Animal and Plant Health Inspection Service

Veterinary Services

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Processing CVB Reference and Reagent Test Reports

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Vault: CVB-Released

Section/Area: CVB-WI-IC

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Notes:

Processing CVB Reference and Reagent Test Reports

Source Document: CVB-SOP-3001, *Reference Reagent Review and Release.*

The CVB Laboratory may process CVB Reagents and References either hard copy or electronic. They are working on switching to completely electronic, but this may take a few years to move over completely. This document provides guidance on processing packets regardless of the format.

Each binder will have a formatted Section which should have some type of data within each.

1. Documents to be received at CVB-IC

CVB-FRM-0008, *CVB Reference and Reagent Test Report*:

- One copy with Blocks 1-15 completed with original signature (may be digital)
- This must be filled out completely.

CVB-FRM-0009 (Form 0009), *Reagent Production Sign-off Form*

- This form must have applicable supervisory signatures.

Reagent Data Sheet
Production Protocol used to prepare the reference or reagent

2. CVB Processing

- The packet may be received by the Lead BCA or Product Manager.

If Hard Copy Packet

- The Lead BCA stamps the date received at IC on the Form 0008 in Block 11, CVB-FRM-0009 (Form 0009), *Reagent Production Sign-off Form*, and the Reagent Data Sheet in the bottom right hand corner.
- The Lead BCA routes the documents to the assigned Biologics Specialist.

If Electronic

- The Laboratory Personnel may route the forms directly to the Biologics Specialist through a Child-loop (IC Reagent Review)

3. Specialist Review

- The Assigned Specialist reviews the Form 0008, Form 0009, and the Reagent Data Sheet and compares them with the Production Protocol for the product and the records. The Production Protocol and Production Records may be available on the QM SharePoint Site for the Laboratory if they are electronic.

- If the submitted Form 0008 and the Reagent Data Sheet are acceptable, the assigned Specialist checks “Test Completed Satisfactory” disposition in Block 16 of the Form 0008 and signs their name in Block 17. The Specialist also sign off on the Form 0009, the Reagent Data Sheet, and the Production Protocol, if applicable.

- If the submitted Form 0008 and/or Reagent Data Sheet are not acceptable, the assigned Specialist contacts the PEL Section Agent/Test Contact for resolution and/or resubmission. This may be done within the Mail Log.

If Hard Copy: All approved documents are returned to the Lead BCA for processing and sent back to the Laboratory contact.

If Electronic, the Mail log Child Loop may be closed to route back to the initiating laboratory personnel.

4. Final Processing

- The Reagent Data Sheet and Form 0008 are scanned by IC and added to the Mail Log item.
- The Lead BCA reviews Block 16 of Form 0008 for disposition. (If a disposition is not checked, the Lead BCA returns the documents to the Specialist.) Blocks 18 and 19 (title and date) are stamped with the date the Lead BCA processes the paper. When processing is complete, the Lead BCA initials the Form 0008 on the top right-hand corner and returns the Reference Reagent Folder laboratory contact.
- The hard copy Reference/Reagent Folder is returned to the originating Section by BCA, unless otherwise instructed by the assigned Specialist.