

**National Veterinary Services Laboratories**  
**African Swine Fever (ASF) Virus**  
**Proficiency Test Summary**

- 1. Composition of proficiency test panel:** The panel consists of eight 350 µl samples of an inactive construct. The panel contains blind duplicate samples as well as a positive and negative extraction control (PEC and NEC). Within the panel is at least one blind negative sample. The samples are assigned position within the panel using a random number generator. Multiple arrangements are prepared for each lot of panels. Each sample within a panel is labeled with a number from 1-6.
- 2. Cost of proficiency test to users:** There is no charge to approved laboratories at this time.
- 3. Storage conditions:** Upon arrival at the laboratory, the proficiency panels should be stored at 4°C for up to one week. After that, panels should be stored at -70°C.
- 4. Sample preparation/selection criteria:** A limit of detection assay is performed on the originating construct. Samples with high, medium and low concentrations of the target analyte are chosen for incorporation into the panel. Each panel construct is characterized by multiple technicians.
- 5. Panel quality control:** Stability of the panels is monitored throughout the lifespan of the panels. Ten per cent of each lot of proficiency panels is used to determine intra- and inter-laboratory variation.
- 6. Timing of the proficiency test distribution and data collection:** The ASF proficiency panel is administered to select laboratories by arrangement with the NAHLN program office and the Proficiency Test program manager (PT program manger).
- 7. Test method:** Performance and interpretation of the ASF proficiency test should be performed using the extraction assay as outlined in SOP-PVS-9057 and the real-time PCR assay as outlined in SOP-PVS-4017, SOP-PVS-4018, or SOP-PVS-4019.
- 8. Submitting test results:** This proficiency test is administered to individuals rather than laboratories. Each individual is required to submit results data no more than four weeks after panel distribution. Results are reported to the PT program manager at Proficiency and Validation Services Section of the Foreign Animal Disease Diagnostic Laboratory (FADDL) by electronic delivery, e-mail or fax. Archived copies of the PCR run should be retained by the test participant for three (3) months or until the results have been verified with the proficiency test report. Results for all laboratories are sent to the NAHLN Program Office with one copy being retained by the PT program manager. Proficiency test results are kept for seven years, with the raw data being retained for five years.
- 9. Scoring of individual panel samples:** For each sample, a participant must correctly supply Ct data and interpretation of Ct values as to positive, inconclusive, or negative.
- 10. Laboratory pass/fail criteria:** The final score is based on the identification of positive and negative samples. Interpretation is weighted as 50% of the grade. The Ct value

results are analyzed with correct results being within one standard deviation higher or two standard deviations lower than the mean. A final score of  $\geq 90\%$  is considered passing.

**11. Reporting laboratory test scores:** Results for each laboratory are reported only to the individual laboratory director. The director is asked to share the results with each individual participant. The Final Report on the Proficiency Panel Test is compiled and sent to laboratory directors within 60-90 days of the receipt of participants results.

**12. Remedial actions required for failing laboratories:** Individual personnel from a laboratory that do not pass on the first attempt are given a retest. Failure to pass on the retest means that a participant is not allowed to administer the failed procedure. If all participants from a laboratory do not successfully complete the proficiency test, that laboratory is not cleared for testing for that disease. Those laboratories that show repeated unsuccessful attempts are encouraged to contact Proficiency and Validation Services Section for discussion of potential areas of concern. These laboratories are asked to test again in the next round of testing. If requested by the laboratory, additional training panels may be provided to the laboratory for practice purposes.

**13. Special requirements:** Only those laboratory personnel who have been trained at FADDL and/or trained as part of the ASF training program are eligible for performing proficiency panel testing.