

UNITED STATES ANIMAL HEALTH ASSOCIATION - 2008

RESOLUTION

RESOLUTION NUMBER: 47 APPROVED

SOURCE: COMMITTEE ON TUBERCULOSIS

SUBJECT MATTER: FUND EXPANDED COLLECTION OF WELL-CHARACTERIZED SERUM FROM CATTLE AND CERVIDS ROUTINELY TESTED TO SUPPORT THE EVALUATION OF NEW RAPID TESTS FOR TUBERCULOSIS IN CATTLE AND CERVIDS TO ENHANCE BOVINE TUBERCULOSIS ERADICATION PROGRAM

BACKGROUND INFORMATION:

The need for gathering quality samples for new tuberculosis (TB) test validation work has been supported by multiple recent United States Animal Health Association (USAHA) resolutions. This has led to the National Veterinary Services Laboratories (NVSL) working hard to implement a sera bank during the last two years. The initial work focused on cervid sample collection, which has been followed by cattle sample collection. The estimated number of total samples at the NVSL from these efforts is 2,500 cervid samples and 380 cattle samples. Only 53 cervid and fewer than 10 cattle samples are well-characterized positives which are the samples needed for sensitivity validation of any new test. This resolution seeks to overcome the significant limitation of the current sera bank and ask for the United States Department of Agriculture (USDA) to support the work of collecting up to 1,000 new well-characterized positive cattle and Cervid samples, along with added negative cattle samples from TB Accredited Free States. From the report of the Committee on Tuberculosis updating the criteria for evaluating TB test performance for official test status, the number of positive samples needed per species is estimated to be 500 or more. This is far greater than the 10 and 53 positive samples that are available, respectively, for cattle and cervid test validation in the NVSL sera bank today. Without these samples being collected, no new test will be validated.

At the 2006 USAHA 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. USAHA urges USDA-APHIS-VS to take the lead in organizing a pilot project with industry so that prior to each single cervical test injection in captive cervids a blood sample is collected and serum submitted to the National Veterinary Services Laboratory (NVSL) for evaluation of the VetTB Stat-Pak™ rapid test for one year. Serum should be banked for evaluation of a future serology test. Results of this evaluation should be submitted for review by the Scientific Advisory Subcommittee on Tuberculosis".

This Resolution had the following response: "The United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Veterinary Services (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, 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 within the industry. Implementation of this project is also dependent on the availability of time, personnel, and financial resources. VS fully intends to pursue.”

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 cervids to enhance surveillance for TB.”

This Resolution had the following response: “The U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services recognizes the United States Animal Health Association’s concerns and appreciates the opportunity to respond. The Serology Section of the Diagnostic Bacteriology Laboratory of the National Veterinary Services Laboratories (NVSL) is currently working with various cervid producer associations to obtain serum samples from a variety of cervid species. A cervid serum bank has been established; the number of species and the number of samples for each species are increasing. As of January 1, 2008, there were 1,273 serum samples in the bank. The NVSL continues to create panels of blind samples to assist in the evaluation of cervid TB serological tests being developed.”

There are promising tests awaiting these additional samples to complete their validation work. At the 2007 USAHA Annual Meeting the following resolution was approved as Resolution 27: “The United States Animal Health Association (USAHA) urges the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS) to designate the PriTest SeraLyte-Mbv™, Chembio BovidTB STAT-PAK™, and Chembio Mapia™ tests as provisional tests for *Mycobacteria bovis* diagnosis in cattle.” These tests are being developed for cervid TB testing as well.

The Resolution had the following response: “The U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services (VS) recognizes the United States Animal Health Association’s concerns and appreciates the opportunity to respond. Official use of specific test kits is determined by VS National Animal Health Program and Policy staff, with input from the TB Scientific Advisory Subcommittee. Due to confidential business information constraints, the Center for Veterinary Biologics (CVB) cannot comment on the licensure status of these three kits, but it is the CVB’s opinion that these products should follow the standard process for licensure.”

RESOLUTION:

The United States Animal Health Association (USAHA) requests the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS) to request funding and establish specific goals and timelines to gather the required numbers of well-characterized samples that will allow new and promising tests for tuberculosis (TB) to be scientifically validated.

RESPONSE:

USDA, APHIS, Veterinary Services

The U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services (VS) recognizes the United States Animal Health Association's concerns. VS is fully supportive of the effort to develop the tuberculosis serum bank, and we continue to work with industry and State animal health partners to collect and bank sera from cattle and cervids. The number of samples in the serum bank increased from 1,273 in January 2008 to 3,144 in January 2009. For fiscal year 2009, VS developed a proposal and requested funding to expand this program, which emphasizes obtaining well-characterized samples from naturally infected cattle and cervids as well as samples from uninfected animals. At the time of this response, VS is awaiting a decision regarding funding.