

National Veterinary Services Laboratories
***Brucella abortus* Serology**
Proficiency Test Summary

1. Composition of proficiency test panel: The panel consists of 20 samples of bovine serum. Each panel may be used for up to nine (9) different brucellosis serology tests (see section #7 below). Sample kits are provided in three (3) different volumes (0.25 ml, 1.0 ml, or 1.25 ml), as required to perform the number of tests each participant is assigned to perform.

2. Cost of proficiency test: There is no charge for proficiency testing as part of the Cooperative State-Federal Brucellosis Eradication Program. For other purposes, the charge is \$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: Serum samples are selected to create a panel with three expected result categories: strong positive, intermediate, and negative. No more than two samples in each category are used in duplicate in the panel. Samples are assigned to each category according to prior test results. Samples are tested at least 2-3 times over a period greater than one year, and the entire panel is tested by the Serology Section of the Diagnostic Bacteriology Laboratory, at NVSL, after sterile filtering and prior to bottling for shipment, to participating laboratories.

5. Panel quality control: Samples are monitored for sterility, stability, and reproducibility. Sera are filtered and tested for sterility prior to bottling. Samples with results that vary widely between participating laboratories (less than 66% agreement after acceptable standard deviations are determined) 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 Brucellosis Serology Proficiency Test is administered once a year, generally in May, for United States approved laboratories.

7. Test method: Performance and interpretation of the Brucellosis Serology Proficiency Test should be conducted using the current version of the NVSL test protocol or the manufacturer's kit insert for each test that the participant wishes to be certified in: Standard Plate Test - SPT (SEROPRO1023), BAPA (SEROPRO1024), Standard Tube Test - STT (SEROPRO1026), CFT (SEROPRO1022), Rivanol (SEROPRO1025), Card Test (SEROPRO1027), RAP (SEROPRO1028), PCFIA (kit insert), FPA (microplate - SEROPRO1050, tube - SEROPRO1051).

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 Brucellosis Proficiency Test Coordinator by fax, e-mail, or mail. Reporting results via e-mail using electronic score sheets provided is preferred in order to increase efficiency and decrease transcription errors.

Test results are reported as follows:

BAPA and Card: 0 (Negative), 1 (Positive).

Rivanol, SPT and STT: 0 (Negative), 1 to 8 (Incomplete @ 1:25 to Positive @ 1:200).

RAP: Numerical values to determine mean scores, then converted to Positive/Negative

PCFIA: Numerical values.

FPA: Negative/Positive

CFT: 0 (Negative), 1-28 (1+ 1:10 to 4+ 1:640).

9. Scoring of individual panel samples: For each sample tested by a qualitative test (BAPA, Card), a result is considered as passing if a known negative sample is identified as negative and if a known positive sample is identified as positive. For each sample tested by a quantitative test (Rivanol, SPT, STT, RAP, PCFIA, FPA, CFT), a result is considered as passing based on a statistical analysis of the dispersion of the result from the mean of the results from all participants (e.g., within one standard deviation from the mean).

10. Laboratory pass/fail criteria: A final score of $\geq 90\%$ correct results for each test is considered passing. Individual participants from a laboratory must pass the proficiency test for each test in order for that person to perform that particular test (e.g., Card, STT, etc.). Laboratories are considered to be certified for a particular test if at least one individual from that laboratory has passed the current proficiency test.

11. Reporting laboratory test scores: Results for each laboratory are reported only to the individual laboratory director or brucella proficiency test contact, the AVIC, and appropriate APHIS Brucella Program staff. Final results are compiled and reported within 60-90 days of the deadline for 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 offered a retest. Failure to pass on the retest may mean that participant is not allowed to administer the failed procedure. If all personnel from a laboratory fail, the laboratory is not certified to perform that particular test. Those laboratories that show repeated failed attempts are encouraged to contact the Brucella and Mycobacteria Reagents Team (BMRT) Leader at the Diagnostic Bacteriology Laboratory, at NVSL, for discussion of remedial actions. 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: The *Brucella abortus* Serology Proficiency Test is intended to certify individual technicians in approved laboratories to perform official testing as part of the Cooperative State-Federal Brucellosis Eradication Program.