



Cervid TB DPP Testing August 2017

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Why Use the Serologic Test?

- ✓ Employ newer, accurate diagnostic test technology
- ✓ Minimizes capture and handling events for animal safety
- ✓ Expected to promote additional cervid TB testing
 - Requested by USAHA and cervid industry
- ✓ Comparable sensitivity and specificity to skin tests

Historical Timeline

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- ❑ Stat-Pak licensed for elk and red deer, 2009
 - ❑ White-tailed and fallow deer, 2010-11
- ❑ 2010 - USAHA resolution - USDA evaluate Stat-Pak as official TB test
- ❑ 2011 – Project to evaluate TB serologic tests in cervids (Cervid Serology Project); USAHA resolution to approve
- ❑ Oct 2012 – USDA licenses the Dual-Path Platform (DPP) secondary test for elk, red deer, white-tailed deer, and fallow deer
 - ❑ Improved specificity compared to Stat-Pak
- ❑ Oct 2012 – USDA approves the Stat-Pak (primary) and DPP (secondary) as official bovine TB tests in elk, red deer, white-tailed deer, fallow deer and reindeer

Recent Actions

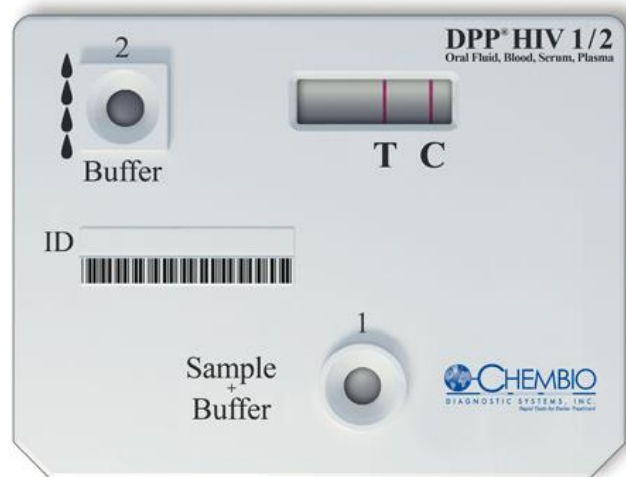
- ❑ Stat-Pak is no longer in production
- ❑ 9 CFR 77.20 has been amended to approve the DPP as official TB program test. An interim rule was published on 9 January 2013
- ❑ USDA APHIS created a Guidance Document (6701.2) to provide instructions for using the tests
 - ❑ https://www.aphis.usda.gov/animal_health/animal_diseases/tuberculosis/downloads/vs_guidance_6701.2_dpp_testing.pdf

Cervid Serology Project Objective

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- ❑ Evaluate TB detection tests for official bovine tuberculosis (TB) program use in captive and free-ranging cervids
 - ❑ North American elk (*Cervus canadensis*)
 - ❑ White-tailed deer (*Odocoileus virginianus*)
 - ❑ Reindeer (*Rangifer tarandus*)
- ❑ Primary/screening test **AND** Secondary Test:
 - ❑ Dual Path Platform (DPP)
 - Rapid immunochromatographic lateral-flow serology test
 - Detect antibodies to *M. tuberculosis* and *M. bovis* proteins

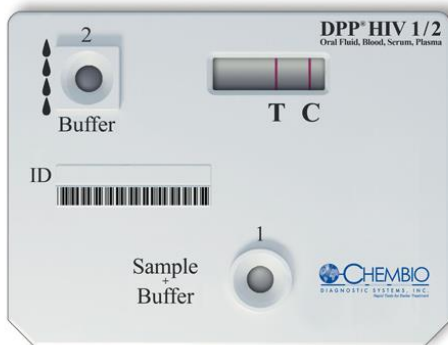
ChemBio Diagnostic Systems, Inc. Test Cassette



Dual-Path Platform (DPP)

Detect antibodies to *M. tuberculosis* and *M. bovis* proteins

Need for a Secondary Test



DPP
1° and 2° Test



CCT is not an appropriate
secondary test.

- Cell-mediated versus humoral responses







Necropsy as
a
confirmatory
test




Licensure vs. Official Program Approval

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Licensure

-  Responsibility of the Center for Veterinary Biologics (CVB)
-  Tests are evaluated for sensitivity, specificity, ruggedness, repeatability, and suitability
-  Includes review of manufacturing process and test labels
-  Details are in VS Memo 800.73

Official TB program approval

-  Focuses on sensitivity, specificity, and comparison to currently approved program tests
-  Collaborative effort with CVB, Regions, NVSL, CEAH, ARS, States
-  VS Memo 552.40

Cervid Serology Project

- ❑ Evaluated ChemBio CervidTB DPP
 - ❑ Licensed for elk, red deer, fallow deer, and white-tailed deer
- ❑ 1,783 cervids tested
 - ❑ Elk
 - ❑ White-tailed deer
 - ❑ Reindeer

Jeffrey T. Nelson, Kathleen A. Orloski, Audra L. Lloyd, Mark Camacho, Mark A. Schoenbaum, Suelee Robbe-Austerman, Bruce V. Thomsen, and S. Mark Hall: *Evaluation of Serodiagnostic Assays for Mycobacterium bovis Infection in Elk, White-Tailed Deer, and Reindeer in the United States*, Veterinary Medicine International Volume 2012 (2012)
<http://www.hindawi.com/journals/vmi/2012/563293/>



REMEMBER - SENSITIVITY VS. SPECIFICITY?

- Sensitivity:
 - How likely a test will correctly identify truly diseased animals

(In low-TB prevalence populations like cervids, a negative result suggests with a high probability that the animal is truly negative)
- Specificity:
 - How likely a test will correctly identify truly non-diseased animals

SCT/CCT* and Stat-Pak/DPP Series Specificity

	SCT/CCT (95% CI)	Stat-Pak/DPP (95% CI)
Elk**	90.4% (87.4 – 92.9)	100% (98.3 – 100.0)
Deer**	87.1% (84.5-89.4)	99.3% (96.7 – 99.3)
Reindeer	Not available	98.4% (95.3 – 99.7)

*Reference by Norden, et al (1996)

**The Stat-Pak/DPP results are significantly different from the SCT/CCT results, $p < 0.05$.

SAMPLE COLLECTION



Sample Collection (Cont'd)

- Who may collect and submit serum samples for CervidTB DPP testing in Wisconsin?
 - Only Accredited Veterinarians who complete the TB Certification through DATCP
 - Veterinarians wanting to become TB certified to submit samples for DPP testing, MUST read this PowerPoint presentation, the USDA APHIS guidance document, attend a certification meeting, and self-report upon completion of requirements.

Sample Collection (Cont'd)

- ❑ Specimen to be tested is serum
- ❑ Collect blood in 10 ml Red Top tube or serum separator tube
- ❑ Collect a minimum of 10 ml blood
- ❑ If testing for brucellosis, you **MUST** collect an additional tube of blood to be submitted to an approved brucellosis testing laboratory.



Sample Processing and Handling

- ❑ Allow blood to clot at room temperature
- ❑ Centrifuge sample and remove serum from clot; place serum in a new clean tube
- ❑ Refrigerate serum samples; **Do Not Freeze**
- ❑ Label tube with sample number and official animal ID
- ❑ Keep samples refrigerated until shipped

Sample Processing and Handling (Cont'd)

- ❑ Refrigerated serum should be shipped to NVSL within 48 hours
- ❑ Do not ship to arrive at NVSL over the weekend
- ❑ Excessive hemolysis in the serum may make samples untestable

Sample Submission to NVSL

- ❑ Currently NVSL is the only testing lab
- ❑ Submission form is a VS Form 10-4/10-4a
- ❑ Record tube/sample number and official ID for each animal on the form
- ❑ Inventory lists, spreadsheets, or VS Form 6-22 (TB test record) may be attached to the VS 10-4/10-4a in lieu of listing each animal on the form

Sample Submission to NVSL (cont'd)

- VS Form 10-4/10-4a can be downloaded at
http://www.aphis.usda.gov/animal_health/lab_info_services/forms_publications.shtml
- OPTIONAL: TB DPP specimen submission kits are available from NVSL for \$42.50 by:
 - Specimen kits include supplies for sampling and submissions (shipping labels, shipping box, etc.)
 - Downloading, completing, and submitting the order form at:
http://www.aphis.usda.gov/library/forms/pdf/VS_Form4_9.pdf
- You ARE NOT required to order the specimen kits
- You can submit samples without requesting the kit

Sample Submission to NVSL (cont'd)

- ❑ Cost of submission/shipping kit also includes the cost of return shipping to NVSL
- ❑ Ship specimens by next-day or 2nd-day delivery
- ❑ Ship UPS or FedEx

Test Results

- Results are sent to testing veterinarian, usually less than a week after submission. A copy sent to State and Federal Animal Health Officials.
- Please be advised that recent test kit shortages have caused lengthy delays in test completion and animal movement.
- Until test kits are available, skin testing is recommended.
- Contact NVSL to set up account and payment information at 515-337-6200. For specifics on testing contact Dr. David Kinker (Head of Serology) 515-337-7963

For additional information

- Contact Wisconsin DATCP **(608) 224-4872**
 - Instructions and forms
 - VS Form 10-4, 10-4a, and 6-22 (TB test record)
 - Information for enrolling herds in the TB Qualified or Accredited Herd program
 - TB certification training for veterinarians

FAQs

- Q. Can the DPP be used on any species of cervid?
- A. The DPP test is approved for use in elk, red deer, white-tailed deer, fallow deer, and reindeer. DPP IS NOT APPROVED FOR USE IN MULE DEER OR SIKA DEER

FAQs (cont'd)

- Q. What is the advantage of using the DPP test over the single cervical skin test?
- A. The cervids only have to be handled one time so a blood sample can be collected versus two handling events for the skin tests – one for tuberculin injection and a second for interpreting the tests.

FAQs (cont'd)

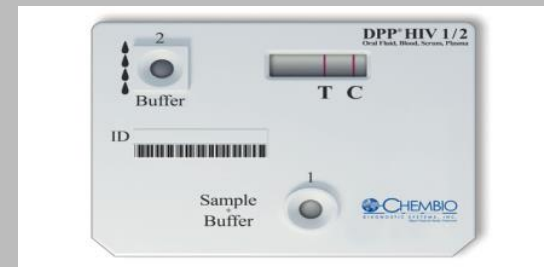
- Q. If I am also testing the animals for brucellosis, may I just collect one blood sample and submit it to NVSL?
- A. No. When also testing for brucellosis, an additional tube of blood must be collected and submitted to an approved brucellosis testing laboratory accompanied by a properly completed submission form.

FAQs (cont'd)

- Q. What happens if the DPP test is positive?
- A. If the DPP test has a positive result, the animal is classified as a TB suspect and must undergo additional testing to determine its status
 - A second serum sample collected >30 days from the initial sample may be collected by a regulatory veterinarian for a second DPP test.
 - If second DPP is positive, the animal is classified as a reactor and must be sacrificed for further TB testing
 - Alternatively, owners may elect to sacrifice a suspect animal without indemnity for confirmatory TB testing

Samples Testing Positive on Initial DPP Test

- Animals testing positive on initial DPP are considered suspects
- A second serum sample is collected by regulatory veterinarian >30 days following initial test



FAQs (cont'd)

- Q. Can the DPP test be run on cervids that respond to the single cervical skin test?
- A. No. Cervids classified as responders (positive) on the single cervical skin test must be retested using the comparative cervical skin test. Likewise, cervids positive on the DPP test cannot be retested using skin testing.

FAQs (cont'd)

- Q. If an animal was recently skin tested for TB, can I perform the DPP test?
- A. DPP test may be performed for sale or export purposes at any time unless the recent skin test was suspect or responder.

VS10-4a
(Continuation Sheet)

FORM APPROVED-OCTOBER 1978-DS-1036

U.S. DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE
NATIONAL VETERINARY DIAGNOSTIC LABORATORIES
7-15, NEW Bldg., 1500 SAWYER AVENUE
AMES, IOWA 50010
(515) 281-0121

INSTRUCTIONS: Use a separate form for each species and each new browser. See instructions for completing VS FORM 1-14 for definitions (lines 12) and instructions for identification(s) 2D.

PAGE

OF

SPECIMEN SUBMISSION

2. NAME OF OWNER

1. NAME OF SUBMITTER

Mailing Address (Street, City, State and Zip Code)

CITY

STATE

3. LOCATION OF ANIMALS

COUNTRY

PLANTS

Phone No.

FAX No.

4. PAYMENT METHOD: (*If applicable item and provide information)

NO/VISA NO.

EXP.

DATE

☐ CASH OR BY ACCOUNT NO.

☐ CHECK/NOTE OTHER ENCLOSURE MADE payable to "USDA" in U.S. Dollars

5. SEND/VOICE RATES

6. EXAMINATIONS REQUESTED

9. COLLECTED BY

7. NO. IN IMMEDIATE APPLICABLE

11. DATE COLLECTED

8. NO. IN REFERENCE CASE

13. AUTHENTICATED BY

12. NUMBER OF SPECIMENS (*If one instruction for definition) ☐ Intersperse ☐ Movement

☐ General Virology ☐ Serology/Blood ☐ Immunology

☐ FPD/R Diagnostic ☐ Developmental Research ☐ Parasitology

☐ Virus Isolation Diagnostic ☐ Reagent Evaluation ☐ TB

14. COUNTRY OF ORIGIN/DESTINATION

16. SUPPLEMENTAL NOTES

15. PRESERVATION (*If applicable to type)

☐ None ☐ Dry Pack ☐ Dry Ice ☐ Formalin ☐ Borax ☐ Alcohol ☐ Other (specify) _____

17. SPECIMENS CONTAINER (*If applicable to weight)

17. TOTAL NUMBER OF SPECIMENS SUBMITTED

☐ Blood ☐ Plasma ☐ Paraffin ☐ Serum ☐ Tissue ☐ Whole Bird

☐ Clot ☐ Culture ☐ Fluid ☐ Soil ☐ Urine ☐ Puss

☐ Extract ☐ Milk ☐ Semen ☐ Sweat ☐ Water ☐ Other (specify) _____

18. SPECIES ON BOX (*If one)

19. NUMBER OF ANIMALS AVAILABLE

☐ Canine ☐ Horse ☐ Reagent ☐ Chicken ☐ Bison ☐ Deer ☐ Other (specify) _____

☐ Cat ☐ Goat ☐ Turkey ☐ Dog ☐ Elk

☐ Sheep ☐ Donkey ☐ Pet Bird ☐ Cat ☐ Fish

20. IDENTIFICATION (See instructions)

IDENTIFICATION (See instructions)

Sample ID	Animal ID/Owner	Age	Sex	Sample ID	Animal ID/Owner	Age	Sex
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21. ADDITIONAL DATA (History, clinical signs, post mortem findings, remarks, tentative diagnosis, etc. Use additional sheets if necessary.)

SLR NO:

NO Formulin Boxes:

NR Other Boxes:

2. ALIQUOTS OF SUBMITTER AND DATE

CONDITION	PRIORITY	ANALYSIS USES	DISTRIBUTION	RECEIVED BY
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VVEL ACCESSION NO

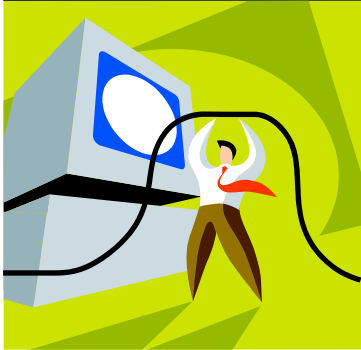
VS FORM 1-14 (JULY 97)

[illegible][illegible]

MIM Software

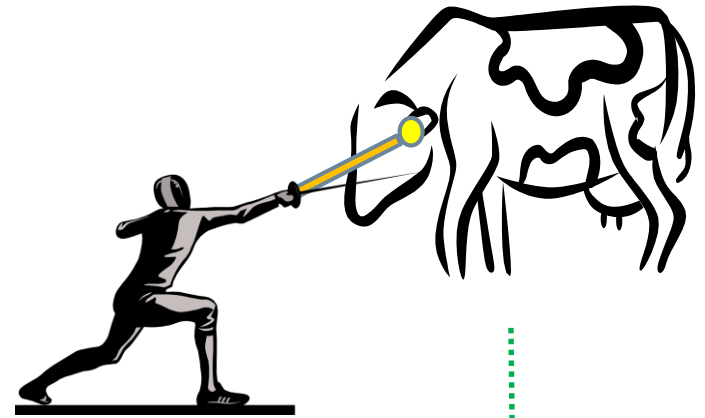
- Works with PDA
- Stand alone software for Desktop
- Create:
 - ❖ TB Test Charts (6-22 A & B)
 - ❖ Brucellosis Vaccination Charts
 - ❖ Brucellosis testing
 - Spreadsheets to submit samples to WVDL
 - » Contact WVDL @ 608-262-5432
 - ❖ Exportable Spreadsheets of identification of animals

DC 305



ID, Age, Breed, Sex

Farm Name, Vet Info,
Testing Info



MIM Software In Computer

TB Form

PDA w/MIM

Who Can Collect DPP Test Samples?

Do not conduct any TB tests in Wisconsin until you are licensed, accredited, TB certified, and complete additional certification for cervid DPP testing in Wisconsin

Questions Contact DATCP

608-224-4872



Acknowledgements

- USDA APHIS VS Cervid Health Staff
 - Owen Henderson, DVM
 - Nancy Hannaway, DVM
 - Crystal Climer, veterinary student extern