

RESOLUTION No. 26

**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 International Committee adopted Resolution No. XXIX endorsing the principle of validation and certification of diagnostic assays (test methods) for infectious 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 assay is taken by the OIE International Committee,
2. The Resolution has established that 'fitness for purpose' should be used as a criterion for validation,
3. The aim of the procedure for diagnostic kits is to produce a register of recognised assays for OIE Member Countries and for diagnostic kit manufacturers,
4. OIE Member Countries need assays that are known to be validated according to OIE criteria in order to improve the quality of assays, to ensure that the test can be used to correctly establish animal disease status and to enhance confidence in assays,
5. The OIE register of recognised assays 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 International Committee 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 the recommendation of the OIE Aquatic Animal Health Standards Commission, the Director General add the following to the register of diagnostic kits certified by the OIE as validated as fit for purpose:

Name of the diagnostic kit	Name of the Manufacturer	Fitness for purpose
IQ Plus™ WSSV Kit with POCKIT System	Genereach Biotechnology Corporation	Fit for the diagnosis of white spot disease in target tissues (Shrimp tissue of ectodermal and mesodermal origin) of <i>Litopenaeus vannamei</i> and for the following purposes: <ol style="list-style-type: none"><li>1. To certify freedom from infection (&lt;10 virions/reaction) in individual animals or products for trade/movement purposes;</li><li>2. To confirm diagnosis of suspect or clinical cases (confirmation of a diagnosis by histopathology or clinical signs);</li><li>3. To estimate prevalence of infection to facilitate risk analysis (surveys/herd health schemes/disease control).</li></ol>

2. In accordance with the recommendation of the OIE Biological Standards Commission and of the OIE Aquatic Animal Health Standards Commission, the Director General renew 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
BioChek Avian Influenza Antibody test kit	BioChek UK Ltd	<p>Fit for serological diagnosis of type A avian influenza in chickens (specific to IgG in serum) and for the following purposes:</p> <ol style="list-style-type: none"> <li>1. To demonstrate historical freedom from infection in a defined population (country/zone/compartments/herd);</li> <li>2. To demonstrate re-establishment of freedom after outbreaks in a defined population (country/zone/compartments/herd);</li> <li>3. To confirm diagnosis of suspect or clinical cases;</li> <li>4. To estimate prevalence of infection to facilitate risk analysis in non-vaccinated populations (surveys/herd health schemes/disease control);</li> <li>5. To determine immune status in individual animals or populations (post-vaccination).</li> </ol>
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"> <li>1. To certify freedom from infection (&lt;10 virions/reaction) in individual animals or products for trade/movement purposes;</li> <li>2. To confirm diagnosis of suspect or clinical cases (confirmation of a diagnosis by histopathology or clinical signs);</li> <li>3. To estimate prevalence of infection to facilitate risk analysis (surveys/herd health schemes/disease control).</li> </ol>
Prionics®-Check WESTERN	Prionics®	<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"> <li>1. To confirm diagnosis of suspect or clinical cases (includes confirmation of a positive screening test);</li> <li>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;</li> <li>3. To confirm a non-negative test result obtained during active surveillance with a different type of test.</li> </ol>

(Adopted by the World Assembly of Delegates of the OIE on 30 May 2013)