

WOAH Collaborative Centre Reports Activities 2022

Activities in 2022

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Centre Information

Title of WOA Collaborating Centre	
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Website:	https://www.csiro.au/en/about/facilities-collections/ACDP/About-ACDP
Name Director of Institute (Responsible Official):	Prof Trevor Drew
Name (including Title and Position) of Head of the Collaborating Centre (WOAH Contact Point):	Dr Axel Colling (Head)
Name of the writer:	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

Diagnostic Test Validation Science	
Title of activity	Scope
	The CC is an international scientific consortium made of the Australian Centre for Disease Preparedness (ACDP, CSIRO),

<p>Diagnostic Test Validation and Result Interpretation</p>	<p>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 combine expertise in diagnostics, epidemiology, result interpretation 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.</p>
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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
<p>Review of validation chapter 1.1.6. in WOAH terrestrial manual</p>	<p>Update and review validation chapter 1.1.6 Principles and methods for the validation of diagnostic tests for infectious applicable to wildlife in WOAH manual based on the Special Issue. "Diagnostic test validation science: a key element for effective detection and control of infectious animal diseases (2021) Rev. Sci. Tech. Off. Int. Epiz., 40 (1).</p>	<p>Laboratory expertise Training and education health management Wildlife health and biodiversity</p>
<p>Review of validation chapter 2.2.1. in WOAH terrestrial manual</p>	<p>Update and review of validation chapter 2.2.1. Development and optimization of antibody detection assays in WOAH Manual based on the Special Issue. "Diagnostic test validation science: a key element for effective detection and control of infectious animal diseases (2021) Rev. Sci. Tech. Off. Int. Epiz., 40 (1).</p>	<p>Laboratory expertise Training and education health management Wildlife health and biodiversity</p>
<p>Review of validation chapter 2.2.2. in WOAH terrestrial manual</p>	<p>Update and review of validation chapter 2.2.2. Development and optimization of antigen detection assays in WOAH Manual based on the Special Issue. "Diagnostic test validation science: a key element for effective detection and control of infectious animal diseases (2021) Rev. Sci. Tech. Off. Int. Epiz., 40 (1).</p>	<p>Laboratory expertise Training and education health management Wildlife health and biodiversity</p>
<p>Review of validation chapter 2.2.3. in WOAH terrestrial manual</p>	<p>Update and review of validation chapter 2.2.3. Development and optimization of nucleic acid detection assays in WOAH Manual based on the Special Issue. "Diagnostic test validation science: a key element for effective detection and control of infectious animal diseases (2021) Rev. Sci. Tech. Off. Int. Epiz., 40 (1).</p>	<p>Laboratory expertise Training and education health management Wildlife health and biodiversity</p>
	<p>Update and review of validation chapter 2.2.4.</p>	

<p>Review of validation chapter 2.2.4. in WOAH terrestrial manual</p>	<p>Measurement Uncertainty in WOAH Manual based on the Special Issue. "Diagnostic test validation science: a key element for effective detection and control of infectious animal diseases (2021) Rev. Sci. Tech. Off. Int. Epiz., 40 (1).</p>	<p>Laboratory expertise Training and education</p>
<p>Review of validation chapter 2.2.5. in WOAH terrestrial manual</p>	<p>Update and review of validation chapter 2.2.5. Statistical approaches for test validation in WOAH Manual based on the Special Issue. "Diagnostic test validation science: a key element for effective detection and control of infectious animal diseases (2021) Rev. Sci. Tech. Off. Int. Epiz., 40 (1).</p>	<p>Laboratory expertise Training and education Wildlife health and biodiversity</p>
<p>Review of validation chapter 2.2.6. in WOAH terrestrial manual</p>	<p>Update and review of validation chapter 2.2.6. Selection and use of reference samples and panels in WOAH Manual based on the Special Issue. "Diagnostic test validation science: a key element for effective detection and control of infectious animal diseases (2021) Rev. Sci. Tech. Off. Int. Epiz., 40 (1).</p>	<p>Laboratory expertise Training and education</p>
<p>Review of validation chapter 2.2.7. in WOAH terrestrial manual</p>	<p>Update and review of validation chapter 2.2.7. Principles and methods for the validation of diagnostic tests for infectious diseases applicable to wildlife in WOAH Manual based on the Special Issue. "Diagnostic test validation science: a key element for effective detection and control of infectious animal diseases (2021) Rev. Sci. Tech. Off. Int. Epiz., 40 (1).</p>	<p>Laboratory expertise Training and education</p>
<p>Review of validation chapter 2.2.8. in WOAH terrestrial manual</p>	<p>Review of validation chapter 2.2.8. Comparability of assays after minor changes in a validated test method in WOAH Manual based on the Special Issue "Diagnostic test validation science: a key element for effective detection and control of infectious animal diseases (2021) Rev. Sci. Tech. Off. Int. Epiz., 40 (1).</p>	<p>Laboratory expertise Training and education</p>
<p>Diagnostic validation of point-of-care (PoC) tests for WOAH-listed viral diseases using field samples</p>	<p>Uses of PoCTs (synonyms: point-of-need, penside, or pondside tests) at a population level can be broadly categorized as: (1) screening for notifiable diseases which might be WOAH-listed, (2) aiding management of outbreaks of notifiable diseases, and (3) diagnosing and rapid response management of non-notifiable endemic diseases. For scenarios 1 and 2, it is important to note that PoCT are an adjunct to laboratory testing in control programs for notifiable diseases and official confirmation of infection is usually necessary using other tests e.g. lab-based qPCR or virus isolation. Regardless, criteria for validation of a PoCT are identical regardless of the ease of use, cost, or</p>	<p>Laboratory expertise Training and education Wildlife health and biodiversity</p>

training needed for operators.

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

Yes

Name of OIE CC/RL/other organisation(s)	Location	Region of networking Centre	Purpose
FAO Reference Centre for Zoonotic Coronaviruses Head of Laboratory of Experimental Animal Models and Alternative Methods Istituto Zooprofilattico Sperimentale delle Venezie Viale dell'Università, 10 35020 Legnaro - Padova Tel. +39-049-8084371 Location Padova	Italy	Africa Americas Asia and Pasific Europe MiddleEast	SARS-COV2 reagents for standardization of diagnostic tests.
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	Australia	Americas Asia and Pasific	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	New Zealand	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	Canada	Americas Asia and Pasific	Test validation science, aquatic epidemiology, collaboration, Bayesian latent class analysis (BLCA) and validation standards. Collaboration with Andrea Pena, Pathovet, Chile on publication of a ring trial paper of qPCR for Salmon Rickettsial Syndrome and Win Surachetpong, Kasetsart University, Thailand on validation of an ELISA for Tilapia Lake Virus.

<p>UC Irvine Department of Statistics Irvine 92697, California, USA 2232 Bren Hall wjohnson@uci.edu Location Irvine, California, USA</p>	<p>USA</p>	<p>Americas Asia and Pasific</p>	<p>Test validation Science Bayesian latent class analysis (BLCA) and validation standards.</p>
<p>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</p>	<p>Australia</p>	<p>Asia and Pasific</p>	<p>Aquatic epidemiology, validation, Bayesian Latent Class Analysis.</p>
<p>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</p>	<p>Australia</p>	<p>Asia and Pasific</p>	<p>New test development validation science, collaboration, new technologies.</p>
<p>Animal Production and Health Section Joint FAO/IAEA Division of Nuclear Techniques in Food and Agriculture Department of Nuclear Sciences and Applications International Atomic Energy Agency Vienna International Centre, PO Box 100, 1400 Vienna, Austria Email: G.J.Viljoen@iaea.org T: (+43-1) 2600-26053 M: (+43) 699-165-26053 F: (+43-1) 26007</p>	<p>Austria</p>	<p>Africa Americas Asia and Pasific Europe MiddleEast</p>	<p>IAEA Regional TC Project 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) 2022-2024. Collaboration with ZODIAC, VetLab and IVetNet projects.</p>
<p>ELISA and Molecular Techniques, Disease Diagnosis FAO/IAEA Animal Production and Health Laboratory, Seibersdorf, Austria g.cattoli@iaea.org</p>	<p>Austria</p>	<p>Africa Americas Asia and Pasific Europe MiddleEast</p>	<p>Collaboration and training in diagnostic test validation, proficiency testing, establishing quality systems (ISO 17025). Review of the SOPs for generic verification of serological and molecular techniques (September – October 2022) Verification training course which will start the process of delivering the new verification SOPs to member countries. Workshop 6-10th Feb 2023 South Korea.</p>
<p>National Parks Board Singapore (NParks), Animal and Veterinary Service</p>			<p>Collaboration for test validation workshop Brunei, Cambodia, Indonesia</p>

(AVS), ASEAN Regional Reference Centre for Bio-Risk Management and Quality Assurance (OIE) charlene_fernandez@nparks.gov.sg	Singapore	Asia and Pasific	Malaysia, Myanmar, Philippines, Singapore, Thailand. Exploring validation of eDNA/eRNA methods.
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TOR4 AND 5: NETWORKING AND COLLABORATION

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

Yes

NAME OF EXPERT	KIND OF CONSULTANCY	SUBJECT
Axel Colling	IAEA Regional TC Project 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) 2022-2024.	Course instructor Introduction to test validation.
Axel Colling	Chair of 2 WOH ad hoc working group for certification of diagnostic kits	Certification of diagnostic kits for MERS and Mycobacterium bovis
Axel Colling and Ian Gardner	OIE Biological Standards Commission, 7 February 2022	Discuss review of 8 validation chapters in OIE Manual for Terrestrial Animal https://www.woah.org/fileadmin/Home/eng/Health_standards/tahm/2.02.00_INTROE OIE - doc.oie.int - Record (ongoing).
	SRDK validation	Review new OIE validation template and discuss validation, registration and certification

Axel Colling	template review	https://www.woah.org/app/uploads/2021/06/a-sop-may-2021.pdf (ongoing)
Nagendra Singanallur Balasubramanian	Chair of WOAHO ad hoc working group for certification of diagnostic kits	Assessment of validation dossier for OIE certification of multiplex assays for shrimp
Simon Firestone	External consultancy to applicant (diagnostic test developer) supporting and undertaking Bayesian latent class analyses for development of WOAHO dossier	Assessment of validation dossier for WOAHO certification of multiplex assays for shrimp
Ian Gardner	Chair of OIE ad hoc working group for certification of 2 diagnostic kits on behalf of SRDK	Assessment of validation dossier for OIE certification of kits
Kim Newberry	Reviewer / trainer	Review of the SOPs for generic verification of serological and molecular techniques (September-October 2022) Verification training course which will start the process of delivering verification SOPs to member countries. Training provided 6-10th Feb 2023 in South Africa

TOR7: SCIENTIFIC AND TECHNICAL TRAINING

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

Yes

Please, see 8)

- IAEA Regional TC Project Latin America, RLA 5085 with > 20 countries. Strengthening the Capacity of Official Laboratories for Monitoring and Response to an Outbreak of Priority Animal and Zoonotic Diseases (ARCAL CLXXIV) 2022-2024. Two lectures were delivered about principles and methods diagnostic test validation. A follow-up workshop is planned in 2023.

- In June (2022) FVAS, Massey University and Cognosco Animal Health (New Zealand) ran a one day workshop on diagnostic test interpretation. Course material available at: https://epi.vet.unimelb.edu.au/Courses/NZVA_Jun-2022/
The focus was Dx test interpretation at both the individual and herd level and case studies, e.g. Cognosco (Scott McDougall) had a case study on Johne's disease and interpreting tests at the herd level – this was an addition to the training material that was already produced for the workshop in "Epi in the Valley", 2019.

Ayesha Salgado and Alison Cheung and Simon Firestone provided support on *Mycoplasma bovis* diagnostics to assist the NZ government's eradication campaign.

8. Did your Collaborating Centre provide scientific and technical training, within the remit of the mandate given by WOAHP, to personnel from WOAHP Members?

Yes

a) Technical visit : 3

b) Seminars : 2

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	Ian Gardner visited ACDP 16-25 November 2022 to have discussions on validation methods for point-of-care tests and eNA and met to review results on current validation of pooled tests for WSSV and YHV1 with aquatic group	Australia	10
a	WOAH DDG Monique Eloit visited at ACDP 12 November 2022 to discuss the different reference RL and CC activities	Australia	20
a	Uni Melbourne hosted Dr Kotaro Sawai from the Division of Transboundary Animal Diseases Research, National Institute of Animal Health, Japan.	Australia	10
b	Diagnostic test evaluation and result interpretation	> 18 countries from Latin America (Argentina, Belize, Brazil, Chile, Colombia, Costa Rica, Cuba, Dominican Republic, Ecuador, El Salvador, Guatemala, Honduras, Nicaragua, Panama, Paraguay, Peru, Uruguay, Venezuela)	> 18 countries from Latin America
b	Diagnostic test evaluation (online) Uni Melbourne prepared	Cambodia, Indonesia, Laos, PNG, Philippines, Timor Leste and Vietnam. Asia Pacific Consortium of Veterinary	> 139 participants

	and taught 12/36 modules	Epidemiology (APCOVE) https://www.apcove.com.au/	
c	Training in verification, internal test monitoring and quality assurance. One other ACDP staff member was also training in risk assessment and biosafety with the group during the week and we took training in turns as all staff wanted to be involved in most aspects.	Indonesia	25 participants
c	Verification of Porcine Epidemic Diarrhoea Virus commercially produced indirect ELISA as an example for training in verification techniques at RAHO6 in Vietnam as part of a WOAH funded twinning project (2018 to 2022).	Vietnam	2 staff from RAHO6 lab (Ho Chi Minh City) and 2 staff from NCVD (Hanoi) were trained for a two week period in Nov 2022. 7 staff from RAHO serology and virology department were trained for one week in December 2022.

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?

No

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:

8

ACDP

Moody NJG, Mohr PG, Williams LM, Cummins DM, Hoad J, Slater J, Valdeter ST, Colling A, Nagendrakumar B, Singanallur, Gardner IA, Gudkovs N, St. J. Crane M. 2022. Performance characteristics of two real-time, Taqman polymerase chain reaction assays for the detection of White Spot Syndrome Virus in clinically-diseased and apparently-healthy prawns. *Dis. Aquac. Org.* 18 August 2022, Vol 150. 169-182. <https://doi.org/10.3354/dao03687>.

Balkema-Buschmann A., Fischer K., McNabb L., Diederich S., Balasubramanian N.S., Ziegler U., Keil G., Kirkland P., Penning M., Sadeghi B., Marsh G., Barr J., Colling A. Serological Hendra Virus Diagnostics using an indirect ELISA-based DIVA Approach with recombinant Hendra virus G and H proteins. *Microorganisms* 2022, 10, 1095, p1-19. [file://nexus.csiro.au/AAHL/Users/col473/Downloads/microorganisms-10-01095-v2%20\(1\).pdf](file://nexus.csiro.au/AAHL/Users/col473/Downloads/microorganisms-10-01095-v2%20(1).pdf)

Uni Melbourne

Tolpinrud A, Stenos J, Chaber A, Devlin J, Herbert C, Pas A, Dunowska M, Stevenson M, Firestone S (2022) Validation of an indirect immunofluorescence assay and commercial Q fever enzyme-linked immunosorbent assay for use in macropods. *Journal of Clinical Microbiology* 60. DOI: 10.1128/jcm.00236-22.

Salgado A, Cheung A, Schibrowski M, Wawegama N, Mahony T, Stevenson M, Browning G, Barnes T, Firestone S (2022) Bayesian latent class analysis to estimate the optimal cut-off for the MilA ELISA for the detection of *Mycoplasma bovis* antibodies in sera, accounting for repeated measures. *Preventive Veterinary Medicine* 205, 105694. DOI: 10.1016/j.prevetmed.2022.105694.

Salgado A, Firestone S, Watt A, Thilakarathne D, Condello A, Siu D, Masukagami Y, Tivendale K, Stevenson M, Mansell P, Browning G, Wawegama N (2022) Evaluation of the MilA ELISA for the diagnosis of herd infection with *Mycoplasma bovis* using bulk tank milk and estimation of the prevalence of *M. bovis* in Australia. *Veterinary Microbiology* 270. DOI: 10.1016/j.vetmic.2022.109454.

Moser, R.J., Franz, L., Firestone, S.M., Sellars, M.J., 2022. Enterocytozoon hepatopenaei real-time and Shrimp MultiPath™ PCR assay validation for South-East Asian and Latin American strains in Penaeid shrimp. *Dis. Aquat. Organ.*

Sellars, M.J., Firestone, S.M., Franz, L.M., Genz, B., Moser, R.J., under review. Shrimp MultiPath™ multiplexed PCR White Spot Syndrome virus detection in Penaeid shrimp. *Dis. Aquat. Organ.*

Abeykoon, A.M.H., Firestone, S.M., Stevenson, M.A., Wiethoelter, A.K., Vincent, G.A., 2022. Performance evaluation and validation of air samplers to detect aerosolized *Coxiella burnetii*. *Microbiology Spectrum*

b) International conferences:

5

ACDP

Reid T, Singanallur NB, Waugh C, Bowden TR, Newberry K, Colling A. Validation of veterinary diagnostic tests for infectious diseases: A review of challenges and opportunities. In: *Proceedings of the International Symposium on Sustainable Animal Production and Health Current Status and Way Forward, 28 June – 2 July, 2021, Vienna, Austria.* (accepted for publication 7 April 2022).

Kim Newberry participated in a virtual International conference presenting on verification processes and the need for sound verification of off the shelf tests, NRL, Asian Summit, Melbourne, Australia, 23-24 May 2022.

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Firestone S. M. and APCOVE Training and Evaluation Committee members (2022) Using Field Projects to Strengthen Veterinary Epidemiology Capacity in the Asia-Pacific Region. In, *Proceedings of the 16th Symposium of the International Society for Veterinary Epidemiology and Economics, Halifax, Nova Scotia, Canada, p. 21*

Cheung A, Salgado A, Wood C, Woldeyohannes S, Barnes T, Loh M, Hollier J, Singanallur N, Stevenson M, Firestone S (2022) The Swiss-army knife Bayesian latent class model for diagnostic test evaluation with complex data structures In, *Proceedings of the 16th Symposium of the International Society for Veterinary Epidemiology and Economics, Halifax, Nova Scotia, Canada, p. 300*

Salgado A, Burroughs A, Johnstone T, Wawegama N, Stevenson M, Browning G, Firestone S (2022) Bayesian latent class analysis to estimate the optimal cut-off for the IDVet ELISA for the detection of *Mycoplasma bovis* antibodies in bulk tank milk in New Zealand. In, *Proceedings of the 16th Symposium of the International Society for Veterinary Epidemiology and Economics, Halifax, Nova Scotia, Canada, p. 618.*

c) National conferences:

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

5

Epi centre NZ

*Vallee, Froud, Kean, Chew, Heuer, Tolich (2022). Chapter 4 Estimation of the diagnostic sensitivity and specificity of kauri dieback visual assessment and *Phytophthora agathidicida* soil baiting, culturing and morphological identification using Bayesian latent class analysis. In 2021 Waitākere Ranges kauri population health monitoring survey. Prepared for Auckland Council. Technical Report 2022/8*

ACDP produced example based templates for validation of nucleic acid detection assays, serological tests and extension of validated assays are available online at <https://www.agriculture.gov.au/agriculture-land/animal/health/laboratories/tests/test-development/validation-nucleic-acid-detection>; <https://www.agriculture.gov.au/agriculture-land/animal/health/laboratories/tests/test-development/validation-serological-assays> and <https://www.agriculture.gov.au/agriculture-land/animal/health/laboratories/tests/test-development/validation-existing-assay>

Uni Melbourne developed an epidemiology app which has some useful diagnostic test interpretation functions. See: iPhone: <https://apps.apple.com/vn/app/epi-tools/id1611139482>

Android: <https://play.google.com/store/apps/details?id=au.melbourne.uni.epitools>

The validation team at ACDP holds fortnightly meetings and Melbourne Veterinary School holds monthly meetings (Epi Think Tank) at <https://shiny.vet.unimelb.edu.au/epi/schedule/index.htm>.

For the publication of the publication of the WOAHA Special Issue the ACDP validation team received the CSIRO "Further Together" Award.

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

The validation team has used the new information generated in "Diagnostic test validation science: a key element for effective detection and control of infectious animal diseases (A. Colling & I.A. Gardner, eds). (2021) Rev. Sci. Tech. Off. Int. Epiz., 40 (1)" to update and review chapter 1.1.6. about principles and methods for diagnostic test validation.

Similarly the information from the Special Issue will be used to update / review the supporting validation chapters 2.2.1.-2.2.8.

In addition a new chapter about validation of new technologies such as point of care tests (POCT) is in preparation and others such as for validation of environmental (e-)DNA/RNA and Next Generation Sequencing (NGS) are to follow.

12. Additional comments regarding your report: