National Veterinary Services Laboratories Contagious Equine Metritis

Proficiency Test Summary

- 1. **Composition of proficiency test panel:** The Contagious Equine Metritis (CEM) panel consists of 10 lyophilized simulated culture swab samples and accompanying sterile swabs. The samples are labeled with numbers 1-10. Each kit is individually randomized and labeled with a unique kit number which is used for reporting.
- 2. Cost of proficiency test: See the <u>current NVSL Catalog of Reagents</u>
- 3. **Storage conditions:** Store lyophilized samples at 4° C. Once reconstituted, samples must be plated within 1-2 hours.
- 4. **Sample preparation/selection criteria:** Samples consist of 1 ml lyophilized samples spiked with cellsuspensions of *Taylorella spp*. (low, moderate and high concentrations) and/or common equine contaminants. Samples are shipped overnight on ice packs and should arrive cool or cold.
- 5. **Panel quality control:** Following production, at least three of each negative sample and three to six of each positive sample are tested following the current version of NVSL SOP-BI-0106. Following kit assembly, four randomly selected kits are tested for homogeneity. Two additional kits are tested for stability on or after the results due date following simulated normal shipping and storage.
- 6. **Timing of the proficiency test distribution and data collection:** The CEM proficiency test is administered annually or as needed following NVSL training courses.
- 7. **Test method:** To rehydrate, remove metal ring and disinfect stopper with 70% ethanol. Aseptically remove stopper, add 1ml sterile water to vial. Allow to rest 1-2 minutes or until cake is fully reconstituted. Dip the provided swab and gently stir to saturate. Inoculate media with swab and streak for isolation. Treat each sample as if it were an individual submission (non-cervical/uterine). Follow institutional safety and biosafety requirements for BSL-2 bacterial cultures. Performance and interpretation of CEM proficiency must be conducted as described in the current version of NVSL SOP-BI-0106.
- 8. **Submitting test results:** Results are reported to the NVSL via the APHIS PT Portal (formerly NAHLN Portal). The results due date is typically 30 days from shipment and will be provided at the time of shipment.
- 9. **Scoring of individual panel samples:** For each sample, scoring is based on correct identification of *Taylorella* suspect, negative, and invalid tests due to overgrowth or no growth.

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- 10. **Participant pass/fail criteria:** A final score of greater than 80 percent correctly identified is considered a passing score. This is subject to change based on compiled results from participating laboratories. Each participating technician is evaluated individually and must pass proficiency.
- 11. **Reporting participant test scores:** A report is prepared summarizing proficiency test and overall results of participants. Individual results are prepared as a certificate for each passing participant indicating their score. The report and certificates are posted in the APHIS PT Portal. Each participant can access their pass/fail result and laboratory administrators can access the certificates and report. Final results are compiled and reported within 90 days of the deadline for receipt of participants' results.
- 12. Remedial actions required for failing participants: Participants that do not pass on the first attempt are given the option of obtaining a second panel for a retest. Participants 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 participant declines to take or does not pass the retest, the participant is removed from the list of approved personnel for CEM testing. Participants that are removed from the approved list are advised that retraining through the NVSL CEM training course is needed for reconsideration of approval. Laboratories for which all approved personnel are removed are no longer approved CEM testing laboratories and must go through the laboratory approval process as described in VS Guidance document 15202.
- 13. **Special requirements:** Restrictions: This test is offered in conjunction with the Contagious Equine Metritis program. Within the United States, only laboratory personnel who have been trained at NVSL are eligible to participate in CEM proficiency testing. See VS Guidance document 15202 for the laboratory and personnel approval process. All laboratory personnel who perform CEM culture testing are required to take and pass this proficiency test when offered. Laboratories outside of the United States may participate in this proficiency test and are not subject to the US laboratory approval process.

For laboratories inside of the United States, a valid USDA transport permit is required to receive the proficiency test. A copy of the permit must be provided to NVSL prior to shipment. The permit is form 16-6A, United States Veterinary Permit for Importation and Transportation of Controlled Materials and Organisms and Vectors. If you do not have a permit you can apply for one at https://epermits.aphis.usda.gov. It can take several weeks to receive your permit so apply early. Laboratories outside the United States must provide a permit or a statement from their permitting institution stating that a permit is not required.

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