
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 \geq 0.3, must be examined postmortem for evidence of TB.
 - c. Animals nonnegative on the CFT and the IDEXX Ab test, S/P ratio \geq 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
http://www.aphis.usda.gov/animal_health/animal_diseases/tuberculosis/


John R. Clifford
Deputy Administrator

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

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 0579-0090, 0101, and 0212. The time required to complete this information collection is estimated to average 5 hours per response for 0579-0090, 1 hour per response for 0579-0101, and 333 hours per response for 0579-0212, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

OMB Approved
0579-0090, 0579-0101,
and 0579-0212

UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE NATIONAL VETERINARY SERVICES LABORATORIES P.O. BOX 844, 1920 DAYTON AVENUE, AMES, IA 50010 (515) 337-7514		SPECIMEN SUBMISSION			PAGE OF
INSTRUCTIONS: Use a separate form for each species and each owner/broker. See "Instructions for Completing VS Form 10-4" for definitions.					
1. SUBMITTER NAME (including Business Name)		2. NVSL SUBMITTER ID	3. NAME OF OWNER		<input type="checkbox"/> Check if wildlife (no owner)
EMAIL ADDRESS			OWNER CITY	STATE/COUNTRY	
PHONE NO.		FAX NO.	4. LOCATION OF ANIMALS		
MAILING ADDRESS (Street, City, State, ZIP Code)			PREMISES ID		
			COUNTY	STATE/COUNTRY	
5. PAYMENT METHOD					
<input type="checkbox"/> USER FEE ACCOUNT NO.		<input type="checkbox"/> CHECK/MONEY ORDER (Enclosed, payable to USDA in US dollars)		<input type="checkbox"/> CREDIT CARD Number: Exp. Date:	
6. HERD/FLOCK SIZE	9. EXAMINATIONS REQUESTED			10. COLLECTED BY	
7. NO. IN HERD/FLOCK AFFECTED				11. DATE COLLECTED	
8. NO. IN HERD/FLOCK DEAD				12. AUTHORIZED BY	
13. PURPOSE OF SUBMISSION (See instructions for definitions)			14. COUNTRY OF ORIGIN/DESTINATION		
<input type="checkbox"/> Interstate Movement	<input type="checkbox"/> Import	<input type="checkbox"/> TB	<input type="checkbox"/> Reagent Evaluation		
<input type="checkbox"/> Export	<input type="checkbox"/> FAD/EP Diagnostic	<input type="checkbox"/> General Diagnostic	<input type="checkbox"/> NVSL Intralab	15. REFERRAL NUMBER	
<input type="checkbox"/> Pre-Import	<input type="checkbox"/> Surveillance	<input type="checkbox"/> Developmental Research			
16. PRESERVATION					
<input type="checkbox"/> None <input type="checkbox"/> Ice Pack <input type="checkbox"/> Dry Ice <input type="checkbox"/> Formalin <input type="checkbox"/> Borax <input type="checkbox"/> Alcohol <input type="checkbox"/> Other (Specify)					
17. SPECIMENS SUBMITTED ("X" applicable item(s))					18. TOTAL NUMBER OF SPECIMENS SUBMITTED
<input type="checkbox"/> Blood	<input type="checkbox"/> Feces	<input type="checkbox"/> Parasite	<input type="checkbox"/> Serum	<input type="checkbox"/> Tissue (specify)	<input type="checkbox"/> Whole Animal
<input type="checkbox"/> Culture	<input type="checkbox"/> Feed	<input type="checkbox"/> Plant	<input type="checkbox"/> Soil	<input type="checkbox"/> Urine	<input type="checkbox"/> Fetus
<input type="checkbox"/> Extract	<input type="checkbox"/> Milk	<input type="checkbox"/> Semen	<input type="checkbox"/> Swab (specify)	<input type="checkbox"/> Water	<input type="checkbox"/> DNA/RNA
19. SPECIES OR SOURCE ("X" ONLY one)					20. NUMBER OF ANIMALS SAMPLED
<input type="checkbox"/> Cattle	<input type="checkbox"/> Goat	<input type="checkbox"/> Chicken	<input type="checkbox"/> Bison	<input type="checkbox"/> Fish	<input type="checkbox"/> Other (specify)
<input type="checkbox"/> Swine	<input type="checkbox"/> Horse	<input type="checkbox"/> Turkey	<input type="checkbox"/> Deer (specify)	<input type="checkbox"/> Environment	
<input type="checkbox"/> Sheep	<input type="checkbox"/> Donkey	<input type="checkbox"/> Other bird (specify)	<input type="checkbox"/> Elk	<input type="checkbox"/> Reagent	
21. IDENTIFICATION (See instructions <250 samples per form)					
IDENTIFICATION			IDENTIFICATION		
Sample ID	Animal ID	Breed	Age	Sex	Sample ID
					Animal ID
					Breed
					Age
					Sex
22. ADDITIONAL DATA (History, clinical signs, post mortem findings, remarks, tentative diagnosis, special instructions. Use additional sheets if necessary).					
23. SIGNATURE OF SUBMITTER AND DATE					NVSL USE ONLY
X					
NVSL USE ONLY					
CONDITION	PRIORITY	DISTRIBUTION	RECEIVED BY		

VS FORM 10-4
AUG 2009

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

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 0579-0090, 0101, and 0212. The time required to complete this information collection is estimated to average .5 hours per response for 0579-0090, 1 hour per response for 0579-0101, and .333 hours per response for 0579-0212, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.	OMB Approved 0579-0090, 0579-0101, and 0579-0212
UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE VETERINARY SERVICES CONTINUATION SHEET FOR SPECIMEN SUBMISSION	INSTRUCTIONS: Use this form only as a continuation of information on VS Form 10-4 see "Instructions for completing VS Form 10-4".
PAGE: _____ OF _____	

3. NAME OF OWNER/BROKER Check if wildlife (no owner)

OWNER CITY	OWNER STATE/COUNTRY
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15. REFERRAL NUMBER

21. IDENTIFICATION (See instructions)					IDENTIFICATION				
Sample ID	Animal ID	Breed	Age	Sex	Sample ID	Animal ID	Breed	Age	Sex

VS FORM 10-4A
AUG 2009

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

VS Guidance

6702.1

Date 04/26/13

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 0579-0084. The time required to complete this information collection is estimated to average .3 hours per response, including the time for reviewing instructions, search existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

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

COUNTY	TWP	SEC	HERD OWNER'S NAME - LAST	FIRST	MI	PREVIOUS TEST DATE	VET CODE	TOTAL	REA	SUS
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		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.					

COUNTY	TOWNSHIP OR DISTRICT	SEC.	FARM NO.	SUMMARY			PRACTITIONER'S SIGNATURE			TELEPHONE NO			
REASON FOR TEST				COMPLETE HERD TEST OF ALL ELIGIBLE ANIMALS <input type="checkbox"/> YES <input type="checkbox"/> NO NO. ELIGIBLE ANIMALS IN HERD				NEG-ATIVE			PRACTITIONER'S NAME (Please print)		
AREA 1 RETEST 6				KIND OF HERD <input type="checkbox"/> DEER <input type="checkbox"/> ELK <input type="checkbox"/> CATTLE <input type="checkbox"/> BISON <input type="checkbox"/> OTHER				SUS-PECT			INJECTION		
HERD (RE) ACCREDIT 2 TRACING REG. KILL 7				METHOD OF TEST <input type="checkbox"/> CAUDAL FOLD (CFT) <input type="checkbox"/> SNG CERVICAL (CST) (Cervix) <input type="checkbox"/> CERVICAL (CT) (Sovine) <input type="checkbox"/> OTHER				REAC-TOR			DATE		
MILK ORDINANCE 3 TRACING REACTORS 8								TOTAL			REACTORS TAGGED AND BRANDED DATE		
SALE-SHOW 4 TRACING EXPOSED 9											AGREE CODE		
IMPORTED 5 OTHER 10													

1	IDENTIFICATION NUMBER	AGE	BREED	SEX	RESULTS		REACTOR TAG NO.	1	IDENTIFICATION NUMBER	AGE	BREED	SEX	RESULTS		REACTOR TAG NO.
					SIZE	NRS							SIZE	NRS	
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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