

SECTION 3.6.

RECOMMENDATIONS FOR VALIDATION OF DIAGNOSTIC TESTS

INTRODUCTORY NOTE

The OIE has adopted a formal standard entitled Principles and Methods of Validation of Diagnostic Assays for Infectious Diseases, referred to as the OIE Validation Standard. Its most recent version, adopted in May 2013, may be found on the OIE website as chapter 1.1.6 of the Terrestrial Manual:

http://www.oie.int/fileadmin/Home/eng/Health_standards/tahm/1.01.06_VALIDATION.pdf

or chapter 1.1.2 of the Aquatic Manual:

http://www.oie.int/index.php?id=2439&L=0&htmlfile=chapitre_validation_diagnostics_assays.htm

Part 3 of the Terrestrial Manual includes specific recommendations for laboratories. The chapters in Part 3 supplement and give explanatory content in support of the standards included in Parts 1 and 2. The following section of Recommendations for Validation of Diagnostic Tests is such a supplement, dealing with the use of the OIE Validation Standard and its implementation for specific requirements such as different types of assay (antibody, antigen or nucleic acid detection), and an elaboration of some of the tools used in validation studies (measurement of uncertainty, statistical approaches, reference panels). There is also a chapter addressing some of the particular challenges in validating tests for wildlife species. All of the chapters have been written by experts in the respective fields, and have been subjected to an extensive process of consultation in arriving at the final texts.

None of these chapters should be used in isolation. Each is designed to complement and inform the application of the OIE Validation Standard to specific situations.

Chapter 3.6.1. Development and optimisation of antibody detection assays:

http://www.oie.int/fileadmin/Home/eng/Health_standards/tahm/3.6.01_ANTIBODY_DETECT.pdf

Chapter 3.6.2. Development and optimisation of antigen detection assays:

http://www.oie.int/fileadmin/Home/eng/Health_standards/tahm/3.6.02_ANTIGEN_DETECT.pdf

Chapter 3.6.3. Development and optimisation of nucleic acid detection assays:

http://www.oie.int/fileadmin/Home/eng/Health_standards/tahm/3.6.03_NAD_ASSAYS.pdf

Chapter 3.6.4. Measurement uncertainty:

http://www.oie.int/fileadmin/Home/eng/Health_standards/tahm/3.6.04_MEASUREMENT_UNCERT.pdf

Chapter 3.6.5. Statistical approaches to validation:

http://www.oie.int/fileadmin/Home/eng/Health_standards/tahm/3.6.05_STATISTICAL_VALIDATION.pdf

Chapter 3.6.6. Selection and use of reference samples and panels:

http://www.oie.int/fileadmin/Home/eng/Health_standards/tahm/3.6.06_REFERENCE_SAMPLES.pdf

Chapter 3.6.7. Principles and methods for the validation of diagnostic tests for infectious diseases applicable to wildlife:

http://www.oie.int/fileadmin/Home/eng/Health_standards/tahm/3.6.07_WILDLIFE.pdf

Chapter 3.6.8. Comparability of assays after changes in a validated test method:

http://www.oie.int/fileadmin/Home/eng/Health_standards/tahm/3.6.08_COMPARABILITY_ASSAYS_AFTER_CHANGES.pdf