RESOLUTION No. 20

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 establish 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 standards in order 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 validate and certify tests marketed 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 5 years,

7. During the 74th General Session of the OIE in May 2016, 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,

8. The *Validation Studies Abstracts* are available as annexes to the report of the OIE Biological Standards Commission of 17-20 September 2019 for the VetMAX™ African Swine Fever Virus Kit and of 11-14 February 2020 for the Check&Trace Salmonella and the *Salmonella* Abortusovis Test,

THE ASSEMBLY

DECIDES THAT

1. In accordance with the OIE procedure for registration of diagnostic kits and the recommendations of the OIE Biological Standards Commission, the Director General renews 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**
BOVIGAM® *Mycobacterium bovis* Gamma interferon test kit for cattle	Thermo Fisher Scientific 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 provisionally for sheep 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.

2. In accordance with the OIE procedure for registration of diagnostic kits and the recommendations of the OIE Biological Standards Commission, the Director General proposes the inclusion in the OIE Register of the following two diagnostic kits certified by the OIE for a period of 5 years:

Name of the diagnostic kit	**Name of the Manufacturer**	**Fitness for purpose**
Salmonella Abortusovis Test	DIATHEVA s.r.l.	Fit for the detection of IgG anti-*Salmonella* Abortusovis in sheep serum samples. The test is designed to be used for the diagnosis of abortive salmonellosis infection and evaluation of antibody response to vaccination, as an ancillary test in conjunction with other methods for serological prevalence survey, or diagnosis and management of *S.* Abortusovis infection within herds, for the following purposes: 1. To demonstrate freedom from infection in a defined population (country/zone/compartment/herd) – historical freedom; 2. To confirm, but not negate, diagnosis of suspect or clinical cases, including confirmation of positive screening tests in individual animals and in herds with infection prevalence ranging from very low to high, based on detection of antibodies in sheep serum; 3. To determine immune status in individual animals or populations (post vaccination). The test does not distinguish between vaccinated and infected sheep.
VetMAX™ African Swine Fever Virus Detection Kit	Thermo Fisher Scientific LSI S.A.S.	Fit for the detection of African Swine Fever virus from blood, serum and tissues of pigs and wild pigs (including wild boars).

3. In accordance with the OIE procedure for registration of diagnostic kits and the recommendations of the OIE Biological Standards Commission, the Director General proposes to amend the OIE validation of certification and fitness for purpose in the OIE Register of the following diagnostic kit certified by the OIE for a period of 5 years, or the next scheduled renewal:

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 (using shortened test protocol): 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 1,4,[5],12:i:-) and Virchow.

(Adopted by the World Assembly of Delegates of the OIE on 29 May 2020
in view of an entry into force on 30 May 2020)