National Veterinary Services Laboratories Bovine Leukosis Virus Antibody Proficiency Test Summary

- 1. Composition of proficiency test panel: The enzootic bovine leukosis (BL) virus antibody panel consists of twenty 0.6 ml samples of bovine 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., BL 2013), a panel set number (e.g. Set 101), 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 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 $4^{\circ} \pm 2^{\circ}$ 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 antibodies to BL virus are chosen for incorporation into the panel. Antibody levels arise from naturally acquired infections. Each panel member is tested at least three (3) times using licensed test kits by a minimum of two NVSL technicians.
- **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 affect 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 BL proficiency test is administered annually, customarily in the month of May.
- **7. Test method:** Performance and interpretation of the BL proficiency should be conducted using USDA licensed test kits and following manufacturer's directions.

Bovine Leukosis 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 BL proficiency test is an annual test of laboratories approved to conduct official BL testing. Procedures for approved laboratories are described in VS Memorandum 555.8. Official BL tests are defined as those tests conducted for the purpose of certifying animals or products for international movement. One result for each sample is reported per laboratory. Sample results are reported as positive or negative.

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- **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 respective laboratory director and to the appropriate AVIC for the laboratory's location. Reports include individual laboratory results for each sample as well as the due date 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 official BL testing. Laboratories that are removed from the approved list are advised that retraining at NVSL is needed for reconsideration of laboratory approval. All appeals are documented and evaluated on a case-by-case basis.
- 13. Special requirements: Licensed kits for diagnostic testing for BL antibody are commercially available to veterinary diagnostic laboratories. A list of laboratories approved for official (export) BL testing is maintained by APHIS/VS. As of 2013, approximately 60 laboratories are approved for official BL serology testing.

 The current list of approved laboratories can be found at: http://www.aphis.usda.gov/animal_health/lab_info_services/approved_labs.shtml
 International requests for the BL proficiency panel are considered on a case-by-case basis and must follow applicable authorization and permit requirements.

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