

DRAFT RESOLUTION No. 31

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,

THE ASSEMBLY

DECIDES THAT

1. In accordance with 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 kits certified by the OIE as validated as fit for purpose:

Name of the diagnostic kit	Name of the Manufacturer	Fitness for purpose
Newcastle Disease Virus Antibody Test Kit	BioChek UK Ltd	Fit to detect Newcastle disease virus specific IgG antibodies in chicken sera and for the following purposes: 1. To demonstrate historical freedom from infection in a defined population (country/zone/compartments/flock); 2. To determine immune status in individual animals or populations (post-vaccination); 3. To monitor infection or disease in unvaccinated populations;

		4. To estimate prevalence of infection to facilitate risk analysis in non-vaccinated populations (surveys/ flock health schemes/disease control).
TeSeE™ Western Blot	Bio-Rad Laboratories	<p>Fit for the post-mortem detection of transmissible spongiform encephalopathies (TSEs) in cattle (bovine spongiform encephalopathy, BSE), in ovines and caprines (BSE and scrapie), and in cervids (chronic wasting disease, CWD), and for the following purposes:</p> <ol style="list-style-type: none"> 1. To confirm TSE suspected positive samples detected at the screening laboratories in countries with active/passive surveillance programmes. Any 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; 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.

2. In accordance with 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 diagnostic kit certified by the OIE 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	<p>Fit for the detection of antibody to <i>Mycobacterium bovis</i> in cattle serum samples, to be used as an ancillary test in conjunction with other methods for serological prevalence surveys, or diagnosis and management of <i>M. bovis</i> infection within herds, for the following purposes:</p> <ol style="list-style-type: none"> 1. 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 bovine serum. 2. To detect <i>Mycobacterium bovis</i> infected animals not positive by single intradermal comparative cervical tuberculin (SICCT) or interferon gamma release assay (IFNγ) tests, based on detection of antibodies in bovine serum. 3. To confirm, but not negate, infection in animals giving inconclusive reactions in the SICCT, based on detection of antibodies in bovine serum. 4. As a screening test, to identify animals most likely to have visible lesions by scoring the number of <i>M. bovis</i> antigens recognised by seropositive animals with bovine tuberculosis.

		<p>Species and specimens: This test has been validated and approved for testing serum samples from cattle, as noted above.</p> <p>Regarding intended use 4 above, during the first 5 years of registration, additional data will be required to better qualify and categorise the relationship between the number of <i>M. bovis</i> antigens and the likelihood of visible lesions.</p> <p>This test is also 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 <i>M. bovis</i> infection.</p>
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