

WOAH Collaborative Centre Reports Activities 2023

Activities in 2023

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Centre Information

Title of WOA Collaborating Centre	Diagnostic Test Validation Science in the Asia Pacific Region
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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 WOA

Category	Title of activity	Scope
Disease control (true)	Diagnostic Test Validation Science in the Asia-Pacific Region	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.

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

Proposal title	Scope/Content	Applicable area

Assist WOAHA to review its process for the validation, certification and registration of diagnostic kits	Assist WOAHA to review its validation, certification and registration process for diagnostic kits.	Laboratory expertise Training and education health management Animal production Wildlife health and biodiversity
Published chapter 1.1.6. "Validation of diagnostic assays for infectious diseases in terrestrial animals" in Terrestrial Manual	This fully reviewed chapter 1.1.6. is based on papers published in Special Issue "Diagnostic Test Validation Science" 40 (1), 2021. The chapter includes new examples for all testing purposes and highlights purpose-specific relevant parameters including likelihood ratios. Examples highlighting the importance of source and target populations for test validation are presented. Chapter 1.1.6. was published in Terrestrial Manual May 2023.	Laboratory expertise Training and education health management Animal production Wildlife health and biodiversity
Review of chapter 2.2.4. "Measurement uncertainty" in Terrestrial Manual	Chapter 2.2.4. "Measurement Uncertainty" includes examples how to calculate MU for serology and molecular test using the "Top-down approach". It is based and has been updated with papers published in Special Issue "Diagnostic Test Validation Science" 40 (1), 2021. The chapter has been reviewed and it has been found that terminology and statistics require further review.	Laboratory expertise Training and education
Review of chapter 2.2.6. "Reference samples" in Terrestrial Manual	Selection and use of reference samples and panels has been fully reviewed. It includes a roadmap which samples and panels to use for different purposes, e.g. proof of concept, comparability, repeatability, reproducibility etc. The chapter has been submitted and is being reviewed by WOAHA.	Laboratory expertise Training and education
Review of chapter 2.2.8. "Comparability of assays after changes in a validated method" in Terrestrial Manual	This fully revised edition of chapter 2.2.8. about comparability of assays after changes in a validated method. The chapter focuses on molecular tests and includes new examples for the most relevant statistical analysis for comparability studies. It refers to the Special Issue "Diagnostic Test Validation Science" 40 (1), 2021 and has been submitted to WOAHA for review.	Laboratory expertise Training and education Veterinary products
"Diagnostic validation of Point-of-Care Tests (POCT) tests for WOAHA-listed viral diseases using field samples" in preparation.	Validation of Point-of-Care Tests (POCT) for WOAHA-listed viral diseases using field samples is in preparation and a first draft has been submitted review to WOAHA. It contains design considerations for validation of POC tests and prerequisites to be included in a prospective study and an outline with sample collection, handling and transportation, field testing, data recording, testing in reference laboratory and analysis of test results.	Laboratory expertise Training and education Veterinary products Wildlife health and biodiversity
"Principles and methods of validation of diagnostic assays for infectious diseases of aquatic animals" in preparation.	Validation of diagnostic assays for infectious diseases of aquatic animals. This chapter focuses on the criteria that must be fulfilled during assay development and validation of all assay types and the metrics used to characterise test performance.	Laboratory expertise Training and education health management Animal production Wildlife health and biodiversity
Evaluation of Point of Care (POC) Tests for White Spot Syndrome Virus (WSSV)	To determine the analytical and diagnostic performance characteristics (analytical sensitivity and specificity, diagnostic sensitivity and specificity, repeatability and applicability) of five commercially available WSSV POC test kits for the detection of WSSV in clinically affected prawns.	Laboratory expertise Training and education health management
Evaluation of antibody detection ELISA for LSD in Australian cattle and buffaloes.	To determine accuracy of a prototype antibody detection ELISA for LSD in Australian cattle and buffaloes.	Laboratory expertise Training and education health management

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

Yes

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 WOAAH 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 WOAAH Collaborating Centres (CC), Reference Laboratories (RL), or organisations designated for the same specialty, to coordinate scientific and technical studies?

Yes

Name of WOAAH CC/RL/other organisation(s)	Location	Region of networking Centre	Purpose
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 mark.stevenson1@unimelb.edu.au URL:http://fvas.unimelb.edu.au	Melbourne, Australia	Africa Americas Asia and Pasific Europe	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, 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 C.Heuer@massey.ac.nz URL: http://epicentre.massey.ac.nz	Palmerston North, New Zealand	Africa Americas Asia and Pasific	Veterinary epidemiology, statistics and test validation.
Atlantic Veterinary College, University of Prince Edward Island 50 University Ave. Charlottetown, Prince Edward Island, C1A 4P3 iagardner@upe.ca; Mobile: 902-394-6823	Prince Edward Island, Canada	Americas Asia and Pasific Europe	Veterinary epidemiology, statistics and test validation. Review of chapters 1.1.6., 2.2.1.-2.2.8. Produce a new chapter titled: "Diagnostic validation of point-of-care (PoC) tests for WOAAH-listed viral diseases using field samples" and submit to WOAAH for review. Review of WOAAH's validation, certification and registration process.

UC Irvine Department of Statistics Irvine 92697, California, USA 2232 Bren Hall wjohnson@uci.edu Location Irvine, California, USA	Irvine, USA	Americas Asia and Pasific Europe	Bayesian Latent Class models applicable for test validation of diagnostic tests in wildlife. Bayesian latent class models and validation standards.
School of Animal and Veterinary Sciences The University of Adelaide, Roseworthy Campus, Roseworthy, South Australia, 5371, Australia +61-8-8313 1245 charles.caraguel@adelaide.edu.au	Adelaide, Australia	Asia and Pasific	Veterinary epidemiology, statistics and test validation.
WOAH Headquarters	Paris, France	Africa Americas Asia and Pasific Europe MiddleEast	Discuss review of validation chapters in terrestrial manual and WOA process for validation, certification and registration of diagnostic kits Review WOA validation template including a practice run with Bluetongue Ref labs using molecular data.
IAEA Headquarters and Seibersdorf laboratory	Vienna/Seibersdorf, Austria	Africa Americas Asia and Pasific Europe MiddleEast	- Workshop on diagnostic test validation and result interpretation - Production of guidelines and training for verification of test performance - Production of guidelines and training for production of secondary standards for molecular and serological methods - Review of chapter 2.2.1.
AVR, Agriculture Victoria Department of Jobs, Precincts and Regions Adjunct Professor in Animal and Veterinary Bioscience, La Trobe University AgriBio, 5 La Trobe University, Ring Road, Bundoora T: 61 3 90327229, M: 0428 581788 grant.rawlin@agriculture.vic.gov.au	Melbourne, Australia	Asia and Pasific	Validation/verficiation of non-structural FMD ELISA for ovine and caprine sera

TOR4 AND 5: NETWORKING AND COLLABORATION

5. Did your Collaborating Centre maintain a network with other WOA 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 WOA?

Yes

NAME OF EXPERT	KIND OF CONSULTANCY	SUBJECT
Dr Axel Colling	WOAH CC	Assist WOA to review it process for the validation, certification and registration of diagnostic kits.
		Workshops on diagnostic test validation and result

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 WOAHS SRDK for certification of validation as per the WOAHS 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 WOAHS, to personnel from WOAHS Members?

Yes

a) Technical visit : 4

b) Seminars : 1

c) Hands-on training courses: 3

d) Internships (>1 month) : 2

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	Analysis of historical data for brucellosis in cetaceans using BLCM (online)	Costa Rica	1
A	Validation of a method for the diagnosis of varroosis in bees (online)	Ecuador	2
A	Using limit of detection for comparability studies (online)	Singapore	1
A	Validation and verification (online)	Vietnam	1
B	Use of Bayesian Latent Class Models for diagnostic test validation	Australia	10
C	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)	Belize, Bolivia, Brazil, Chile, Colombia, Costa Rica, Cuba, Dominican Republic, Ecuador, El Salvador, Guatemala, Mexico, Nicaragua, Panama, Paraguay, Peru, Uruguay	20
C	Verification of diagnostic tests (guidelines and practical exercises) (The expert who provided the training was from Australia and the participants from the South East Asia)	South East Asia	20
	APCOVE fellowship visit developing models		

D	of leptospirosis and African swine fever in Vietnam. (Course organizer Uni Melbourne)	Vietnam	2
D	Epi In The Valley: Causality and Directed acyclic graphs for the design and analysis of epidemiological studies (Course organizer Uni Melbourne)	Nepal, South Korea, Indonesia, Vietnam, PNG	15
C	Verification of diagnostic assays	South Korea, Philippines, Mongolia, Sri Lanka, India, Malaysia	29

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 WOA?H

Yes

NATIONAL/INTERNATIONAL	TITLE OF EVENT	CO-ORGANISER	DATE (MM/YY)	LOCATION	NO. PARTICIPANTS
International	Review WOA's process of validation, certification and registration of diagnostic kits and validation chapters	WOAH/CC	2023-08-28	Paris	6

TOR9: DATA AND INFORMATION DISSEMINATION

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

a) Articles published in peer-reviewed journals:

6

On diagnostic test validation (Uni Melbourne):

-Genz, B., Franz, L.M., Salgado, A., Firestone, S.M., Sellars, M.J., Moser, R.J., in press. Detection of Infectious Myonecrosis Virus in *Penaeus vannamei* using the multiplexed PCR platform Shrimp MultiPath. *Aquaculture*.

-Moser, R., Firestone, S.M., Franz, L., Genz, B., Sellars, M., 2023. Shrimp MultiPath multiplexed PCR white spot syndrome virus detection in penaeid shrimp. *Dis. Aquat. Organ.* 153, 95-105.

-Reeves, H., Ryan, S.D., Firestone, S.M., Milne, M.E., 2023. A repeatable CT protocol for quantifying caudal vena cava growth in medium and large breed dogs. *Vet Radiol Ultrasound*.

Or with researchers from other Member States:

-Le, V.P., Lan, N.T., Canevari, J.T., Villanueva-Cabezas, J.P., Padungtod, P., Trinh, T.B.N., Nguyen, V.T., Pfeiffer, C.N., Oberin, M.V., Firestone, S.M., Stevenson, M.A., 2023. Estimation of a Within-Herd Transmission Rate for African Swine Fever in Vietnam. *Animals* 13, 571.

-Oberin, M., Hillman, A., Ward, M.P., Holley, C., Firestone, S.M., Cowled, B., 2023. The potential role of wild suids in African swine fever spread in Asia and the Pacific region. *Viruses*.

-Subharat, S., Meunsene, D., Phouthana, V., Tiwari, H., Firestone, S.M., 2023. Field Epidemiology Capacity of the National Veterinary Services of Lao PDR: An online survey. *Frontiers in Veterinary Science*.

b) International conferences:

c) National conferences:

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

8

- 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

comparison study organized by WOAAH for which reports were submitted.

-Reid T, Singanallur NB, Waugh C, Bowden TR, Newberry K, Colling A. 2023. Validation of veterinary diagnostic tests for infectious diseases: A review of challenges and opportunities. In: Viljoen, G., Garcia Podesta, M., & Boettcher P. (eds) 2023. *International Symposium on Sustainable Animal Production and Health - Current Status and Way Forward*. Vienna, Austria 28 June – 2 July 2021. Rome, FAO <https://doi.org/10.4060/cc2530en>

-Comparison of molecular tests for WSSV Report, Stacey Valdeter

Uni Melbourne

-Koolhof, I.S., Beeton, N., Bettiol, S., Charleston, M., Firestone, S.M., Gibney, K.B., Neville, P.J., Jardine, A., Markey, P., Kurucz, N., Warchot, A., Krause, V., Onn, M., Rowe, S., Franklin, L., Fricker, S., Williams, C., Carver, S., 2024. Testing the intrinsic mechanisms driving the dynamics of Ross River Virus across Australia. *PLoS Pathog.*

-Hampton, J.O., Pain, D.J., Buenz, E., Firestone, S.M., Arnemo, J.M., 2023. Lead contamination in Australian game meat. *Environ. Sci. Pollut. Res.*

-Hou, K.W., Firestone, S.M., Stevenson, M.A., 2023. Scenario tree modelling to inform surveillance design for maintaining freedom from *Coxiella burnetii* infection in Australian commercial dairy goat herds. *Prev. Vet. Med.*

-McLure, A., Smith, J., Firestone, S.M., Kirk, M.D., Fearnley, E., French, N., Wallace, R.L., Valcanis, M., Bulach, D.M., Moffat, C., Selvey, L., Jennison, A.V., Cribb, D.M., Glass, K., 2023. Source attribution of campylobacteriosis in Australia 2017-2019. *Risk Anal.*

-Nzabanita, D., Shen, H., Stephen, G., Lewis, P., Hampton, J.O., Firestone, S.M., Hufschmid, J., Nugegoda, D., 2023. Exposure to POPs in Australian waterbirds. *Environ. Toxicol. Chem.*

11. What have you done in the past year to advance your area of focus, e.g. updated technology?

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 WOAAH 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>.