



UNITED STATES ANIMAL HEALTH ASSOCIATION

2013 RESOLUTION

117TH ANNUAL MEETING

OCTOBER 17-23, 2013 ~ SAN DIEGO, CA

RESOLUTION NUMBER: 30 - APPROVED

SOURCE: COMMITTEE ON TUBERCULOSIS

SUBJECT MATTER: APPROVAL OF THE USE OF THE CHEMBIO DUAL PATH PLATFORM (DPP®) VETTB ASSAY FOR REPLACEMENT OF THE ELEPHANT TB STAT-PAK® ASSAY AS A PRESUMPTIVE OR SCREENING TEST FOR TUBERCULOSIS SURVEILLANCE IN CAPTIVE ELEPHANTS

BACKGROUND INFORMATION:

The Elephant TB STAT-PAK® Assay is recommended for use in surveillance for tuberculosis in elephants. As with the Elephant TB STAT-PAK® Assay, the DPP® VetTB Assay is Center for Veterinary Biologics approved for use in the detection of tuberculosis in elephants. The DPP® VetTB Assay provides equivalent sensitivity [100% (95% CI, 84-100%)] and superior specificity [100% (95% CI, 97-100%) vs 95% (95% CI, 90-98%)] to the Elephant TB STAT-PAK® Assay (Greenwald et al., 2009). With the DPP® VetTB Assay, seroreactivity to MPB83 and CFP10/ESAT-6 are independently evaluated; thereby, improving the ability to distinguish exposure to non-tuberculous *Mycobacteria spp.* from infection with *Mycobacterium tuberculosis* complex organisms as compared to the Elephant TB STAT-PAK® Assay (all 3 antigens are included in a single test line). With the DPP® VetTB Assay, the test sample and antibody detection reagents are each applied to separate nitrocellulose strips allowing independent migration of the sample and detection reagents to the antigen and control lines. Separate migration of the sample and detection reagents reduces interference associated with impurities in the test sample (e.g., red blood cells, hemolysis, contaminants, etc.). Only 5 microliters of test sample is required for the DPP® VetTB Assay as compared to 30 microliters for the Elephant TB STAT-PAK® Assay, thus, minimizing the impact of sample impurities on test performance. Similarly, smaller colloidal gold particles (30-40 nm gold particles vs 300 nm latex beads) used with the DPP® VetTB Assay limit the possibilities for interference with impurities within the test sample. For detection of antibody, protein A/G is used with the DPP® VetTB Assay whereas blue latex beads coated with test antigen are used for detection with the Elephant TB STAT-PAK® Assay. Thus, the DPP® VetTB Assay detects only IgG reactive with *M. tuberculosis* complex antigens whereas the Elephant TB STAT-PAK® Assay detects all isotypes of antibody, increasing the possibility of detection of non-specific IgM responses. Each of these aspects (i.e., independent antigen detection, separate migration of antibody detection reagents and test sample, smaller sample

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volume, smaller colloidal gold particles, and protein A/G conjugate to detect IgG responses only) improves the specificity of the assay. The DPP® VetTB Assay also has operational benefits as compared to the Elephant TB STAT-PAK® Assay. These include: (1) ease of use with enhanced visibility of test bands for determining test status and (2) availability of a reader to provide an objective measure of band intensity, thereby, affording better communication between diagnostic laboratory staff and regulatory agencies, attending veterinarians, and clients.

The Elephant Tuberculosis Subcommittee of the USAHA Tuberculosis Committee has recommended the replacement of the Elephant TB STAT-PAK® Assay with the DPP® VetTB Assay as a presumptive or screening test for tuberculosis in elephants.

RESOLUTION:

The United States Animal Health Association (USAHA) requests that the United States Department of Agriculture, Animal and Plant Health Inspection Services, Animal Care replace the Elephant TB STAT-PAK® Assay, with the DPP® VetTB Assay as a presumptive or screening test for tuberculosis in elephants.



United States Department of Agriculture

Animal and Plant
Health Inspection
Service

December 17, 2013

4700 River Road
Riverdale, MD 20737

Stephen K. Crawford, DVM
President, USAHA
4221 Mitchell Avenue
Saint Joseph, MO 64507

Dear Dr. Crawford:

The United States Department of Agriculture (USDA) thanks the United States Animal Health Association for its continuing support for the scientific advancement of tuberculosis diagnosis in elephants. We have reviewed Resolution 30 as presented in your letter of November 21, 2013.

As this resolution provides for an alternative to the currently unavailable Elephant TB StatPak® in the 2008 and 2010 versions of the "Guidelines for the Control and Treatment of Tuberculosis in Elephants," USDA will make those changes in the information maintained on our website, as well as notifying elephant holders of the approved changes to available serological tests that meet the recommendations of the guidelines.

Thank you for your continued collaboration with USDA for the improvement of animal health.

Sincerely,

A handwritten signature in black ink that reads "Chester A. Gipson". The signature is written in a cursive style.

Chester A. Gipson
Deputy Administrator
USDA APHIS Animal Care