

UNITED STATES ANIMAL HEALTH ASSOCIATION—2007

RESOLUTION NUMBER: 27 APPROVED

SOURCE: COMMITTEE ON TUBERCULOSIS

SUBJECT MATTER: DESIGNATION OF TUBERCULOSIS SEROLOGICAL
TESTS FOR PROVISIONAL STATUS

DATES: RENO, NEVADA OCTOBER 18 – 24, 2007

BACKGROUND INFORMATION:

Preliminary data presented at the Scientific Advisory Subcommittee (SAS) on Tuberculosis (TB) on October 20, 2007, indicates that the PriTest SeraLyte-Mbv™, Chembio BovidTB STAT-PAK™, and Chembio Mapia™ *Mycobacterium bovis* test technologies show promise for potential use in the national Bovine TB Eradication Program. Test sensitivity values reported were 81.5%, 70.4% and 70.4% respectively. Additional data is now needed to more critically evaluate these tests according to proposed use in an official capacity. Designation of these tests as provisional, as per applicable United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS) memoranda will support the collection of additional data for evaluation by the TB SAS and USDA-APHIS.

This designation will initiate a more formal process allowing USDA-APHIS to work with the test developers in identifying specific uses for these tests in the national Bovine TB Eradication Program and to provide guidance regarding additional test samples needed for further consideration and evaluation as official TB program tests.

RESOLUTION:

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.

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 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 Committee. 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.