UPDATE ON THE OIE PROCEDURE FOR THE REGISTRATION OF DIAGNOSTIC KITS

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The OIE Procedure for the registration of diagnostic kits was launched in May 2005.

The aim of the procedure is to certify commercial diagnostic kits as validated ‘fit for purpose’; this means that they have been validated for certain specific purpose(s), animal species and pathogen(s). The aim is also to produce a register of recognised diagnostic kits for use by OIE Member Countries.

The procedure is open to all diagnostic kits for diseases, including zoonoses, caused by pathogens present in animals. It is a dossier-based procedure. Any diagnostic kit manufacturer interested in having its kit(s) certified by the OIE can complete the dossier for the procedure and submit it to the OIE.

The dossier is evaluated by a panel of experts (three in general). The mission of this panel of experts is to inform the relevant OIE Specialist Commission (Biological Standards Commission for terrestrial animals or Aquatic Animal Health Standards Commission for aquatic animals) if the kit can be certified by the OIE for the purposes, species and pathogens mentioned by the kit manufacturer. Based on the final report of the expert panel and on the dossier, the Specialist Commission has to decide whether or not to propose the kit for inclusion in the OIE register of recognised diagnostic kits; inclusion is by vote of the World Assembly of Delegates (meet every year in May).

The Standard Operating Procedure (SOP) was updated in 2012 to clarify the pathway of the procedure, to streamline the renewal procedure and to harmonise the text with the current OIE editing policy.

The future aim would be to involve the OIE Reference Laboratories more and more in the validation of the kits, to have access to an extended panel of OIE international standards for the recommended diagnostic test methods, and to have a network of Collaborating Centres dedicated to this procedure. We would thus have a global system that ranges from the design of validation studies and the use of OIE standards to the registration of the kits following the OIE Procedure.

All information on the procedure, including the SOP, the dossier and the OIE register is available on the OIE website.