

RESOLUTION No. 24

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 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, and
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

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
IDEXX M. bovis Antibody Test Kit	IDEXX Laboratories	Fit for the detection of antibody to <i>Mycobacterium bovis</i> (<i>M. bovis</i>) in cattle serum and plasma samples and to be used as a supplemental test, in conjunction with other methods, for diagnosing and managing tuberculosis infection. The test also has utility when performing sero-surveys to understand prevalence and risk at a herd management level.

(Adopted by the World Assembly of Delegates of the OIE on 23 May 2012)