



## **ChemBio Granted USDA License For Its ElephantTB STAT-PAK<sup>®</sup> Assay**

### ***Rapid Serological Screening for TB in Elephants***

New York, December 1, 2007- (OTCB: CEMI) – ChemBio Diagnostic, Inc. (OTC BB: CEMI.OB – News) announces that it has been issued an United States Department of Agriculture (USDA) license for its ElephantTB STAT-PAK Assay designed to rapidly (< 20 minutes) detect tuberculosis (TB) in both Asian and African elephants. ChemBio’s other rapid serological TB assay – PrimaTB STAT-PAK received USDA licensure earlier this year. Both products belong to a larger family of rapid immunochromatographic assays currently under development at ChemBio for the detection of TB in animals. Those include CamelidTB STAT-PAK, CervidTB STAT-PAK, and BovidTB STAT-PAK Assay kits that all employ ChemBio’s recently patented technology, (U.S. Patent Number 7,192,721 – Universal Rapid Test and Method for Detection of Tuberculosis in Multiple Host Species).

While TB has been recognized for over 2,000 years in elephant, it has recently been recognized as an important reemerging disease in captive elephants, particularly Asian elephants. *M. tuberculosis*, the most common cause TB classically, causes the same infection in humans as in elephants. Transmission of TB between elephant and human (zoonoses) has been documented.

TB remains a serious threat to captive elephants world-wide. Since 1994, TB has been diagnosed in over 12% of the US Asian elephant population. One-fourth (~15,000) of all the Asian elephants reside in captivity in 13 Asian countries. The high incidence of TB among humans in Asia suggests that many elephants within Asia may be also infected. Further information about TB in elephant is available from Elephant Care International ([www.elephantcare.org](http://www.elephantcare.org)).

Largely in response to the confirmed occurrence of TB in two captive elephants, Guidelines for the Control of Tuberculosis in Elephants were first developed and accepted as a policy by the USDA in 1998. These same Guidelines were again updated in 2000 and 2003. Testing elephant for TB is an essential component of elephant health care. The veterinary care of elephant is monitored by USDA under the Animal Welfare Act (AWA). The only available diagnostic test for TB in elephants, until the licensure of ChemBio’s ElephantTB STAT-PAK Assay, was mycobacterial culture of trunk wash specimens, a procedure similar to obtaining a sputum sample for TB in humans.

There is considerable evidence that this method has poor sensitivity and can only identify animals with extensive shedding of the organisms which typically occurs late in the disease. Recent published studies on Chembio's ElephantTB STAT-PAK Assay indicate that serology is able to detect TB in elephant as much as 4 years prior to culture of TB from trunk washes. The current 2007 proposed ElephantTB Guidelines, under review by the TB subcommittee of the United States Animal Health Association (USAHA), recommend incorporating Chembio's ElephantTB STAT-PAK Assay as an integral component in monitoring and managing TB in the US elephant population.

There is a growing body of evidence that suggests that Chembio's ElephantTB STAT-PAK Assay has a wider applicability across multiple host species than just elephants. Studies presented at the 2006 & 2007 Conferences of American Association of Zoological Veterinarians (AAZV) utilized Chembio's ElephantTB STAT-PAK to detect TB in rhinos, sea lions, jaguars, and tapirs. In these species ante-mortem TB diagnostic methods, such as skin testing, either do not exist or are known to be less reliable. Serology is proving to be more sensitive and easier to apply. Chembio recognizes that the potential market for its ElephantTB STAT-PAK Assay may, therefore be much greater than just elephants. The assay may prove to be an effective aid in the detection of TB in a wide variety of free-ranging and captive wildlife species in zoo conservation communities.

Chembio's ElephantTB STAT-PAK Assay is a lateral flow, onsite animal side test for the rapid detection of antibodies to TB in elephants. The test employs a unique and patented cocktail of recombinant proteins or antigens to both *M. tuberculosis* and *M. bovis*. The assay utilizes whole blood, serum, or plasma in very small aliquots of 30 µl to produce a qualitative result in less than 20 minutes.

USDA restricted the use of the assay in the US to only laboratories approved by state and federal animal health officials, of which currently the only one is NVSL (National Veterinary Services Laboratory) in Ames, Iowa. Therefore, Chembio's ElephantTB STAT-PAK Assay is currently commercially available for purchase only outside the US. Contact Chembio's website at [www.chembio.com](http://www.chembio.com), e-mail your request to [info@chembio.com](mailto:info@chembio.com), or contact Les Stutzman at [LStutzman@chembio.com](mailto:LStutzman@chembio.com) for more information.

## **ABOUT CHEMBIO**

Chembio Diagnostics, Inc., a developer and manufacturer of rapid diagnostic tests for infectious diseases, is on the frontlines of the global battle against the AIDS pandemic. The Company has received marketing approval from the FDA for its SURE CHECK(R) HIV 1/2 and HIV 1/2 STAT-PAK(R) rapid tests, marketed in the United States by Inverness Medical Innovations. The Company also manufactures rapid tests for veterinary Tuberculosis and Chagas Disease. In March 2007 Chembio was issued a United States patent for the Dual Path Platform (DPP(TM)), a next generation lateral flow platform. DPP has demonstrated significant advantages over currently available

lateral flow methods, including increased sensitivity, sample flexibility, and multiplexing capabilities.

Further information please visit [www.chembio.com](http://www.chembio.com)

#### **FORWARD-LOOKING STATEMENTS**

*Statements contained herein that are not historical facts may be forward-looking statements within the meaning of the Securities Act of 1933, as amended. Forward-looking statements include statements regarding the intent, belief or current expectations of the Company and its management. Such statements are estimates only, as the Company has not completed the preparation of its financial statements for those periods, nor has its auditor completed the audit of those results. Actual revenue may differ materially from those anticipated in this press release. Such statements reflect management's current views, are based on certain assumptions and involve risks and uncertainties. Actual results, events, or performance may differ materially from the above forward-looking statements due to a number of important factors, and will be dependent upon a variety of factors, including, but not limited to Chembio's ability to obtain additional financing, to obtain regulatory approvals in a timely manner, and the demand for Chembio's products. Chembio undertakes no obligation to publicly update these forward-looking statements to reflect events or circumstances that occur after the date hereof or to reflect any change in Chembio's expectations with regard to these forward-looking statements or the occurrence of unanticipated events. Factors that may impact Chembio's success are more fully disclosed in Chembio's most recent public filings with the U.S. Securities and Exchange Commission.*

#### **Contact:**

Matty Arce - 631-924-1135 ext 123.