RESOLUTION No. XXVII

Register of Diagnostic Tests 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 establishes 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 Members and for test manufacturers,

4. OIE Members 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 process of producing an OIE register of recognised assays will provide 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. 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 Members,

7. To render the process transparent, all results of the test validation procedure carried out by the OIE will be included in detailed form on the OIE web site,

THE COMMITTEE

RESOLVES THAT

1. In accordance with the recommendation of the OIE Biological Standards Commission, the Director General adds the following to the register of test 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	Fit for serological diagnosis of type A avian influenza in chickens (specific to IgG in serum) and for the following purposes: 1. To demonstrate historical freedom from infection in a defined population (country/zone/compartment/herd); 2. To demonstrate re-establishment of freedom after outbreaks in a defined population (country/zone/compartment/herd);

		3. To confirm diagnosis of suspect or clinical cases; 4. To estimate prevalence of infection to facilitate risk analysis in non-vaccinated populations (surveys/herd health schemes/disease control); 5. To determine immune status in individual animals or populations (post-vaccination).
IQ 2000™ WSSV Detection and Prevention System	Genereach Biotechnology Corporation	Fit for the diagnosis of white spot disease in crustaceans and for the following purposes: 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).
Prionics®-Check WESTERN	Prionics®	Fit for the post-mortem diagnosis of bovine spongiform encephalopathy in cattle and for the following purposes: 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.

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(Adopted by the International Committee of the OIE on 29 May 2008)