/25/2019 12:50 AM	Vitals

B6

FDA-CVM-FOIA-2019-1704-006523

Patient History

02/25/2019 12:50 AM	Treatment
02/25/2019 12:50 AM	Treatment
02/25/2019 12:50 AM	Vitals
02/25/2019 02:11 AM	Treatment
02/25/2019 02:11 AM	Vitals
02/25/2019 02:11 AM	Vitals
02/25/2019 02:12 AM	Treatment
02/25/2019 02:12 AM	Vitals
02/25/2019 02:15 AM	Treatment
02/25/2019 02:15 AM	Vitals
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02/25/2019 03:09 AM	Vitals
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02/25/2019 04:42 AM	Treatment
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02/25/2019 05:32 AM	Vitals
02/25/2019 05:32 AM	Treatment
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02/25/2019 05:35 AM	Treatment
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02/25/2019 05:41 AM	Treatment
02/25/2019 05:41 AM	Vitals
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02/25/2019 05:41 AM	Vitals
02/25/2019 05:45 AM	Treatment
02/25/2019 05:45 AM	Vitals
02/25/2019 05:45 AM	Treatment
02/25/2019 05:45 AM	Vitals
02/25/2019 05:58 AM	Treatment
02/25/2019 05:58 AM	Vitals
02/25/2019 05:58 AM	Vitals
02/25/2019 05:59 AM	Treatment

B6

FDA-CVM-FOIA-2019-1704-006524

Patient History

02/25/2019 05:59 AM	Vitals
02/25/2019 07:26 AM	Treatment
02/25/2019 07:26 AM	Vitals
02/25/2019 07:28 AM	Treatment
02/25/2019 07:28 AM	Vitals
02/25/2019 07:28 AM	Vitals
02/25/2019 07:52 AM	Treatment
02/25/2019 07:52 AM	Vitals
02/25/2019 07:52 AM	Vitals
02/25/2019 07:54 AM	Treatment
02/25/2019 07:54 AM	Vitals
02/25/2019 08:32 AM	Deleted Reason
02/25/2019 08:33 AM	Purchase
02/25/2019 09:01 AM	Treatment
02/25/2019 09:01 AM	Vitals
02/25/2019 09:01 AM	Vitals
02/25/2019 09:09 AM	Treatment
02/25/2019 09:09 AM	Vitals
02/25/2019 09:22 AM	Treatment
02/25/2019 09:22 AM	Vitals
02/25/2019 09:43 AM	Treatment
02/25/2019 10:03 AM	Treatment
02/25/2019 10:03 AM	Vitals
02/25/2019 10:03 AM	Vitals
02/25/2019 10:21 AM	Treatment
02/25/2019 10:21 AM	Vitals
02/25/2019 10:22 AM	Treatment
02/25/2019 10:22 AM	Vitals
02/25/2019 10:22 AM	Treatment
02/25/2019 10:25 AM	Vitals
02/25/2019 10:26 AM	Treatment
02/25/2019 10:51 AM	Treatment
02/25/2019 10:51 AM	Vitals
02/25/2019 10:51 AM	Vitals
02/25/2019 10:57 AM	Treatment
02/25/2019 10:57 AM	Vitals
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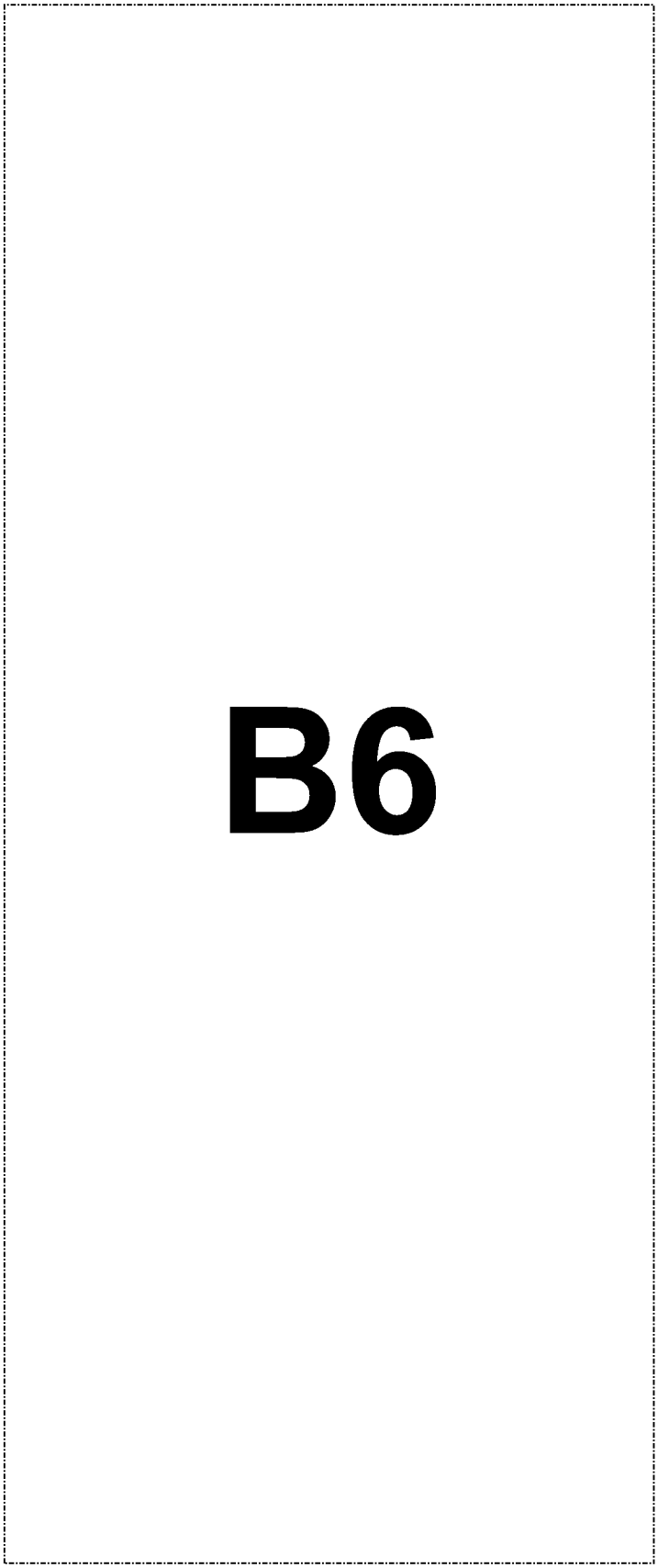
02/25/2019 12:03 PM	Vitals



FDA-CVM-FOIA-2019-1704-006525

Patient History

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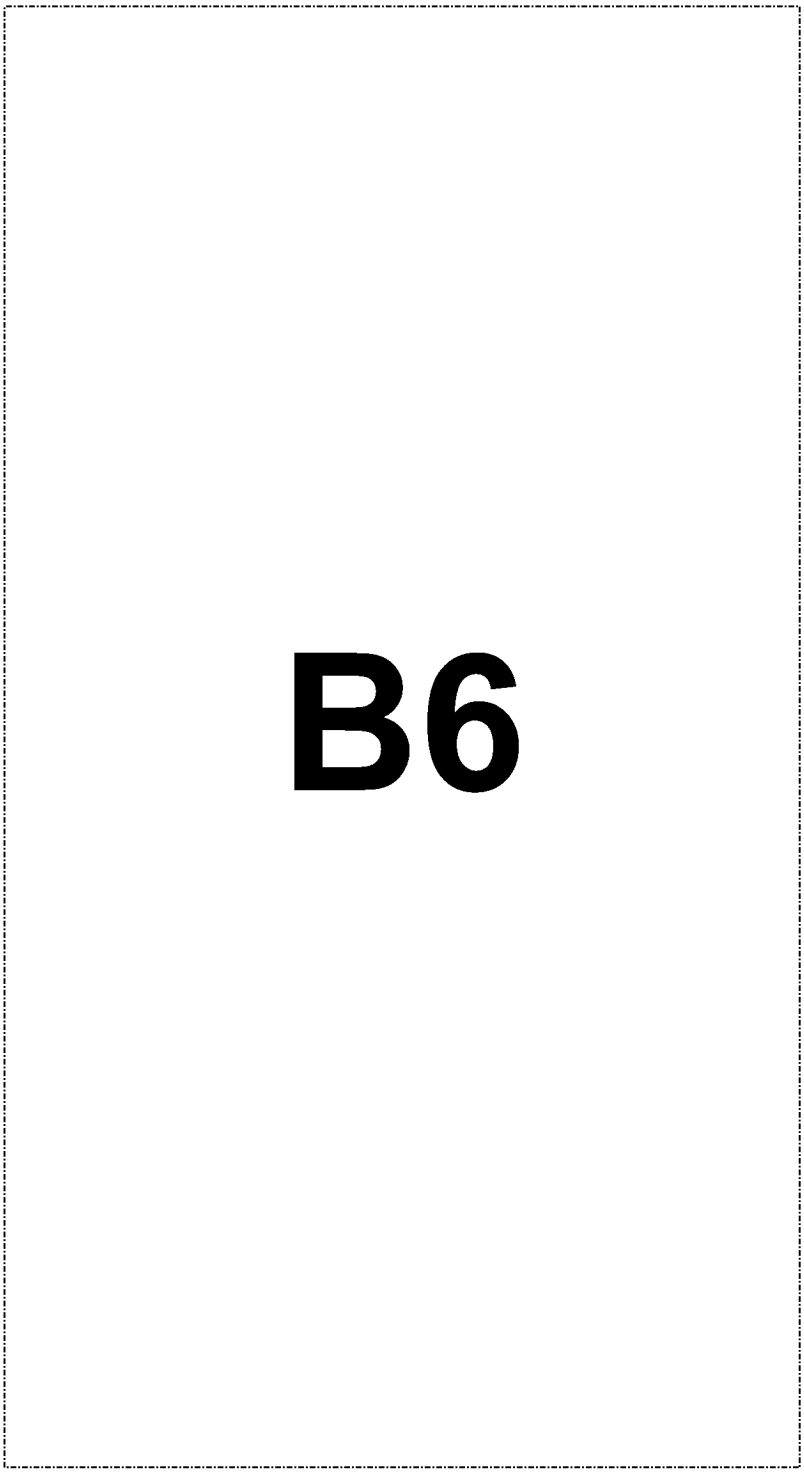
02/25/2019 12:03 PM	Vitals
02/25/2019 12:59 PM	Treatment
02/25/2019 12:59 PM	Vitals
02/25/2019 12:59 PM	Vitals
02/25/2019 12:59 PM	Treatment
02/25/2019 01:00 PM	Treatment
02/25/2019 01:00 PM	Vitals
02/25/2019 01:06 PM	Treatment
02/25/2019 01:06 PM	Vitals
02/25/2019 01:07 PM	Treatment
02/25/2019 01:07 PM	Vitals
02/25/2019 01:19 PM	Prescription
02/25/2019 01:33 PM	Purchase
02/25/2019 01:33 PM	Treatment
02/25/2019 01:58 PM	Treatment
02/25/2019 01:58 PM	Vitals
02/25/2019 01:58 PM	Vitals
02/25/2019 01:59 PM	Treatment
02/25/2019 01:59 PM	Vitals
02/25/2019 02:49 PM	Treatment
02/25/2019 02:49 PM	Vitals
02/25/2019 02:49 PM	Vitals
02/25/2019 02:49 PM	Treatment
02/25/2019 02:49 PM	Vitals
02/25/2019 03:40 PM	Prescription
02/25/2019 03:40 PM	Prescription
02/25/2019 03:41 PM	Prescription
02/25/2019 03:41 PM	Prescription
02/25/2019 03:47 PM	Treatment
02/25/2019 03:47 PM	Vitals
02/25/2019 03:47 PM	Vitals
02/25/2019 03:47 PM	Treatment
02/25/2019 03:47 PM	Vitals
02/25/2019 03:53 PM	Purchase
02/25/2019 04:34 PM	UserForm



FDA-CVM-FOIA-2019-1704-006526

FDA-CVM-FOIA-2019-1704-006527

FDA-CVM-FOIA-2019-1704-006528

FDA-CVM-FOIA-2019-1704-006529

Cummings
Veterinary Medical Center
AT TUFTS UNIVERSITY

B6

B6 Male (Neutered)
Canine Boxer Brindle
Patient ID: B6

STANDARD CONSENT FORM

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

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

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

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

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

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

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

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

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

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

I do further agree that should any payment, or the full amount of the sum stated above, become overdue more than 20 days from the above agreed upon time of payment or payments, the entire balance shall be considered in default and become due and payable. I further agree to be responsible for any or all collection agency and/or attorney fees necessary to collect the full amount.

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

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

Owner's name: B6 Date: 2/22/2019

Owner's address: B6

B6 — 2/22/19

Date

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

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

Authorized Agent – Please Print

Agent's Signature

Street Address

Date

Town/City State Zip

Cummings Veterinary Medical Center AT TUFTS UNIVERSITY

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

Treatment Plan

Estimated Charges

02/22/2019

B6

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

Patient	Description	Low Qty	Low Extended	High Qty	High Extended
B6					

B6

Doctor of Record: **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 pet's care.

High Total	**B6**
Low Total	
75% Deposit	

Printed Friday, February 22, 2019

FDA-CVM-FOIA-2019-1704-006532

Cummings
Veterinary Medical Center
AT TUFTS UNIVERSITY

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

Radiology Request & Report

Patient
Name: B6
Species: Canine
Brindle Male (Neutered) Boxer
Birthdate: B6

Owner
Name: B6
Address: B6

Patient ID: B6
Date of request: 2/22/2019

Attending Clinician: B6 DVM (Intern - SAM) **Student:**

Date of exam: 2/22/2018

Patient Location: Ward/Cage: Weight(lbs) 0.00

- ☐ Inpatient
- ☐ Outpatient Time:
- ☐ Waiting
- ☐ Emergency

Sedation
- ☐ BAG
- ☐ OBAG
- ☐ 1/2 dose OBAG
- ☐ DexDomitor/Butorphanol
- ☐ Anesthesia to sedate/anesthetize

Examination Desired:
3 view chest

Presenting Complaint and Clinical Questions you wish to answer:
Emergency

Pertinent History:
Arrythmia
FROM SOAP: "owner has been gone for a week, B6 was at home with husband. In July primary vet noticed heart arrythmia due to symptom of wheezing. rDVM Started on sotalol, owners gave that for a couple weeks and wheezing resolved, stopped sotalol. 1 week ago started wheezing again (sporadic), became clingy and lethargic. No vomting/heaving. drinking water, didn't finish food this morning which is abnormal. unknown diarrhea, appetite status while owner was gone. Did restart B6 on Tuesday."

Findings:
THORAX, THREE VIEWS.

B6

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B6

Conclusions:
- Cardiopulmonary changes are consistent with left-sided congestive heart failure. Given moderate generalized cardiomegaly and moderate left atrial enlargement, consider DCM given breed. Echocardiography is recommended and repeat thoracic radiographs to monitor response to therapy.
- Impression of faint rounded soft tissue opacities mixed in with the intersitital pattern may represent peribronchial cuffing and end on vessels, pulmonary nodules are thought less likely. Follow-up radiographs to reassess the lungs are recommended after resolution of cardiogenic pulmonary edema.
- Concurrent mild diffuse bronchial pattern likely represents a component of lower airway disease.

Radiologists
Primary: B6, DVM
Reviewing:

Dates
Reported: 2/22/2019
Finalized:

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Discharge Instructions

Patient
Name: B6
Signalment: B6 Years Old Brindle Male (Neutered) Boxer

Owner
Name:
Address: B6

Patient ID: B6
Emergency Clinician: B6 DVM
Consulting Clinician: B6 DVM

ER Supervisor:

B6

Admit Date: B6 9:12:55 AM
Check Out Date: B6

Diagnosis:
1. Dilated cardiomyopathy (DCM) with congestive heart failure
2. Malignant ventricular arrhythmia

Case Summary:
B6 has been diagnosed with a primary heart muscle disease called dilated cardiomyopathy (DCM). This disease is more common in large and giant breed dogs and is characterized by thinning of the walls of the heart, reduced cardiac pump function, and enlargement of the upper chambers of the heart. Many dogs with DCM will also have significant arrhythmias (like B6) 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.

Diagnostic test results and findings:
- **Chest radiograph (x-ray) findings:** The heart is enlarged and there is fluid in the lungs
- **Echocardiogram findings:** All chambers of the heart are enlarged and there is fluid in the lungs
- **ECG findings:** The ECG showed irregular heart rhythm
- **Labwork findings:** The kidney values are mildly elevated; Liver values (ALT) slightly elevated

History:
B6 presented to Tufts ER on B6 for further evaluation of a one week history of wheezing. You report that your family vet noted a heart arrhythmia in July (was evaluated for wheezing) and B6 was started on B6 . The wheezing resolved and the medication was discontinued. B6 didn't finish his breakfast the morning before presentation to ER, and this is abnormal for him.

Physical exam:
On presentation, B6 was bright and alert and his vital were normal except an elevated heart rate (160). He was noted to have a grade 2-3/6 heart murmur and an arrhythmia. He had moderate respiratory difficulty, and some wheezing and

coughing was noted intermittently. The rest of his physical exam was unremarkable.

Diagnostic/Treatment plan:

B6 *had x-rays of his chest that showed evidence of left sided congestive heart failure and a moderate cardiomegaly (enlarged heart). He also had an echocardiogram which showed findings consistent with dilated cardiomyopathy (poor contractile function of the heart), active congestive heart failure, and frequent ventricular arrythmia.* B6 *also had bloodwork which showed mild elevations in one of his liver values (ALT). On re-check bloodwork the next day, the liver value (ALT) was improved by still elevated. His kidney values also increased slightly, suspect due to the* B6

While in the hospital, B6 *was closely monitored with a continuous EKG, and he was given several medications to treat his conditions, including* B6

B6

Monitoring at home:

1. Please monitor for any signs of lethargy, weakness, pale gums, cough, shortness of breath, inappetence, or collapse. If a collapsing episode is noted, please check your dog's gum color and try to get a sense of whether the heart rate is slow or fast. If you have an iPhone or Android smartphone device, you may want to explore the option of purchasing the Kardia device (www.alivecor.com or search 'Kardia' on www.amazon.com). If you have an iPhone, download the 'Veterinary Alive' app. If you have an Android device, download the 'Kardia' app. Both are free to download. This will allow you to monitor the heart rate and rhythm at home. If you have any concerns, please call or have your dog evaluated by a veterinarian. Our emergency clinic is open 24 hours/day.

2. We would like you to monitor your dog's breathing rate and effort at home, ideally during sleep or at a time of rest. The doses of drugs will be adjusted based on the breathing rate and effort. In general, most dogs with heart failure that is well controlled have a breathing rate at rest of less than 35 to 40 breaths per minute. In addition, the breathing effort, noted by the amount of belly wall motion used for each breath, is fairly minimal if heart failure is controlled. An increase in breathing rate or effort will usually mean that you should give an extra dose of B6 If difficulty breathing is not improved by within 30-60 minutes after giving B6 then we recommend that a recheck exam be scheduled and/or that your dog be evaluated by an emergency clinic. There are instructions for monitoring breathing, and a form to help keep track of breathing rate and drug doses, on the Tufts HeartSmart web site (http://vet.tufts.edu/heartsmart/at-home-monitoring/).

Recommended Medications:

B6

Diet suggestions:

Dogs with arrhythmia may benefit from the addition of omega-3 fatty acids (fish oil) to the diet. Diets such as the Royal Canin Boxer or Early Cardiac diet or Hill's j/d have ample fish oil and may not require much (or any) additional supplementation.

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/). You can also find additional information on supplements such as fish oil or other supplements that you might have questions about may be found on the Tufts HeartSmart web site: (http://vet.tufts.edu/heartsmart/diet/).

- The FDA is currently investigating an apparent association between diet and a type of heart disease called dilated cardiomyopathy. The exact cause is still unclear, but it appears to be associated with boutique diets and those containing exotic ingredient or are grain-free. Therefore, we are currently recommending that dogs do not eat these types of diets.
- We recommend switching B6 to commercial diet made by a well-established company that is not grain-free and does not contain any exotic ingredients, such as kangaroo, duck, lamb, venison, lentils, peas, beans, buffalo, tapioca, barley, and chickpeas.
- The FDA issued a statement regarding this issue (https://www.fda.gov/AnimalVeterinary/NewsEvents/CVMUpdates/ucm613305.htm) and a recent article published by Dr. Lisa Freeman on the Cummings School's Petfoodology blog can further explain these findings (http://vetnutrition.tufts.edu/2018/06/a-broken-heart-risk-of-heart-disease-in-boutique-or-grain-free-diets-and-exotic-ingredients/).
- Our nutritionists have compiled a list of dog foods that are good options for dogs with heart disease.

Dry Food Options:
Royal Canin Early Cardiac (veterinary diet)
Royal Canin Boxer
Purina Pro Plan Adult Weight Management
Purina Pro Plan Bright Mind Adult Small Breed Formula
Canned Food Options:
Hill's Science Diet Adult Beef and Barley Entree
Hill's Science Diet Adult 1-6 Healthy Cuisine Roasted Chicken, Carrot, and Spinach Stew
Royal Canin Mature 8+

We recommend slowly introducing one of the diets on the above list as follows: 25% of the new diet mixed with 75% old diet for 2-3 days, then 50:50, etc.
Hopefully you can find a diet on the list tha B6 will enjoy!

If your dog has special nutritional needs or requires a homecooked diet, we recommend you schedule an appointment with our nutritionists (508-887-4696).

Exercise recommendations:
For the first 7 to 10 days after starting anti-arrhythmic medications and medications for heart failure, and until we know that the medications are effectively controlling arrhythmia, we recommend very limited activity. Leash walk only is ideal, and short walks to start. Once the arrhythmia and heart failure has been well controlled then slightly longer walks are acceptable. However, repetitive or strenuous high-energy activities (repetitive ball chasing, running fast off-leash, etc.) are not recommended as these activities may result in worsened arrhythmia or even sudden death.

Recheck/Follow-up:
A recheck exam is usually recommended in 7 to 14 days to check and see if the arrhythmia and heart failure is well controlled. If you wish to have the Cardiology service at Tufts assist with ongoing care of your pet's heart disease, please contact the Cardiology service by sending an email to cardiovet@tufts.edu within 24-48 hours after your pet has been discharged to set up an appointment. After you have made an appointment with the Cardiology service, the Cardiology service will then be able to answer questions regarding the care of your pet. If instead you would like to continue care with

your primary care veterinarian, then please have your veterinarian contact us with any questions regarding the treatment of your pet. As always, if your pet again encounters an emergency, the Emergency Service is available to see you 24 hours a day, 365 days a year.

Thank you for entrusting us with B6 's care. Please contact our Cardiology liaison at (508)-887-4696 or email us at cardiovet@tufts.edu for scheduling and non-emergent questions or concerns. Our emergency clinic is also open 24 hours/day.

Thank you for entrusting us with B6 care. He is such a sweet boy!

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

B6

Patient ID: B6
B6 Canine
Years Old Male (Neutered) Boxer
Brindle BW: Weight(lbs) 0.00

Cardiology Inpatient
ENROLLED IN DCM DIET STUDY

Date B6
Weight: Weight(lbs) 25kg
Attending Cardiologist:
☐ John E. Rush DVM, MS, DACVIM (Cardiology), DACVECC

B6

Cardiology Resident:

B6

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

Patient location:
ER

Presenting complaint and important concurrent diseases:
Previously diagnosed arrhythmia at rDVM in July, was started on B6 but discontinued after a few weeks due to resolution of symptoms (wheezing). Owner reports that while she was away last week his wheezing returned. Owner started B6 again last Tuesday. Now lethargic, decreased appetite. No other significant history.

Current medications and doses:
B6 (unknown concentration): 1/2 tab BID

At-home diet: (name, form, amount, frequency)
Royal canin boxer dry

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

Questions to be answered:
Does he have current heart disease/heart failure? degree of arrhythmia?

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

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- [ ] Yes (explain):
- [x] No, owner waiting in lobby

STOP - remainder of form to be filled out by Cardiology

Physical Examination

B6

Muscle condition:

- [ ] Normal
- [ ] Mild muscle loss
- [x] Moderate cachexia
- [ ] Marked cachexia

Cardiovascular Physical Exam

Murmur Grade:

- [ ] None
- [ ] I/VI
- [x] II/VI to
- [x] III/VI
- [ ] IV/VI
- [ ] V/VI
- [ ] VI/VI

B6

Jugular vein:

- [ ] Bottom 1/3 of the neck
- [x] Middle 1/3 of the neck
- [ ] Top 2/3 of the neck
- [ ] 1/2 way up the neck

Arterial pulses:

- [ ] Weak
- [x] Fair
- [ ] Good
- [ ] Strong
- [ ] Bounding
- [x] Pulse deficits
- [ ] Pulsus paradoxus
- [ ] Other (describe):

Arrhythmia:

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

Gallop:

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

Pulmonary assessments:

- [ ] Eupneic
- [x] Moderate dyspnea
- [ ] Marked dyspnea
- [ ] Normal BV sounds
- [ ] Pulmonary Crackles
- [ ] Wheezes
- [ ] Upper airway stridor
- [x] Other auscultatory findings: Cough

Abdominal exam:

- [x] Normal
- [ ] Abdominal distension

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☐ Hepatomegaly ☐ Mild ascites

Echocardiogram Findings:

B6

Doppler findings:

B6

ECG findings:

B6

Radiographic findings:

B6

Assessment and recommendations:

Findings consistent with DCM with active CHF and frequent ventricular arrhythmia. Patient has enough malignant arrhythmia that hospitalization and B6 monitoring is recommended. B6 and depending how well he responds, maybe we can decrease to q6-8h overnight. Patient has historically been on grain free diet for years before been switched to current diet. It is unclear whether this is a primary DCM, ARVC with DCM phenotype, or diet-induced cardiomyopathy, but B6 are also recommended. Apparently patient tolerated well B6 in the past, but we generally avoid it at this point due to potential beta-blocker effects that may worsen systolic function. Thus, recommend bloodwork and if liver values are normal, B6 should be started. Howeverm since he tolerated it in the pas B6 could be considered once CHF is resolved if liver values are elvated. Fish oil may also be effective helping decrease ventricular arrhythmia density. Recommend addition of an B6 . Recommend repeat echocardiogram in 3 months or sooner in case patient develops clinical signs consistent with progression of the disease (shortness breath, collapse, syncope, exercise intolerance, pale mucous membrane). Client can be instructed on how to use AliveCor and assess heart rate and rhythm from home if patient at rest and calm at home.

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Addendum 02/25/2019:
The patient continues to have persistent ventricular tachycardia despite being on the B6 for almost 3 days. It was elected to B6. The owner elected to take the patient home today despite poor arrhythmia controlled. Recheck ECG is recommended in 7-10 days.

Treatment Plan:

- o
- o
- o
- o
- o
- o

B6

Final Diagnosis:
Severe cardiomegaly with poor contractile function - r/o primary DCM, diet-induced cardiomyopathy, ARVC, tachycardiac induced cardiomyopathy.
Malignant ventricular arrhythmia - non-sustained VTach and frequent polymorphic VPCs;
Left sided congestive heart failure.

Heart Failure Classification Score:
ISACHC Classification:

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

ACVIM CHF Classification:

- ☐ A
- ☐ B1
- ☐ B2
- ☑ C
- ☐ D

M-Mode		
IVSd		cm
LVIDd		cm
LVPWd		cm
IVSs		cm
LVIDs		cm
LVPWs		cm
EDV(Teich)		ml
ESV(Teich)		ml
EF(Teich)		%
%FS		%
SV(Teich)		ml
M-Mode Normalized		
IVSdN		(0.290 - 0.520)
LVIDdN		(1.350 - 1.730) !
LVPWdN		(0.330 - 0.530)

B6

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IVSsN		(0.430 - 0.710) !
LVIDsN		(0.790 - 1.140) !
LVPWsN		(0.530 - 0.780) !
2D		
SA LA		cm
Ao Diam		cm
SA LA / Ao Diam		
IVSd		cm
LVIDd		cm
LVPWd		cm
EDV(Teich)		ml
IVSs		cm
LVIDs		cm
LVPWs		cm
ESV(Teich)		ml
EF(Teich)	B6	%
%FS		%
SV(Teich)		ml
LVId LAX		cm
LVAd LAX		cm
LVEDV A-L LAX		ml
LVEDV MOD LAX		ml
LVIs LAX		cm
LVAs LAX		cm
LVESV A-L LAX		ml
LVESV MOD LAX		ml
HR		BPM
EF A-L LAX		%
LVEF MOD LAX		%
SV A-L LAX		ml
SV MOD LAX		ml
CO A-L LAX		l/min
CO MOD LAX		l/min
Doppler		
MR Vmax		m/s
MR maxPG	B6	mmHg
PV Vmax		m/s
PV maxPG		mmHg

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Fax (508) 839-7951
http://vetmed.tufts.edu/

Cardiology Liaison: 508-887-4696

Discharge Instructions

Patient
Name: B6
Species: Canine
Brindle Male (Neutered) Boxer
Birthdate: B6

Owner
Name: B6
Address: B6

Patient ID: B6

Attending Cardiologist:
John E. Rush DVM, MS, DACVIM (Cardiology), DACVECC
B6

Cardiology Resident:
B6

Cardiology Technician:
B6

Student:

Admit Date: B6 9:12:55 AM
Discharge Date: B6

Diagnoses:
- Suspected Arrhythmogenic right ventricular cardiomyopathy (ARVC) versus Dilated cardiomyopathy
- Active Congestive heart failure
- Ventricular arrhythmia - Not currently controlled -

Clinical findings:
Thank you for bringing B6 to Tufts University.

He presented to our ER last Friday after it was noticed that he had a decreased appetite and overall was not feeling like his normal self. He was previously diagnosed with an arrhythmia (irregular heart rate) back in July by your primary care veterinarian but had never been seen by a cardiologist.

Upon presentation to the ER, B6 was noticed to have increased respiratory effort and rate in addition to a non-productive cough. Also, his heart rate was faster than normal and he had very frequent irregular premature beats. Chest radiographs were then performed and were suspicious for accumulation of fluid within the lungs, a condition consistent with active congestive heart failure.

B6 was then seen by the Cardiology department where an echocardiogram (ultrasound of the heart) was performed. has been diagnosed with a primary heart muscle disease called arrhythmogenic right ventricular cardiomyopathy (ARVC). This disease is common in Boxers and bulldogs and is also sometimes referred to as "Boxer Cardiomyopathy". The condition is characterized by replacement of the normal heart muscle by fat and/or scar tissue which may result in serious ventricular arrhythmias (abnormal heart rhythms originating from the lower chamber of the heart), cardiac enlargement

and congestive heart failure, or both. Dogs with ARVC may experience syncope (fainting) or sudden death as the result of ventricular arrhythmia.

As we discussed over the phone, another possibility to explain the changes within B6 heart is a type of heart disease called dilated cardiomyopathy (DCM). This disease is more common in large and giant breed dogs and is characterized by thinning of the walls of the heart, reduced cardiac pump function, and enlargement of the upper chambers of the heart. Many dogs with DCM will also have significant arrhythmias which can be life-threatening and also require medical management.

B6 was then admitted to the hospital for further monitoring and management of his cardiac disease. Over the course of his stay in the hospital, it was noted that B6 respiratory rate and effort progressively improved to the point of being back to normal today. However, his arrhythmia is fairly resistant to our current treatment. However, as we discussed every dog is different and require a different antiarrhythmic management at home. At this point of time, we are trying a new combination of medications with the hope that this will decrease the frequency of his arrhythmia.

Though we cannot reverse the changes in the heart muscle, we can control the arrhythmias with medical management and dogs without serious cardiac dilation can do well for months to even years after diagnosis with appropriate therapy and careful monitoring.

Monitoring at home:

- We would like you to monitor your dog's breathing rate and effort at home, ideally during sleep or at a time of rest. The doses of drugs will be adjusted based on the breathing rate and effort.
- In general, most dogs with heart failure that is well controlled have a breathing rate at rest of less than 35 to 40 breaths per minute. In addition, the breathing effort, noted by the amount of belly wall motion used for each breath, is fairly minimal if heart failure is controlled.
- An increase in breathing rate or effort will usually mean that you should give an extra dose o B6 If difficulty breathing is not improved by within 30-60 minutes after giving e B6 en we recommend that a recheck exam be scheduled and/or that your dog be evaluated by an emergency clinic.
- There are instructions for monitoring breathing, and a form to help keep track of breathing rate and drug doses, on the Tufts HeartSmart web site (http://vet.tufts.edu/heartsmart/at-home-monitoring/).
- We also want you to watch for weakness or collapse, a reduction in appetite, worsening cough, or distention of the belly as these findings indicate that we should do a recheck examination.
- If you have an iPhone or Android smartphone device, you may want to explore the option of purchasing the Kardia Mobile device which will allow you to monitor the heart rate and rhythm at home (www.alivecor.com). If you have any concerns, please call or have your dog evaluated by a veterinarian. Our emergency clinic is open 24 hours/day.

Recommended Medications:

B6

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B6

Diet suggestions: Dogs with ARVC may benefit from the addition of omega-3 fatty acids (fish oil) to the diet. Diets such as the Royal Canin Boxer or Early Cardiac diet, or Hill's j/d have ample fish oil and may not require much (or any) additional supplementation. Additional information on supplements such as fish oil or other supplements that you might have questions about may be found on the Tufts HeartSmart web site: (http://vet.tufts.edu/heartsmart/diet/).

- The FDA is currently investigating an apparent association between diet and a type of heart disease called dilated cardiomyopathy. The exact cause is still unclear, but it appears to be associated with boutique diets and those containing exotic ingredient or are grain-free. Therefore, we are currently recommending that dogs do not eat these types of diets.
- We recommend switching B6 to commercial diet made by a well-established company that is not grain-free and does not contain any exotic ingredients, such as kangaroo, duck, lamb, venison, lentils, peas, beans, buffalo, tapioca, barley, and chickpeas.
- The FDA issued a statement regarding this issue (https://www.fda.gov/AnimalVeterinary/NewsEvents/CVMUpdates/ucm613305.htm) and a recent article published by Dr. Lisa Freeman on the Cummings School's Petfoodology blog can further explain these findings (http://vetnutrition.tufts.edu/2018/06/a-broken-heart-risk-of-heart-disease-in-boutique-or-grain-free-diets-and-exotic-ingredients/).
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Royal Canin Mature 8+

We recommend slowly introducing one of the diets on the above list as follows: 25% of the new diet mixed with 75% old diet for 2-3 days, then 50:50, etc.
Hopefully you can find a diet on the list th B6 will enjoy!

If your dog has special nutritional needs or requires a homecooked diet, we recommend you schedule an appointment with our nutritionists (508-887-4696).

Exercise recommendations: For the first 7 to 10 days after starting anti-arrhythmic medications, and until we know that the medications are effectively controlling arrhythmia, we recommend very limited activity. Leash walk only is ideal, and

short walks to start. Once the arrhythmia has been well-controlled then slightly longer walks are acceptable. However, repetitive or strenuous high energy activities (repetitive ball chasing, running fast off-leash, etc.) are not recommended as these activities may result in worsened arrhythmia or even sudden death.

Recheck visits:
A recheck ECG is recommended 1-2 weeks after any antiarrhythmic medication adjustments are made.

Since B6 was enrolled in the DCM study, we will need to see him back in 3, 6, and 9 months.

Thank you for entrusting us with B6 care. Please contact our Cardiology liaison at (508)-887-4696 or email us at cardionet@tufts.edu for scheduling and non-emergent questions or concerns.

Sincerely,

B6

Please visit our HeartSmart website for more information
http://vet.tufts.edu/heartsmart/

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

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

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

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Case: B6 Owner: B6 Discharge Instructions

Cummings
Veterinary Medical Center
AT TUFTS UNIVERSITY

Foster Hospital for Small Animals
55 Willard Street
North Grafton, MA 01536
Telephone (508) 839-5395
Fax (508) 839-7951
http://vetmed.tufts.edu/
Referring Vet Direct Line 508-887-4988

Notice of Patient Admit

Date: B6 9:12:55 AM
Referring Doctor: B6
Client Name:
Patient Name: B6

Case No: B6

Dear Colleague,

Your patient presented to our Emergency service. Please make note of the following information to facilitate communication with our team.

The attending doctor is: Dr. B6
The reason for admission to the FHSA is: ARVC, poor systolic function, L-CHF

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

Thank you for your referral to our Emergency Service.

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Fax (508) 839-7951
http://vetmed.tufts.edu/
Referring Vet Direct Line 508-887-4988

Notice of Patient Admit

Date: B6 9:12:55 AM **Case No:** B6
Referring Doctor: B6
Client Name:
Patient Name: B6

Dear Dr. B6

Your patient presented to our Emergency service. Please make note of the following information to facilitate communication with our team.

The attending doctor is: Dr. B6
The reason for admission to the FHSA is: ARVC, L CHF

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

Thank you for your referral to our Emergency Service.

FDA-CVM-FOIA-2019-1704-006549

Cummings
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North Grafton, MA 01536
Telephone (508) 839-5395
Fax (508) 839-7951
http://vetmed.tufts.edu/Charlie

B6 Male (Neutered)
Canine Boxer Brindle
B6

B6

Daily Update From the Cardiology Service

Today's date: B6
Dear Drs at B6

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

Your patient B6 was admitted and is being cared for by the Cardiology Service.

Today, B6

- [x] is in stable condition
- [ ] is still in the oxygen cage
- [ ] is critically ill
- [x] discharged from the hospital today

Today's treatments include:

- [x] bloodwork planned/pending
- [x] echocardiography -
  Severe cardiomegaly with poor contractile function - r/o primary DCM, diet-induced cardiomyopathy, ARVC, tachycardiac induced cardiomyopathy. Left sided congestive heart failure.
- [ ] cardiac catheter procedure planned
- [x] ongoing treatment for CHF secondary to DCM
- [ ] ongoing treatment for thrombosis
- [x] ongoing treatment for arrhythmia - Malignant ventricular arrhythmia - non-sustained VTach and frequent polymorphic VPCs

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 **cardiovet@tufts.edu** if you have any questions.
Thank you!

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Attending Clinician: B6 **DVM (Resident, Cardiology)**
Faculty Clinician: B6 **DVM,DACVIM**
Senior student: