OIE PRINCIPLES AND METHODS OF VALIDATION OF DIAGNOSTIC TESTS

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The current version of the Terrestrial and Aquatic Manual Chapter on Principles and Methods of Validation of Diagnostic Assays for Infectious Diseases was approved in May 2013. Seven guidelines that provide additional guidance on test validation (with an eighth one on method comparison still in development) have also been approved and are available on the OIE website at: /www.oie.int/en/international-standard-setting/terrestrial-manual/access-online/.

These guidelines cover the following topics: Development and optimisation of antibody detection assays, antigen detection assays and nucleic acid detection assays; Measurement uncertainty, Statistical approaches to validation; Selection and use of reference samples and panels; and Principles and methods for the validation of diagnostic tests for infectious diseases applicable to wildlife. These guidelines were developed by experts, endorsed by the Biological Standard Commissions and eventually adopted by the World Assembly of Delegates during the General Session in May 2014.

Points to be further discussed are in the areas of:
1) methods comparison to avoid the expense associated with full revalidation of an assay,
2) consideration of how applicable existing guidance is to new technology such as multiplex PCR assays and dynamic microfluidics PCR systems, and
3) standards for use of samples from experimental infection studies, where they are the only source of samples for estimation of diagnostic sensitivity and specificity.