National Veterinary Services Laboratories
Anaplasmosis (*Anaplasma marginale*) Serology
Proficiency Test Summary

1. Composition of proficiency test panel: The panel consists of 20 samples of bovine serum. Individual samples consist of 0.25 ml of serum provided in bottles with rubber stoppers and aluminum seals.

2. Cost of proficiency test: Click here to view 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: Short term (up to 7 days) store at 4° ± 2° C. Long term (over 7 days) store at <-20° C in a non-frost free freezer.

4. Sample preparation/selection criteria: Serum samples are selected to create a panel 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 the years by both the cELISA and CF tests for Anaplasmosis, and the panel is retested by the Serology Section of the Diagnostic Bacteriology Laboratory prior to shipment to participating laboratories to ensure that the samples are giving expected results.

5. Panel quality control: Samples are monitored for sterility, stability and reproducibility. Bulk volumes of serum are filtered using a 0.22 µm filter, and tested for sterility prior to bottling. Samples with results that vary widely between participating laboratories (less than 66% agreement) 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 Anaplasmosis Serology Proficiency Test is administered once a year, generally in October.

7. Test method: Performance and interpretation of the Anaplasmosis Serology Proficiency Test should be conducted using the manufacturer's kit insert for the commercial cELISA currently available in the U.S. (Anaplasma Antibody Test Kit, VMRD, Inc., Pullman, WA).

8. Submitting test results: Participants are required to have data submitted for scoring no more than 4 weeks after panel distribution. Results are reported to the Anaplasmosis Proficiency Test Coordinator by fax, email, or mail. Both qualitative (positive/negative) and quantitative results (percent inhibition) are reported for each sample and serum controls.

9. Scoring of individual panel samples: For each sample, a result is considered as passing based on a combination of correctly identifying known positive and negative samples, and a statistical analysis of the dispersion of the quantitative result from the mean of the results from all participants (e.g., within one standard deviation from the mean). Strong positive and negative samples must be identified correctly, but samples with result values that lie close to the positive threshold are evaluated primarily by statistical means.

10. Laboratory pass/fail criteria: A final score of ≥ 80% correct results for the sample panel is considered passing. Laboratories submitting a passing proficiency test are approved to perform the cELISA for anaplasmosis. Each individual that performs the test is not required to pass the test.

11. Reporting laboratory test scores: Results for each laboratory are reported to the individual laboratory director or Anaplasmosis Proficiency Test contact. Final results are compiled and reported within 60-90 days of the deadline for receipt of participants' results. Results of individual laboratories are reported only to that laboratory, and summary results from all labs are provided as part of the final report.

12. Remedial actions required for failing laboratories: Laboratories that do not pass on the first attempt are offered a retest. Failure to pass on the retest does not preclude a laboratory from performing the cELISA for anaplasmosis.

13. Special requirements: The Anaplasmosis Serology Proficiency Test is intended to provide NVSL certification of the proficiency of laboratories to test cattle by the commercial cELISA for anaplasmosis. This certification is not required to purchase or perform the cELISA, and there is no official disease control or eradication program for anaplasmosis in the U.S. The purpose of the proficiency test is to provide a means for certification of testing laboratories by the NVSL to perform the Anaplasma cELISA, as requested by certain foreign countries as part of their animal and animal product import regulations.