WOAH Collaborative Centre Reports Activities 2023

Activities in 2023

This report has been submitted: 21 juin 2024 06:07

Centre Information

<table>
<thead>
<tr>
<th>Title of WOAH Collaborating Centre</th>
<th>Diagnostic Test Validation Science in the Asia Pacific Region</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address of WOAH Collaborating Centre</td>
<td>Australian Centre for Disease Preparedness (ACDP), CSIRO, 5 Portarlington Rd, 3219 East Geelong, Vic, Australia</td>
</tr>
<tr>
<td>Tel:</td>
<td>+61 3 5227 5000</td>
</tr>
<tr>
<td>E-mail address:</td>
<td><a href="mailto:axel.colling@csiro.au">axel.colling@csiro.au</a></td>
</tr>
<tr>
<td>Website:</td>
<td><a href="https://www.csiro.au/en/about/facilities-collections/acdp">https://www.csiro.au/en/about/facilities-collections/acdp</a></td>
</tr>
</tbody>
</table>

Name Director of Institute (Responsible Official): Dr Debbie Eagles

Name (including Title and Position) of Head of the Collaborating Centre (WOAH Contact Point): Dr Axel Colling

Name of the writer: Dr Axel Colling

TOR1 AND 2: SERVICES PROVIDED

1. Activities as a centre of research, expertise, standardisation and dissemination of techniques within the remit of the mandate given by WOAH

<table>
<thead>
<tr>
<th>Category</th>
<th>Title of activity</th>
<th>Scope</th>
</tr>
</thead>
<tbody>
<tr>
<td>Disease control (true)</td>
<td>Diagnostic Test Validation Science in the Asia-Pacific Region</td>
<td>The CC is an international scientific consortium made of the Australian Centre for Disease Preparedness (ACDP, CSIRO), Faculty of Veterinary and Agriculture Science, Uni Melbourne (FVAS) and EpiCentre at Massey University, NZ and experts from other national and international research organisations, which combines expertise in diagnostics, epidemiology and modelling. The Centre’s mission is to generate new knowledge and techniques that improve the use and interpretation of diagnostic tests used in human and animal health and to promote dissemination of that knowledge to the wider medical and veterinary communities.</td>
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</tbody>
</table>

TOR3: HARMONISATION OF STANDARDS

2. Proposal or development of any procedure that will facilitate harmonisation of international regulations applicable to the main focus area for which you were designated

<table>
<thead>
<tr>
<th>Proposal title</th>
<th>Scope/Content</th>
<th>Applicable area</th>
</tr>
</thead>
</table>

WOAH Collaborative Centre Reports Activities 2023
Assist WOAH to review its process for the validation, certification and registration of diagnostic kits.

Published chapter 1.1.6. “Validation of diagnostic assays for infectious diseases in terrestrial animals” in Terrestrial Manual


Review of chapter 2.2.6. “Reference samples” in Terrestrial Manual


“Diagnostic validation of Point-of-Care Tests (POCT) tests for WOAH-listed viral diseases using field samples” in preparation.

“Principles and methods of validation of diagnostic assays for infectious diseases of aquatic animals” in preparation.

Evaluation of Point of Care (POC) Tests for White Spot Syndrome Virus (WSSV)

Evaluation of antibody detection ELISA for LSD in Australian cattle and buffaloes.

In exercising your activities, have you identified any regulatory research needs relevant for WOAH?
Research need: 1

Please type the Research need: A chapter which describes the steps for verification of diagnostic tests would be useful to help with the standardization of this process.

Relevance for WOAH Disease Control, Standard Setting, Facilitation of international collaboration,

Relevance for the Codes or Manual Code, Manual,

Field: Epidemiology and Surveillance, Diagnostics, Vaccines,

Animal Category: Terrestrial, Aquatic,

Disease:

Kind of disease (Zoonosis, Transboundary diseases): Zoonosis, Transboundary diseases,

If any, please specify relevance for Codes or Manual, chapter and title

(e.g. Terrestrial Manual Chapter 2.3.5 - Minimum requirements for aseptic production in vaccine manufacture)

Answer: The chapter would fit under section 2.2. validation of diagnostic tests.

Notes:

Answer: Two new chapters a) for the validation of POCT and b) for the validation of diagnostic tests for infectious diseases of aquatic animals are in preparation. Standardization and references for the validation of POCT is becoming a pressing need as the demand and use of these tests is increasing rapidly. A separate validation chapter (other than 1.1.6. from the terrestrial manual) for the aquatic manual is needed because of the different purposes and testing environments of aquatic species.

4. Did your Collaborating Centre maintain a network with other WOAH Collaborating Centres (CC), Reference Laboratories (RL), or organisations designated for the same specialty, to coordinate scientific and technical studies?

Yes

<table>
<thead>
<tr>
<th>Name of WOAH CC/RL/other organisation(s)</th>
<th>Location</th>
<th>Region of networking Centre</th>
<th>Purpose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Faculty of Veterinary and Agricultural Sciences (FVAS) The University of Melbourne Parkville, Victoria 3010, Australia Tel: +61 3 9035 4114 Fax: +61 3 8344 7374 <a href="mailto:mark.stevenson1@unimelb.edu.au">mark.stevenson1@unimelb.edu.au</a> URL: <a href="http://fvas.unimelb.edu.au">http://fvas.unimelb.edu.au</a></td>
<td>Melbourne, Australia</td>
<td>Africa Americas Asia and Pacific Europe</td>
<td>Quantitative and spatial epidemiology, modelling of infectious diseases and analysis of complex datasets including the use and development of latent class models to validate diagnostics for a range of endemic pathogens.</td>
</tr>
<tr>
<td>EpiCentre, School of Veterinary Science, Massey University Private Bag 11-222 Palmerston North 4412, New Zealand Tel: +64 6 350 5270 Fax: +64 6 355 7955 <a href="mailto:C.Heuer@massey.ac.nz">C.Heuer@massey.ac.nz</a> URL: <a href="http://epicentre.massey.ac.nz">http://epicentre.massey.ac.nz</a></td>
<td>Palmerston North, New Zealand</td>
<td>Africa Americas Asia and Pacific</td>
<td>Veterinary epidemiology, statistics and test validation.</td>
</tr>
<tr>
<td>Atlantic Veterinary College, University of Prince Edward Island 50 University Ave. Charlottetown, Prince Edward Island, C1A 4P3 <a href="mailto:iagardner@upei.ca">iagardner@upei.ca</a>; Mobile: 902-394-6823</td>
<td>Prince Edward Island, Canada</td>
<td>Americas Asia and Pacific Europe</td>
<td>Veterinary epidemiology, statistics and test validation. Review of chapters 1.1.6., 2.2.1.-2.2.8. Produce a new chapter titled: &quot;Diagnostic validation of point-of-care (PoC) tests for WOAH-listed viral diseases using field samples&quot; and submit to WOAH for review. Review of WOAH's validation, certification and registration process.</td>
</tr>
</tbody>
</table>
## TOR4 AND 5: NETWORKING AND COLLABORATION

5. Did your Collaborating Centre maintain a network with other WOAH Collaborating Centres, Reference laboratories, or organisations in other disciplines, to coordinate scientific and technical studies?

No

## TOR6: EXPERT CONSULTANTS

6. Did your Collaborating Centre place expert consultants at the disposal of WOAH?

Yes

<table>
<thead>
<tr>
<th>NAME OF EXPERT</th>
<th>KIND OF CONSULTANCY</th>
<th>SUBJECT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dr Axel Colling</td>
<td>WOAH CC</td>
<td>Assist WOAH to review its process for the validation, certification and registration of diagnostic kits.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Workshops on diagnostic test validation and result interpretation</td>
</tr>
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WOAH Collaborative Centre Reports Activities 2023
Dr Axel Colling and Dr Nagendra Singanallur
WOAH CC
interpretation (see 8).

Dr Nagendra Singanallur
WOAH CC Chair of validation panel
Evaluation of 2 dossiers submitted to WOAH SRDK for certification of validation as per the WOAH guidelines.

**TOR7: SCIENTIFIC AND TECHNICAL TRAINING**

7. Did your Collaborating Centre provide advice/services to requests from Members in your main focus area?
   Yes
   *International Atomic Energy Agency (IAEA) Regional Technical Cooperation Project for Latin America, (RLA 5085). Strengthening the Capacity of Official Laboratories for Monitoring and Response to an Outbreak of Priority Animal and Zoonotic Diseases (ARCAL CLXXIV), Workshop Diagnostic test validation and result interpretation, Seibersdorf Laboratories, Austria, 14-18 August 2023. 18 participants from Latin America and 2 ACDP staff organised and facilitated the workshop (please also see 8).*

8. Did your Collaborating Centre provide scientific and technical training, within the remit of the mandate given by WOAH, to personnel from WOAH Members?
   Yes
   a) Technical visits: 4
   b) Seminars: 1
   c) Hands-on training courses: 3
   d) Internships (>1 month): 2

<table>
<thead>
<tr>
<th>TYPE OF TECHNICAL TRAINING PROVIDED (A, B, C OR D)</th>
<th>CONTENT</th>
<th>COUNTRY OF ORIGIN OF THE EXPERT(S) PROVIDED WITH TRAINING</th>
<th>NO. PARTICIPANTS FROM THE CORRESPONDING COUNTRY</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Analysis of historical data for brucellosis in cetaceans using BLCM (online)</td>
<td>Costa Rica</td>
<td>1</td>
</tr>
<tr>
<td>A</td>
<td>Validation of a method for the diagnosis of varroosis in bees (online)</td>
<td>Ecuador</td>
<td>2</td>
</tr>
<tr>
<td>A</td>
<td>Using limit of detection for comparability studies (online)</td>
<td>Singapore</td>
<td>1</td>
</tr>
<tr>
<td>A</td>
<td>Validation and verification (online)</td>
<td>Vietnam</td>
<td>1</td>
</tr>
<tr>
<td>B</td>
<td>Use of Bayesian Latent Class Models for diagnostic test validation</td>
<td>Australia</td>
<td>10</td>
</tr>
<tr>
<td>C</td>
<td>Validation of diagnostic tests and result interpretation (Experts (n=2) who provided the training were from Australia and the participants from state laboratories in Latin America)</td>
<td>Belize, Bolivia, Brazil, Chile, Colombia, Costa Rica, Cuba, Dominican Republic, Ecuador, El Salvador, Guatemala, Mexico, Nicaragua, Panama, Paraguay, Peru, Uruguay</td>
<td>20</td>
</tr>
<tr>
<td>C</td>
<td>Verification of diagnostic tests (guidelines and practical exercises) (The expert who provided the training was from Australia and the participants from South East Asia)</td>
<td>South East Asia</td>
<td>20</td>
</tr>
<tr>
<td></td>
<td>APCOVE fellowship visit developing models</td>
<td></td>
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WOAH Collaborative Centre Reports Activities 2023
TOR8: SCIENTIFIC MEETINGS

9. Did your Collaborating Centre organise or participate in the organisation of scientific meetings related to your main focus area on behalf of WOAH?

Yes

<table>
<thead>
<tr>
<th>NATIONAL/INTERNATIONAL</th>
<th>TITLE OF EVENT</th>
<th>CO-ORGANISER</th>
<th>DATE (MM/YY)</th>
<th>LOCATION</th>
<th>NO. PARTICIPANTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>International</td>
<td>Review WOAH’s process of validation, registration of diagnostic kits and validation chapters</td>
<td>WOAH/CC</td>
<td>2023-08-28</td>
<td>Paris</td>
<td>6</td>
</tr>
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</table>

TOR9: DATA AND INFORMATION DISSEMINATION

10. Publication and dissemination of any information within the remit of the mandate given by WOAH that may be useful to Members of WOAH

a) Articles published in peer-reviewed journals:


Or with researchers from other Member States:


b) International conferences:

c) National conferences:

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

- A manuscript about the accuracy and comparison of 4 molecular tests for Tilapia Lake Virus is in preparation. This is a follow up from an international TiLV interlaboratory
There is an increasing demand to validate/verify new and unique diagnostic reagents coupled with many novel assay platforms, e.g. although Point of Care Tests (POCT) are increasingly present as diagnostic tools often only little is known about their true diagnostic performance and fitness for purpose. To close that knowledge gap we have submitted a draft chapter for the validation of Point of Care Tests to the BSC for consideration and have received a first feedback on which we are working on.

We also have received a request from WOAH to produce a chapter for the validation of diagnostic assays for infectious diseases of aquatic animals in the aquatic manual and a draft is in preparation for review by the Aquatic Animal Health Standard Commission.

In 2023 the focus of publications continued to be on validation chapters 1.1.6, 2.2.1, 2.2.3, 2.2.4, 2.2.5, 2.2.6, 2.2.7, 2.2.8 and 1.1.2 and a draft for the validation of POCTs. This has absorbed most resources and had an impact on other publication records, e.g. in peer reviewed journals.

Another area of development is the standardization of verification methods.

12. Additional comments regarding your report:
The validation team at ACDP and the Veterinary School Melbourne hold monthly meetings (Epi Think Tank) at https://shiny.vet.unimelb.edu.au/epi/schedule/index.htm.