

UNITED STATES ANIMAL HEALTH ASSOCIATION - 2005

RESOLUTION: 33 and 42 Combined APPROVED

SOURCE: COMMITTEE ON SHEEP AND GOATS
COMMITTEE ON BRUCELLOSIS

SUBJECT MATTER: BRUCELLA OVIS TESTING STANDARDIZATION

DATES: Hershey, Pennsylvania – November 3-9, 2005

BACKGROUND INFORMATION:

In 2004, the United States Animal Health Association (USAHA) passed a resolution recommending that the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS), National Veterinary Services Laboratories (NVSL) provide a standardized *Brucella ovis* (*B. ovis*) Enzyme Linked Immunosorbent Assay (ELISA) test. The rationale was that control sera and antigens produced and provided by NVSL for the *B. ovis* test were inconsistent in quality. The test resulted in both false positive results and a high proportion of suspects. Many animal health laboratories responded to this situation by in-house modification of the *B. ovis* test to attempt to minimize these effects. The result is that the *B. ovis* test offered by one laboratory often produces a different range of negative, suspect and positive results compared to other laboratories. This creates a lack of consumer confidence in the test, and in the competence of laboratories offering the test. Several laboratories have voluntarily stopped offering the test. These inconsistencies are affecting their reputation with producers. As a result of the 2004 resolution, the NVSL began work on an improved *B. ovis* test.

RESOLUTION:

The United States Animal Health Association (USAHA) requests that the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS), and the National Veterinary Services Laboratories (NVSL) alert all animal health diagnostic laboratories, state veterinarians and the sheep industry that it recognizes there is a serious problem associated with the current *Brucella ovis* (*B. ovis*) test.

USAHA requests that USDA-APHIS-VS-NVSL, animal health diagnostic laboratories, and the sheep industry work together to generate a panel of control sera that can be used in test validation. NVSL and the diagnostic laboratories should work together to establish the serum bank necessary to validate the new test methods and participate in inter-laboratory testing of the reagents. Alternate sources of antigen should be evaluated in parallel. USAHA requests that USDA-APHIS-VS-NVSL host a working group to evaluate these data and report these results.

The USAHA requests an update from USDA-APHIS-VS-NVSL on when the revised testing protocol for *B. ovis* will be available.

An immediate need for *B. ovis* testing exists and USAHA requests USDA-APHIS-VS to encourage commercial interests to supply validated *B. ovis* test kits and further requests that approval of test kits by USDA-APHIS-VS-Center for Veterinary Biologics (CVB) be a high priority.

RESPONSE:

ANIMAL AND PLANT HEALTH INSPECTION SERVICE, VETERINARY SERVICES (APHIS-VS)

The Diagnostic Bacteriology Laboratory (DBL) of the National Veterinary Services Laboratories (NVSL) has evaluated a new ELISA format with the World Organization for Animal Health recommended antigen, REO 198. The NVSL has taken the lead in conducting interlaboratory comparison of the new method. The reagents and a panel of sera were sent to 16 laboratories. The results are due February 17, 2006. Conference calls have been planned to discuss the comparison and results. All results will be reported to participating laboratories and USAHA. Future work at DBL will be focused on enlarging the serum bank for proficiency tests for *B. ovis* ELISA. Two commercial interests have been contacted and are aware of the interlaboratory comparison.