



# 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 Complaints

- 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 all foods given to the animal, and
  - 4.1.6 concomitant drugs, and/or 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 at 301-210-4685.



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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 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 requested 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 for necropsy or conduct a routine necropsy examination. Record your findings in detail and submit. Histopathology and microbiological cultures should be submitted 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.



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

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 serum, EDTA blood, urine (if available)

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, submits samples.

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

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

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

6.5 Vet-LIRN case numbers should be provided by 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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6.6 All samples received for investigational testing (including food, clinical and tissue samples, etc.) become the property of FDA Vet-LIRN.

### **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 (opened 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 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.