National Veterinary Services Laboratories Equine Infectious Anemia Virus Antibody Proficiency Test Summary

1. Composition of proficiency test panel: The equine infectious anemia (EIA) virus antibody panel consists of twenty, 0.6 ml samples of equine serum. The panel contains negative, weak positive and strong positive samples, and includes blind duplicates. The samples are labeled with the test acronym and calendar year (e.g., EIA 2013), a panel set number (e.g., Set 254), and a sample number (Sample 1 through 20). The samples are scrambled between sets.

2. Cost of proficiency test: Click <u>here</u> to view current NVSL Catalog of reagents. Additional information on diagnostic reagents, including ordering, payments, shipping details and fees, is located at <u>www.aphis.usda.gov/nvsl</u>. Then click on the Reagents and Proficiency Tests link.

3. Storage conditions: Short term (up to 7 days) store at $4^{\circ} \pm 2^{\circ}$ C. Long term (over 7 days) store at or below -20° C in a non-frost free freezer.

4. Sample preparation/selection criteria: Samples with high, medium, and low concentrations of EIA antibody are chosen for incorporation into the panel. Antibody levels arise from naturally acquired infections. Each panel member is tested at least seven (7) times. At least three NVSL technicians perform the testing and all licensed test kits are utilized in the sample selection testing. Note: NVSL is an OIE reference laboratory for EIA.

5. Panel quality control: Samples are monitored for stability and reproducibility. Stability testing of the panel has determined that normal shipping and handling conditions do not change the panel. Panel sets of each lot of proficiency panels are used to confirm stability after final preparation.

6. Timing of the proficiency test distribution and data collection: The EIA proficiency test is administered annually, customarily in the month of May.

7. Test method: Performance and interpretation of the EIA proficiency must be conducted using licensed kit manufacturer's directions or as described in NVSL SOP-EO-0034.

The EIA AGID and ELISA tests at NVSL are ISO17025 accredited.

8. Submitting test results: Participating laboratories are required to have data submitted for scoring no more than four (4) weeks after panel distribution. Results are reported to the NVSL by fax, mail, or email. One set of results is reported from each laboratory, along with test kit information.

9. Scoring of individual panel samples: The EIA proficiency test is an annual test of approved EIA laboratories. Procedures for approved laboratories are found in 9CFR part 75.4 and in VS Memorandum 555.16. One result for each sample is reported per laboratory. Sample results are reported as positive or negative.

10. Laboratory pass/fail criteria: The final score is based on the identification of positive and negative samples. An NVSL/CVB statistician is consulted to determine the appropriate pass/fail cutoff.

11. Reporting laboratory test scores: Results for each laboratory are reported to the individual laboratory director and to the appropriate AVIC for the laboratory's location. Reports include individual laboratory results for each sample as well as summary results of participants in the proficiency test. Results are compiled and reported within 30-60 days of the due date for receipt of participants' results.

12. Remedial actions required for failing laboratories: Laboratories that do not pass on the first attempt are given the option of purchasing a second panel for a retest. Laboratories that fail the proficiency test are encouraged to contact subject matter experts at NVSL for discussion of methods and resolution of potential areas of concern. If a failing laboratory declines to take, or does not pass, the retest the laboratory is recommended for removal from the list of approved laboratories for EIA testing according to 9CFR Part 75.4. Laboratories that are removed from the approved list are advised that retraining through the NVSL EIA training course is needed for reconsideration of approval. All appeals are documented and evaluated on a case-by-case basis.

13. Special requirements: Restrictions - The EIA proficiency test is only provided in the United States to laboratories that are currently approved for EIA testing. As of 2013, there are approximately 460 approved EIA laboratories in the United States.

The current list of approved laboratories can be found at:

http://www.aphis.usda.gov/animal_health/lab_info_services/approved_labs.shtml

Licensed EIA testing reagents may only be purchased by approved laboratories. International requests for the EIA proficiency panel are considered on a case-by-case basis and must follow applicable authorization and permit requirements.