Cervid TB DPP Testing
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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
<table>
<thead>
<tr>
<th>Year</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>2009</td>
<td>Stat-Pak licensed for elk and red deer, 2009</td>
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<tr>
<td></td>
<td>- White-tailed and fallow deer, 2010-11</td>
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<tr>
<td>2010</td>
<td>USAHA resolution - USDA evaluate Stat-Pak as official TB test</td>
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<tr>
<td>2011</td>
<td>Project to evaluate TB serologic tests in cervids (Cervid Serology Project); USAHA resolution to approve</td>
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<tr>
<td>2012</td>
<td>USDA licenses the Dual-Path Platform (DPP) secondary test for elk, red deer, white-tailed deer, and fallow deer</td>
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<td></td>
<td>Improved specificity compared to Stat-Pak</td>
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<tr>
<td>2012</td>
<td>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</td>
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</tbody>
</table>
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
### Cervid Serology Project Objective

- 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

- CCT is not an appropriate secondary test.
  - Cell-mediated versus humoral responses

DPP 1° and 2° Test

Necropsy as a confirmatory test
Licensure vs. Official Program Approval

- **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

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

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


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

- **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:

- You ARE NOT required to order the specimen kits
- You can submit samples without requesting the kit
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
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**
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.
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.
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.
Animals testing positive on initial DPP are considered suspects.

A second serum sample is collected by regulatory veterinarian >30 days following initial test.
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.
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.
Forms

VS 10-4
(Continuation Sheet)

VS10-4a

VS 6-22
(TB test record)
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

MIM Software In Computer

ID, Age, Breed, Sex

Farming Name, Vet Info,
Testing Info

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