

Issuance of Special Request (SR) for Lab Testing of Master Seeds and Master Cells

1. Reviewer:

- a. Reviews firm's MS report (and APHIS Form 2008, if submitted) and SIF (If applicable) for completeness and accuracy, in accordance with VSM 800.109
 - i. Confirm that all required tests have been conducted and the results are satisfactory
 - ii. Confirm that firm has provided detailed procedures for non-codified tests
 - iii. If the seed/cell is a recombinant see additional instructions below.
- b. From the mail log item for the MS report, creates a child loop (Develop Test Plan) to the appropriate lab coordinator based on the type of seed and uploads Firm's MS report, APHIS Form 2008 and SIF.
 - i. [REDACTED]
- c. Uses Outlook Calendar to schedule a Special Request Planning meeting with all lab section testing contacts [REDACTED] and risk manager (Recombinants) to be held within 7 to 14 business days. Note MS mail log number in meeting invite.

2. Lab contacts:

- a. Determine if testing is required by their section and accepts or declines the meeting invitation.
- b. Lab contacts review the mail log submission(s) of the MS report, APHIS 2008 and SIF (if applicable) and distribute information to appropriate lab staff for additional review of documents and input on tests to be conducted.
 - i. Confirm that firm has provided sufficiently detailed procedures for non-codified tests.
 - ii. If there are any problems (such as insufficient information for a test procedure), the lab testing contact notifies the reviewer prior to the Special Request Planning meeting.
 - iii. Generate a list of tests that will be performed and reagents needed, to be shared at the SR planning meeting.

3. Reviewer: (Optional if additional information is needed)

- a. Requests additional information or protocols from the firm. (Lab contact opens a Request from Submitter loop off of the Develop Test Plan activity.)
- b. Cancels the Special Request Planning meeting and reschedules after additional information or testing protocols have been received from the firm.

4. Special Request Planning meeting

- a. Participants: reviewer, lab contacts, and appropriate lab staff
- b. Lab contacts will complete a testing plan containing:
 - i. List of tests that will be performed (LSRTIS codes) by each section
 - ii. List of reagents needed to conduct testing from all lab sections
- c. Laboratory coordinator is designated based on the type of MS

5. Laboratory coordinator:

- a. Initiates SR in LSRTIS (See additional instructions below for entering a Special Request)
- b. Transfers the SR to the reviewer's queue
- c. Completes Testing Plan Worksheet (LABFRM0002) and uploads to ML item. Closes mail log child loop once plan is uploaded.
- d. Emails testing plan to reviewer, lab contacts and risk manager (recombinants).

6. Reviewer:

- a. Drafts letter to firm using test authorization letter template

- b. The letter authorizing the firm to submit samples should not be signed off by the Super Reviewer or the Section Leader before ensuring the Testing Plan Worksheet has been uploaded to the ML item.
 - c. Initiates a new ML record to account for the letter that will be written later to communicate the CVB test results to the firm. Cite the test auth # in the Brief Description. Immediately deploy a child loop (Testing by Lab) from the Primary Review activity and assign to the lab coordinator. The mail log system will then automatically deploy a Request from Submitter loop from the Testing by Lab loop.
7. Laboratory coordinator:
 - a. Requests reagents from firm. When samples and reagents arrive, close the Request from Submitter loop and enter the date of receipt as the exit date for the loop. Notify lab contacts upon arrival of samples and reagents
 8. Lab contacts:
 - a. Coordinate testing plans within sections and notify reviewer and lab coordinator of any changes in testing status.
 9. Lab coordinator:
 - a. Uploads any testing summaries not detailed in LSRTIS and closes the Testing by Lab loop.
 - b. Email notification to reviewer and risk manager (recombinants) upon completion of testing.
- 10. Reviewer:**
- a. Writes a letter to the firm communicating the results of confirmatory testing.

Additional instructions for recombinant Master Seeds

1. In addition to reviewing MS report, reviewer, in conjunction with risk manager, reviews firm's preliminary SIF
 - a. Uploads SIF to Mail Log
 - b. Confirm that the description of the construction steps is complete
 - c. Confirm that the firm's genetic characterization is complete and the firm's actual (not theoretical) sequence for the insert and flanking regions is provided
 - d. Confirm that the firm's phenotypic characterization is adequate
 - e. Confirm that firm has provided sufficiently detailed procedures for the tests performed
2. Once the IBC number is issued, the reviewer creates a child loop (Develop Test Plan) to the appropriate lab coordinator and schedules the Special Request Test Planning meeting described in steps 1b&c of the main instructions
3. **Note: The IBC number must be issued prior to creating the "Develop test plan" child loop to the lab coordinator and scheduling the SR planning meeting.**