United States Department of Agriculture
Center for Veterinary Biologics

Standard Operating Policy/Procedure

LSRTIS Special Test Request Procedures for Inspection and Compliance

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Contact: Jeanette M. Watson, (515) 337-6119
Becky R. Rasmussen, (515) 337-6138

Approvals:

/s/Steven A. Karli Date: 10Aug17
Steven A. Karli, Director
Inspection and Compliance
Center for Veterinary Biologics

United States Department of Agriculture
Animal and Plant Health Inspection Service
P. O. Box 844
Ames, IA 50010

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Entered into CVB Quality Management System
by: /s/Linda S. Snavely 10Aug17
Linda S. Snavely Date
Quality Management Program Assistant

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1. Purpose and Scope

The Center for Veterinary Biologics-Inspection and Compliance (CVB-IC) may request special testing on samples submitted by the manufacturer or on samples collected during an inspection or investigation as part of the regulations listed in title 9, *Code of Federal Regulations* (9 CFR), part 113.6. This document covers the procedure to be used when requesting testing in response to firm requests, such as reprocessing, rebottling or extension of dating; in response to a suspected non-compliance or action item identified on an inspection report; or during an investigation.

This document also describes the CVB-IC testing policy and guidelines for entering special test requests (STR or SR) into the Licensing, Serial Release, and Testing Information System (LSRTIS) and the processing of these requests.

Additional information regarding Special Request Testing associated with investigations is covered in the current version of **CVBSOP0101**, *Tests Requested to Assist Investigations – Processes and Responsibilities*.

2. Definitions/Acronyms

2.1 Licensing, Serial Release, and Testing Information System (LSRTIS): This system is the laboratory information management system used by the CVB.

2.2 Laboratory: The CVB Laboratory Sections (may be one or more Sections)

2.3 Special Request: A request for testing to be conducted at the Laboratory, sometimes referred to as a special test request, STR or SR.

2.4 Originator: The CVB-IC Biologics Specialist, Product Specialist, Senior Biologics Specialist, Section Leader, or Director requesting the test.

2.5 CBI: Confidential Business Information

2.6 PC: Program Coordinator

2.7 Verified: The process when complete test results are validated by a Laboratory Section Leader or designee.

3. CVB-IC Test Request Policy

3.1 While it is CVB policy to select and initiate testing on product samples within 7 calendar days of receipt and on diagnostic test kits within 3 calendar days of receipt

(Center For Veterinary Biologics Notice No. 12-25) for the purposes of check testing, CVB-IC personnel may also request a special test for the purposes noted below.

a. Prior to market release of the serial, serials may be tested by the CVB after the samples have passed the selection period if there is a question regarding the purity, potency, or safety. This may be information submitted on the APHIS Form 2008 or other information received by CVB.
b. Serials may be tested in conjunction with an investigation.

NOTE: If a serial has been released for market, the firm will be notified that serials/products are being placed on test and at risk for regulatory action upon unfavorable results (reference CVBSOP0101 for specifics).

4. Submitting a Special Test Request

Table 1: Special Request Test Purposes used by CVB-IC

Inspection and Compliance Test Purposes	Applicability
Problem	Test triggered by a firm event or deviation
Complaint	Test triggered by a customer complaint
Unlicensed	Investigation involving unlicensed product
Extension of Dating	Firm request to extend expiration of serial
Reprocessed	Further manipulation of licensed product
Rebottling	Manipulation involving fill of completed product

4.1 The Specialist determines the need to test a serial of product and discusses plans with their Section Leader.

- **Contacts the Agent/Test Contact or Policy, Evaluation, and Licensing (PEL) Section Leader for concurrence on the need and availability of test resources.**
- If a test intended for a special request is not in the test system within LSRTIS, then a test may be added by using Test Definitions after consulting with the Laboratory. The test must be entered as a Test Definition, however, to continue; for example, CAV Detection for egg outbreaks or 9 CFR purity testing for firms conducting EU purity tests.
- The originator enters the request in LSRTIS, see **ICWI0103**, *Special Test Requests Initiated by Inspection and Compliance Staff*, on procedures of entry.

4.2 No APHIS Form 2008 on file: The Specialist will contact the Agent/Test Contact or PEL Section Leader for concurrence on the need and availability of test

resources. If the product to be tested is from an antigen lot, the Specialist will assign the Product Code and Serial Number to use for the STR. This Product Code and Serial Number must match the sample submitted by the firm, the information on the STR, and must be documented in writing as a request from the CVB to the firm.

Also, ensure if the firm will be creating subserials (in cases of reprocessing) prior to entering STRs.

5. Laboratory Response to the Request

If test samples are already in the Sample Processing repository, the request for testing is released to the Laboratory for a response. If samples have not yet been submitted, the link in LSRTIS for laboratory actions will highlight the product under the Waiting Samples Section. When samples arrive, the Laboratory is notified at real time through LSRTIS and can respond to the request by entering the tests that will be conducted, projected off test dates, and the number of samples needed.

6. Review of the Special Request and Biologics Test Results

6.1 The LSRTIS database will indicate the status of Laboratory testing. Cancelled testing will not appear on the test report.

When testing is complete, the serial appears on the Action Sheet in the Ready for Approval Section. A Test Report hyperlink will be positioned next to record to be printed out by the Biologics Compliance Assistant (BCA). The test result includes:

Table 2: Test Results

Definition	
No Test	Designation used when a deficiency in the test system has rendered a test unsuitable for drawing a valid conclusion. However, when testing at the CVB Laboratory, a No Test may be used as a final test conclusion when management decision has deemed not to continue testing.
Satisfactory	Designation is a final conclusion given to a valid test with results that meet the release criteria stated in the filed Outline of Production or Standard Requirement.
Unsatisfactory	Designation is a final conclusion given to a valid test with results that do not meet the release criteria stated in the filed Outline of Production or Standard Requirement.

Definition	
Inconclusive	Designation used for an initial test when a sequential test design established in the filed Outline of Production or Standard Requirement allows further testing if a valid initial test is not satisfactory.

7. LSRTIS STR View

Under LSRTIS, use the Special Request, Testing module to search for the progress of the Special Requests and to print the status of the STR.

This search result may list the STRs in progress and completed. The Specialist may open the STR and check the status of the STR. Select "Auth Num."

8. References

8.1 CVBSOP0101, *Processes and Responsibilities for Requesting, Performing, and Reporting Tests Associated with Veterinary Biologics Investigations*

8.2 ICSOP0010, *Processing Serial Records*

9. Summary of Revisions

Version .02

- The procedures have been removed and incorporated in the applicable work instructions.