



**Animal and Plant
Health Inspection
Service**

Veterinary Services

**Center for Veterinary
Biologics**

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Special Test Requests Initiated by Inspection and Compliance Staff

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Notes:

Special Test Requests Initiated by Inspection and Compliance Staff

Source Document: Title 9, *Code of Federal Regulations*, part 113.6; CVB-SOP-0101, *Tests Requested to Assist Investigations - Processes and Responsibilities*; and CVB-SOP-0032, *Processing Serial Records*

Background:

Special Test Requests (STR) related to issues observed during the review of information on the APHIS Form 2008 (Form 2008). The Center for Veterinary Biologics-Inspection and Compliance (CVB-IC) uses the Form 2008 information utilizing a risk assessment to determine the need for check testing. In addition, STRs may be initiated in conjunction with a Veterinary Biologics Investigation (VBI).

If it is determined testing is not the appropriate route, requesting the firm's bench records for the fraction in question is an acceptable method to further investigate the situation. This may be done by auditing the Form 2008 back to the firm, or contacting them to submit via the 2048 submission in NCAH Portal or email is acceptable means.

If the serial is not to be tested by CVB, the normal process for the Form 2008s should be followed as documented in **CVB-SOP-0032**, *Processing Serial Records*.

If the serial is to be tested after discussion as specified above, the Specialist will do the following:

Procedure:

1. Specialist

- a. Discuss with the Lab Coordinator (see below) and/or Supervisory Microbiologist testing needed to determine if resources are available.
The discussion with the Lab Contact should include the following points:
 1. Availability of CVB-Laboratory resources to perform the test in question; personnel, media, cells, equipment
 2. The merits of the test requested, including reproducibility and ruggedness of the test
 3. Does CVB have sufficient experience with the test – due to limited resources, we do not routinely perform all Section V testing
- b. If the laboratory has the resources, create a ML for the CVB lab testing plan (Submission Type = Product Correspondence or Investigation, depending on the type of issue). Ensure that any pertinent information the laboratory would need to know is uploaded to the ML or informationally linked from another ML. If related to a VBI, ensure the VBI number is tagged in the ML. Also, remember to select a tag of "Suppress Response from Portal" if necessary.
- c. In the ML item, create a child loop (Request Misc Info from CVB Employee) and in comments add "For testing plan". Assign the child loop to the appropriate Lab Coordinator based on the product type:
 - i. Viral and Recombinant Products – Alethea Fry
 - ii. Bacterial Products and Diagnostic Test Kits – Sophia Campbell

Optional: A meeting may be held with the Lab Coordinator prior to initiation of a STR to discuss testing concerns.

2. Lab Coordinator

- a. Create a draft Testing Plan by uploading the current version of **CVB-FRM-0106, CVB Laboratory Testing Plan for Special Request Testing**, to the ML (as Internally Routed attachment type). Throughout the planning process, use the draft Testing Plan to record the tests to be performed, the number of vials required, and reagents and supplies needed. Save the updated draft Testing Plan to the ML.
- b. Create a draft Reagent and Supply List. Save the updated Reagent and Supply List to the ML as Internally Routed.
- c. When additional lab review is needed for the submission(s), or if input from other laboratory staff is needed, create a child loop in the ML item and select Program Input. Enter routing comments and assign the child loop to the appropriate staff member(s).
- d. Initiate one STR per serial in LSRTIS. Transfer each STR to the Specialist's queue.
- e. Complete the Testing Plan and Reagent and Supply List and upload the final version to the ML. The Reagent and Supply List should be uploaded as Internally Routed. Close child loop for Testing Plan.
- f. Email the Specialist and Test Contact(s) to notify them that the Testing Plan has been uploaded to the ML and the STR(s) have been initiated in LSRTIS.

Note: An alternate Lab Coordinator, one who has specific expertise or knowledge regarding the testing, may be assigned at any point during the review and STR initiation process. The Lab Coordinator must inform the Specialist of the alternate Lab Coordinator assignment.

3. Specialist

- a. After the Lab Coordinator has uploaded the Testing Plan, Reagent and Supply List, and closed their child loop, determine if the information needs to be forwarded to the firm. There may be reasons not to contact the firm, so if there are questions, discuss with supervisor or Investigation Manager. If information needs to be sent to the firm, write a letter and include in the notification the appropriate lab coordinator.
Note: It may be easier to allow the laboratory coordinator to contact the firm directly via e-mail. If this is the route chosen, ensure that the lab coordinator cc's the Specialist on all communication with the firm.
- b. If a 2008 was NOT sent in by the firm (still active), then include the test report in the ML item to account for the testing report and potentially letter that will be written to communicate the confirmatory test results to the firm.
 - i. Cite the STR number(s) and the reason for testing in the Brief Description section.
 - ii. Create an informational link between the new ML item and the previous ML item.

- iii. Create a child loop and select Request info from CVB Employee. Assign the child loop to the appropriate Lab Coordinator. Note in comments for lab test report.
- c. If a 2008 was sent in by the firm, upon completion and verification of the testing, the test report and disposition of the serial by APHIS will be sent back to the firm via the serial release process. It may be helpful to also create a ML item for the test reports, especially if the testing is part of a VBI or ongoing problem. This makes it easier to access all related test reports in one location. Create the ML item for the test reports as noted in Section 3.b.

4. Lab Coordinator

- a. If the Specialist has sent a letter to the firm requesting samples/reagents, await notice of the expected shipment date.
- b. Notify the Test Contact(s) of the expected sample arrival date, if known, so they can prepare for testing.

5. Test Contact(s)

- a. Conduct confirmatory testing according to the Testing Plan. Notify the Specialist and Lab Coordinator of any changes in testing status or if testing is halted for any reason.
- b. LSRTIS notifies the Lab Coordinator and Specialist by email when testing is complete.

6. Lab Coordinator

- a. Upload testing report to ML as internally routed.
- b. Upload testing summaries to the ML item that are not sufficiently detailed in LSRTIS.
- c. Close the child loop when all confirmatory testing is complete.

Note: If confirmatory testing is halted at any time, create a child loop and select Request Info from Submitter. When testing is resumed or canceled, close the loop and proceed as necessary.

7. Specialist

- a. If needed, move the final LSRTIS test report(s) to the ML as an Outgoing Enclosure.
*Notes the tag "Suppress Info from Portal" will have to be removed from the ML.
- b. If needed, write a letter to the firm communicating the results of the testing.
- c. If a and b are not needed, review testing in LSRTIS, and sign the APHIS Form 2008 as indicated by the testing results of the firm and the lab.

Note: Withholding marketing release of serials based on testing after initial release, must be approved by an IC Section Leader or Director. Any other inquiries should be directed to the Specialist who requested the STR, Product Specialist, or Section Leader.