The IDEXX Antibody (Ab) Serological Test for Diagnosing Bovine Tuberculosis (TB) in TB-Affected Cattle Herds

1. Purpose and Background

The caudal fold tuberculin skin test (CFT), the gamma interferon test, and the cervical tuberculin skin test have been the only official tests for *Mycobacterium bovis* for use during the removal phase of test-and-remove management plans for TB-affected cattle herds. Veterinary Services (VS) is hereby approving the IDEXX Ab test and is adding it to the list of approved tests for bovine TB for use during the removal phase of test-and-remove management plans for TB-affected cattle herds.

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 until 4/26/16

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 et seq.
- 7 CFR 371.4
- 9 CFR 77.5

B. References:

- VS Form 6-22, Tuberculosis Test Record, (2/99, page 8)
- VS Form 10-4, Specimen Submission, (8/09, page 6)
- VS Form 10-4A, Continuation Sheet for Specimen Submission, (8/09, page 7)
C. Definitions

**Regulatory veterinarian**– A veterinarian employed by a State, Tribal, or Federal animal health agency.

5. Audience

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

6. Guidance

A. Test Usage

1. The IDEXX Ab test may be used during the removal phase of test-and-remove management plans in TB-affected cattle herds. Other uses will be considered on a case-by-case basis.

2. The IDEXX Ab test is approved for cattle 3 months of age and older.

3. Use of the IDEXX Ab test is at the discretion of the Designated TB Epidemiologist (DTE) or Area Epidemiology Officer (AEO) with approval required by the Regional TB Epidemiologist.

B. Sample Collection, Processing, and Shipping for IDEXX Ab testing at National Veterinary Services Laboratories (NVSL)

1. Regulatory veterinarians will collect blood samples for the IDEXX Ab test. Technicians employed by State or Federal governments and approved by such governments may collect blood for the IDEXX Ab test when directly supervised by State or Federal animal health veterinarians.

2. Blood samples for IDEXX Ab testing must be collected no sooner than 7 days after the CFT is injected and no more than 60 days after the CFT is injected. To ensure rapid identification and removal of potentially infected animals, VS recommends collecting blood samples between 7 and 14 days after the CFT is injected.

C. Collecting Samples

1. Collect blood in 10-ml red top (clot) tubes or 10 ml serum separation tubes.

2. Collect 10 ml of whole blood to obtain 2 ml of serum to be submitted for testing.

3. DO NOT place freshly collected tubes directly on ice.
D. Sample Processing and Handling

1. Allow the blood to clot at room temperature.

2. 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.

3. Label the tubes with official identification (ID) so they can be easily correlated to the animal’s official ID as listed on the submission forms and test charts. This helps laboratory personnel verify all the samples were received and correlate the results to individual animals.

4. Ship serum samples within 24 hours of collection by first- or second-day delivery.

E. Completing Submission Forms and Paperwork

1. Fill out the original VS Form VS 6-22 (Tuberculosis Test Record) accurately and completely with each animal’s official identification (and all other ID), age, breed, and gender and submit to the State veterinarian and Area Veterinarian in Charge within 5 business days of sample collection.

2. 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.)

   a. Official ID (and all other ID), age, breed, and gender for each animal must be included.

   b. Animal ID 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, a spreadsheet or printout of the animals with official ID corresponding to their blood tube numbers can be attached to the VS Form 10-4 in place of the VS Form 10-4A.

   c. A copy of the completed (all above information) VS Form VS 6-22 (Tuberculosis Test Record) with the corresponding blood tube numbers must also be included to show the CFT injection date.

3. Submit the original VS Forms 10-4 and 10-4A and a copy of the VS 6-22 to NVSL as part of the sample submission described in Section 6 (F) of this guidance document.
F. Sample Submission to NVSL

1. 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.

2. 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.

3. Ship the samples along with the completed VS 10-4 (and the 10-4A or spreadsheet as needed) and a copy of the VS 6-22 to NVSL as described in this guidance document.

4. Use overnight or 2-day delivery for shipping the samples. 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; the U.S. Postal Service does not deliver directly to NVSL. Do not ship the samples so they will arrive at NVSL on the weekend or a holiday.

G. Sample Testing

1. Valid serum samples will be tested using the IDEXX Ab test following test kit instructions and internal NVSL standard operating procedures.

2. Results of the IDEXX Ab test will be distributed according to NVSL’s Labware reporting protocols and policies.

3. The AEO or DTE will classify the animals interpreting the CFT and IDEXX antibody tests in parallel.

   a. Animals negative on the CFT and IDEXX Ab test, S/P ratio < 0.3, should be classified as negative.

   b. Animals nonnegative on the CFT or the IDEXX Ab test, S/P ratio ≥ 0.3, must be examined postmortem for evidence of TB.

   c. Animals nonnegative on the CFT and the IDEXX Ab test, S/P ratio ≥ 0.3, must be examined postmortem for evidence of TB.
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


[Signature]
John R. Clifford
Deputy Administrator
UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE
NATIONAL VETERINARY SERVICES LABORATORIES
P.O. BOX 814, 1929 DAYTON AVENUE, AMER, IA 50013
(515) 337-7914

VS Guidance

6702.1
Date 04/26/13

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not 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 0575-0036. 1 hour per response for 0575-0036; 1 hour per response for 0575-0191; and, 833 hours per year for 0575-0212, in reviewing the existing data burden, gathering and maintaining the data needed, and completing and reviewing the collection of information.

OMB Approvals:
0575-0036, 0575-0191, and 0575-0212

SPECIMEN SUBMISSION

| 1. SUBMITTER NAME (marketing Business Name) | 2. NVS SUBMITTER ID | 3. NAME OF OWNER | 4. CHECK (If desirable no owner) |
| 5. PHONE NO. | 6. EMAIL ADDRESS | 7. MAILING ADDRESS (Street, City, State, ZIP Code) | 8. OWNER CITY | 9. STATE/COUNTRY |

| 10. LOCATION OF ANIMALS |
| 11. COUNTY |
| 12. STATE/COUNTRY |

5. PAYMENT METHOD

| USER FEE ACCOUNT NO. | CHECK/MONEY ORDER (Enclosed, payable to USDA in US dollars) | CREDIT CARD |

6. HERD/DROP SIZE

7. NO. IN HERD/DROP AFFECTED

8. NO. IN HERD/DROP DEATH

9. PURPOSE OF SUBMISSION (See instructions for definitions)

| Interstate Movement | Import | TB | Reagent Evaluation |
| Export | FAD/FEP Diagnostic | General Diagnostic | NVS/Intralab |
| Pre-Import | Surveillance | Developmental Research |

10. COLLECTED BY

11. DATE COLLECTED

12. AUTHORIZED BY

14. COUNTRY OF ORIGIN/DESTINATION

15. REFERRAL NUMBER

16. PRESERVATION

| Bone | Blood | Parasite | Serum | Tissue (specify) | Whole Animal | Other (specify) |
| Face | Feed | Plant | Soil | Urine | Fetus |
| Other (specify) | Milk | Serum | Swab (specify) | Water | DNA/RNA |

17. SPECIMENS SUBMITTED (Check applicable item(s))

| Cow | Goose | Pig | Sheep |
| Horse | Turkey | Deer (specify) | Elk |
| Other (specify) | |

18. TOTAL NUMBER OF SPECIMENS SUBMITTED

19. SPECIES OR SOURCE (X ONLY if applicable)

| Cattle | Goat | Horse | Turkey |
| Bin | Fish | Deer (specify) | Environment |
| Other (specify) | Elk | Reagent |

20. NUMBER OF ANIMALS SAMPLED

21. IDENTIFICATION (See instructions <250 samples per form)

<table>
<thead>
<tr>
<th>Sample ID</th>
<th>Animal ID</th>
<th>Breed</th>
<th>Age</th>
<th>Sex</th>
<th>Sample ID</th>
<th>Animal ID</th>
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22. ADDITIONAL DATA (History, clinical signs, postmortem findings, remarks, tentative diagnosis, special instructions. Use additional sheets if necessary.)

23. SIGNATURE OF SUBMITTER AND DATE

X

NVI E USE ONLY

CONDITION | PRIORITY | DISTRIBUTION | RECEIVED BY

US FORM 19-4
AUG 2009
According to the Paperwork Reduction Act of 1995, no persons are 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 0579-0094. 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.

### VS Guidance 6702.1

Date 04/26/13

**COOPERATIVE STATE - FEDERAL TUBERCULOSIS ERADICATION PROGRAM**

**TUBERCULOSIS TEST RECORD**

<table>
<thead>
<tr>
<th>COUNTY</th>
<th>TOWNSHIP OR DISTRICT</th>
<th>REASON FOR TEST</th>
<th>COMPLETE HERD TEST OF ALL ELIGIBLE CATTLE</th>
<th>METHOD OF TEST</th>
<th>RESULTS</th>
<th>CERTIFICATION</th>
<th>REACTOR TAG NO.</th>
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**FARM NO.**

- **REACTOR**
- **ISSUER**
- **SIGNATURE**
- **DATE LISTED**
- **TELEPHONE NO**

**REACTOR TAG NO.**

- **DATE**
- **HOUR**

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**RT - Retag**

**NA - Natural Addition**

**PA - Purchased Addition**

**VS FORM 6-22 (FEB 99)**

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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**