Validation of diagnostic tests in the OIE Manual of Diagnostic Tests for Aquatic Animals

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As defined in Chapter 1.1.2. Principles and methods of validation of diagnostic assays for infectious diseases of the World Organisation for Animal Health (OIE) Manual of Diagnostic Tests for Aquatic Animals (Aquatic Manual), validation is the process that determines the fitness of an assay, which has been properly developed, optimised and standardised, for a specific, defined diagnostic purpose.

There are four stages in the pathway for validation of an assay. The results generated for the different assay validation criteria should be documented prior to the implementation of the assay. Any criteria that are still to be determined should also be documented. Subsequent monitoring of the assay after implementation is an important activity for ongoing collation of data regarding test performance, as validation is a continuing process.

This presentation discusses the validation status of a number of assays in the Aquatic Manual, with particular reference to the molecular detection methods for abalone herpesvirus and white spot syndrome virus. A number of possible improvements will also be suggested, including documentation of the stage of assay validation achieved for diagnostic tests and access to this information by users of the Aquatic Manual.