



UNITED STATES ANIMAL HEALTH ASSOCIATION

Resolution

114th Annual Meeting ~ November 11-17, 2010
Minneapolis, MN

RESOLUTION NUMBER: 1 and 37 Combined **APPROVED**

SOURCE: COMMITTEE ON CAPTIVE WILDLIFE AND ALTERNATIVE LIVESTOCK
COMMITTEE ON TUBERCULOSIS

SUBJECT MATTER: FUNDING FOR EVALUATION OF THE CHEMBIO ANTIBODY TEST AS
AN OFFICIAL TUBERCULOSIS PROGRAM TEST FOR CERVIDS

BACKGROUND INFORMATION:

Infection with *Mycobacterium bovis* (*M. bovis*) continues to plague the United States cattle and cervid industries with a significant number of tuberculosis (TB) infected herds detected annually. During 2009-2010, TB strains were detected in cattle and captive cervid herds that were similar to strains from TB outbreaks in captive cervid herds found during the 1990's. Until 2009, these strains had not been detected in cattle for at least ten years.

The single cervical tuberculin (SCT) test is the primary screening test used in the cervid TB program. A major disadvantage of this test is that it requires animals to be handled twice, once for the tuberculin 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.

Advances in the science of tuberculosis testing have led to the development of antibody tests. The availability of antibody tests for farmed cervids would decrease the need for handling of these species, and would allow for increased interest in tuberculosis testing by producers. Blood based antibody tests for use in cervid species would lead to increased participation of farmed herds in the tuberculosis eradication program.

The CervidTB Stat-Pak has recently become licensed by the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Center for Veterinary Biologics (CVB), and is pending evaluation as an official TB Program Test.

At the 2006 United States Animal Health Association Annual Meeting the following resolution was approved as Resolution 21: "The United States Animal Health Association (USAHA) recommends that the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS) validate a serological tuberculosis test for captive cervids..."

The Resolution had the following response: "The United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Veterinary Service (VS) maintains interest in enhancing and approving new, reliable tests for tuberculosis. We specifically look forward to testing methods that will exceed the accuracy of our current tests and reduce the impact of testing on producers and their livestock. For these reasons, USDA-APHIS-VS fully supports this recommendation. Implementation of this project will be heavily dependent on the industry for providing samples, providing assistance with the purchase of suspects and reactors for confirmatory testing, assistance during testing, and with the promotion of this effort with the industry. Implementation of this project is also dependent on the availability of time, personnel, and financial resources. USDA-APHIS-VS fully intends to pursue this project as long as the required resources and industry support are available."

At the 2007 USAHA Annual Meeting the following resolution was approved as Resolution 26: “The United States Animal Health Association (USAHA) urges the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS) to expedite the validation process for tuberculosis (TB) serological tests for cervid’s to enhance surveillance for TB.”

At the 2009 USAHA Annual Meeting the following resolution was approved as Resolution 23: “The United States Animal Health Association (USAHA) urges the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Services (APHIS), Center for Veterinary Biologics (CVB) to work with the bovine tuberculosis program staff to prioritize the review of new *Mycobacterium bovis* antibody test submitted to CVB for approval.”

The Resolution had the following 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.”

The USAHA has recognized in recent years through discussion and these resolutions that many companies are generating promising data on antibody based TB diagnostic tests. Antibody based tests have the potential to be more widely accepted by producers, due to reduced handling and subsequent injury and death. Increased acceptance would in turn result in improved surveillance and herd management for bovine TB in captive cervids. Blood based antibody tests represent viable alternatives to current TB test methods and many such tests have demonstrated promising results.

RESOLUTION:

The United States Animal Health Association urges the United States Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services to prioritize funding to allow evaluation of the Chembio CervidTB Stat-Pak® test as an official tuberculosis test for the Cervid Tuberculosis Eradication Program.

INTERIM RESPONSE:

The U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services (VS) supports the request of the United States Animal Health Association’s Committee on Tuberculosis to prioritize funding to evaluate the Chembio CervidTB Stat-Pak® as an official tuberculosis (TB) test for the Cervid Tuberculosis Eradication Program.

VS is funding a project to evaluate the Stat-Pak as a primary test for official bovine TB program use in captive and free-ranging *Cervus canadensis* (North American elk), *Odocoileus virginianus* (white-tailed deer), and reindeer (*Rangifer tarandus*). Approximately 2,300 animals will be tested using the Stat-Pak, which will be compared to the single cervical tuberculin test. The project began in December 2010 and will continue through September 2011.

FINAL RESPONSE:

The U.S. Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS) recognizes the concerns of the United States Animal Health Association (USAHA) and appreciates the opportunity to respond.

USDA APHIS VS supported the request of the United States Animal Health Association's (USAHA) Committee on Tuberculosis to prioritize funding to evaluate the Chembio CervidTB Stat-Pak® as an official tuberculosis (TB) test for the Cervid Tuberculosis Eradication Program. The Stat-Pak® is a rapid antibody detection assay that employs a unique cocktail of selected recombinant antigens of *M. bovis* and *M. tuberculosis*.

VS funded a project to evaluate the CervidTB Stat-Pak® as a primary test for official bovine TB program use in captive and free ranging *Cervus canadensis* (North American elk), *Odocoileus virginianus* (white tailed deer) and reindeer (*Rangifer tarandus*). From December 2010 through August 1, 2011, about 1,600 animals were tested using the Stat-Pak® and compared to the single cervical tuberculin (SCT) test. The project goal was to test 2,300 animals. Non-negative animals on the Stat-Pak® were tested by the comparative cervical tuberculin (CCT) test then euthanized for diagnostic necropsy. The project results will be presented to the TB Scientific Advisory Committee at the 2011 USAHA annual conference and a project summary will be circulated to the State and Federal animal health officials after the conference. USDA plans to continue the project during fiscal year 2012 (contingent on receiving funding) to achieve the desired sample size for test evaluation.