

# Diagnostic Kits

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## Registration of Diagnostic Kits

### Legal Basis

During WOA's 71st General Session (founded as OIE) in May 2003, the International Committee adopted Resolution No. XXIX. This Resolution endorses the principle of validation and certification of diagnostic assays (test methods) for infectious animal diseases by WOA and gives a mandate to the WOA Director General to set up the specific standard procedures to be used before the final decision on the validation and certification of the diagnostic assay is taken by the WOA International Committee.

The Resolution establishes that 'fitness for purpose' should be used as a criterion for validation.

The concept of 'fitness for purpose' indicates the purpose of the test, e.g.:

1. To demonstrate population 'freedom' from infection (prevalence apparently zero)
  - a) 'free' with and/or without vaccination,
  - b) historical 'freedom',
  - c) re-establishment of 'freedom' following outbreaks;
2. To demonstrate freedom from infection or agent in individual animals or products for trade purposes;
3. To demonstrate efficiency of eradication policies;
4. To confirm diagnosis of clinical cases;
5. To estimate prevalence of infection to facilitate risk analysis (surveys, classification of herd health status, implementation of disease control measures);
6. To determine immune status in individual animals or populations (post-vaccination).

The Resolution states that the WOA Director General should make provisions to establish a registry of assays with levels of validation specified. He is given the mandate to review the procedures involved in the timely approval of assays and is authorised to recover, if necessary, any costs incurred in the process of validation, certification and registry of such assays.

Resolution No. XXIX establishes that WOA Reference Laboratories should be intimately involved with the validation procedures and that they should establish serum/sample reference collections to be used for validation in line with their mandates.

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