The diagnostic tests are an essential tool for confirming the health status of animals. They play a key role not only in facilitating safe trade but also in many other areas such as the early detection of new or emerging diseases and the control of animal diseases. However they need to be well validated according to internationally agreed standards and guidelines in order to ensure confidence in the tests results.

Over the past decade, the OIE has worked to provide laboratories worldwide with internationally accepted test methods for the OIE listed diseases as well as other diseases of global importance and also with general principles and guidelines for the validation of test methods. This information is available in three publications: the OIE Quality Standard and Guidelines for Veterinary Laboratories, the OIE Manual for Diagnostic Tests and Vaccines for Terrestrial Animals and the OIE Manual for Diagnostic Tests of Aquatic Animals.

Besides this work and based on the fact that more and more national laboratories use commercial diagnostic kits to carry out their tests, the OIE, its Members and international partners felt that there was a need for a more strategic framework to certify commercial diagnostic kits as validated fit for specific purposes and to produce a register of these certified kits.

The OIE Procedure for validation and certification of diagnostic assays was set up to reply to these objectives and meet the needs of the OIE Members. Launched in May 2005, it is a dossier-based procedure where independent and internationally recognised experts are nominated to evaluate the application submitted. The conclusions of this panel are forwarded to the relevant OIE Specialist Commission for an opinion. In the case of a favourable opinion, the diagnostic kit is officially proposed for inclusion for specific purposes in the OIE Register, subject to final endorsement by the World Assembly of Delegates at the General Session held every May.

The OIE intends, through this procedure and all its related standards, guidelines and general principles, to provide a framework for a harmonised approach of the validation and registration of veterinary diagnostic assays across the world.