DRAFT RESOLUTION No. 30

Register of terrestrial animal diseases diagnostic kits validated and certified by WOAH

CONSIDERING THAT

1. During the 71st General Session of WOAH in May 2003, the Assembly adopted Resolution No. XXIX endorsing the principle of validation and certification of diagnostic assays for animal diseases by WOAH, and giving a mandate to the Director General 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 World Assembly of Delegates,

2. The Resolution has established that "fitness for purpose" should be used as a criterion for validation,

3. The aim of WOAH's procedure for registration of diagnostic kits is to establish a register of recognised kits for WOAH Members and for diagnostic kit manufacturers,

4. WOAH Members need kits that are known to be validated according to WOAH standards in order to enhance confidence in kits,

5. WOAH's 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 WOAH Standard Operating Procedure, registration of diagnostic kits included in the Register has to be renewed every 5 years,

7. During the 74th General Session in May 2006, the Assembly adopted Resolution No. XXXII on the importance of recognising and implementing WOAH standards for the validation and registration of diagnostic assays by Members,

8. The *Validation Studies Abstracts* are available as annexes to the report of the Biological Standards Commission of 6-9 February 2023 (for the VDRG® FMDV 3Diff/PAN Ag Rapid kit, Enferplex Bovine TB antibody test (*additional claim*), BOVIGAM® – Mycobacterium bovis Gamma interferon test kit for cattle (*extension of the claim*), and Rapid MERS-CoV Ag Test (renewal with new studies). There is no Validation Studies Abstract for *Mycobacterium bovis* Antibody Test Kit, as this is a renewal without any additional data evaluation or changes.

THE ASSEMBLY

DECIDES THAT

1. In accordance with WOAH's procedure for registration of diagnostic kits and the recommendations of the Biological Standards Commission, the Director General proposes the inclusion in WOAH's Register of the following new terrestrial diagnostic kit certified by WOAH for a period of 5 years:

Name of the diagnostic kit	Name of the Manufacturer	Fitness for purpose
VDRG® FMDV 3Diff/PAN Ag Rapid kit	MEDIAN Diagnostics Inc	The VDRG® FMDV 3Diff/PAN Ag Rapid kit is a lateral flow test or pen-side test intended for the universal detection of foot-and-mouth disease virus (FMDV) of serotypes A, O and Asia-1 in tissue samples (epithelium) or fluid from blisters or ruptured lesions of suspected swine or cattle. The test is designed to be used for the rapid diagnosis of foot-and-mouth disease virus infection in samples from swine or cattle.

2. In accordance with WOAH procedure for registration of diagnostic kits and the recommendations of the Biological Standards Commission, the Director General proposes to **amend WOAH validation of certification and fitness for purpose** in WOAH' s Register of the following diagnostic kits certified by WOAH for a period of 5 years:

Name of the diagnostic kit	Name of the Manufacturer	Fitness for purpose
Enferplex Bovine TB antibody test	Enfer Scientific ULC	***Additional claim***: Fit for the detection of antibody to *Mycobacterium bovis* in bovine milk samples (May 2023) to be used as an ancillary test in conjunction with other methods for serological prevalence surveys, or diagnosis and management of *M. bovis* infection within herds, in particular for the following purposes: 1. To confirm, but not negate, diagnosis of suspect or clinical cases, including confirmation of positive screening tests in individual animals and in herds based on detection of antibodies in individual bovine milk samples excluding colostrum and first milk samples taken within 4 days of calving. 2. As a screening test to identify herds with *Mycobacterium bovis* infection based on detection of antibodies in bovine bulk tank milk samples excluding colostrum and first milk samples taken within 4 days of calving. ** In 2019 this test was **provisionally approved** for testing milk samples from cattle as a herd screening test or as a supplemental confirmatory test for use in individual animals, when used in conjunction with other methods for diagnosing and managing *M. bovis* infection (Resolution No.31)
BOVIGAM® Mycobacterium *bovis* Gamma interferon test kit for cattle	Prionics Lelystad B.V.	***Extension of the claim*** The BOVIGAM® - *Mycobacterium bovis* Gamma interferon test kit is an indirect assay intended for the detection of interferon-gamma (IFNγ) response elicited to specific stimulation by *M. bovis* specific peptides or proteins, in plasma obtained from stimulated blood samples of suspected **water buffalos** (*Bubalus bubalis).* ** The original registration with Resolution No. 34 was adopted by the World Assembly of the OIE/WOAH Delegates in 2015. This test was renewed (Resolution No.20) without any additional data evaluation or changes in 2020

3. In accordance with WOAH procedure for registration of diagnostic kits and the recommendations of the Biological Standards Commission, the Director General proposes **to renew** for a period of five additional years the inclusion in the WOAH's Register of the following diagnostic kit certified by WOAH as validated as fit for purpose:

Name of the diagnostic kit	**Name of the Manufacturer**	**Fitness for purpose**
BIONOTE® Rapid MERS-CoV Ag Test Kit	BioNote, Inc	Certified by WOAH fit for the qualitative detection of Middle East Respiratory Syndrome Coronavirus antigens from nasal swabs in dromedary camels in the laboratory for the following purposes: - Detection of MERS CoV infected herds (herd test) with acutely infected animals with high virus loads; - When used as a supplemental test, to estimate prevalence of infection to facilitate risk analysis, e.g. surveys, herd health schemes and disease control programs **The original registration Resolution No.15 was adopted in May 2016 by the World Assembly of the OIE/WOAH Delegates
Mycobacterium bovis Antibody Test Kit	IDEXX Laboratories	Certified by WOAH as fit for the detection of antibodies to *M. bovis* in cattle serum and plasma samples, to be used as a supplemental test, in conjunction with other methods, for diagnosing and managing *M. bovis* infection. The test also has utility when performing sero-surveys to understand prevalence and risk of *M. bovis* infection at a herd management level. **The original Resolution No. 24 was adopted in May 2012 and renewed by the World Assembly of the OIE/WOAH Delegates by Resolution No. 19 in 2017