

Processing CVB Reference and Reagent Test Reports

1. Documents to be received at CVB-IC

CVBFRM0008 (FRM0008), *CVB Reference and Reagent Test Report*:

- One copy with Blocks 1-15 completed with original signature
- One copy of the Reagent Data Sheet
- One copy (if applicable) of the Production Protocol used to prepare the reference or reagent

2. CVB Processing

- The packet is received by the Lead BCA.
- The Lead BCA stamps the date received at IC on the Form 0008 in Block 11, CVBFRM0009 (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.

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. The Production Protocol is available on the QM SharePoint Site.
- 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 signs the Form 0009. The Specialist initials the CVB-IC copy of the Reagent Data Sheet and the Production Protocol, if applicable, next to the date stamp.
- 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.

All approved documents are returned to the Lead BCA for processing

4. Final Processing

- 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 to the QM Program Assistant.

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- The Reagent Data Sheet and FRM0008 are scanned by the QM Program Assistant and uploaded to the CVB QMS SharePoint site, “Released Reagents” [REDACTED]. The Reference/Reagent Folder is returned to the originating Section by the QM Program Assistant unless otherwise instructed by the assigned Specialist.