

Special Test Requests in Response to Information on the APHIS Form 2008 and associated with Risk Based Check Testing

Background:

The number of Special Test Requests (STR) related to issues observed during the review of information on the APHIS Form 2008 (Form 2008) decreased from the early 1990's. Given the current resources, the Center for Veterinary Biologics (CVB) would like to use this information as a part of a risk based check testing system. This system will be used for testing related to the Virology and Bacteriology Sections.

Instructions:

1. Specialist or Program Coordinator (PC) review all Form 2008s with test results coded as Inconclusive (I) or No Test (NT). Depending on the explanation provided, the Specialist may consider requesting a Special Test prior to release of the serial.
2. The Specialist will contact (by email or phone) the Laboratory Test Agent Contact to discuss the results observed on the Form 2008 and decide if the serial should be tested by CVB. Agent Assignments can be found on the LSRTIS system.
3. If the serial is not to be tested by CVB, the normal process for Form 2008s as documented in **ICSOP0010**.
4. If the serial is going to be tested, the Specialist will enter the Special Test Request, using the testing code provided by the Laboratory Test Agent Contact.

Note: If you are the PC, please make a copy of the STR for the Specialist responsible for the firm.

5. The Specialist prints STR and initials.
6. The Specialist scans the Form 2008 in question and emails this to the Laboratory Test Agent Contact along with the STR#.
7. Give the STR and Form 2008 back to the Biologics Compliance Assistant (BCA) for entry and filing.
8. When the CVB Laboratory responds to the STR, the BCA should note this and check the next day's Action Report to ensure the information concerning the testing is listed and the firm is notified. If the testing is not listed the next day, the BCA should contact the firm and inform them of the Code and Serial on test and the proposed off test date. Any other inquiries should be directed to the Specialist who requested the STR, Product Manager, or Inspection Section Leader.