

RESOLUTION No. 19

Register of diagnostic kits validated and certified by the OIE

CONSIDERING THAT

1. During the 71st General Session of the OIE in May 2003, the Assembly adopted Resolution No. XXIX endorsing the principle of validation and certification of diagnostic assays for animal diseases by the OIE, and giving a mandate to the Director General of the OIE to set up the specific standard procedures to be used before the final decision on the validation and certification of a diagnostic kit is taken by the Assembly,
2. The Resolution has established that “fitness for purpose” should be used as a criterion for validation,
3. The aim of the OIE procedure for registration of diagnostic kits is to produce a register of recognised kits for OIE Member Countries and for diagnostic kit manufacturers,
4. OIE Member Countries need kits that are known to be validated according to OIE criteria in order to improve the quality of kits and to enhance confidence in kits,
5. The OIE register of recognised diagnostic kits provides greater transparency and clarity of the validation process, and a means for recognising those manufacturers that produce validated and certified tests in kit format,
6. According to the OIE Standard Operating Procedure, registration of the diagnostic kits included in the OIE Register has to be renewed every five years,
7. During the 74th General Session of the OIE, the Assembly adopted Resolution No. XXXII on the importance of recognising and implementing OIE standards for the validation and registration of diagnostic assays by Member Countries,

THE ASSEMBLY

DECIDES THAT

1. In accordance with OIE procedure for registration of diagnostic kits and the recommendations of the OIE Biological Standards Commission and the Aquatic Animal Health Standards Commission, the Director General renews for a period of five additional years the inclusion in the OIE Register of the following diagnostic kits certified by the OIE as validated as fit for purpose:

Name of the diagnostic kit	Name of the Manufacturer	Fitness for purpose
Avian Influenza Disease Antibody Test Kit	BioChek UK Ltd	Fit for serological diagnosis of type A avian influenza in chickens (specific to IgG in serum) and for the following purposes: <ol style="list-style-type: none">1. To demonstrate historical freedom from infection in a defined population (country/zone/compartments/herd);2. To demonstrate re-establishment of freedom after outbreaks in a defined population (country/zone/compartments/herd);3. To confirm diagnosis of suspect or clinical cases;

		<p>4. To estimate prevalence of infection to facilitate risk analysis in non-vaccinated populations (surveys/herd health schemes/disease control);</p> <p>5. To determine immune status in individual animals or populations (post-vaccination).</p>
Prionics®-Check WESTERN	Prionics AG	<p>Fit for the post-mortem diagnosis of bovine spongiform encephalopathy in cattle and for the following purposes:</p> <ol style="list-style-type: none"> 1. To confirm diagnosis of suspect or clinical cases (includes confirmation of a positive screening test); 2. To estimate prevalence of infection to facilitate risk analysis (surveys/herd health schemes/disease control, e.g. surveys, implementation of disease control measures) and to assist in the demonstration of the efficiency of control policies; 3. To confirm a non-negative test result obtained during active surveillance with a different type of test.
IQ 2000™ WSSV Detection and Prevention System	GeneReach Biotechnology Corporation	<p>Fit for the diagnosis of white spot disease in crustaceans and for the following purposes:</p> <ol style="list-style-type: none"> 1. To certify freedom from infection (<10 virions/sample) in individual animals or products for trade/movement purposes; 2. To confirm diagnosis of suspect or clinical cases (confirmation of a diagnosis by histopathology or clinical signs); 3. To estimate prevalence of infection to facilitate risk analysis (surveys/herd health schemes/disease control).
IQ Plus™ WSSV Kit with POKIT System	GeneReach Biotechnology Corporation	<p>Fit for the detection of white spot disease in target tissues (Shrimp tissue of ectodermal and mesodermal origin) of <i>Litopenaeus vannamei</i> and for the following purposes:</p> <ol style="list-style-type: none"> 1. To certify freedom from infection (<10 virions/reaction) in individual animals or products for trade/movement purposes; 2. To confirm diagnosis of suspect or clinical cases (confirmation of a diagnosis by histopathology or clinical signs); 3. To estimate prevalence of infection to facilitate risk analysis (surveys/herd health schemes/disease control).

(Adopted by the World Assembly of Delegates of the OIE on 22 May 2018
in view of an entry into force on 25 May 2018)