

SECTION 2.2.

VALIDATION OF DIAGNOSTIC TESTS

INTRODUCTORY NOTE ON WOAH VALIDATION RECOMMENDATIONS

WOAH has adopted a formal standard entitled Validation of diagnostic assays for infectious diseases of terrestrial animals, referred to as the WOAHS Validation Standard. Its most recent version, adopted in May 2023, may be found as chapter 1.1.6 of this Terrestrial Manual.

Section 2.2 Validation of Diagnostic Tests deals with the use of the WOAHS 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 WOAHS Validation Standard to specific situations.

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NB: FIRST ADOPTED IN 2014.