RESOLUTION No. 34

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. 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 Biological 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**
BOVIGAM® *Mycobacterium bovis* Gamma interferon test kit for cattle	Prionics AG	Fit for the detection of cell mediated immune response to infection with *Mycobacterium bovis* and other mycobacteria belonging to the tuberculosis complex on analysis of whole blood specimens in cattle, buffalo (*Syncerus caffer*), goat and sheep (provisionally) for the following purposes: 1. Historical freedom; 2. Re-establishment of freedom after outbreaks;

		3. Certify freedom from infection or agent in individual animals or products for trade/ movement purposes; 4. Eradication of infection from defined populations; 5. Confirmatory diagnosis of suspect or clinical cases (includes confirmation of positive screening test); 6. Estimate prevalence of infection to facilitate risk analysis (surveys/herd health schemes/ disease control); 7. Ancillary test for eradication of tuberculosis.

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(Adopted by the World Assembly of Delegates of the OIE on 27 May 2015
in view of an entry into force on 30 May 2015)