

RESOLUTION No. 26

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 establishes 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 Members and for diagnostic kit manufacturers,
4. OIE Members 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 process of producing an OIE register of recognised assays will provide 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 Members,
7. To render the process transparent, all results of the test validation procedure carried out by the OIE will be included in detailed form on the OIE web site,

THE COMMITTEE

RESOLVES THAT

1. In accordance with the recommendation of the OIE Biological Standards Commission, the Director General adds 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
TeSeE™ WESTERN BLOT	Bio-Rad	Fit for the post mortem detection of Transmissible Spongiform Encephalopathies (TSEs) in cattle (Bovine Spongiform Encephalopathy, BSE), in ovine and caprine (BSE and scrapie), and in cervids (Chronic Wasting Disease, CWD) and as validated fit for the following purposes: 1. To confirm TSE suspected positive samples detected at the screening laboratories in countries with active/passive surveillance programmes. Any

		<p>sample with a negative result according to the TeSeE™ WESTERN BLOT assay interpretation criteria, following a positive rapid test result, should be tested with one of the other OIE certified confirmatory methods, Immunohistochemistry (IHC) or SAF-Immunoblot;</p> <ol style="list-style-type: none">2. To confirm the prevalence of infection with one of the TSE associated diseases (BSE, scrapie, CWD) in the context of an epidemiological survey in a low prevalence country;3. To estimate prevalence of infection to facilitate risk analysis (e.g. surveys, implementation of disease control measures) and to assist the demonstration of the efficiency of eradication policies.
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(Adopted by the International Committee of the OIE on 28 May 2009)