## National Veterinary Services Laboratories Bovine Spongiform Encephalopathy (BSE) and Chronic Wasting Disease (CWD) ELISA Proficiency Test Summary

- **1. Composition of proficiency test panel:** The BSE/CWD panel consists of a minimum of five samples. The samples are sheep brain homogenates for the BSE PT and/or CWD brain and/or lymph node homogenates for the CWD PT. A varying number of Positive and Not Detected samples will be used.
- **2.** Cost of proficiency test: Click <a href="here">here</a> to view current NVSL Catalog of Reagents. Additional information on diagnostic reagents, including ordering, payments, shipping details and fees, is located at <a href="https://www.aphis.usda.gov/nvsl">www.aphis.usda.gov/nvsl</a>. Click on the Reagents and Proficiency Tests link.

Currently there is no charge to NAHLN approved laboratories (subject to change). Currently there is no charge to other laboratories (subject to change).

- **3. Storage conditions:** Samples are stored frozen at a temperature -20°C or lower.
- **4. Sample preparation/selection criteria:** Known scrapie positive and negative sheep brain samples and/or CWD brain and/or lymph nodes for the CWD PT (as determined by IHC) are homogenized and pooled. These pooled samples are then tested by ELISA and if determined to be appropriate Positive samples (> 0.500 OD) and Not Detected (no more than three times the mean negative control value) are used in the panels.
- **5. Panel quality control:** The samples are first identified by IHC as positive, and NVSL tests the pooled homogenates by ELISA prior to sending out the panels.
- **6. Timing of the proficiency test distribution and data collection:** The PT is issued annually with a target of the 2<sup>nd</sup> FY quarter (Jan-Mar). PTs may be sent to laboratories upon request, at the discretion of the PT manager.
- **7. Test method:** The PT samples are tested by ELISA.
- **8. Submitting test results:** The testing is done in duplicate. Participants are required to have both sets of ELISA results submitted to NVSL (Head of Pathology, Parasitology, and Entomology and/or designee) not later than 10 days after panel has been received by the participant.
- **9. Scoring of individual panel samples:** For each panel a score is based on number of homogenates with correct interpretation by the participant.
- **10.** Laboratory pass/fail criteria: A final score of 100 percent correctly identified samples is considered as a passing score.
- 11. Reporting laboratory test scores: Participating laboratories are required to run the Page 1 of 2

ELISA samples in duplicate on different days. The participant laboratory should run the samples and report the ELISA results to the appropriate NVSL personnel. The laboratory should wait for an affirmative response from NVSL before running the second test. Final run results should be reported within 10 days of receipt. NVSL will share by (email/postal mail), the results with each individual participant (Laboratory Director or designee) within 10 days from receipt of the last panel results.

- **12. Remedial actions required for failing laboratories:** If discrepant results are obtained an investigation as to the cause will be done by NVSL, the participating laboratory, and others as required. If the apparent cause of the discrepant results are determined and rectified to the satisfaction of NVSL no additional corrective actions may be needed. At the discretion of NVSL, additional PT panels or additional training of personnel may be required. A second failure of a PT may be grounds for removal of testing approval.
- **13. Special requirements**: Restrictions: A USDA permit is required to obtain the panel. Failure on the part of participate laboratories to maintain current permits may result in withdrawal of approval until such time as a permit and PT test can be administered.