World Organisation for Animal Health

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WOAH Collaborative Centre Reports Activities 2025

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CENTRE INFORMATION

***Title of WOAH Collaborating Centre**	Diagnostic Test Validation Science in the Asia-Pacific Region
***Address of WOAH Collaborating Centre**	CSIRO Australian Centre for Disease Preparedness, 5 Portarlington Road, 3219 East Geelong, Victoria, Australia
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Website:	https://www.csiro.au/en/about/facilities-collections/ACDP
***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, Principal Research Consultant
***Name of the writer:**	Dr Axel Colling

TOR 1 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

Category	Title of activity	Scope
Disease control (true)	To explore probabilistic methods to better manage inconclusive or indeterminate results with the goal to reduce uncertainty and assist in the interpretation of inconclusive results and improved test algorithms.	Probabilistic methods are applied to reduce uncertainty of results which leads to better information about the true status of the test sample.
Epidemiology, surveillance, risk assessment, (true)	To generate new knowledge and science-based methods to improve design and interpretation of validation studies, particularly for emerging diagnostic modalities including point of care tests, biomarker assays and whole genome sequencing.	To assist WOAH with improved modern validation methods, results outcome and interpretation for new diagnostic diagnostic platforms, reagents and protocols.
	1) To improve global understanding of test validation principles and methods by developing and delivering training materials and workshops. 2) To provide scientific and technical training for	1) Standardization, application and extension of test validation principles and method. 2) To organize a workshop with a focus on the WOAH validation pathway and the use of Bayesian Latent Class Models. 3) For example for AI, ASF, BTV, Hendra & Nipah virus, Abalone,Yellow Head Virus genotype 1, Epizootic Haematopoietic Necrosis Virus and

Training, capacity building (true)	personnel from WOAH Member countries. 3) There is inhouse cross-fertilization between the validation activities and objectives of the WOAH Collaborating Centre and ACDP's multiple roles as Reference laboratory. 4) To explore the use of online applications for Bayesian Latent Class tools, e.g. https://shiny.vet.unimelb.edu.au/epi/blcm/. 5) To participate in regional WOAH meetings.	WOAH Collaborating Centre for New and Emerging Diseases and Laboratory Capacity Building. 4) Simplify complex Bayesian computations through user-friendly applications will enable the use of such models for laboratory diagnosticians and test developers with limited statistical and mathematical knowledge. 5) Collaboration, exchange updated and new information and dissemination of knowledge through presentations and workshops.
Wildlife (true)	To progress validation chapter 2.2.7. for wildlife to be submitted to WOAH for publishing.	The review of this chapter includes the use of Bayesian Latent Class Models which is likely to lead to a decrease in sample numbers needed to estimate assay accuracy. The chapter will provide example-based guidance for the validation of diagnostic assays used in wildlife.
Veterinary medicinal products (true)	To assist in the development of a new procedure for the validation, certification and registration of diagnostic tests.	A more efficient management of WOAH's test validation, certification and registration procedure will facilitate a broader use and uptake of diagnostic kits with published performance parameters.
Diagnostic Test Validation Science in the Asia-Pacific Region (true)		
1) (true)	To support WOAH's global leadership in developing science-based guidelines and standards for test validation for infectious diseases of terrestrial, aquatic and wild animals.	Development and harmonization of design, analysis and interpretation of validation studies based on best practice.
2) (true)	To develop a new chapter for the validation of point-of-care tests (POCT).	A new chapter that focuses on the validation of POCTs will capture specific parameters that are relevant for these assays, e.g. platform, reagents, protocol, exposure to environmental variations, differences in operator proficiency.
3) (true)	To assist in writing a new chapter for the validation of diagnostic tests for infectious diseases of aquatic animals (1.1.2.) and submit it to WOAH for publishing.	Infectious diseases of aquatic animals propagate and manifest in different ways and age groups than in terrestrial animals. The new chapter will address specific parameters for aquatic species and assist in the harmonization of modern validation principles and methods.
4) (true)	To consolidate and extend laboratory validation networks to increase exchange of knowledge and overcome limitations.	To enhance and extend collaboration with international networks to be better prepared and overcome new challenges.
5) (true)	To explore probabilistic methods to determine sample size for test validation studies.	Using probabilistic methods has the potential to reduce the need of large sample numbers. This has the potential to facilitate validation studies even if numbers of samples are scarce.
6) (true)	To improve or develop new latent class models (selection and weight of priors, sample size, different prior requirements when cut-off is changed, multiple tests) and introduce online applications for statistical analysis of test validation data, when the true	To overcome limitations of frequentist methods will lead to more accurate and precise results and decision-making regarding fitness for purpose. A guideline that determines the criteria to select and weight priors will assist in the harmonization of this

	infection status of animals that are sampled in a validation study is unknown.	process.

TOR 3: HARMONISATION OF STANDARDS

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

Proposal title	Scope/Content	Applicable Area
1) To assist in the development of a new procedure for the validation, certification and registration of diagnostic tests.	1) An ad hoc group is tasked with revamping the WOAH validation, certification and registration procedure. If successful at the end there will be a transparent, standardized and objective procedure to assess diagnostic tests sustainably whether they are fit for purpose. This is of relevance for the kit industry as well as for kit developer and user.	Laboratory Expertise Training and Education Health Management Veterinary Products Wildlife Health and Biodiversity
2) To develop a new chapter for the validation of point-of-care tests (POCT).	2) A new chapter that focuses on the validation of POCTs will capture specific parameters that are relevant for these assays, e.g. platform, reagents, protocol, exposure to environmental variations, differences in operator proficiency.	
3) Review/ rewrite chapter 2.2.7. Validation of diagnostic tests used for wildlife	3) Validating diagnostic tests in wildlife is challenging. The review of this chapter includes the use Bayesian Latent Class Models, which may lead to a decrease in sample numbers needed to estimate assay accuracy.	
4) To assist in writing a new chapter for the validation of diagnostic tests for infectious diseases of aquatic animals (1.1.2.) and submit it to WOAH for publishing.	4) Infectious diseases of aquatic animals propagate and manifest in different ways and age groups than in terrestrial animals. The new chapter will address specific parameters for aquatic species and assist in the harmonization of modern validation principles and methods.	
5) To develop and explore the use of online applications for Bayesian Latent Class tools, e.g. https://shiny.vet.unimelb.edu.au/epi/blcm/.	5) Simplify complex Bayesian computations through user-friendly applications will enable the use of such models for laboratory diagnosticians and test developers with limited statistical and mathematical knowledge and contribute to the harmonisation of such methods.	

3. In exercising your activities, have you identified any regulatory research needs* relevant for WOAH?

Yes

Research need 1

Please type the Research need: 1) A chapter for the validation of point of care tests (POCT) 2) A chapter for the validation of diagnostic tests for the diagnosis of infectious diseases of aquatic animals 3) A chapter for the validation of biomarker-based (continuous and dichotomous) diagnostic tests for use in infectious diseases 4) A guideline for the verification of diagnostic tests

Relevance for WOAH Disease Control, Capacity Building, Other, Standard Setting, Facilitation of international collaboration, Advanced methods for test validation ,

Relevance for the Code or Manual Manual,

Field Epidemiology and Surveillance, Diagnostics,

Animal Category Terrestrial, Aquatic,

Disease:

Kind of disease (Zoonosis, Transboundary diseases) Not disease specific,

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: Terrestrial Manual Chapter 1.1.6. and Chapter 2.2.; Aquatic Manual Chapter 1.1.2.; Table 1 fitness for purpose in disease chapters

Notes:

Answer:

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

Name of WOAH CC/RL/other organisation(s)	Location	Region of networking Centre	Purpose
Sustainable Animal Health Laboratory Network in Southeast Asia and the Pacific through targeted technical laboratory twinning engagement (Laboratory Network Twinning).	Not defined	Asia y el Pacífico	Foreign Affairs and Trade (DFAT), for the purpose of strengthening the capacity and creating a Sustainable Animal Health Laboratory Network in Southeast Asia and the Pacific through targeted technical laboratory twinning engagement (Laboratory Network Twinning) for review.
Several countries in Southeast Asia (focus).	Not defined	Asia y el Pacífico	Hosting of visiting scientists, scholars and fellows, through various funding sources.
The Asia Pacific consortium of Veterinary Epidemiology (APCOVE).	Not defined	Asia y el Pacífico	Support of APCOVE Fellows.
The ASEAN laboratory technical advisory group (labtag).	Not defined	Asia y el Pacífico	Provision of technical advice.
Pacific Heads of Veterinary and Animal Production services (PHOVAPS) and the secretariat (SPC) on laboratory and diagnostics.	Not defined	Asia y el Pacífico	Technical support.
ELISA and Molecular Techniques in			Regional Training Course for the Verification of Serological and Technical Tests NT5157-

Animal Disease Diagnosis, FAO/IAEA Animal Production and Health Laboratory, Seibersdorf, Austria	Not defined	América	EVT2406278, 10-14 March 2025, Tecamac, Mexico, ~20+ participants from Latin America. Presentation "Introduction to WOAH's Test Validation and Verification pathways"
Atlantic Veterinary College, University of Prince Edward Island, Canada	Canada	Asia y el Pacífico	Validation of point-of-care tests.
University of California, Irvine, USA	USA	Asia y el Pacífico	Development and use of Bayesian Latent Class Analysis, data analysis and interpretation, measurement Uncertainty.
Veterinary Epidemiological Consultant, Geelong, Australia	Australia	Asia y el Pacífico	Validation of biomarkers for Johne's Disease.
Faculty of Veterinary and Agricultural Sciences (FVAS) The University of Melbourne Parkville	Australia	Asia y el Pacífico	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.
EpiCentre, Institute of Veterinary and Biomedical Sciences, Massey University Palmerston North	New Zealand	Asia y el Pacífico	Veterinary epidemiology, statistics and test validation.

TOR 4 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?

Yes

Name of WOAH CC/RL/other organisation(s)	Location	Region of networking Centre	Purpose
Australian Government HPAI Taskforce, Department of Agriculture, Fisheries and Forestry Agriculture House, 70 Canberra ACT 2601, Australia (AI)	Australia	Americas Asia and Pacific Europe	Developing validation methods for new diagnostic platforms such as such as point-of-care tests for Avian Influenza Virus.
			Developing validation

Agriculture Victoria Research, AgriBio Centre for AgriBioscience, Bundoora, VIC, Australia	Australia	Asia and Pacific	methods for new diagnostic platforms such as such as point-of-care tests for AIV. Validation/verification of non-structural FMD ELISA.for ovine and caprine sera. Validation of POCT for ASF.
Biosecurity Sciences Laboratory, Department of Agriculture and Fisheries, Biosecurity Queensland, Brisbane, QLD, Australia	Australia	Asia and Pacific	Developing and validating a point-of-care test for the early detection of ASF in pigs.
School of Veterinary Science (SVS) and School of Environment (SENV) The University of Queensland, Australia	Australia	Asia and Pacific	Development and validation of a point-of-care test for the detection of Hendravirus in horses.

TOR 6: EXPERT CONSULTANTS

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

Yes

Name of expert	Kind of consultancy	Subject
Axel Colling	WOAH working group (11 members)	Revamping the WOAH test validation, certification and registration process.
Axel Colling	IAEA	Invited guest speaker to an international online workshop in Mexico about test validation and verification. Reviewing SOPs.
Caryll Waugh	ACDP staff, International Program	Measurement Uncertainty, test validation and verification in Indonesia.

TOR 7: SCIENTIFIC AND TECHNICAL TRAINING

7. Did your Collaborating Centre provide advice/services to requests from Members in your main focus area?

Yes

Indonesia and Mexico requested training from ACDP in test validation, verification, MU and SOPs for laboratory staff.

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 visit : 1

b) Seminars : 1

c) Hands-on training courses: 2

d) Internships (>1 month) : 0

Type of technical training provided (a, b, c or d)	Content	Country of origin of the expert(s) provided with training	No. participants from the corresponding country

A	Our collaborator from Irvine University, Prof. Wesley Johnson, visited ACDP for 2 weeks to collaborate with the CC in the use of statistical methods for measurement uncertainty (MU) and Bayesian Latent Class Analysis (BLCM)	Australia	10
B	Training in the use of Bayesian Latent Class Analysis	Australia	30
C	Training was provided to staff from Indonesia in test validation, verification and MU.	Indonesia	1
C	A presentation describing WOAH's principles and methods for test validation and verification was given followed by a q+a session to laboratory staff.	Mexico and other countries from Latin America.	20

TOR 8: 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

National/International	Title of event	Co-organiser	Date	Location	No. Participants
Internationally	Bayesian Methods for Biomarker Modelling, Disease Diagnosis, Test Accuracy Estimation, Pooled Testing and Prevalence Estimation.	ACDP and Uni Melbourne	2025-07-16	Australia	30

TOR 9: 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:

4

Hulse L., Izzard L., Balasubramanian N.S., Colling A., Underwood, D. Driver L., Diallo I., Williams D.T, Ahern B. Evaluation of Two Point-of-Care Molecular Diagnostic Platforms for Rapid Detection of Equine Hendra Virus: DARQ RT-LAMP versus real-time RT-qPCR (submitted for publication)

McNabb, L.; McMahon, A.; Woube, E.G.; Agnihotri, K.; Colling, A.; Broder, C.C.; Kucinskaite-Kodze, I.; Petraityte-Burneikiene, R.; Bowden, T.R.; Halpin, K. Development and Validation of a Differentiating Infected from Vaccinated Animals (DIVA) Enzyme-Linked Immunosorbent Assay (ELISA) Strategy for Distinguishing Between Hendra-Infected and Vaccinated Horses. Viruses 2025, 17, 354. https://doi.org/10.3390/v17030354

S Ye, NS Balasubramanian, O Dolezal, A Foord, G Beddome, WP Michalski, BJ Shiell and GR Peck. Development and characterisation of a fully recombinant competition ELISA for the diagnosis of foot-and-mouth disease virus infection. Australian Veterinary Journal 2025, 103(9), 533-541. https://doi.org/10.1111/avj.13467

Seeyo, K.B., Choonnasard, A., Chottikamporn, J. et al. Evaluation and comparison of performances of six commercial NSP ELISA assays for foot and mouth disease virus in Thailand. Sci Rep 14, 23958 2024. https://doi.org/10.1038/s41598-024-75793-4

b) International conferences:

0

c) National conferences:
0

d) Other (Provide website address or link to appropriate information):
Webpage for WOAH Collaborating Centre for Test Validation Science:

https://www.csiro.au/en/about/facilities-collections/ACDP

https://mvs.unimelb.edu.au/research/partnerships/woah-dx

http://fvas.unimelb.edu.au/research/research-centres/oie-dx/contact

Webpage for epidemiology teaching tools, including Beta buster, sample size estimator and other tools for diagnostic test evaluation studies.

http://fvas.unimelb.edu.au/research/research-areas/veterinary-epidemiology-melbourne/resources

epiR statistical library for the R statistical package, including functions for epidemiological calculations such as those required for or diagnostic test evaluation studies: https://cran.r-project.org/web/packages/epiR/index.html

https://shiny.vet.unimelb.edu.au/epi/blcm/.

https://www.massey.ac.nz/about/colleges-schools-and-institutes/college-of-sciences/school-of-veterinary-science/

11. What have you done in the past year to advance your area of focus, e.g. updated technology?
The CC has further progressed a new validation chapter for Point of Care Tests (POCT) though a national work group and in-house activities, e.g. a large new project is looking into the validation and comparison of commercial POCTs for Avian Influenza Virus (AIV). In addition the development of new POCTs for Hendra virus and ASF virus provided useful example-based validation requirements for these platforms.

During this reporting period our focus was to continue to update validation chapters in the Manual and we plan to submit the chapter for validation of tests applied to wildlife within the next review period. By completing this task all validation chapters in the Manual will be updated and in agreement with the Special Issue published in 2021.

The validation of biomarker assays is also progressing.

We are developing probabilistic methods that facilitate test validation and accuracy estimates with smaller sample numbers.

We are looking into new ways how measurement uncertainty can be applied in veterinary diagnostic testing.

The visit from Latent Class expert Wesley Johnson was highly productive for the CC and has stimulated discussions around probabilistic approaches for sample numbers and result interpretation.

12. Additional comments regarding your report:
In 2025 the team has focused to review and write new example-based validation chapters. With the submission of the chapter for validation of diagnostic tests applied to wildlife in the near future all validation chapters (n=9) will be updated and referenced to the Special Issue, 2021 "Diagnostic Test Validation Science".

A few minor comments
It is great to see that the new and reviewed disease chapters in the terrestrial manual do contain detailed information about the level of validation and the reasoning behind being selected as fit-for purpose.

In our view it is difficult to search and find a specific reference lab or collaborating centre on the WOAH webpage. Would this be easier with a search function.

This applies also to the disease chapters, e.g. they are not easy to be found and downloaded and a search function would help.