Network Procedures for Veterinary Laboratory Investigation and Response Network Case Investigations

Network Procedures for Vet-LIRN Laboratories

1. Introduction

The purpose of this Network Procedure is to facilitate basic interactions between Vet-LIRN Program Office (VPO) and laboratories 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 veterinarian and owner are helping with the government's investigation of a regulated product.

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

1.1.3 The 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:
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: Consumer complaints contain non-public information, usually in the form of protected personal information (such as names, addresses, etc.). You must keep this protected personal information confidential and not disclose it pursuant to the terms of your Information Sharing Agreement (ISA) with FDA and U.S. laws and regulations.

3. Communications

3.1 Vet-LIRN will discuss the case with the referring veterinarian and/or the owner.

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

3.3 Vet-LIRN 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 Vet-LIRN proposes the tests to be conducted and prepares billing documents.

3.5 Vet-LIRN makes arrangements with the veterinarian to obtain and ship samples.

4. Sample submissions

4.1 Normally, Vet-LIRN prefers that the veterinarian, and not the pet owner, submits samples.

4.2 A Vet-LIRN Sample Submission Form listing the approved tests, given by Vet-LIRN to the veterinarian, should accompany all samples.

4.3 A Shipping Inventory Sheet, given by Vet-LIRN to the veterinarian, should also be submitted with all samples, and should be filled out by the laboratory then faxed to Vet-LIRN at 301-210-4685.

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

4.5 Sample tracking should be part of the laboratory's normal operations and those routine business processes should be followed.

4.6 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 the appropriate forms to the network laboratory.

5. Sample types

5.1 Entire bodies (fresh or frozen)

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

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

5.4 Food samples (opened products from the owner)

6. Testing

6.1 Tests conducted will depend on the sample type and the complaint.

6.2 Typically, tests will fall into 3 categories:

- 6.2.1 Pathology
- 6.2.2 Microbiological (bacteria/fungal food safety pathogens)
- 6.2.3 Toxicological (primarily those involved in feed contamination events)

6.3 Test Methods: The methods used to test will be agreed on prior to beginning the testing. In some cases, Vet-LIRN may require use of standard methods (such as FDA BAM) if they are available for the matrix being tested. In some cases, especially if the matrix is not typical, the participating laboratory's customary validated methods will be used or adapted to the matrix. Methods used should be included in the report.

6.4 Pathology:

- 6.4.1 A complete gross necropsy examination with histopathology and microbiological cultures as appropriate is routinely requested.
- 6.4.2 Histopathology tissues:
  - 6.4.2.1 Thyroid, thymus, lung, heart, liver, spleen, adrenal, kidney, pancreas, stomach, duodenum, jejunum, ileum, colon, urinary bladder, skeletal muscle, brain.
  - 6.4.2.2 Make a duplicate set of H&E for submission to Vet-LIRN for archiving.
- 6.4.3 Toxicology: freeze and hold tissues for evaluation after gross necropsy and histopathology results are reviewed.
  - 6.4.3.1 brain (for organophosphates and carbamates),
  - 6.4.3.2 liver, kidney, brain, stomach content, fat,
  - 6.4.3.3 serum, EDTA blood, urine (if available).

6.5 Microbiology

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

6.5.2 Retain isolates and check with Vet-LIRN if isolates should be sent to Vet-LIRN for additional characterization and archiving.

6.6 Toxicology

6.6.1 Samples should be retained during necropsy examination if there is any indication that a toxic substance may be involved.

6.6.2 Following a review of histopathology, Vet-LIRN may select tissues to be analyzed.

6.6.3 Vet-LIRN may have tissues sent to another laboratory for confirmation.

6.6.3.1 Retain subsamples of all organs analyzed.

6.6.3.2 When the case is closed by Vet-LIRN, samples can be disposed of after consulting with VPO directly.

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

7. Reporting

7.1 Vet-LIRN Case Numbers:

7.1.1 Include Vet-LIRN case number in all correspondence and reporting.

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

7.2 Submitting Reports:

7.2.1 All reports should be submitted to Vet-LIRN.

7.2.2 Vet-LIRN will forward reports to the veterinarian.

7.2.3 If appropriate, Vet-LIRN will forward reports to the owner.

7.2.4 Name of test methods should be included in the report.

7.2.4.1 Detailed method description or citation should be available to the VPO if requested.

8. Billing

8.1 Grant laboratories with Vet-LIRN funding will charge their grants.

8.2 Other laboratories must provide estimates so a Purchase Order (PO) can be prepared.

- 8.2.1 Estimates should include additional charges such as accession fees and potential shipping charges.
- 8.2.2 A billing contact must be provided and include name, address, telephone and fax numbers, and email.
- 8.2.3 A PO must be in place prior to the start of testing.
- 8.2.4 Additional testing may only be initiated after authorized by Vet-LIRN with an additional PO.
- 8.2.5 Laboratories must provide an invoice to Vet-LIRN upon the completion of work before they can be paid.
- 8.2.6 The invoice must include work completed on a specific case; cases cannot be lumped together for billing purposes.
- 8.2.7 The invoice should include the Vet-LIRN case number.

9. Communications with Owners

9.1 General:

- 9.1.1 Most owner communications about cases should be with VPO.
- 9.1.2 If an owner brought the sample/body to your laboratory, please advise the owner that results will go to VPO and will be forwarded by VPO to the veterinarian.
- 9.1.3 If there is no referring veterinarian, VPO will report results to the owner directly.
- 9.1.4 Occasionally, a laboratory may have questions for the owner, and VPO may suggest contacting the owner directly. Please keep the VPO in the loop on such communications.

9.2 Additional Testing by Owner:

- 9.2.1 If the owner wants more testing than the tests requested by Vet-LIRN, the laboratory may conduct this testing and bill the owner directly (without a conflict of interest).
- 9.2.2 However—since the case is actively being investigated by FDA, we request that all test results be forwarded to Vet-LIRN (this avoids conflict of interest).
- 9.2.3 The owner should be informed **PRIOR** to conducting additional testing that the Vet-LIRN laboratory is obligated to report results to VPO.

10. Communications with Media

10.1 Report media inquiries to the VPO.

10.2 VPO will coordinate a response with CVM's Communications Staff.