National Veterinary Services Laboratories Equine Piroplasmosis - *Babesia caballi* and *Theileria (Babesia) equi* Proficiency Test Summary - cELISA

- 1. **Composition of proficiency test panels:** The equine piroplasmosis test panel consists of 15 vials of characterized equine serum for both species. Individual samples consist of 0.5 ml of serum provided in bottles with rubber stoppers and aluminum seals.
- 2. **Cost of proficiency test:** Click <u>here</u> to view the current NVSL Catalog of Reagents. Additional information on diagnostic reagents, including ordering, payments, shipping details and fees, is located at www.aphis.usda.gov/nvsl. Then click on the Reagents and Proficiency Tests link.
- 3. **Storage conditions:** Store at $4^{\circ} \pm 2^{\circ}$ C for short term storage (up to 30 days).
- 4. Sample preparation/selection criteria: Serum samples are selected to create panels with an expected test result range from negative to strong positive. No more than two samples in each category are used in duplicate in the panel. Sample panels consist of well characterized control sera that have been evaluated extensively over time by the VMRD cELISA for equine piroplasmosis. The panels are retested by the Serology Section of the Diagnostic Bacteriology Laboratory (DBL), NVSL, prior to shipment to participating laboratories to ensure that the samples are giving expected results.
- 5. **Panel quality control:** Samples are monitored for stability and reproducibility. Bulk volumes of serum are filtered using a 0.45 µm filter and tested prior to bottling. Samples with results that vary widely between participating laboratories are considered to be outliers, and are not used in determining the pass/fail criteria.
- 6. **Timing of the proficiency test distribution and data collection:** The Equine Piroplasmosis Serology Proficiency Test is administered once a year. The month targeted for distribution is October for annual renewals. Individuals may order the test throughout the year if additional testers are required by the laboratory prior to the annual test.
- 7. **Test method:** Performance and interpretation of the Equine Piroplasmosis Serology Proficiency Test should be conducted according to the manufacturer's kit inserts for the commercial cELISAs currently available in the United States (*Babesia caballi* and *Babesia equi* Antibody Test Kits, cELISA, VMRD Inc., Pullman, WA).
- 8. **Submitting test results:** Participants are requested to have data submitted for scoring no more than 30 days after test panel distribution. Results are reported to the Piroplasmosis Proficiency Test Coordinator by fax, e-mail or mail. Both qualitative (positive/negative) and quantitative (percent inhibition) results must be reported for each sample and for the serum controls.
- **9. Scoring of individual panel samples:** For each sample, a result is considered to be correct based on correctly identifying the sample as positive or negative. The percent inhibition values are not used as criteria for scoring the proficiency test.
- 10. **Laboratory pass/fail criteria:** A participant must correctly identify all positive sera, and may miss up to 2 negative sera in order to pass the proficiency test. A laboratory is required

to have at least one participant that passes the proficiency test in order to be approved to order and to perform the commercial cELISA kits for equine piroplasmosis. Individual participants in an approved laboratory are required to pass the proficiency test before performing the test on an official basis.

- 11. **Reporting laboratory test scores:** Results for each laboratory are reported to the Piroplasmosis Proficiency Test contact. Final results are compiled and reported within 30 days of receipt of participants' results. Results of individual laboratories are reported only to that laboratory.
- **12. Remedial actions required for failing laboratories:** Laboratories that do not have any individual participants passing the proficiency test on their first attempt may purchase additional test panels and retake the test. Additional individuals may be added to the list of approved participants at any time by successfully passing the proficiency test.
- 13. Special requirements: The Piroplasmosis Serology Proficiency Test is intended to provide the NVSL with evidence of the proficiency of laboratories and individuals to test equids by the commercial cELISAs for equine piroplasmosis. This approval is required to purchase and to perform the cELISA for the purposes of export and for intra- and interstate movement of equids. Testing for other purposes, such as import and Foreign Animal Disease investigations, is reserved for the NVSL.