

**United States Department of Agriculture
Center for Veterinary Biologics
Standard Operating Policy/Procedure**

Tests Requested to Assist Investigations – Processes and Responsibilities

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Tests Requested to Assist Investigations – Processes and Responsibilities

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Tests Requested to Assist Investigations – Processes and Responsibilities

1. Scope

This document describes the processes and responsibilities for reviewing, requesting, performing, and reporting testing conducted at the Center for Veterinary Biologics (CVB) in support of the Veterinary Biologics Investigative process. The CVB requests tests of veterinary biologics to implement the provisions of the Virus-Serum-Toxin Act to ensure veterinary biologics available for the diagnosis, prevention, and treatment of animal diseases are not worthless, contaminated, dangerous or harmful.

2. Background

The Inspection and Compliance Unit (IC) routinely initiates documented investigations (Veterinary Biologics Investigations – VBI) associated with the licensed and unlicensed entities. Occasionally, to support the investigation, IC may request the CVB Laboratory to perform testing.

3. Purpose

The purpose of this document is to establish and define processes and responsibilities regarding special request testing at the CVB as it relates to IC investigations.

4. The Investigation Testing Processes and Responsibilities

Veterinary Services Memorandum No. 800.1 delegates authority to the IC Director to direct investigations of the Virus-Serum-Toxin Act (VSTA) and regulations (title 9, *Code of Federal Regulations* (9 CFR), parts 101-121). Specific processes and responsibilities for maintaining chain of custody, documentation, and confidentiality of a Veterinary Biologics Investigation (VBI) are described in the current version of **ICSOP0016**, *Investigation and Processing of Alleged Violations of the Virus-Serum-Toxin Act*.

4.1 Test Determination and Initiation

Based on the evaluation of information available, the Biologics Specialist and Laboratory personnel discuss product testing options.

- The Biologics Specialist is responsible for notifying the Laboratory Agent/Test Contact of the intent to submit a Special Test Request (STR) and to determine the most appropriate test(s) to be conducted.
- Testing of an unlicensed product requires the coordination of the Compliance Section Leader, Manager, Director and appropriate Laboratory personnel. Testing protocols and procedures must be determined in advance with approval of the Compliance Section Leader.

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- The most current filed version of the applicable Outline of Production or Special Outline, should be used. If a Supplemental Assay Method (SAM) is used by the CVB Laboratory, the Laboratory Agent/Test Contact should inform the Biologics Specialist. If an APHIS Form 2008 (Form 2008) is available, the Biologics Specialist may send a copy to the Laboratory Agent/Test Contact if requested.
- When the proposed CVB Laboratory testing deviates from the Outline of Production, Special Outline, or published SAM, the Laboratory Agent/Test Contact will provide a validated testing protocol to the Biologics Specialist.
- The Biologics Specialist will notify the firm in writing that a released product is being placed on-test at the CVB Laboratory and is at risk for regulatory action. The notification must be communicated to the firm before testing is initiated, unless the investigation warrants testing be done prior to notifying the firm. The Biologics Specialist should consult with the Compliance Section Leader or Manager prior to initiating the notification as circumstances surrounding the investigation may not warrant notification.
- The Biologics Specialist will inform the Laboratory Agent/Test Contact if the biologics manufacturer is being informed of product testing. A copy of the written notification is forwarded to the Laboratory Agent/Test Contact through the CVB mail log system.
- The Laboratory Agent/Test Contact is responsible for supplying the appropriate test code(s) for the STR and providing the Biologics Specialist the projected test on and off dates.

4.2 Requesting Special Testing

Step 1. The Biologics Specialist enters a STR into the Licensing, Serial Release, and Testing Information System (LSRTIS) following the procedures in the current version of **ICSOP0043**, *LSRTIS Special Test Request Procedures for Inspection and Compliance*. **The VBI file number is included in the STR comments.**

- The Laboratory Agent/Test Contact checks with the Laboratory Resource Unit (LRU) for availability of samples. If samples are not available, the Biologics Specialist is responsible for assuring that the Laboratory obtains the appropriate samples. The Biologics Specialist provides the STR number to the firm to include on the APHIS Form 2020 (Form 2020) to facilitate routing.
- The Laboratory Agent/Test Contact may contact the firm directly after consulting with the Biologics Specialist regarding any needed reagents after the firm has been notified of planned testing by the Biologics

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Specialist, and the Laboratory Agent/Test Contact has received a copy of the written notification from the Biologist Specialist.

- In the case of an unlicensed company, the Compliance Section Leader will work with Investigative and Enforcement Services (IES) personnel or other associated investigative personnel to obtain product and/or, in some instances, reagents by appropriate means.
- The Biologics Specialist initials the original printed copy of the STR and gives it to the Biologics Compliance Assistant (BCA) assigned to the firm, who files one copy in the Firm/Product pending file and an additional copy in the VBI file.

Step 2. The testing Laboratory Section receives a real-time notification from LSRTIS indicating that the STR has been entered into the system.

Step 3. If/when samples are available/received in the LRU repository, the Laboratory Agent/Test Contact will be notified real-time through LSRTIS.

- The Laboratory Agent/Test Contact enters a response, projected off test dates, test code(s), and number of samples needed for testing in LSRTIS. The Laboratory response to the STR is updated automatically in LSRTIS.

4.3 Performing Testing

The Laboratory Agent/Test Contact or technician conducts the test(s).

- The Laboratory Agent/Test Contact has the responsibility to assure that testing is conducted according to an approved test protocol (e.g., current Production or Special Outlines, SAM, CVB or firm protocol, standard operating procedure (SOP), etc.) and documented in accordance with 9 CFR 116.1(a)(1)(2).
- The Laboratory Agent/Test Contact will notify the Section Leader and the Biologics Specialist responsible for the VBI in a timely manner in the event of unsatisfactory results, test delays, or other significant testing concerns to discuss further action.
- The Biologics Specialist is responsible for contacting the firm regarding testing delays, when appropriate.

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4.4 Reporting Test Results

Step 1. Laboratory personnel enter and validate the test results, as per current laboratory SOPs for review and signing of the test results.

- The Laboratory Agent/Test Contact has the responsibility to notify the Biologics Specialist when the test has been completed and validated so that the Biologics Specialist can expect to print the CVB Laboratory test results. The specialist also should be reviewing the expected off date in LSRTIS to expect results.
- The Laboratory Agent/Test Contact is responsible for creating a Memo to the Record that specifically documents or addresses all test results other than satisfactory (e.g., details of extraneous agents tested, clarifications of “no test” or “inconclusive” test results, test system limitations, etc.). A copy of this memo must be sent to the Biologics Specialist within 7 working days of completion of the test.
- The Laboratory Agent/Test Contact copies all bench records associated with the test and supplies them to the Biologics Specialist for inclusion into the VBI record.

Step 2. The Biologics Specialist reviews the current version of **ICSOP0043, Section 6.**

Step 3. The Biologics Specialist obtains copies of all bench records associated with the CVB Laboratory testing. Any other copies of records associated with the testing can be requested from the Laboratory Agent/Test Contact at this time (animal acquisition, calibration substantiation, etc.) The documentation is reviewed prior to **Step 4** and placed in the VBI folder.

Step 4. When appropriate, the Biologics Specialist notifies the firm regarding test results and any compliance action(s), as directed by the Compliance Section Leader using the test report or official letter.

5. Documentation of Communication

Communication processes are critical and must be documented in an auditable fashion. All communication records associated with the investigation (originating both from IC and from the Laboratory) need to be included in the VBI folder. For example, a telephone log (including signature or initials and date) is required to be maintained documenting communication by telephone.

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6. Process Audits

Process Audits will also be conducted if requested by the Directorate when process failures occur which have an “across-unit-impact”.

Findings from Process Audits will be distributed to CVB management for review and problem solving.

7. Summary of Revisions

Version .04

- **1:** The scope was updated to be consistent with VSTA language.
- **2:** References to nonprocedural information was removed.
- **3:** The purpose of the document was clarified.
- **4.1:** Section heading changed from “Review of Testing” to “Test Determination and Initiation.”
- **4.1:** Section was updated to provide more precise descriptions and to include needed guidance.
- **4.4:** Added to Step 1, “The Laboratory Agent/Test Contact copies all bench records associated with the test and supplies them to the Biologics Specialist for inclusion into the VBI Record.”
- **4.4:** Added to Step 3, “Any other copies of records associated with the testing can be requested from the Laboratory Agent/Test Contact at this time (animal acquisition, calibration substantiation, etc.).”
- **6:** Section updated to reflect current practices.

Version .03

- The Contact information was updated.
- Title of the document was updated to reflect that is a policy document.
- **1:** The scope was clarified further to reflect the purpose of test to assist investigations.
- **1:** The word “standard operating procedure (SOP)” was removed and replaced with the word “document” throughout the document.

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- **2:** The background was updated to reflect the use of a new electronic laboratory information management system. The change from VBIS to LSRTIS was edited throughout the document. Procedures specifically for VBIS were changed to procedures done in LSRTIS throughout the document.
- **4:** The title of **ICSOP0016**, *Investigation and Processing of Alleged Violations of the Virus-Serum-Toxin Act*, was added.
- **4.2: ICSOP0021** was changed to ICSOP0043, *LSRTIS Special Test Request Procedures for Inspection and Compliance*.
- **4.2:** The acronym BMPS was replaced with the actual acronym for the Laboratory Resource Unit (LRU).
- **4.4:** The processes were clarified to reflect current practices.
- **4.4:** The review of test bench records was added as clarification of current practices.

Version .02

- This version represents a complete revision of the document to further clarify roles and responsibilities of involved parties.
- Joseph Hermann has been added as a Contact for this document.
- **4:** The reference of ICSOP0016 has been added for information on the investigation process.
- **4.2:** The Laboratory will not contact the firm until a copy of the written notification from the Biologics Specialist has been received and the Biologics Specialist has been notified.

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