

DRAFT RESOLUTION No. 30

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 Members and for diagnostic kit manufacturers,
4. OIE Members 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 Members,

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 5 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
Pourquier® IIF <i>Taylorella equigenitalis</i>	IDEXX Laboratories	Fit for the detection of <i>Taylorella equigenitalis</i> bacterial bodies from the swabs of the reproductive tract of stallions and mares for the following purposes: <ol style="list-style-type: none">1. Certify freedom from infection or agent in individual animals or products for trade or movement purposes;2. Estimate prevalence of infection to facilitate risk analysis (surveys, herd health schemes or disease control);3. Control of infection in stallions and mares at the start of the breeding season.