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VALIDATION OF DIAGNOSTIC ASSAYS: OIE GENERAL PRINCIPLES AND PROCEDURES

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After the 2007 pre-WAVLD (World Association of Veterinary Laboratory Diagnosticians) workshop: "Test validation, from Theory to Practice" in Melbourne, OIE decided to create an *ad hoc* Group on validation of diagnostic assays to review the chapter and the pathway on test validation. The Group met three times and at its recent meeting in January presented final drafts of the new chapter "Principles and methods of validation of diagnostic assays for infectious diseases" and seven best practice documents.

The essential changes in these OIE principles and methods of diagnostic tests validation are:

- 1) The OIE *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals (Terrestrial Manual)* now has only one chapter on test validation including nucleic acid detection tests (NADs). Before there were two chapters, i.e. one with a focus on serological tests and one for NADs;
- 2) The chapter includes principles and methods for test validation;
- 3) The chapter has seven appendixes that are best practice documents
 - Development and optimisation of antibody detection tests
 - Development and optimisation of antigen detection tests by direct and immunological means
 - Development and optimisation of nucleic acid detection tests
 - Measurement of uncertainty
 - Statistical approaches to test validation (including modern Non-Gold Standard methods, such as Bayesian statistics)
 - Method comparison or equivalence testing (equivalency)
 - Selection and use of reference panels
- 4) The *ad hoc* Group is also finalising guidelines on the use of the OIE validation template (available on the OIE website) in agreement with this new chapter;
- 5) The Biological Standards Commission supported the proposition of the Group to publish all the documents as an OIE book with cross-references in the new validation chapter in the OIE *Terrestrial Manual*.

Future development: there is a need to produce best practice documents for other modern diagnostic tests, such as multiplex Polymerase chain reaction (PCR), Luminex, Loop-mediated isothermal amplification (LAMP), Microarrays, Point of Care tests (POC) and other modern diagnostic applications. An FAO/IAEA consultants meeting to develop a roadmap for the global implementation of modern OIE principles and methods of diagnostic test validation is expected in the second half of 2010 in Vienna, Austria.



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