

## **FREQUENTLY ASKED QUESTIONS ABOUT THE NEW ELEPHANT TB TEST**

### **Why wasn't the Stat-Pak licensed for use in the field like it was intended to be used?**

The Stat-Pak is licensed for use only by approved laboratories. Because of the potential for fraudulent use, the product has a restricted license. There are now trained certified AC veterinarians who are authorized to conduct the test in the field. Licensees will have the choice of having the test conducted in the field or sending the blood to an approved laboratory for testing. The blood draw for the official test must be monitored by AC personnel.

### **Why was the primate test licensed for field use? Can't veterinarians just use the primate test for other animals such as elephants and cattle?**

The antigens used for the primate test are significantly different than the ones used for the Elephant Stat-Pak. If used with other animals, the results are not reliable. This would be considered an off label use of the test.

### **Why is NVSL the only laboratory authorized to run the elephant Stat-Pak test?**

NVSL is the first laboratory authorized to run Stat-Pak tests. If other labs would like to run the test, they need to apply to APHIS/AC for credentialing procedures.

### **Why can't licensed veterinarians use the test in the field?**

If licensed veterinarians are credentialed through APHIS/AC, they can purchase and use the test in the field. The yearly official test for regulatory purposes will still need to be conducted by a Federal veterinarian.

### **Isn't this approach heavy handed?**

TB in elephants is a zoonotic disease with public health implications. In order to verify that the annual testing for this disease is done properly, the blood draws must be witnessed and the test performed by a Federal veterinarian. In an effort to further the health and well being of elephants, it is important to make further progress in determining how widespread TB is in the U.S.

### **Why doesn't the trunk wash have to be witnessed by a Federal veterinarian?**

The trunk wash is a direct test and is not subject to the same potential for fraudulent results. We will be monitoring trunk wash procedures at all facilities during the testing to verify that they are being properly conducted.

### **What if we get a reactive Stat-Pak?**

There are provisions in the new guidelines for a reactive Stat-Pak. Any reactors should be followed with a MAPIA.

### **Aren't there a lot of false positive with the Stat-Pak test?**

The Stat-Pak test is considered a screening test and the results are categorized as reactor or non-reactor. There are places in the 2008 Guidelines that do refer to positive and negative Stat-Pak tests, but they should be more correctly referred to as reactor or non

reactor to avoid confusion. If the test is reactive, the serum should be sent to the lab for a MAPIA which will show whether the sample is indicative of MTb. Even if the MAPIA is indicative of MTb, only a trunk wash positive sample is considered as a definite positive.

**What is the protocol if the Stat Pak and MAPIA tests are indicative of an exposure to M. tuberculosis/bovis; how do we determine which elephant should be treated, what will happen if an elephant is not treated (quarantine etc.)**

The section under Group 3 of the GUIDELINES FOR THE CONTROL OF TUBERCULOSIS IN ELEPHANTS 2008 addresses that scenario. In part:

*Elephants that are culture negative, ElephantTB STAT-PAK<sup>®</sup> positive and MAPIA<sup>™</sup> positive should be considered to be at increased risk of having TB. Factors to consider in the decision to administer treatment vs. increased monitoring include exposure history, age, whether the elephant travels, potential exposure of personnel or public, side effects of treatment, concurrent health problems, etc. Increased monitoring by culture (triple sample method) is recommended every 2–3 months. If culture results during any of the follow-up testing become positive, the individual elephant will move to Category 4.*

The guidelines should be followed in these cases but on a case by case basis, we will be available to consult with the attending veterinarian and if necessary, with the help of expert consulting veterinarians assist in the determination of the best course of action for individual facilities and elephants.

The goal is to protect the health and well being of the elephants and to help ensure any people in contact with these elephants take proper precautions for bio safety.

**Who has the authority to impose treatment of an animal and what happens to that animal if it has severe secondary effects.**

Treatment of any elephant for TB is under the medical authority of the attending veterinarian. We will be available to consult on a case by case basis to help determine the best course of action for each facility and individual elephants.

**Will the results of these tests be kept confidential as part of the medical record of the animals.**

The results of the Stat-Pak testing will be handled like any other medical records. Results will not be listed on inspection reports.

**Why didn't the USDA go to AAZV or other professional groups for advice on this test and the new guidelines?**

USDA did not select the group that recommended the guidelines revision. A Subcommittee of the United States Animal Health Association (USAHA) TB Committee

reviewed and revised the guidelines and they were then recommended to USDA for acceptance and implementation by USAHA. The subcommittee consisted of veterinary experts in the fields of immunology, epidemiology, elephant medicine and TB. We have accepted the guidelines from USAHA.

**Can the test be conducted in the field?**

The official Stat-Pak test can now be run in the field by Animal Care VMOs. AC inspectors will contact licensees to schedule the testing to coincide with the official trunk washes.

**Will there be more detailed instructions for performing a trunk wash?**

Federal veterinarians will monitor each facilities performance of the trunk wash to verify that the test is being done correctly and will be prepared to offer suggestions if appropriate for collecting better samples.

**Who will pay for the annual test?**

Licensees are responsible for paying for the test just as they are responsible for the cost of other diagnostic tests for animals in their care.