Report of the 2014 USAHA Bovine Tuberculosis Scientific Advisory Subcommittee

Kansas City, Kansas

October 20, 2014

Presentations

Integration of Models and Dense Phylogenetic Sampling to Understand BTB epidemiology in Cattle and Wildlife

Professor Rowland Kao, Institute of Biodiversity Animal Health and Comparative Medicine, University of Glasgow, Glasgow, UK.

Effect of Skin Test on Serum Antibody Responses to *Mycobacterium bovis* Infection in Cattle

Ray Waters[1], Jeff Nelson[2], Tyler Thacker[1], Mayara Maggioli[1], Molly Stafne[3], Kristin Bass[4], Rick Linscott[5], John Lawrence[5], and Mitch Palmer[1]

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[4]Bethyl Laboratories, Montgomery, Texas

[5]IDEXX Laboratories, Westbrook, Maine

Presentations

Comparison of CSL and Lelystad PPD in the Bovigam under field trial conditions in the US- Dr. Bjoern Schroeder, Thermo Fisher Scientific, Prionics AG, Schlieren-Zurich, Switzerland.

Distribution of *Mycobacterium bovis* genotypes in infected deer and the implication for whole genome sequencing epidemiology

Tyler C Thacker[1], Mitchell V. Palmer[1], Suelee Robbe-Austerman[2], Tod P. Stuber[2], W. Ray Waters[1]

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Update on the NVSL bTB serum bank and use of Chembio DPP in captive cervids- Dr. Jeff Nelson, USDA, APHIS, National Veterinary Services Laboratories, Ames, IA, USA.

Use of the Chembio Dual Path Platform (DPP) VetTB Assay® as a primary test

Request- Comment on the use of the Dual Path Platform (DPP) VetTB Assay® as a stand-alone primary and secondary test for *Mycobacterium bovis* (bTB) in cervids.

Question- Is it scientifically valid to change the Cervid TB serological testing protocol at NVSL by eliminating the CervidTB Stat-Pak® as the primary test and instituting the use of the DPP VetTB Assay® as the primary serological test and also using the DPP VetTB Assay® as the confirmatory test 30 days after the initial positive serological test?

TB SAS Comments

1. As Chembio will discontinue the manufacture of the CervidTB Stat-Pak®, a change in protocol is requisite. Replacing a subjective, visually interpreted assay with an objective assay that uses electronically determined, numeric values for status classification is considered a positive change.

1. From a regulatory perspective, terminology may be important; therefore, categorizing the second DPP as a “repeat test” is more accurate than using terminology such as “confirmatory test”.

TB SAS Comments

3. It appears that the DPP does not categorize as positive, samples categorized as negative by the Stat-Pak.

This conclusion is based on a sample size determined to be statistically valid by a CVB statistician (i.e. 150 samples each of the two most commonly tested species). This is the basis of the critical assumption that 8285 Stat-Pak negative samples would have also been DPP negative if tested, thus yielding the specificities of 99.76% for the 1st DPP and 99.89% for the 2nd DPP.

Presuming this assumption is valid; it appears scientifically acceptable to make the proposed change in the Cervid TB testing protocol.

Use of Lelystad PPD in Bovigam®

Request-Comment on data from 2012 and 2014 on comparison of PPD from 2 different sources (CSL and Lelystad) in order to demonstrate equivalence of product performance. This was done to fulfill requirements for approval of the Bovigam® kit containing Lelystad PPD in place of CSL PPD.

Question- Can Lelystad PPD be used in place of current CSL PPD in the Bovigam® without compromising test sensitivity or specificity?

TB SAS Comments

The 2014 submission provides side-by-side comparisons of Lelystad and CSL PPDs using samples from confirmed *M. bovis* infected cattle (confirmation by culture or PCR) from herds in Michigan and Colorado, and presumed non-infected herds in Texas, Idaho, Minnesota and Pennsylvania. Data from a total of 84 confirmed *M. bovis* infected animals and 711 non-infected animals are presented.

Bovigam® sensitivity was 73.8% for Lelystad PPD and 45.2% for CSL PPD, Bovigam® specificity was 96.9% for Lelystad PPD and 95.1% for CSL PPD

2014 data, combined with that reviewed in 2012, demonstrates that Lelystad PPD performs with superior sensitivity and equivalent specificity to CSL PPD in the Bovigam® assay. It is the opinion of the TB SAS that approval of Lelystad PPD for use in the Bovigam® assay would be appropriate.