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**The Stat-Pak® and DPP Serological Tests for Diagnosing Bovine Tuberculosis (TB) in Captive Elk, Red Deer, White-Tailed Deer, Fallow Deer, and Reindeer**

**1. Purpose and Background**

Historically, the single cervical tuberculin skin test (SCT) and the comparative cervical tuberculin skin test (CCT) have been the only approved official tests for *Mycobacterium bovis* in captive cervids. Recently, Veterinary Services (VS) approved the Stat-Pak® as a primary test and the DPP test as a secondary test for official program testing to diagnose TB in captive elk, red deer, white-tailed deer, fallow deer, and reindeer when the test is conducted at an approved laboratory. Both of these tests are serological tests that offer the advantage of decreased handling of animals when compared to skin testing.

This guidance document represents the Agency's position on this topic. It does not create or confer any rights for or on any person and does not bind the U.S. Department of Agriculture (USDA) or the public. The information it contains may be made available to the public. While this document provides guidance for users outside VS, VS employees may not deviate from the directions provided herein without appropriate justification and supervisory concurrence.

**2. Document Status**

- A. Valid through 11/26/2015
- B. This is a new document.

**3. Reason for Reissuance**

Not applicable.

**4. Authority and References**

- A. Authorities (*Code of Federal Regulations* (CFR) and U.S. Code (U.S.C.)):
  - 7 U.S.C. 8301–8317
  - 7 CFR 2.22
  - 7 CFR 2.80
  - 7 CFR 371.4
  - 9 CFR 77.33
- B. References
  - VS Form 6-22, Tuberculosis Test Record, (2/99)
  - VS Form 10-4, Specimen Submission, (8/09)
  - VS Form 10-4A, Continuation Sheet for Specimen Submission, (8/09)

**5. Audience**

VS employees, other affected Federal and State agencies, and affected members of the public.

**6. Guidance**

**A. Test Administration, Ordering, and Payment**

- 1) Accredited veterinarians who receive supplemental training and are certified as Designated Accredited Veterinarians (DAVs) (VS-accredited veterinarians specially trained and approved to conduct specific tuberculosis program tests and activities) may perform the SCT in cervids. They are also authorized to submit serum specimens from captive elk, red deer, white-tailed deer, fallow deer, and reindeer to the National Veterinary Services Laboratories (NVSL) for serological tests such as the Stat-Pak. Current DAVs do not need additional training to draw samples for cervid TB serological testing.
- 2) Cervid TB Stat-Pak serum submission kits may be ordered from NVSL by calling 515-337-6200 or emailing NVSL\_userfee@aphis.usda.gov. Each kit, costing about \$30.00, contains shipping instructions, an ice pack, VS Forms 10-4 (Specimen Submission Form) and 10-4A (Continuation Sheet), and a pre-paid shipping label to NVSL. DAVs may also submit serum samples using their own shipping box, which should include ice or gel packs as well as the laboratory submission forms. VS Forms 10-4 and 10-4A have been approved by the Office of Management and Budget for submitting all diagnostic samples to NVSL.
- 3) Before drawing blood samples, the veterinarian will:
  - a. Call the Area Veterinarian in Charge (AVIC) in the State where the animals are located to verify that their State's current animal health regulations allow the Stat-Pak and DPP serological tests for bovine TB to be used.
  - b. Obtain permission from the AVIC to send samples to NVSL, and confirm that all necessary paperwork is being completed and submitted.
  - c. If testing for interstate movement, verify that the receiving State will also accept the negative serological test results for entry.
- 4) The submitting DAV must pay for routine screening Stat-Pak tests. This may be done by setting up an account with the NVSL business office by calling 515-337-6200, providing a credit card number on the submission form, or including a check made out to NVSL with the samples and submission form.

**B. Sample Collection, Processing, and Shipping for CervidTB Stat-Pak Testing at NVSL**

- 1) Collecting samples
  - a. Blood samples are to be collected in a 10-ml red top (clot) tube or 10 ml serum separation tubes.
  - b. 10 ml of whole blood needs to be collected to obtain 2 ml of serum to be submitted for testing.
  - c. DO NOT place freshly collected tubes directly on ice.
- 2) Sample processing and handling
  - a. Allow the blood to clot at room temperature.
  - b. Once clotted, remove the serum from the clot and place it into a new, clean tube. If necessary, centrifuge the clotted blood sample to obtain at least 2 ml of serum. It is essential that the serum contains minimal hemolysis. Place the serum tubes in a refrigerator until shipped to NVSL.
  - c. Submitted tubes should be numbered and labeled with official identification so they can be easily correlated to the animal's official ID as listed on the submission forms. This helps laboratory personnel verify all the samples were received and correlate the results to individual animals.
  - d. Ship serum samples within 24 hours of collection by first- or second-day delivery.
  - e. If also testing for brucellosis, submit a separate red top tube of blood to an approved brucellosis testing laboratory.
- 3) Completing submission forms and paperwork
  - a. Fill out the VS Form 10-4 and VS Form 10-4A accurately and completely. (See the attached sample VS Forms 10-4 and 10-4A. These forms can also be found at [http://www.aphis.usda.gov/animal\\_health/lab\\_info\\_services/forms\\_publications.shtml](http://www.aphis.usda.gov/animal_health/lab_info_services/forms_publications.shtml).)
    1. Official identification (and all other ID), species of cervid (e.g., elk, red deer, white-tailed deer, fallow deer or reindeer), age, and gender for each animal must be included.
    2. Animal identification does not need to be written on the submission form as long as there is an attached list with all of the above information. If preferred, attach to the VS Form 10-4 a spreadsheet or printout of the animals with official ID corresponding to their blood tube numbers or attach a copy of the completed (all above information) VS Form VS 6-22 (Tuberculosis Test Record) with the corresponding blood tube numbers.

- b. Submit the original VS Forms 10-4 and 10-4A to NVSL as part of the sample submission described in Section 6 (B)(4) of this guidance document.
- c. Fill out the VS Form VS 6-22 (Tuberculosis Test Record) accurately and completely identifying the cervid species (e.g., elk, red deer, white-tailed deer, fallow deer or reindeer), ID, age, and gender, and submit to the State veterinarian and AVIC.
- d. Submit the VS Form 6-22 to the State veterinarian or AVIC in your State within 5 business days of sample collection.

4) Sample submission to NVSL

- a. Organize the serum tubes into a tube box in the same order as animals are listed on the submission form or attached list. This allows the receiving laboratory personnel to quickly verify and test the submitted samples. If sample submission kits from NVSL are needed, they should be obtained prior to collecting the blood samples.
- b. Make sure that submitted sample tubes are packed with frozen gel packs, but not in direct contact with the frozen packs in the container used to ship the samples to NVSL. Refrigerate all serum samples until they are shipped.
- c. Ship the samples along with the completed form VS 10-4/10-4A to NVSL as described in this guidance document. If shipping materials are needed, please contact NVSL at 515-337-6200 or [NVSL\\_userfee@aphis.usda.gov](mailto:NVSL_userfee@aphis.usda.gov) to order a serum submission kit.
- d. Serum samples should be shipped using overnight or 2-day delivery. VS prefers that you use a shipper such as Federal Express or United Parcel Service if not using prepaid NVSL shipping containers, as they deliver directly to the NVSL facility. Do not ship the samples so they will arrive at NVSL on the weekend or a holiday. The U.S. Postal Service does not deliver directly to NVSL.

5) Sample testing

- a. Valid serum samples will be tested using the Stat-Pak test following test kit instructions and internal NVSL standard operating procedures.
- b. If the Stat-Pak test result obtained is non-negative (either positive or inconclusive), additional serum from the same sample will be tested using the DPP test following the test kit instructions. The DPP test will not be used as a screening test for animals of unknown TB status.

- c. Results of the Stat-Pak and, where applicable, the DPP, will be reported to the submitting veterinarian and the State animal health official, AVIC, and Area epidemiology officer or designated TB epidemiologist of the State where the animals are located.
- d. The Area epidemiology officer or designated TB epidemiologist (DTE) will classify the animals.
  1. Animals negative on the Stat-Pak test should be classified as negative.
  2. Animals non-negative on the Stat-Pak test and negative on the DPP test should be classified as negative.
  3. If the DPP test is performed on non-negative Stat-Pak samples, a second VS Form 6-22 must be completed for those animals by the DTE.
  4. Animals non-negative on the Stat-Pak test and non-negative on a single DPP test should be classified as suspect unless the designated or regional TB epidemiologist determines that a reactor classification is warranted.
  5. Animals classified as suspect by a single DPP test may be retested with the DPP test only with a new blood sample drawn no sooner than 30 days after the initial sample was obtained.
  6. Animals that are non-negative on two successive DPP tests should be classified as reactor.
- e. Any exceptions to reactor classification must be justified by the designated TB epidemiologist in writing and have the concurrence of the regional TB epidemiologist.
- f. The animal is then handled according to its classification following TB program regulations as stated in the 1999 TB UM&R and 9 CFR part 77, subpart C.

**C. TB Program Testing Protocol**

- 1) If an animal tests non-negative to the Stat-Pak serological test, it must be retested using the DPP serological test as the secondary test.
- 2) If an animal tests non-negative to the SCT, it must be retested using the CCT as the secondary test.
- 3) The CCT and DPP tests will not be used as a primary test for any animals.

- 4) If parallel testing is performed with the Stat-Pak and SCT tests, it must be completed with permission from and consultation with the DTE and the regional TB epidemiologist. The testing protocol, timing of different tests, interpretation of the tests, classification of the animals, and disposition of the animals must be stated in a written protocol agreed upon before the testing occurs.
- 5) In routine herd testing, different groups of animals within a herd may be tested using the different methods (i.e., bucks tested serologically and does tested via the skin test) provided that a different VS Form 6-22 is used for each group of animals. However, individual animals testing non-negative to a primary test, must be followed up with a secondary test as required in 1) and 2) of this section.
- 6) In affected herds or herds under investigation, a testing protocol using serologic and/or skin tests separately or in series or parallel may be devised and utilized by the DTE and RTE in consultation.

## 7. Inquiries

Please direct any inquiries to:

VS Bovine Tuberculosis Staff Officer  
USDA APHIS Veterinary Services  
National Center for Animal Health Programs  
2150 Centre Avenue, Bldg. B, M/S 3E20  
Fort Collins, CO 80526  
Phone: 970-494-7317  
[http://www.aphis.usda.gov/animal\\_health/animal\\_diseases/tuberculosis/](http://www.aphis.usda.gov/animal_health/animal_diseases/tuberculosis/)



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Deputy Administrator





United States Department of Agriculture  
 Marketing and Regulatory Programs  
 Animal and Plant Health Inspection Service  
 Veterinary Services

VS Guidance

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Date: 11/26/2012

According to the Paperwork Reduction Act of 1995, no person is required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0579-0084. The time required to complete this information collection is estimated to average .3 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

STATE	<b>ALL INCOMPLETE RECORDS WILL BE RETURNED FOR COMPLETION</b>	FORM APPROVED OMB NO. 0579-0084
<b>COOPERATIVE STATE - FEDERAL TUBERCULOSIS ERADICATION PROGRAM</b>		
<b>TUBERCULOSIS TEST RECORD</b>		

COUNTY	TWP	SEC	HERD OWNER'S NAME - LAST	FIRST	MI	PREVIOUS TEST DATE	VET CODE	TOTAL	REA	SJS
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HERD NUMBER	HERD OWNER'S COMPLETE ADDRESS	CERTIFICATION FOR PAYMENT <input type="checkbox"/> State/Federal Expense <input type="checkbox"/> Owner's Expense	DATE LISTED
LESION	TEST	D-B	U

COUNTY	TOWNSHIP OR DISTRICT	SEC.	FARM NO.	I certify that this test was made and read by me on each of the cattle identified below on the dates and with the results as entered in the appropriate spaces. That when payment is claimed at program expense in accordance with agreement number below, no payment has been or will be received from any other source.
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REASON FOR TEST		COMPLETE INFO TEST OF ALL ELIGIBLE ANIMALS		SUMMARY		PRACTITIONER'S SIGNATURE		TELEPHONE NO	
AREA	1	RETEST	6	<input type="checkbox"/> YES	<input type="checkbox"/> NO	NEG-ATIVE	PRACTITIONER'S NAME (Please print)		AGREE CODE
				NO. ELIGIBLE ANIMALS IN HERD					
				KIND OF HERD					
				METHOD OF TEST					
				CATTLE					
				DEER					
				ELK					
				BISON					
				OTHER					
				CALCUL FOLD (CF)					
				SJS CERVICAL (CST) (Cervix)					
				CERVICAL (C) (Bovine)					
				OTHER					
				TOTAL					
				REACTOR TAG NO.					
				REACTOR TAG NO.					

1	IDENTIFICATION NUMBER	AGE	BREED	SEX	RESULTS		REACTOR TAG NO.	1	IDENTIFICATION NUMBER	AGE	BREED	SEX	RESULTS		REACTOR TAG NO.
					SIZE	HR							SIZE	HR	
1								16							
2								17							
3								18							
4								19							
5								20							
6								21							
7								22							
8								23							
9								24							
10								25							
11								26							
12								27							
13								28							
14								29							
15								30							

RT - Retag NA - Natural Addition PA - Purchased Addition	N - Negative S - Suspect R - Reactor	I hereby acknowledge receiving a copy of this record which I have examined and find correct. DATE _____ OWNER'S SIGNATURE _____	THIS AUTHORIZATION TO TEST EXPIRES: _____
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