Diagnostic Test Validation – particular challenges for Aquatic Animal Pathogens (and the way forward)

I. Gardner (1), S. Corbeil (2), M. Crane (2) & N. Moody (2)

(1) University of Prince Edward Island, Charlottetown, Prince Edward Island, Canada
(2) Australian Animal Health Laboratory (AAHL), CSIRO, East Geelong, Victoria, Australia

Chapter 1.1.2 ‘Principles and Methods of Validation of Diagnostic Assays for Infectious Diseases’ in the Manual of Diagnostic Tests for Aquatic Animals (Aquatic Manual) provides methods for test validation for the World Organisation for Animal Health (OIE)-listed diseases of amphibians (n=2), fish (n=10), crustaceans (n=8), and molluscs (n=8) and five non-listed diseases of fish, molluscs and crustaceans. Seven guidelines provide additional information to support the Aquatic Manual chapters.

A Pubmed review of published literature on diagnostic sensitivity and specificity in aquatic animals yielded few published studies, especially in crustaceans and molluscs, where validation had been completed to at least Stage 2 of the OIE Pathway. Furthermore, there is little published evidence that ‘recommended’ or ‘suitable’ tests listed in the table in Section 5 ‘Ratings of tests against purpose of use’ of the disease-specific chapters of the Aquatic Manual have ‘good diagnostic sensitivity and specificity’. Unpublished data supporting these statements likely exist in both OIE Reference Laboratories and academic research laboratories and efforts should be made to publish these findings in peer-reviewed journals and incorporate references into these chapters.

Particular challenges of test validation in aquatic animals include the dependence of many infectious diseases on environmental factors such as water temperature and salinity, variation in species susceptibility, limited availability of reference samples from field cases, reliance on experimental challenge models for many diseases, and lack of benchmarking studies comparing the best existing with newly developed tests on the same set of samples. Funding for studies to estimate diagnostic performance of assays is often difficult to obtain and logistical and confidentiality issues may impede completion of field studies.

In the presentation, an example of a validation study for abalone herpes-like virus will be used to illustrate strengths and weaknesses of design and data analysis methods and key aspects of reporting to make the study of greatest utility to end users of the assay, including those using it for early detection of infected abalone or targeted surveillance to demonstrate freedom from infection.