

National Veterinary Services Laboratories
Pseudorabies –gI Enzyme-Linked Immunosorbent Assay (PRV-gI ELISA)
Proficiency Test Summary

1. Composition of proficiency test panel: The panel consists of twenty 650- μ l samples of sera. The panel contains blind duplicates, positive, and negative sera. The samples are labeled with numbers 1-20.

2. Cost of proficiency test: \$361.00 plus shipping (\$10-US, \$50 Canada, \$150 other).

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

4. Sample preparation/selection criteria: Samples with positive and negative results are chosen for incorporation into the panel. Antibody levels arise from naturally and experimentally acquired infections. Each panel sample is tested at least ten (10) times by a minimum of two technicians in the Diagnostic Virology Laboratory (DVL), at NVSL. Samples with the same test result in a minimum of 18/20 tests are included in the panel.

5. Panel quality control: Samples are monitored for stability and reproducibility. Sera are filtered prior to bottling.

6. Timing of the proficiency test distribution and data collection: The PRV-gI ELISA panel is administered once a year generally in January for United States approved laboratories. The panel is administered internationally upon request.

7. Test method: Performance and interpretation of the Pseudorabies –gI Enzyme-Linked Immunosorbent Assay for sera is per the manufacturer's instructions.

8. Submitting test results: Participants are required to have data submitted for scoring no more than four (4) weeks after panel distribution. Results are reported to the Head of the Bovine/Porcine Section at the DVL, NVSL, or designee by fax, e-mail, or mail.

9. Scoring of individual panel samples: For each sample, a participant is considered as passing if the known negative sample is identified as negative. A participant is considered as passing if the known positive sample is identified as positive.

10. Laboratory pass/fail criteria: The final score is based on the identification of positive and negative samples. Statistical analysis to determine pass/fail level is done by comparing laboratory results when at least 90% of laboratories taking the panel have submitted results.

11. Reporting laboratory test scores (U.S. laboratories only): Results for each laboratory are reported to the individual laboratory director and the AVIC. Pass letters

are sent to laboratory directors within 60-90 days of the deadline for receipt of participants' results.

12. Remedial actions required for failing laboratories (U.S. laboratories only):

Laboratories are given a second chance to pass a proficiency panel. If they fail a second time, PRV testing at the laboratory is stopped, personnel must travel to the NVSL for training, and the laboratory must pass a panel before tasting can begin again.

13. Special requirements (U.S. laboratories only): Laboratories must meet requirements stated in the Code of Federal Regulations (CFR) title 9, part 85.