RESOLUTION No. 15

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 Biological Standards Commission, the Director General add the following kits 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**
Pourquier® IIF *Taylorella equigenitalis*	IDEXX Laboratories	Fit for the detection of *Taylorella equigenitalis* bacterial bodies from the swabs of the reproductive tract of stallions and mares for the following purposes: 1. Certify freedom from infection or agent in individual animals or products for trade or movement purposes; 2. Estimate prevalence of infection to facilitate risk analysis (surveys, herd health schemes or disease control); 3. Control of infection in stallions and mares at the start of the breeding season.

BIONOTE® Rapid MERS-CoV Ag Test Kit	BioNote, Inc.	Fit for the qualitative detection of Middle East Respiratory Syndrome Coronavirus (MERS-CoV) antigens from nasal swabs in dromedary camels for the following purposes: 1. Detection of MERS-CoV infected herds (herd test) with acutely infected animals with high virus loads; 2. When used as a supplemental test, to estimate prevalence of infection to facilitate risk analysis, e.g. surveys, herd health schemes and disease control programmes.

2. In accordance with the recommendation of the OIE Biological Standards, the Director General renew for a period of five additional years the inclusion in the OIE Register of the following diagnostic kit certified by the OIE as validated as fit for purpose:

Name of the diagnostic kit	**Name of the Manufacturer**	**Fitness for purpose**
Check&Trace Salmonella	Check-Points B.V.	Fit for rapid (molecular) confirmation and serotyping of presumptive *Salmonella* spp. of the following 22 serotypes: Agona, Anatum, Bredeney, Derby, Dublin, Enteritidis, Hadar, Heidelberg, Indiana, Infantis, Kottbus, Mbandaka, Montevideo, Newport, Paratyphi B, Paratyphi B v Java, Saintpaul, Senftenberg, Tennessee, Typhimurium (and its monophasic variant 4,12:i:) and Virchow.

(Adopted by the World Assembly of Delegates of the OIE on 24 May 2016
in view of an entry into force on 27 May 2016)