This report has been submitted: 2014-01-29 18:54:00

| Name of disease (or topic) for which you are a designated OIE Reference Laboratory: | Chronic wasting disease |
| Address of laboratory: | National and OIE Reference Laboratory Canadian Food Inspection Agency 3851 Fallowfield Road P.O. Box 11300 Station H, Nepean Ontario K2H 8P9 CANADA |
| Tel.: | +1-343-212-0257 |
| Fax: | +1-343-212-0217 |
| e-mail address: | aru.balachandran@inspection.gc.ca |
| website: | |
| Name (including Title) of Head of Laboratory (Responsible Official): | Karen Jesset Director, Atlantic and Ontario Laboratory Network. |
| Name (including Title and Position) of OIE Reference Expert: | Dr. Aru Balachandran Veterinary Science Advisor; Head, National and OIE Reference Laboratory for Scrapie and CWD |
| Which of the following defines your laboratory? Check all that apply: | Governmental |
**ToR: To use, promote and disseminate diagnostic methods validated according to OIE Standards**

1. Did your laboratory perform diagnostic tests for the specified disease/topic for purposes such as disease diagnosis, screening of animals for export, surveillance, etc.? (Not for quality control, proficiency testing or staff training)

   Yes

<table>
<thead>
<tr>
<th>Diagnostic Test</th>
<th>Indicated in OIE Manual (Yes/No)</th>
<th>Total number of test performed last year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indirect diagnostic tests</td>
<td></td>
<td>Nationally Internationally</td>
</tr>
<tr>
<td>*</td>
<td>*</td>
<td>*</td>
</tr>
<tr>
<td>Direct diagnostic tests</td>
<td></td>
<td>Nationally Internationally</td>
</tr>
<tr>
<td>TeSeE ELISA</td>
<td>Yes</td>
<td>1429</td>
</tr>
<tr>
<td>Immunohistochemistry</td>
<td>Yes</td>
<td>268</td>
</tr>
<tr>
<td>TeSeE Confirm. Western Blot</td>
<td>Yes</td>
<td>143</td>
</tr>
<tr>
<td>Genotyping Elk, White-tailed Deer</td>
<td>Yes</td>
<td>201</td>
</tr>
</tbody>
</table>

**ToR: To develop reference material in accordance with OIE requirements, and implement and promote the application of OIE Standards. To store and distribute to national laboratories biological reference products and any other reagents used in the diagnosis and control of the designated pathogens or disease.**

2. Did your laboratory produce or supply imported standard reference reagents officially recognised by the OIE?

   No

3. Did your laboratory supply standard reference reagents (non OIE-approved) and/or other diagnostic reagents to OIE Member Countries?

   No

4. Did your laboratory produce vaccines?

   No

5. Did your laboratory supply vaccines to OIE Member Countries?
ToR: To develop, standardise and validate, according to OIE Standards, new procedures for diagnosis and control of the designated pathogens or diseases

6. Did your laboratory develop new diagnostic methods validated according to OIE Standards for the designated pathogen or disease?

Yes

7. Did your laboratory develop new vaccines according to OIE Standards for the designated pathogen or disease?

No

<table>
<thead>
<tr>
<th>Name of the new test or diagnostic method or vaccine developed</th>
<th>Description and References (Publication, website, etc.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Evaluation of immuno-PCR for the detection of ultra-low levels of pathologic prion protein</td>
<td>Current testing methods for transmissible spongiform encephalopathies (TSEs) involve the detection of abnormal prion protein (PrPTSE) by immunoochemical methods as the hallmark of infection. Novel technologies that combine higher sensitivity detection with fast, robust, and cost-efficient protocols hold promise for future diagnostic and research applications. Work is in progress to increase the analytical sensitivity of immuno-PCR relative to currently approved test methods and to investigate the applicability for pre-clinical diagnosis and environmental testing.</td>
</tr>
<tr>
<td>Cervid genotyping for CWD resistance/susceptibility</td>
<td>Susceptibility of cervids to CWD infection has been shown to be associated with polymorphisms in the host prion protein gene. Work is in progress to validate recently developed high throughput methods to detect the allelic variants of elk, white-tailed deer at codons 132, and 96 respectively. This information may be used as a component of regulatory control and eradication programs. Measures of sensitivity and specificity do not apply as per diagnostic testing of a disease/infectious agents since this test provides the genotype of a particular animal and not infected/non-infected status. The method used to detect these allelic variants has undergone partial Level 1 formal validation in accordance with the OIE Validation Template (calibration, repeatability studies).</td>
</tr>
<tr>
<td>Rodent bioassay for the quantification and characterization of prion infectivity</td>
<td>Studies utilizing our rodent bioassay platform continue for characterising Canadian scrapie and CWD strain variability, investigating species barriers to infectivity and determining infectivity titres from a variety of matrices. Collaborative research projects are ongoing investigating the utility and validity of novel low-level detection methods such as PMCA and immuno-PCR as well as the reductions of infectivity associated with composting infectious tissues. Research continues towards defining the distribution of infectivity in CWD-infected cervids and if CWD is capable of overcoming a range of species barriers. The rodent bioassay has demonstrated diagnostic utility in discriminating between CWD, atypical and classical scrapie and BSE in diagnostic samples.</td>
</tr>
</tbody>
</table>

ToR: To provide diagnostic testing facilities, and, where appropriate, scientific and technical advice on disease control measures to OIE Member Countries

8. Did your laboratory carry out diagnostic testing for other OIE Member Countries?
9. Did your laboratory provide expert advice in technical consultancies on the request of an OIE Member Country?

Yes

<table>
<thead>
<tr>
<th>Name of the OIE Member Country receiving a technical consultancy</th>
<th>Purpose</th>
<th>How the advice was provided</th>
</tr>
</thead>
<tbody>
<tr>
<td>PERU</td>
<td>OIE laboratory twining proposal formulation</td>
<td>Oral and written communication.</td>
</tr>
</tbody>
</table>

ToR: To carry out and/or coordinate scientific and technical studies in collaboration with other laboratories, centres or organisations

10. Did your laboratory participate in international scientific studies in collaboration with OIE Member Countries other than the own?

Yes

<table>
<thead>
<tr>
<th>Title of the study</th>
<th>Duration</th>
<th>Purpose of the study</th>
<th>Partners (Institutions)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Investigating cross-species transmission of Chronic Wasting Disease (CWD).</td>
<td>Ongoing</td>
<td>To characterize South Korean and Canadian CWD strains using cervid and transgenic mouse models.</td>
<td>Dr. Yoon-Hee Lee, Veterinary Researcher from the Animal, Plant and Fisheries Quarantine and Inspection Agency in South Korea.</td>
</tr>
</tbody>
</table>

ToR: To collect, process, analyse, publish and disseminate epizootiological data relevant to the designated pathogens or diseases

11. Did your Laboratory collect epizootiological data relevant to international disease control?

Yes

12. Did your laboratory disseminate epizootiological data that had been processed and analysed?

Yes

13. What method of dissemination of information is most often used by your laboratory? (Indicate in the appropriate box the number by category)

a) Articles published in peer-reviewed journals: 6
   Biodegradation of specified risk material and fate of scrapie prions in compost.
Experimental chronic wasting disease in wild type VM mice.
Lee YH, Sohn HJ, Kim MJ, Kim HJ, Park KJ, Lee WY, Yun EI, Tark DS, Choi YP, Cho IS, Balachandran A.

Intranasal inoculation of white-tailed deer (Odocoileus virginianus) with lyophilized chronic wasting disease prion particulate complexed to montmorillonite clay.

Oxidation of Methionine 216 in Sheep and Elk Prion Protein Is Highly Dependent upon the Amino Acid at Position 218 but Is Not Important for Prion Propagation.

Kinetics of ozone inactivation of infectious prion protein.

Strain characterization of the Korean CWD cases in 2001 and 2004.
Lee YH, Sohn HJ, Kim MJ, Kim HJ, Lee WY, Yun EI, Tark DS, Cho IS, Balachandran A.

b) International conferences: 2
Chronic wasting disease infectivity in peripheral tissues of white-tailed deer (Odocoileus virginianus).


c) National conferences: 0

d) Other:
(Provide website address or link to appropriate information) 0

ToR: To provide scientific and technical training for personnel from OIE Member Countries
To recommend the prescribed and alternative tests or vaccines as OIE Standards

14. Did your laboratory provide scientific and technical training to laboratory personnel from other OIE Member Countries?
No
ToR: To maintain a system of quality assurance, biosafety and biosecurity relevant for the pathogen and the disease concerned

15. Does your laboratory have a Quality Management System certified according to an International Standard?
Yes

<table>
<thead>
<tr>
<th>Quality management system adopted</th>
</tr>
</thead>
<tbody>
<tr>
<td>ISO 17025</td>
</tr>
</tbody>
</table>

16. Is your laboratory accredited by an international accreditation body?
Yes

<table>
<thead>
<tr>
<th>Test for which your laboratory is accredited</th>
<th>Accreditation body</th>
</tr>
</thead>
<tbody>
<tr>
<td>Detection of spinal cord in beef contaminated meat products by H&amp;E, and GFAP IHC staining</td>
<td>SCC</td>
</tr>
<tr>
<td>Detection of abnormal prion protein for BSE, Scrapie and CWD Diagnosis by Bio-Rad ELISA</td>
<td>SCC</td>
</tr>
<tr>
<td>Genotyping Sheep for Scrapie Susceptibility/Resistance by Real-Time PCR</td>
<td>SCC</td>
</tr>
<tr>
<td>Confirmation of prion protein specific for scrapie and CWD using Bio-Rad’s TeSeE Western Blot Kit</td>
<td>SCC</td>
</tr>
<tr>
<td>Immunohistochemical detection of prion protein in animal TSEs: Scrapie in Sheep and Goats</td>
<td>SCC</td>
</tr>
<tr>
<td>Immunohistochemical detection of prion protein in animal TSEs: Chronic wasting disease (CWD) in Deer and Elk</td>
<td>SCC</td>
</tr>
</tbody>
</table>

17. Does your laboratory maintain a “biorisk management system” for the pathogen and the disease concerned?
Yes

(See Manual of Diagnostic Tests and Vaccines for Terrestrial Animals 2012, Chapter 1.1.3 or Manual of Diagnostic Tests for Aquatic Animals 2012, Chapter 1.1.1)

ToR: To organise and participate in scientific meetings on behalf of the OIE

18. Did your laboratory organise scientific meetings on behalf of the OIE?
No

19. Did your laboratory participate in scientific meetings on behalf of the OIE?
No

ToR: To establish and maintain a network with other OIE Reference Laboratories designated for the same pathogen or disease and organise regular inter-laboratory proficiency testing to ensure comparability of results

20. Did your laboratory exchange information with other OIE Reference Laboratories designated for the same pathogen or disease?

No

21. Was your laboratory involved in maintaining a network with OIE Reference Laboratories designated for the same pathogen or disease by organising or participating in proficiency tests?

No

22. Did your laboratory collaborate with other OIE Reference Laboratories for the same disease on scientific research projects for the diagnosis or control of the pathogen of interest?

Yes

<table>
<thead>
<tr>
<th>Title of the project or contract</th>
<th>Scope</th>
<th>Name(s) of relevant OIE Reference Laboratories</th>
</tr>
</thead>
<tbody>
<tr>
<td>Investigating cross-species transmission of CWD</td>
<td>To define circulating CWD strains in Korea and Canada</td>
<td>QIA, Republic of Korea for CWD</td>
</tr>
</tbody>
</table>

ToR: To organise inter-laboratory proficiency testing with laboratories other than OIE Reference Laboratories for the same pathogens and diseases to ensure equivalence of results

23. Did your laboratory organise or participate in inter-laboratory proficiency tests with laboratories other than OIE Reference Laboratories for the same disease?

Yes

Note: See Interlaboratory test comparisons in: Laboratory Proficiency Testing at:
http://www.oie.int/en/our-scientific-expertise/reference-laboratories/proficiency-testing see point 1.3

<table>
<thead>
<tr>
<th>Purpose for inter-laboratory test comparisons¹</th>
<th>No. participating laboratories</th>
<th>Region(s) of participating OIE Member Countries</th>
</tr>
</thead>
<tbody>
<tr>
<td>Validation of IHC testing</td>
<td>3</td>
<td>☐Africa ☐Americas ☐Asia and Pacific ☐Europe ☐Middle East</td>
</tr>
</tbody>
</table>
ToR: To place expert consultants at the disposal of the OIE

24. Did your laboratory place expert consultants at the disposal of the OIE?

No

25. Additional comments regarding your report: