# UNITED STATES ANIMAL HEALTH ASSOCIATION – 2009 RESOLUTION

**OCTOBER 14, 2009, SAN DIEGO, CA**

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**RESOLUTION NUMBER:** **23** **APPROVED**

**SOURCE:** COMMITTEE ON TUBERCULOSIS

**SUBJECT MATTER:** EXPEDITED APPROVAL OF NEW BOVINE TUBERCULOSIS ANTIBODY TESTS BY THE CENTER FOR VETERINARY BIOLOGICS

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**BACKGROUND INFORMATION:**

Infection with *Mycobacterium bovis* (*M. bovis*) continues to plague the United States cattle industry with a significant number of tuberculosis (TB) infected herds detected in five states in 2009. The caudal fold tuberculin (CFT) test is the primary screening test used in the bovine TB program. A major disadvantage of this test is that it requires cattle to be handled twice, once for the injection and a second time to "read" the test. Further, the person injecting and reading the test must also be adequately trained and sufficiently experienced to "read" the test accurately. Experience is critical; determining a "response" may be subjective, especially if the response to the injection is small.

Currently, Bovigam® is one official supplemental test used in cattle herds with the approval of the State Animal Health Official and Area Veterinarian In Charge (AVIC). This test may be used under direction of the Designated TB Epidemiologist and with concurrence of the Regional TB Epidemiologist. However, this test requires specialized sample shipping and processing and should only be conducted on blood samples collected between three and 30 days after injection for the CFT test.

The lack of funding for herd depopulation has the potential to increase test and remove routines for herds under TB quarantine. Also, regional or risk-based herd approaches would create additional opportunities for targeted testing scenarios using new diagnostic tools. The United States Animal Health Association (USAHA) has recognized in recent years through discussion and resolution that many companies are generating promising data on antibody-based TB diagnostics that would assist with the potential new realities of managing bovine TB.

Serum sample-based antibody tests represent viable alternatives to current TB test methods and many such tests have demonstrated promising results. Antibody detection tests offer the following advantages over current methods:

- An antibody test can be performed in any diagnostic laboratory, and given the Approximate 2-3 hour test protocols; reliable and more consistent results can be provided same or next day
- Testing serum samples requires no additional manipulation such as sensitization with PPD, timing or shipping constraints
- Serum samples currently being collected for other diagnostic or surveillance purposes (Johne's, brucellosis, bovine viral diarrhea virus (BVDV), etc.) would be sufficient for use in a TB antibody test
- Collecting serum samples for laboratory-based testing eliminates the need to make two visits to each animal in order to read skin test responses
- This method allows convenient repeat testing as there is no 30 or 60-day gamma interferon skin test window

- Typical antibody test formats provide objective, numerical results, removing subjectivity and variability associated with reading the skin test

While the pathway to a Center for Veterinary Biologics (CVB) diagnostic kit license is well-defined, CVB continues to experience resource challenges that contribute to the delay in approving new diagnostic tools urgently needed by the cattle industry.

**RESOLUTION:**

The United States Animal Health Association (USAHA) urges the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Center for Veterinary Biologics (CVB) to work with bovine tuberculosis program staff to prioritize and expedite the review of new *Mycobacterium bovis* antibody tests submitted to CVB for approval.

## INTERIM RESPONSE:

The U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services (VS) is fully supportive of the resolution to expedite the review of new bovine tuberculosis (TB) antibody tests. Toward this end, a working group has revised the VS TB Program Memorandum 552.40, "Evaluation of Tests Proposed for Official Use in the Bovine Tuberculosis Eradication Program," which is being distributed for review and clearance. This memorandum provides guidelines for the evaluation of tests proposed for official use in the Bovine TB Eradication Program. It has been revised to describe the protocol for VS' field studies and to clarify the roles and responsibilities of various parties during the evaluation of tests. The working group members included individuals representing the TB Scientific Advisory Subcommittee of the United States Animal Health Association, the Center for Veterinary Biologics (CVB), the National Veterinary Services Laboratories, and the TB Program. Additionally, the CVB has designated one senior staff veterinarian to facilitate and expedite the review of all *Mycobacterium bovis* antibody test kit applications.

VS continues to support the creation of a serum bank for research and validation of new tests for TB antibody detection. The bank will provide well-characterized serum samples with skin test results from uninfected animals, and skin test, histopathology, and TB culture results for samples from infected animals. The samples will assist researchers in developing serologic tests for bovine TB while meeting industry criteria for timely validation of new tests. Our goal is to obtain blood from 250 TB-infected cattle, 1,600 uninfected cattle, and 1,600 uninfected white-tailed deer.