附件 **8**

| National Veterinary Services Laboratories | |
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| Document Title: Quality Assurance: Proficiency Testing and Quality Monitoring of BSE ELISA Contract Laboratories by NVSL | |
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Approved: /s/ Arthur Davis

## 1. Purpose/Scope

As a part of the United States Department of Agriculture's (USDA) ongoing bovine spongiform encephalopathy (BSE) surveillance, the Department's Animal and Plant Health Inspection Service (APHIS) is working to ensure both quality and accuracy of BSE test results reported by BSE contract laboratories. Therefore, APHIS has determined that a standard operating procedure (SOP) is needed to help insure quality of test results from these contract laboratories. This SOP is specific to the Bio-Rad ELISA test system, and additional or amended SOPs will be required for other test methods.

## 2. Definitions

- N/A

## 3. Safety Precautions

- N/A

## 4. Equipment and Materials Required

- N/A

## 5. Procedure

### 5.1. Evaluation Methods

APHIS will use two major methods to evaluate the quality of BSE ELISA testing at BSE contract laboratories.

1. Proficiency test (PT) - an initial proficiency test to evaluate contract laboratories administered by the Pathobiology Laboratory (PL) prior to their beginning real time BSE testing. Upon successful completion of the initial PT, subsequent PTs will be administered by the PL annually in a time not to exceed 24 months between tests. More frequent tests may be administered if deemed necessary by the Director of the PL.
2. Weekly trend monitoring of test performance and comparison of this performance to other labs in the network and to previous performance of the State lab will be conducted.

Each BSE contract laboratory will receive the results of the proficiency panel and updates from the ongoing evaluation of all laboratories testing history. Each laboratory will provide an electronic copy of test results to National Veterinary Services Laboratories (NVSL) - PL to assist the NVSL and the network laboratory in detecting performance change.

Weekly trend monitoring will be performed by the NVSL/PL until no longer deemed necessary by the Director of the NVSL PL, or designee. At such time the weekly trend

monitoring of the optical density (OD) data shall become the responsibility of each individual laboratory.

### 5.2. Proficiency Tests

Each laboratory will run a set of 5 unknown samples prepared and distributed by the NVSL PL at startup and thereafter as stated in #1 in 5.1 above. Positive tissues will be either Scrapie, chronic wasting disease, or other positive testing material that may be available in the future. The samples will be distributed as homogenates or as spiked tissues samples, when appropriate. Each laboratory will run the panel once on 2 different days, for a total of 2 runs from the same homogenate tubes. If laboratories have more than one person performing the BSE ELISA testing, the two runs should be performed by different personal. In the event that more than two people are performing the BSE ELISA testing, the PT testing personnel should be rotated with the next administered PT. Laboratories will be required to derive 5/5 correct answers on each run. Failure to do so will result in consultation, possible re-training, and, in rare cases, site visits and recorded audits. Laboratories that are initially starting up will not be allowed to perform real time testing until the proficiency panel is successfully completed.

### 5.3. Real Time Performance (Weekly) Monitoring

Each laboratory will save, and until advised otherwise, will provide the NVSL with an Excel spreadsheet output from all runs covering ELISA testing for the previous 7 days. The NVSL will collate the data. This data will allow both the NVSL and the partner labs to observe the ODs on control and surveillance samples, which can indicate technical proficiency and allow problems to be identified before they affect program integrity. It will also allow validation of numbers of samples run in the network. Once it is determined that the NVSL no longer needs to monitor this data, each individual laboratory will be required to monitor their own OD data and compare it to historical data. Any abnormalities should be promptly reported to the NVSL. In all cases, the testing laboratories shall maintain electronic copies of all OD data, and make that data available to the NVSL upon request.

## 6. Associated NVSL Quality Documents / References

- N/A

## 7. Revision History

- Version .05: Changed the number of samples to be used and described the testing intervals for administering PTs. Also added comment regarding rotation of personnel performing PTs for BSE ELISA.

## 8. Appendices

- N/A