

**United States Department of Agriculture  
Center for Veterinary Biologics  
Standard Operating Procedure  
Special Test Request Procedures**

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**Special Test Request Procedures**

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## Special Test Request Procedures

### 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. This Standard Operating Procedure (SOP) covers the procedure to be used when requesting testing in response to firm requests, such as reprocessing, rebottling or extension of dating, or in response to a suspected non-compliance or action item identified on an inspection report or during an investigation.

This SOP also describes the CVB testing policy, guidelines and conventions for entering special test requests into the Veterinary Biologics Information System (VBIS) and the processing of these requests. This SOP does not cover requests for prelicensing serials.

Information regarding Special Request Testing associated with investigations is covered in the current version of **CVBSOP0101**.

### 2. Definitions/Acronyms

**2.1 Veterinary Biologics Information System (VBIS):** This HP3000-based system is the laboratory information management system used by the CVB. It is accessed through the computer software program, [REDACTED].

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

**2.3 Concurrent testing:** Condition whereby a serial may be tested at the CVB prior to completion of testing by the firm (see Veterinary Services Memorandum 800.55).

**2.4 Confirmatory testing:** Condition whereby a serial is not tested at the CVB until the firm has completed testing and has submitted a satisfactory APHIS Form 2008 (Form 2008) for the serial (see Veterinary Services Memorandum 800.55).

**2.5 Special Request:** A request for testing to be conducted at the Laboratory. Sometimes referred to as a "23", a slang phrase for the old hardcopy request form, VS Form 14-23.

**2.6 Agent/Test Contact:** The CVB Veterinary Medical Officer or Microbiologist assigned to the organism or agent to be tested.

**2.7 CBI:** Confidential Business Information

**2.8 PC:** Program Coordinator

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## 3. CVB Testing Policy

**3.1** It is CVB policy to select and initiate testing on product samples within 14 calendar days of receipt (VS Memo 800.53 III.B.3.b.) and on diagnostic test kits within 3 working days of receipt. Exceptions to this policy may apply (VS Memo 800.55 III.A., B., and D.).

- Serials will not be tested by the CVB after the samples have passed the selection period (except for end-of-dating stability tests) unless a definite question regarding the purity, potency, safety, or stability of the serial arises. In the event that a serial is to be tested outside the selection period, the firm must first be notified in writing. Exceptions may be made for training purposes; such tests are not official tests and do not place the serial at risk.
- When concerns arise, testing may be authorized by a Special Test Request.

**3.2** The CVB has agreed to test post-licensing serials under a concurrent testing policy.

- If a serial of a product (based on firm and test code) fails under check testing, it is automatically placed on surveillance.
- In practice, the concurrent testing is rescinded after [REDACTED] serials or subserials are tested by the Laboratory and found satisfactory for the specific test. For recombinant products, confirmatory testing is rescinded after [REDACTED] serials are tested by the laboratory and found satisfactory for the specific test. All serials of diagnostic test kits for program diseases are placed on concurrent testing; this testing remains in effect permanently. Testing may be dependent upon Laboratory resources.
- There is currently no mechanism in the VBIS to ensure confirmatory, rather than concurrent testing. If the samples are past their normal eligibility period for testing at the time that the Form 2008 is received, CVB-IC must issue a Special Test Request to initiate testing on the serial.

**3.3** Laboratory tests that have been completed and reviewed by the Section Leader or Designee are to be entered into the VBIS within 1 business day of completion. If multiple tests have been requested under a Special Test Request, a Section may choose to enter the test results once all tests have been completed. The test results are to be validated in the VBIS within 1 business day of being entered into the VBIS. Test reports should print out within 1 business day of validation. If test reports do not print, the Lead Biologics Compliance Assistant (BCA) or Product Manager should contact the Laboratory as soon as possible.

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3.4 The VBIS uses several codes to indicate the status of Laboratory testing. Some of the codes appear only on selected VBIS reports.

Code	Definition
OT	On test--test is underway but not yet completed
TC	Test completed--Results have been entered into VBIS but are not yet validated
RT	Retest
VA	Results have been validated and are available for release
WS	Waiting for samples
PR	Waiting to print (usually seen when multiple tests are linked to print on the same report and not all tests have been entered)
TS	Test scheduled but not yet started (appears only if a start date is specified)
DT	Delayed Test--the testing time has been extended, usually due to invalid/inconclusive test results that necessitate additional testing

3.5 The VBIS has 4 testing categories, but only 2 are actively used at this time. (The original system was designed under the assumption that each product would have its own test code. Under the current system, several products often share one test code, making the active use of certain categories impractical at this time.)

Code	Definition	Actively Used at this Time?
AS	Surveillance	Yes
B	Low Volume Product (<8/year)	No
C	Newly licensed product	No
D	Routine check testing at percentage set by CVB-PEL	Yes

**Note:** *In theory*, when a product is on surveillance, serials eligible for testing under that code should be tested at a rate to ensure [REDACTED] consecutive serials test satisfactory, at which time the product is returned to category D and tested at its original check test rate. *In practice*, the surveillance designation (AS) is used to flag suspect serials on eligible serial reports but does not ensure that they will be tested. The decision to test is left to the discretion of the Agent/Test Contact or CVB-Policy, Evaluation, and Licensing (PEL) Section Leader. Products remain on surveillance until there are [REDACTED] satisfactory results. The Agent/Test Contact may request early removal of the surveillance designation by justifying why the product is no

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**longer under increased suspicion of testing unsatisfactorily (e.g., assay technique has been improved/fixed or approved revisions to the Outline of Production).**

#### 4. Submitting a Special Test Request

Serials may not be tested by the CVB after the samples have passed the 14-day selection period (except end of dating-stability tests), unless a definite question has come up concerning the purity, potency, safety, or stability of the serial. The justification is always filed with a copy of the request in the Pending File. If product has been released, written notification will be sent by the Biologics Specialist (Specialist) to the licensee or permittee before testing is initiated. **In no case should the licensee or permittee be notified if IC has not received the Form 2008.**

##### 4.1 The Specialist

- Determines the need to test a serial of product.
- Contacts the Agent/Test Contact or PEL Section Leader for concurrence on the need and availability of test resources.
- Enters the request directly in the VBIS, CVB-IC menu, Item #91.
- Completes the following fields:
  - a. Originator: The name of the originator or person requesting testing
  - b. Alternate Contact: Name of originator's supervisor
  - c. Office: VBFO (Veterinary Biologics Field Operations), former acronym for CVB-IC
  - d. Establishment Number and Product Code (no spaces, dashes, or periods)  
Example: Est. 189-A, Code 2051.01  
ENTER (Est.) 189A and (Product Code) 205101
  - e. Purpose: Select one of the following purposes:
    - PROB – problem, including compliance issue
    - COMP – consumer complaint, Adverse Event Report
    - EXTD – extension of dating
    - REPR – reprocessing or rebottling

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- f. Serial number(s): If several serials are listed on the same request, the results will be held until all serials have been tested and the results validated. If an employee wishes to have serial test results released independently of each other, each serial must be entered on separate requests.

**Note:**



Examples of serial numbers: 12346M, MG35783, 543X, 2335-566 (would be entered without dashes).

Examples of subserial numbers (usually have an alpha character A-K and are entered with a dash: 12346-A, DF135-B). Test kits are never entered with a dash.

- Exceptions may apply. Checking the serial status, VBIS, CVB-IC menu, Item , is advised.
- g. Request: Provide TEST CODE(s) and test name. The VBIS is programmed for the previous Laboratory designations (see **Appendix**). To ensure the proper routing, the correct test code(s) must be provided. If the Specialist is not certain about the correct test code(s), he/she should contact the appropriate Laboratory Section before proceeding.  
  
This is also the field for entering additional explanatory information (e.g., use assay modification in outline dated 12/31/99, or an investigation number).
- h. Special documentation will follow: Enter Y if additional information will be sent to the Laboratory by interoffice mail.
- i. Section: Select the Laboratory Section to which the request is to be directed (see **Appendix**). If the Section selected is incorrect, the request will be directed by BMPS to the correct Laboratory Section for the test code provided.

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**Note: The request will not be completed in the VBIS until all assigned Sections have responded, so if more than one Section is entered and a Section has no testing to schedule, the request will remain open (report will not be generated). Also, some users have found it difficult to modify the Section assignments and have found it necessary to delete the request and start over when they find an error in routing.**

j. VBIS assigns the Request Number and dates the request.

- Exits using the numerical “Enter” key. A copy of the request will print. Do not use the alpha “Enter” key; a copy of the request will not print.
- Checks the request for accuracy and corrects if necessary.
- Initials the test request.
- Attaches justifying information, if necessary, to the request (with initials and date).
- Gives request and supporting documents, justification for testing, and copies of emails or phone logs to the BCA assigned to the firm for filing in the Form 2008 pending files.

#### 4.2 The BCA

Files the request in the Form 2008 pending file under firm and product code.

## 5. Laboratory Response to the Request

If test samples are already in the BMPS repository, the request for testing is released to the designated Laboratory Section(s) for a response. If samples have not yet been submitted, the Laboratory Sections receive an “alert,” but do not receive a request document to which they can respond.

When samples arrive, the Laboratory is notified and can respond to the request by entering into the VBIS the tests that will be conducted, projected off test dates, and the number of samples needed. A notification that the request has been responded to will print out at the CVB-IC with the next morning’s action reports. Changes to or cancellation of the request by the Laboratory would also print out on the following work day.

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#### 5.1 The BCA

Gives the response and supporting information from the pending file to the Originator.

#### 5.2 The Specialist (Originator)

Reviews and, when approved, initials the response and returns all documents to the BCA.

#### 5.3 The BCA

Files the response and documentation in the Form 2008 pending file; the response replaces the original test request. The original test request is CBI.

### 6. Distribution of the Biologics Test Results

When testing is complete, the serial appears on the Action Sheet with the remark “VS-23 DONE” and test report(s) will print with the morning reports using CVB-IC Menu Item ████

#### 6.1 The BCA

- Gives test results and all information from the pending file to the Originator or PC.
- Marks “to (Specialist)” on the action report to designate who has been given the test results for review.
  - If the Originator is not available, and the PC can not make a determination from the information provided, no further processing is required unless otherwise instructed (a Section Leader may make the final determination on whether to process the test report).
  - If processed during the Originator’s absence, a copy of the test report is routed to the Originator.

#### 6.2 The Specialist (Originator)

- Determines action to take based on results.
- Prepares a statement for the BCA to type on the Form 2008 and/or selects one of the Miscellaneous Responses in the current version of **ICSOP0010**.

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#### 6.3 The BCA

**6.3.1** If a Form 2008 was submitted but the serial has not yet been released by APHIS, the following steps are performed:

- Types or stamps the Specialist's statement or response on the Form 2008 and completes Block 16. Stamps title and date of signature.
- Obtains the Specialist's signature on both copies of the Form 2008.
- Submits the Form 2008 (with original signature) and a copy of the test report for release and filing.
- Mails a copy of the Form 2008 and test report to the appropriate firm after the serial has been released (see the current version of **ICSOP0010**).
- Files a second copy of the report in the respective investigation file if the testing is associated with an adverse event report or an investigation.

**6.3.2** If a previously processed Form 2008 is involved, testing was conducted on a serial that was put back at risk, the following steps are performed:

- Types Specialist's statement or response on both copies of the test report. For example, "Tested in response to VBI-06-003."
- Types an "Authorized Signature" line, title line and date line below the test report on both copies. The title and date lines may be completed using stamps.
- Obtains the Specialist's signature on both copies of the test report.
- Attaches a copy of the test report (with original signature) to the corresponding Form 2008 in the CVB-IC files. The BCA then pulls the record forward for filing in the current year folder "A".
- Makes a copy of the test report to be filed under the firm's product correspondence, if appropriate.
- Mails the other copy of the test report (with original signature) to the appropriate firm.

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- Files a copy of the report in the investigation file if the testing is associated with an adverse event report or an investigation.

**6.3.3** If correspondence is accompanying the test report to the firm, the BCA submits a copy of the test report with the letter for filing in the product correspondence files.

## 7. References

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

**7.2** ICSOP0010, *Processing Serial Records*

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**Appendix**  
**VBIS Laboratory Designations**

Laboratory Section	Former CVB Designation	VBIS Designation	General Categories of Tests Performed
BACT	BB	AR	Potency on aerobic bacterial products except plate counts and <u>poultry</u> products Mycoplasmas, other than poultry Bacterial identity, aerobic organisms Tuberculin Potency
		AN	Potency on anaerobic products Bacterial identity, anaerobic organisms Antitoxin potency
	ST	ST	Sterility and purity tests Plate counts (potency) on live bacterial vaccines Endotoxin testing
VIR	MV	MV	Potency, Anaplasma and rickettsial products Viral Identity
	PY	PY	Potency on viral poultry products Potency on poultry Mycoplasmas
BID	BB	BB	Potency, immunomodulators of non-viral origin Potency, antibody products Total IgG content (for failure of passive transfer)
	MV	MV	Immunomodulators of viral origin Diagnostic kits against viral diseases Potency, antibody products
	PY	PY	Diagnostic kits for viral and mycoplasmal poultry diseases Potency, antibody products
ABRM	CY	CY	Cell identity and purity
Chemistry (NVSL)	CH	CH	Total protein Nitrogen and phenol content, pH

Laboratory Section	Former CVB Designation	VBIS Designation	General Categories of Tests Performed
BACT	BB	AR	Potency on aerobic bacterial products except plate counts and <u>poultry</u> products Mycoplasmas, other than poultry Bacterial identity, aerobic organisms Tuberculin Potency
		AN	Potency on anaerobic products Bacterial identity, anaerobic organisms Antitoxin potency
	ST	ST	Sterility and purity tests Plate counts (potency) on live bacterial vaccines Endotoxin testing
VIR	MV	MV	Potency, Anaplasma and rickettsial products Viral Identity
	PY	PY	Potency on viral poultry products Potency on poultry Mycoplasmas
BID	BB	BB	Potency, immunomodulators of non-viral origin Potency, antibody products Potency, all diagnostic kits Total IgG content (for failure of passive transfer)
	MV	MV	Immunomodulators of viral origin Diagnostic kits against viral diseases Potency, antibody products
	PY	PY	Diagnostic kits for viral and mycoplasmal poultry diseases Potency, antibody products
ABRM	CY	CY	Cell identity and purity
Chemistry (NVSL)	CH	CH	Total protein Nitrogen and phenol content, pH

BACT: Bacteriology

VIR: Virology

BID: Biotechnology, Immunology and Diagnostics

ABRM: Agent Biosecurity and Reference Management

BB: Bacteriology (AR, aerobic; AN, anaerobic)

ST: Sterility

MV: Mammalian Virology

PY: Poultry

CY: Cytology

CH: Chemistry (located within NVSL)

NVSL: National Veterinary Services Laboratories

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