Standard Operating Procedure for OIE Registration of Diagnostic Kits

Guide and Administrative Forms

2021

Standard Operating Procedure for OIE Registration of Diagnostic Kits: Summary

This *Standard Operating Procedure (SOP) for OIE Registration of Diagnostic Kits* provides background information and outlines the procedures for submitting applications to the OIE for recognition and registration of veterinary diagnostic kits. It also includes links to the downloadable *Application Form for the Certification of Diagnostic Kits validated as fit for specific purposes (Application Form)* as well as copies of the Confidentiality Undertaking and *Public Declarations of Interests* forms for completion by Review Panel members in Appendix I.

OIE Members rely on diagnostic kits as essential tools for various specific purposes, including detection of pathogens or related immune responses in individual animals or herds, confirmation of infection in clinically diseased animals, surveillance of infectious animal diseases to support control and eradication programs, and certification of health status for international trade.

To help address the needs of users for access to high quality diagnostic kits that are validated according to standardised criteria, the OIE has established a register of diagnostic kits for recognised assays that have been rigorously assessed by a panel of experts and validated as fit for one or more specific purpose(s).

Tests may include immunological or molecular-based systems relevant to the veterinary sector, focusing on the detection of pathogens or corresponding immune responses associated with transboundary animal diseases and zoonotic diseases that are covered in the OIE *Terrestrial Manual* and *Aquatic Manual.* Where a test system is submitted that involves multiple test procedures, then validation of all tests in that system is required (for example 'Test A' as a screening test, with positive samples submitted to 'Test B' as a confirmatory procedure).

Registration, valid for five years and renewable, will also allow the use of the OIE logo on associated kit labelling materials, recognising the status of a test as having been satisfactorily validated and certified to be fit for the defined purpose(s), according to OIE parameters. Information about registered kits will be posted on the OIE webpage and be recorded in printed documentation. Success in OIE registration will depend on the applicant supplying quality-controlled validation data in accordance with the OIE standards on validation published in the *Terrestrial Manual* and *Aquatic Manual* to demonstrate the fitness for use of the kit for a defined purpose or purposes.

This procedure for the registration of diagnostic kits, therefore, establishes the 'fitness for purpose' of a diagnostic kit through an objective, transparent process. OIE Members are encouraged to authorise or promote the use of these OIE-registered diagnostic kits in their territory where warranted. Manufacturers could also take these established OIE standards into consideration when designing protocols for internal validation of new diagnostic kits.

Application Procedures and Forms

Under this voluntary registration procedure, manufacturers can seek registration of their kit by submitting an *Application Form for the Certification of Diagnostic Kits as validated fit for specific purposes (Application Form)* with supporting data to the OIE Secretariat for Registration of Diagnostic Kits (OIE SRDK). The *Application Form* enables applicants to submit the required data in a standardised format so the OIE scientific Review Panel can objectively assess the test's performance. The *Application Form* and related documents are available for downloading on the OIE website at:

http://www.oie.int/en/scientific-expertise/registration-of-diagnostic-kits/background-information/

The *Application Form*, which includes a concise summary of the supporting data in the form of a *Validation Studies Abstract*, is reviewed by a panel of experts who compiles their conclusions and recommendations into a Final Review Panel Report. The Final Review Panel Report is submitted to the OIE Specialist Commissions (Biological Standards Commission or Aquatic Animal Health Standards Commission) for consideration and potential endorsement. If the decision is favourable, a proposed Resolution, accompanied by the *Validation Studies Abstract*, is forwarded to the Member Countries in advance of the General Session, to allow an informed decision when the *Resolution* is submitted to a vote at the General Session, in which the Delegates are asked to formally approve the conclusions and recommendations of the expert panel and the relevant Specialist Commission (*Biological Standards Commission* or *Aquatic Animal Health Standards Commission*). If approved, the applicants are notified, and the kit is entered into the *OIE Register of Diagnostic Kits validated as fit for purpose* (OIE Register). Product information is subsequently posted on the OIE SRDK publicly accessible web page at:

https://www.oie.int/scientific-expertise/registration-of-diagnostic-kits/the-register-of-diagnostic-kits/

Technical Standards for Validation

The OIE has adopted a formal validation standard that is described in the *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals (Terrestrial Manual)* Chapter 1.1.6 Principles and Methods of Validation of Diagnostic Assays for Infectious Diseases, and also in the *Manual of Diagnostic Tests for Aquatic Animals (Aquatic Manual)* Chapter 1.1.2. Principles and Methods of Validation of Diagnostic Assays for Infectious Diseases. These chapters and other guidance for validation of diagnostic tests can be accessed on the OIE website at:

https://www.oie.int/standard-setting/terrestrial-manual/access-online/
https://www.oie.int/standard-setting/aquatic-manual/access-online/

Validation is a process that determines the fitness of an assay, which has been developed, optimised, and standardised for a specific intended purpose or purposes. All diagnostic assays (laboratory and field assays) should be validated for the species, specimens and the equipment, personnel and conditions in which they will be used. Validation includes estimates of the analytical and diagnostic performance characteristics of a test, including analytical sensitivity and specificity, diagnostic sensitivity and specificity, within laboratory repeatability, and between laboratory reproducibility. In the context of this validation procedure, an assay that has completed the first three stages of the validation pathway including performance characterisation, can be designated as 'validated for the original intended purpose(s)' (see Appendix II. Figure 1. Diagnostic kit assay development and validation pathway, which is excerpted from the *Terrestrial Manual* and *Aquatic Manual*). The specific 'fitness for purpose' criteria are further explained in this document and the *Terrestrial Manual* chapters cited above.

Provisional Recognition for Additional (Secondary) Uses

Kits that have already satisfactorily met the validation requirements to demonstrate fitness for a primary intended use, may be eligible for provisional recognition for additional (secondary) uses (e.g., use of the kit for additional related animal species or with different biological specimens).

Provisional recognition for alternative (secondary) uses would apply in circumstances where there is supplementary supporting data regarding the kit's use in additional species or specimens, however, the test's fitness for use in these specific circumstances has not been fully validated due to factors such as limited availability of test specimens for conducting the required validation studies. This type of provisional recognition could also potentially be applied for rare diseases, emerging diseases, or wildlife. Further information about provisional assay recognition is provided in the *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals (Terrestrial Manual) Chapter 1.1.6. Principles and Methods of Validation of Diagnostic Assays for Infectious Diseases*.

This provisional recognition would ordinarily be granted on an interim basis, for a specified timeframe to allow for collection of the required supporting data (e.g. diagnostic sensitivity, specificity, or reproducibility), or for special situations such as emergencies, minor species, or absence of other tests. In these cases, the *Validation Studies Abstract* and User's Manual must note the limitations of any provisional approvals for alternative (secondary) uses, and these potential alternative uses must be clearly differentiated from the primary intended uses that have been fully validated and approved.

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Section 1 – Background

1.1. Legal basis

During the 71st General Session of the World Organisation for Animal Health (OIE) in May 2003, the International Committee (now renamed as World Assembly of Delegates) adopted Resolution No. XXIX. This Resolution endorsed the principle of validation and certification of diagnostic assays (test methods) for infectious animal diseases by the OIE and gave a mandate to the Director General of the OIE to set up specific standard procedures to be used before the final decision on the validation and certification of the diagnostic assay is taken by the International Committee.

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

The concept of 'fitness for purpose' indicates the purpose of the test, such as:

- Demonstrate freedom from infection in a defined population (country/zone/compartment/herd)
    - "Free" with vaccination.
    - Re-establishment of freedom after outbreaks.
- To demonstrate freedom from infection or agent in individual animals or products for trade purposes;
- To demonstrate efficiency of eradication policies;
- To confirm diagnosis of clinical cases;
- To estimate prevalence of infection to facilitate risk analysis (surveys, classification of herd health status, implementation of disease control measures);
- To determine immune status in individual animals or populations (post-vaccination).

The Resolution stated that the Director General of the OIE should make provisions to establish a registry of assays with levels of validation specified. He/she has been given the mandate to review the procedures for timely approval of assays and is authorised to recover, if necessary, any costs incurred in the process of registry of such assays. Resolution No. XXIX also established that OIE 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.

1.2. Objectives of the procedure

OIE Member Countries need assays that are known to be validated according to OIE criteria in order to improve the quality of diagnostic testing and to ensure that such testing establishes animal disease status with a high level of confidence. A register of recognised diagnostic kits published and updated by the OIE will provide greater transparency and clarity of the validation process and also a means for recognising manufacturers that produce validated and certified tests in the form of a kit. In order to keep the process transparent, a summary of results of the validation of kits by the OIE are accessible on the OIE website.

The *Application Form for the Certification of Diagnostic Kits as validated fit for specific purposes (Application Form)* must be used to apply for certification by the OIE of a diagnostic kit as 'fit for purpose'. The Application Form guides an applicant through the application process by indicating important features of test validation to enable the reviewers to come to a rapid conclusion about any test's validation status (the extent to which data supports the claims for a particular purpose).

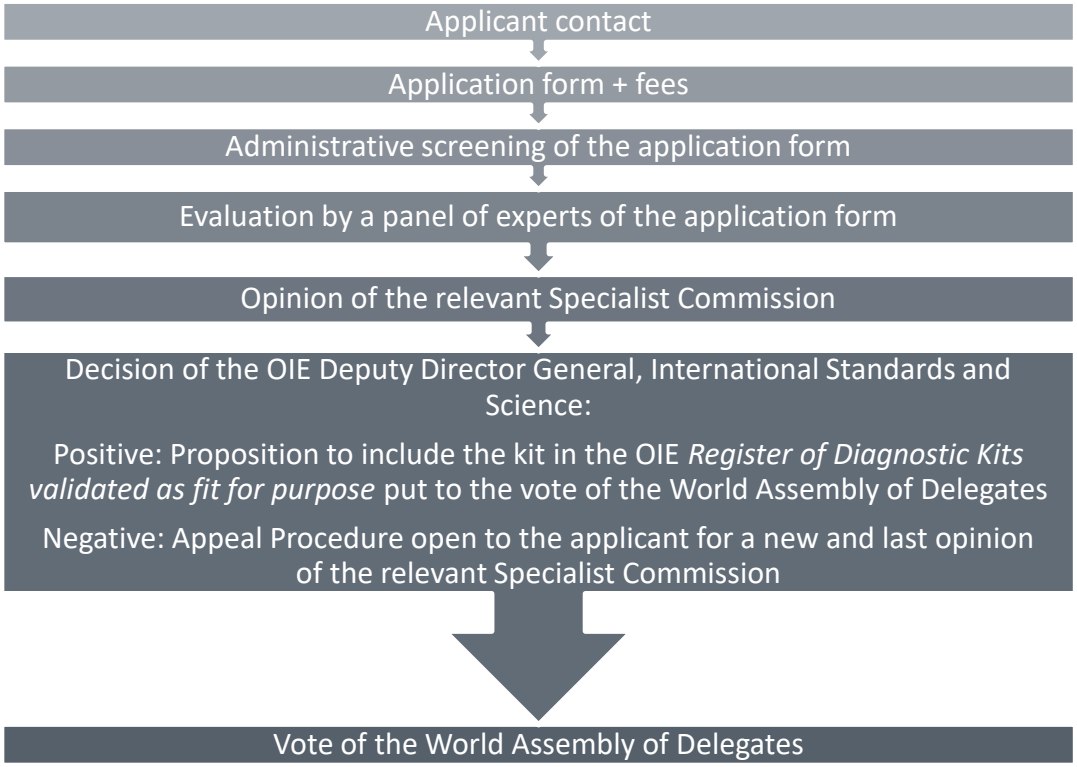
'Fit for purpose' means that the kit has to be validated to demonstrate acceptable performance characteristics of the test for a defined purpose and explicit conditions of use. There is a need to clearly define the purpose of the kit and demonstrate that sufficient data have been obtained to ascribe desired confidence to its use, in statistical terms, to answer a defined question.

Examples:

1. “To detect antibodies against non-structural proteins for FMD” is not specific enough as a purpose of use.
2. “To detect antibodies against non-structural proteins for FMD in pigs, cattle, sheep and goats to allow differentiation of infected and vaccinated animals on a herd basis following an outbreak to declare a country free from disease” is a specific purpose of use.

Section 2 – Details of the Procedure

2.1. General outline



2.2. Procedure step by step

2.2.1. Initiating an application

In order to start the procedure, the *Application Form* duly completed and the applicable fee should be sent by the applicant to the OIE Director General, in one complete electronic copy.

Director General
OIE Procedure for registration of diagnostic kits
OIE
12, rue de Prony
75017 Paris
France
Email: oie@oie.int and copy to oie-srdk@oie.int

The OIE Headquarters, through the OIE Secretariat for Registration of Diagnostic Kits (OIE SRDK) can provide, upon request, more procedural guidance during the pre-submission phase.

OIE SRDK
Secretariat for Registration of Diagnostic Kits
Antimicrobial Resistance and Veterinary Products Department
OIE
12, rue de Prony
75017 Paris, France
Tel: 33 (0)1 44 15 19 69
Fax: 33 (0)1 42 67 09 87
Email: oie-srdk@oie.int

Details on the submission of a dossier, including the formal date of submission, should preferably be agreed upon between the applicant and the OIE SRDK to optimise the timeline of the subsequent assessment.

Communications between the OIE SRDK and the applicant take place by email in principle. Receipt of emails will be acknowledged electronically. Decisions such as the outcome of the screening of dossier or the conclusion of the main assessment are also communicated to the applicant by letter.

Role of the OIE Secretariat for Registration of Diagnostic Kits (OIE SRDK)

The OIE SRDK will operate under the Antimicrobial Resistance and Veterinary Products Department.

The OIE SRDK will be responsible for:

- Providing procedural guidance during the pre-submission phase;
- Regularly monitoring declarations and preliminary appraisals of compatibility of the interests declared by the individuals concerned;
- Co-ordinating completeness and acceptability of the application submitted and monitoring compliance with the timeframe provided for processing the application;
- Providing assistance to the Headquarters, the Applicant, the relevant Specialist Commission of the OIE (Biological Standards Commission or Aquatic Animal Health Standards Commission), the chairperson of the Review Panel (CRP) and reviewer(s);
- Verifying that documents are circulated in a timely manner;
- Organising any meeting, as requested by the Headquarters, the Specialist Commission and the CRP;
- Preparing the scientific dossier (in English) for the Specialist Commission;
- Co-ordinating with the President of the Specialist Commission the preparation of the Specialist Commission's opinion;
- Providing the necessary follow-up to the Specialist Commission's opinion (e.g. variations, post-marketing renewals, etc.), in consultation with the President of the Specialist Commission and, where appropriate, the CRP and the reviewer(s);
- Preparing the Resolution containing the list of recommended validated and certified diagnostic kits to be voted on by the OIE World Assembly of Delegates;
- Updating the *OIE Register of Diagnostic Kits validated as fit for purpose* (OIE Register).

2.2.2. Submission of dossier

The applicant must submit one complete electronic copy of the application (as an email attachment) and one hard copy to the OIE. The application must be completed in **English**.

The applicant must provide, as part of their application, a 'mock-up' or specimen of the diagnostic kit 'ready-to-use': a mock-up is a copy of the flat artwork design (computer generated), providing a two-dimensional replica of both the outer and inner packages with labelling. At this stage, the mock-up may be in black and white and in English only (mock-ups in English, French and Spanish and in full colour must be provided before the vote of the World Assembly of Delegates).

In addition, the applicant must provide evidence that it is duly established as a commercial or public entity and provide documents demonstrating its capacity to perform all the responsibilities required for the manufacturing and marketing of the diagnostic kit. A contact person responsible for the diagnostic kit must be nominated, and postal address, e-mail address, telephone, and fax numbers should also be provided (this is incorporated in the *Application Form*).

The applicant must pay the full assessment fee in Euros, net of all bank charges, to the OIE. Applications are not processed by the OIE until a proof of payment has been received. The fee payable is for the assessment of the diagnostic kit and is separate from the subsequent annual payment required to maintain and renew the OIE validated and certified diagnostic kit status (see sections 2.7. and 2.8.).

The fees received by the OIE are not reimbursable under any circumstances unless stated otherwise in this procedure.

2.2.3. Screening of the dossier by the OIE Secretariat for Registration of Diagnostic Kits

The OIE SRDK sends by email to the applicant an acknowledgement of receipt of the dossier and ensures, within 30 days following receipt of the dossier, to determine whether the application is receivable.

During this screening phase, the OIE SRDK may ask the applicant for additional data, information, or clarification within a specified time limit (should this be the case the clock stops while awaiting arrival of the information requested).

(a) Positive outcome of the screening of the dossier

If the application is considered as suitable for evaluation by a review panel, the OIE SRDK notifies the applicant in writing that the dossier has been accepted. The names of the chairperson and the reviewer(s) (see section 2.2.4), the identification number assigned by the OIE to the application for ease of dossier management, and a proposed timetable for evaluation (see section 2.3.1) are included in the letter confirming the acceptance of the dossier.

(b) Negative outcome of the screening of the dossier

If the applicant fails to provide sufficient data, information, or clarification requested, or if in the view of the OIE the application does not fall within the OIE mandate and the scope of the present procedure, the OIE informs the applicant in writing that the dossier has not been accepted for further evaluation.

The fee paid is reimbursed to the applicant with a reduction of 15% of the full applicable fee to cover administrative costs. The paper and electronic version of the dossier will be destroyed by the OIE.

Should the applicant decide to re-send an application for the same kit with additional data or for another testing purpose, it must initiate a new application process.

2.2.4. Selection of the Chairperson and Reviewer(s)

The appointment of the CRP and the reviewer(s) is made by the OIE Headquarters in consultation with the President of the relevant Specialist Commission of the OIE (Biological Standards Commission or Aquatic Animal Health Standards Commission) after acceptance of the application.

The Review Panel is composed of a chairperson and one or more reviewer(s), according to the type of application.

The CRP and reviewer(s) are chosen from OIE Reference Centres or from amongst other internationally renowned experts.

The names of the CRP and reviewer(s) chosen are communicated by email and letter to the applicant before an evaluation starts. The applicant may refuse the CRP or reviewer(s), giving reason for such objection(s), within 10 days of receiving the email.

To avoid any conflict of interest, the CRP and reviewer(s) are required to declare any possible conflicts of interest by signing a declaration of interest form. They are also required to sign a confidentiality undertaking (see sections 4 and 5).

The OIE SRDK, members of the Specialist Commission, and the appointed CRP and reviewer(s) who have received dossiers, are required to fully protect the confidentiality of the data submitted to them (see section 4).

2.3. Scientific evaluation

2.3.1. Timetable for the evaluation

Once the CRP and the reviewer(s) have been confirmed and they have received the application documents, scientific evaluation starts.

A timetable is prepared by the OIE SRDK, in consultation with the CRP and the reviewer(s), to provide an indication of how the scientific assessment of the application is to be conducted. The applicant is regularly informed by the OIE SRDK of subsequent changes to the timetable.

In summary, the opinion of the relevant Specialist Commission of the OIE (Biological Standards Commission or Aquatic Animal Health Standards Commission) should be obtained within 120 days from the beginning of the scientific evaluation.

Days	Timetable for the evaluation
1	The evaluation starts
10	Reviewer(s) provide a first report to the CRP
15	CRP submits to the OIE SRDK a preliminary assessment report and potential questions to be sent to the applicant. If there are questions, the clock stops until the answers from the applicant are provided to the reviewers
16-59	Exchanges with the applicant take place as necessary to clarify all pending technical matters
60	CRP submits a final assessment report through the OIE SRDK to the Members of the Specialist Commission
61-119	Specialist Commission discusses the final assessment report
120	Specialist Commission adopts its opinion and submits it to the OIE Deputy Director General, International Standards and Science
135	The OIE Director General informs the applicant of the Specialist Commission's opinion (acceptance, rejection or other) In the case of a favourable opinion, the Director General informs the applicant that the diagnostic kit will be proposed for inclusion in the OIE Register by vote of the World Assembly of Delegates at the next General Session (This is possible at the latest 3 months before the General Session which is held every year in May)
(May)	At the General Session, the World Assembly of Delegates votes on a resolution for inclusion of the diagnostic kit(s) in the OIE Register. Within 14 days of the favourable vote of the World Assembly of Delegate, the OIE Register is updated
(June-December)	Mock-ups or specimens of the final outer and inner packages with labelling must be submitted to the OIE

(The Specialist Commission will be expected to meet every 3 months, if required)

2.3.2. Interruption of the evaluation

If the applicant for any reason wishes to stop and abandon the procedure after the scientific evaluation has started, and before day 60, the applicant is reimbursed by 10 to 20% of the fee paid according to the advancement of the assessment, to be determined by the OIE.

After day 60, no reimbursement of fees to the applicant is possible.

2.3.3. Request for additional information

During the scientific assessment, the applicant should liaise with the OIE SRDK as necessary.

If required, the CRP in consultation with reviewers will send a list of questions to the OIE SRDK, which is promptly transmitted to the applicant. The clock stops at this point until the answers are provided to the Review Panel or the lapse of a two-month period, whichever is earlier.

The applicant is expected to respond ideally within two months from the date of receiving the questions, so that the reviews can be concluded without extended delays. This is considered as a reasonable amount of time to prepare responses to the Review Panel's questions. If the applicant is unable to respond within two months, they should consider withdrawing the

application and resubmitting when the full information is available. Alternatively, if additional time will be required to address the Review Panel's questions, the applicant may request a temporary suspension of the review for an extended timeframe, up to 12 months, to allow time to provide the required supplementary data. Requests for a temporary suspension of the review would be considered on a case by case basis, in consultation with the Review Panel members.

The Review Panel may take into consideration any evaluations and decisions from National Authorities on the diagnostic kits if there is any additional information from other sources when available.

2.3.4. Need for samples and sample analysis

Samples for testing the proposed diagnostic kit are not required at the time of submission of the application. However, the OIE SRDK may recommend and request the testing of samples with the diagnostic kit during the assessment of the application. In this case, the CRP and/or reviewer(s) will specify a test protocol in order to complete the relevant information not provided by the applicant in the original submission. This protocol would include the type of samples, number of samples, number of batches, testing to be performed, and specify, in consultation with the OIE Headquarters, which laboratory could carry out the required testing. Such information may be useful where the review panel deems that supplementary independent data are required to complete their evaluation. If the applicant agrees to proceed with supplementary testing, they would be responsible for covering the cost of this testing. The applicant would also have the option of withdrawing the application or temporarily suspending the review pending completion of the required supplementary testing.

2.3.5. Report of the Review Panel to the OIE Secretariat for Registration of Diagnostic Kits and Specialist Commission

The CRP should prepare a report for the OIE SRDK and Specialist Commission, summarising the Review Panel's conclusions regarding the kit's fitness for the proposed purpose(s) of use, and a recommendation from the Review Panel to the Specialist Commission whether or not the kit should be included in the OIE Register. The *Final Review Panel Report* for the Specialist Commission should include a copy of the *Validation Studies Abstract* that has been prepared by the applicant as part of the submission.

2.3.6. Deliberation at the Specialist Commission

The relevant Specialist Commission of the OIE (Biological Standards Commission or Aquatic Animal Health Standards Commission), is requested to provide its opinion on the application, taking into account the final assessment report of the chairperson and reviewer(s) *(Final Review Panel Report)* on or before day 120. The Specialist Commission's opinion, which may be favourable or unfavourable, is to be documented in the meeting report of the Specialist Commission.

The Specialist Commission may request additional information from the CRP or the applicant with a specified deadline. The clock stops for the specified duration of time.

If consensus cannot be reached within the Specialist Commission, the conclusion is drawn on the basis of a majority opinion of the Specialist Commission members. Any minority views, the reasoning behind these views, and the count of votes cast are duly documented in the Specialist

Commission's report. In the absence of a majority position, the Specialist Commission's opinion on the application is considered as negative.

The Specialist Commission's report also includes any follow-up measures the Specialist Commission recommends in conjunction with the application or any particular conditions under which the Specialist Commission accepts the application.

The Specialist Commission seeks to deliberate and adopt its position in a regular meeting where possible, however, may elect to do so by correspondence.

2.3.7. Transmission of the Opinion of the Specialist Commission and Decision of the OIE Director General

(a) Favourable opinion

In the event of a favourable opinion from the relevant Specialist Commission of the OIE (Biological Standards Commission or Aquatic Animal Health Standards Commission), the following documents must be appended to the opinion transmitted to the OIE Deputy Director General, International Standards and Science for action:

- The proposal for inclusion in the OIE Register
- Category of the kit
- Fitness for purpose
- Conditions or restrictions regarding supply and use
- The Specialist Commission's report
- *Validation Studies Abstract*
- *Final Review Panel Report*

Following a favourable opinion from the Specialist Commission, based on the conclusions and recommendations from the Review Panel and subsequent endorsement of the Review Panel report by the Specialist Commission, the OIE Deputy Director General, International Standards and Science informs the applicant by writing that the diagnostic kit is proposed for inclusion in the OIE Register by vote of the World Assembly of Delegates at the following General Session of the OIE.

When a favourable opinion is granted under specific conditions set by the Specialist Commission, these are stated in the letter sent to the applicant from the OIE Director General and the applicant is requested to confirm whether these conditions can be met within an agreed timeframe. When this confirmation is received in time, the kit is proposed for inclusion in the OIE Register by the World Assembly of Delegates at the following General Session of the OIE.

2.3.8. Approval by OIE Delegates at the General Session

If the Review Panel recommends approval (or renewal) of the diagnostic kit, and the recommendation is endorsed by the Specialist Commission, the OIE SRDK prepares a draft *Resolution* and accompanying *Validation Studies Abstract* for further review and endorsement by the OIE Council and Director General. The draft *Resolution* and *Validation Studies Abstract* are then circulated to OIE Delegates for their consideration prior to presenting the *Resolution* for adoption at the OIE General Session.

(b) Unfavourable opinion

In the event of a negative opinion of the relevant Specialist Commission, the OIE Director General informs the applicant in writing (letter with delivery advice) that the application does not satisfy the criteria for inclusion of the kit in the OIE Register, together with the reasons for rejection.

2.4. Appeal to an unfavourable opinion of the Specialist Commission

Within 10 days of the delivery to the applicant of the unfavourable opinion of the relevant Specialist Commission of the OIE (Biological Standards Commission or Aquatic Animal Health Standards Commission), the applicant must notify the OIE Headquarters in writing of its intention to appeal if it intends to do so. If the applicant does not appeal in this time, the rejection of the application becomes final.

The grounds for appeal must be provided to the OIE SRDK in writing and an administrative fee of 650 € must be paid to the OIE within 30 days of the delivery to the applicant of the unfavourable opinion of the SC. If the applicant wishes to meet with the Specialist Commission to orally present its case, such request must also be sent at this stage.

The appeal is assessed by the Review Panel. The OIE Headquarters may decide to appoint a new chairperson of the Review Panel and/or reviewer(s), to assess the appeal. The names of the new chairperson/reviewer(s) chosen are communicated by letter to the applicant before an evaluation starts. The applicant may refuse reviewer(s), giving reason for such objection(s), within 10 days of receiving this letter.

The Review Panel should produce a report within 60 days of the receipt of the appeal. In evaluating the appeal, the Review Panel may request additional information from the applicant with a specified deadline.

The Specialist Commission considers the report of the Review Panel at its following meeting and determines whether to maintain its previous opinion. The Specialist Commission may decide to invite the applicant to make a short oral presentation and respond to questions from the Specialist Commission if any arise.

The opinion of the Specialist Commission is forwarded to the OIE Director General for action (see section 2.3.7.). If the Specialist Commission's opinion is negative for the second time, further appeal is not possible.

2.5. Inclusion of the diagnostic kit in the OIE Register by vote of the World Assembly of Delegates

At the General Session, the inclusion of the diagnostic kit in the OIE Register is put to a vote by the World Assembly of Delegates. If the inclusion is accepted, the OIE Register will be updated within 14 days of the vote.

Once the diagnostic kit is registered by the OIE Headquarters and before the kit is placed on the market, mock-ups or specimens of the final outer and inner packages with labelling must be submitted to the OIE.

The diagnostic kit is certified as validated as fit for the purposes mentioned in the resolution adopted by the World Assembly of Delegates for a period of five (5) years. To prevent any off-label use of the kit, the OIE removes any kit from the OIE Register that has been found to mention other purpose(s) than those described in the resolution of the World Assembly of Delegates. In this case, the applicant or its authorised representatives must no longer state that the kit is validated and certified by the OIE. Any violation of this rule is liable to legal action by the OIE against the applicant.

This procedure for the registration of diagnostic kits establishes the "fitness for purpose" of a diagnostic kit but not its manufacturing quality.

2.6. Changes to a diagnostic kit currently included in the OIE Register

Any proposed change to the kit in the OIE Register must be declared to OIE before implementation of the change. For any proposed changes that might affect assay performance, supplementary data must be provided well in advance in order to enable the OIE to perform an assessment of the proposed changes on fitness for purpose against validation criteria.

The assessment of the proposed changes will be conducted adhering to the above-mentioned timetable for evaluation. The OIE SRDK may be able to set up a shorter timetable if the scope of the changes is considered as minimal or limited. If substantial changes are proposed, a new assessment fee is required (see Section 6 of this document on the fees for applications for the OIE registration of diagnostic kits).

The OIE reserves the right to adapt the purpose(s) for which the kit has previously been certified by the OIE or remove from its Register any kit that does not perform according to the previously validated fitness for purpose.

2.7. Annual review and annual fees

The applicant must send annually, by the end of January, a letter of undertaking stating that the kit is still viable and that no changes to the kit have been made.

Every year between 1 and 15 January, the manufacturer or his authorised representative must pay a loyalty fee proportional to the pre-tax annual cumulated turnover of the previous year gained from sales of the diagnostic kit validated and certified by OIE (see section 6).

The OIE reserves the right to remove from its Register the kit if the applicant fails to submit an annual review or annual loyalty fees as stated above.

2.8. Renewal of registration

Three years after the first registration or a subsequent renewal of registration of the diagnostic kit, the OIE initiates a process for renewal of registration.

First, the OIE SRDK asks the applicant whether changes have been or are being made to the diagnostic kit since its last registration or if the applicant wishes to extend the purposes for which the diagnostic kit has been certified as validated fit for. The OIE SRDK then forwards the reply received from the applicant to the relevant Specialist Commission of the OIE (Biological Standards Commission or Aquatic Animal Health Standards Commission) for consideration.

If the applicant does not wish to extend the purposes for which the diagnostic kit has been certified as validated fit for and if the OIE Headquarters in consultation with the relevant Specialist Commission determine that there is no need for a new assessment since its latest adoption by the World Assembly of Delegates, the OIE Headquarters proposes to the World Assembly of Delegates to renew the registration of the diagnostic kit for another five (5) years. This renewal process is free of charge for the applicant.

If the applicant wishes to extend the purposes for which the diagnostic kit has been certified as validated fit for or if the OIE Headquarters in consultation with the relevant Specialist Commission determine for any reasons that there is a need for a new assessment, the OIE Headquarters requests the applicant to submit a full application one (1) year before the expiration of the current registration period for a new scientific assessment. The application should be accompanied by the assessment fee to be paid.

The assessment of the renewal of registration is conducted according to the above-mentioned timetable for evaluation. The OIE SRDK may be able to set up a shorter timetable if the scope of the changes is considered as minimal or limited.

Section 3 – Validation Pathway

Validation is a continuous process. At various stages of development, a diagnostic kit will be used and data obtained. It is these data that support kit claims and determine the validation status of the kit. Four stages of validation are proposed and OIE acceptance of an application will be linked to a determination of the validation status based on the four stages. The stages rely on the quantity of work done; the number of people and laboratories where the kit is used; the quality of data; and measures taken to routinely examine the kit in use, both directly by users and indirectly through exercises designed to measure repeatability and reproducibility over time. The data presented in the application will determine the validation status. The headings and explanations below are detailed in the *Application Form*.

3.1. Stage 1 validation – Analytical characteristics

Stage 1 validation requires:

3.1.1. Repeatability data

- A minimum of three in-house samples representing activity within linear range of assay.
- Within run tests (quadruplicates preferred).
- Between run tests (a minimum of 20 runs total, two or more operators preferably on separate days, where runs are independent).
- Between serial repeatability, ideally three production batches.
- Data should include mean, SD, Large coefficients of variation (CVs), upper and lower control limits (UCL and LCL) on unprocessed and processed data.

3.1.2. Analytical specificity data

- Cross-reactivity, near-neighbour data.
- Document cross-reactivity by comparing samples from animals infected with organisms with similar clinical presentations and organisms that are genetically closely related.
- Type/group specificity data.
- Documentation affirming serotype or group specificity.

3.1.3. Analytical sensitivity data

- Specify standard of comparison (i.e. currently accepted test method).
- Comparison may include: end-point titrations; earliest time of detection post-exposure.
- Duration of detection post-exposure (if applicable).
- Limit of detection

3.2. Stage 2 validation – Diagnostic characteristics

Stage 2 validation requires:

3.2.1. Study design

Overview of the chosen approach used for determination of diagnostic specificity and sensitivity estimates, including:

- Rationale for statistical design.
- Choice of populations, animals, or animal models.

Numbers of animals used to generate confidence intervals for sensitivity and specificity.

(Note: The study design must be relevant to generate the required validation data for the specifically stated proposed purpose(s)).

3.2.2. Negative reference animals/samples (Complete description)

(Note: negative refers to lack of exposure to or infection with the agent in question)

- Age, sex, breed, etc.
- Immunological status.
- Representativeness of intended target population.
- Selection criteria including historical, epidemiological and/or clinical data.
- Pathognomonic and/or surrogate tests used to define status of animals (case definition) or prevalence within population.
- Sampling plan and procedures.

3.2.3. Positive reference animals/samples (Complete description)

(Note: positive refers to known exposure to or infection with the agent in question)

- Age, sex, breed, etc.
- Immunological status.
- Representativeness of intended target population.
- Selection criteria including historical, epidemiological and/or clinical data.
- Pathognomonic and/or surrogate tests used to define status of animals (case definition) or prevalence within population.
- Sampling plan and procedures.

3.2.4. Experimental animals/samples

- Complete description
  - Age, sex, breed, etc.
  - Immunological status.
  - Representativeness of intended target population.
- Exposure
  - Inoculum, source, dose, etc.
  - Type of exposure – inoculation, aerosol, contact, etc.
  - Sampling plan and procedures.

3.2.5. Threshold determination

- Complete description of method used: empirical, receiver operating characteristic (ROC) curve, mean ± SD, etc.
- Descriptive statistics, frequency distribution diagrams, etc.

3.2.6. Diagnostic sensitivity and specificity estimates – with defined reference animals

- Conventional method using reference animals.
- Individual animals must be selected from negative and positive reference populations.
- Include 2x2 table, calculations for diagnostic sensitivity and specificity including error and confidence.
- Include same calculations for other tests if being compared to the diagnostic kit in question.

3.2.7. Diagnostic sensitivity and specificity estimates – without defined reference animals

- Complete description of model used.
- Bayesian inference, latent class analysis, etc.
- Describe rationale, priors, supporting data.
- Population selection criteria, including prevalence estimates.
- Other test methods evaluated should also include the standard method of comparison.
- Using best available priors, choose test populations with appropriate prevalence and select animals in sufficient numbers to generate estimates of sensitivity and specificity with an allowable error of ± 5% at a level of confidence of 95%.

3.2.8. Comparison of performance between tests

- Provide statistical measures of agreement between the reference method(s) and the diagnostic kit being validated.
- Suggest explanations for result not in agreement.

3.3. Stage 3 validation – Reproducibility

Stage 3 validation requires:

3.3.1. Laboratory identification

- Selection criteria for candidate laboratories.
  - Location, i.e. country.
  - Status, i.e. regional, national, provincial/state.
  - Level of expertise, familiarity with technology.
  - Accreditation status.
- Number of laboratories included.
  - Minimum of three laboratories should also include an OIE Reference Laboratory, if possible.

3.3.2. Evaluation panel

- Description of test panel.
  - Selection criteria, number of samples (minimum of 20).
  - Sample volume, allowable number of repeats.
  - Panel composition, i.e. number of replicates, range of analyte concentrations/reactivities.
  - Sample processing requirements, i.e. extractions, spiking, serial dilutions, preservatives, sterilisation.
  - Coding of unknown (blind) samples.
  - Frequency of testing.

3.3.3. Analysis of reproducibility

- Description of type of data/interpretation.
  - Qualitative (categorical).
  - Quantitative or semi-quantitative data.
  - Single dilution vs titration.
- Description of type of analysis.
  - Pre-determined limits, consensus, Youden plots.
- Descriptive statistics.
  - Include mean, SD, range of results.
  - Should include controls as well as blind samples.
  - Number and proportion of accepted/rejected runs should be included.

3.4. Stage 4 validation – Applications

Stage 4 validation requires:

3.4.1. Diagnostic kit Applications

- Describe functional kit applications (i.e. screening, confirmatory, supplemental applications).
- Integration with other tests into diagnostic regimen.
- Include flowcharts and decision trees where applicable.

3.4.2. Laboratories

- List laboratories where this kit is in current use.
  - Location, i.e., country.
  - Status, i.e. regional, national, provincial/state.
  - Accreditation status.

3.4.3. International reference standards

- List type and availability of international reference reagents.
- Source.
- Negative, weak/ strong positive reference reagents.
- Other key biologicals, e.g. antigens, antibodies, etc.

3.4.4. Inter-laboratory testing programmes

- Describe programmes involving inter-laboratory comparisons using this kit.
- National, international.
- Describe eligibility and number of laboratories participating.

3.4.5. International recognition

- List internationally recognised reference laboratory responsible for the test method used in the kit and/or biologicals.
- Listed international standards containing the test method used in the kit.
- Listed international programmes employing the kit.

Section 4 – Guidance on confidentiality and discretion

The OIE faces potentially conflicting obligations of ensuring public access to information (transparency) and safeguarding confidential information that the OIE holds in its role as international regulatory organisation (see also the OIE Policy on the Protection of Legitimate Confidentiality available on the OIE website at: http://www.oie.int/en/about-us/key-texts/experts-obligations/).

4.1. Duty of confidentiality

Within the framework of the OIE Procedure for Registration of Diagnostic Kits, the respect of confidentiality is an essential part of maintaining a good relationship and balance between the OIE, industry and other parties. The OIE recognises that its staff, the Biological Standards Commission and the Aquatic Animal Health Standards Commission members, and experts from the Review Panel may have access to confidential information related to intellectual property or of commercial concern. For this reason, they are all required to sign a confidentiality undertaking with the obligation to respect confidentiality of information in all circumstances and even after their current assignments/contract.

OIE staff members are subject to a general duty of confidentiality under the Staff Regulations. The attention of new members of staff is drawn to the relevant provisions contained in the Staff Regulations. They acknowledge in writing that they have read and understood the relevant articles on the confidentiality provisions in the Staff Regulations and the related disciplinary measures. Staff members are required to repeat this acknowledgement on renewal of contract.

OIE staff and other individuals involved in the OIE Procedure for Registration of Diagnostic Kits are advised to exercise care when answering questions so as not to supply information to competitors or other interested parties regarding specific products where such information does not belong to the public domain. Discretion should be exercised within or outside the OIE.

Where there is doubt about the management of information, OIE staff members and other individuals involved in the OIE Procedure for Registration of Diagnostic Kits seek guidance from the Director General of the OIE.

4.2. Continuing duty of confidentiality

Members of the OIE Specialist Commissions, experts from the Review Panel and staff have a life-long duty of confidentiality even after they have ceased their relationship with the OIE.

Section 5 – Guidance on conflicts of interests

5.1. Introduction

In order to safeguard the neutrality of the OIE, the Specialist Commission (Biological Standards Commission and Aquatic Animal Health Standards Commission) members, CRP and reviewer(s) must not have financial or other interests with a Diagnostic Kit Manufacturer (DKM) submitting an application that could affect their impartiality. All direct and indirect interests that the above-mentioned individuals may have with a commercial entity must be declared to the OIE (see also the OIE Policy on Conflicts of Interest available on the OIE website at: http://www.oie.int/en/about-us/key-texts/experts-obligations/). This requirement is extended to all OIE staff and other persons involved in the OIE Procedure for Registration of Diagnostic Kits.

5.2. Who should declare?

- Members of the Specialist Commissions;
- CRPs and reviewers;
- All OIE staff involved in the OIE Procedure for Registration of Diagnostic Kits.

5.3. What to declare?

Each individual is responsible for the declaration of his/her interests and those held by members of his/her household[1]. Interests may include those held by members of his/her household, membership of an interest group etc. In order to maintain privacy, the names of household members do not need to be declared.

5.3.1. What is an interest?

There are essentially three categories of interests:

a) Financial interests

Any financial interests with a DKM, including holding of stocks and shares, equity, bonds, partnership interests[2] in the capital of a DKM, one of its subsidiaries or a company in which it has a holding in the capital.

The holding of financial interests connected with a pension scheme previously contracted prior to the nomination as a Member of the Commission or as a reviewer or appointment as a member of the OIE staff, and/or interests in non-nominal unit trusts or similar arrangements would not, in principle, have particular consequences providing the individual has no influence on financial management.

1 Spouse or partner and dependent children living in the same household.

2 When declaring financial interests, e.g. stocks and shares, only the kind, number and company name need be stated.

b) Work carried out for a DKM

During the preceding 5 years, all activities performed for or on behalf of a DKM[3], whether or not these activities have been subject to regular or occasional remuneration in cash or kind, including:

- Participation in the internal decision-making of a DKM (e.g. Board membership, executive or non-executive directorship);
- Permanent or temporary member of the personnel of a DKM. Other activities performed within a DKM (e.g. traineeship) are also subject to declaration;
- Work contracted out by DKMs, through consultancy or otherwise.

c) Other links with industry

During the preceding 5 years, all assistance and support received from related industry, whether associated with direct or indirect pecuniary or material benefits, including:

- Grants for study or research allocated by related industry;
- Fellowships or sponsorships endowed by DKMs.

5.3.2. What are direct and indirect interests?

Interests can be direct or indirect depending on their likely or potential impact on the individual's behaviour at a given point in time.

a) Direct interests

Interests of personal benefit to the individual at the time of declaration, likely to influence or give the appearance of influencing his/her behaviour (e.g. employment with a DKM, financial interests of a certain magnitude). In order to remain in office, the individual concerned would have to take appropriate action to suppress the conflict.

b) Indirect interests

Other interests that may have some influence over the individual's behaviour and therefore have to be neutralised. Indirect interests should be scrutinised so that precautions can be taken in order to ensure impartiality of decision taking. Appropriate actions could include precluding the individual from certain functions or tasks (e.g. CRP, reviewer, OIE SRDK) or requiring abstention from part of the relevant voting in the meetings of the Specialist Commissions.

5.4. When to declare?

Improvements to the declaration of interests' forms have been introduced with a view to providing more guidance to all parties concerned on how to fill out and update them.

5.4.1. Initial declaration

Upon nomination as a member of the Specialist Commission involved in the assessment or appointment as a CRP/reviewer or appointment as a member of the OIE staff, each individual is required to fill out a declaration of interests form.

[3] Company or public laboratory name, position held and activities performed should be set out clearly and precisely. Where activities relate to specific product(s), declarations must indicate product name and nature of the work.

5.4.2. Appointment as chairperson of the Review Panel or reviewer

Experts should not accept appointment as the CRP or reviewer for an application if it is apparent that there could be a conflict of interest because he/she has been in any way associated with the studies contained in the dossier.

5.4.3. Subsequent declarations

If during assessment or advisory work, a potential conflict becomes apparent to a member or reviewer, then it must be declared to the OIE Headquarters and appropriate action agreed upon. This would include, in particular, the situation where a reviewer is asked to assess data from his/her own research or his/her own reviewer report in a dossier. If at any time during the course of their duties, OIE staff members and Specialist Commission members become aware of any potential conflict, they must immediately inform the OIE Headquarters, which will determine any appropriate action.

5.4.4. Updates

If there is no change in the status concerning the person's interests during the period of this person is involved in this OIE Procedure, he/she can choose not to send a new declaration. In this case, the OIE considers that the latest declaration is still valid.

Declarations of interests must be updated as soon as an update is required for any new situation arising.

5.5. Operational aspects

5.5.1. Tasks of the OIE Secretariat for Registration of Diagnostic Kits

The OIE SRDK is under the direct responsibility of the OIE Headquarters and undertakes the following:

- Remind all parties concerned of their obligation to declare their interests;
- Regularly monitor declarations and preliminary appraisal of compatibility of interests declared with general or specific office or duties of the individuals concerned;
- Initiate and facilitate dialogue within the appropriate forum (e.g. Specialist Commissions or Review Panel).

The OIE SRDK ensures, under the responsibility of the OIE Headquarters, the availability of all declarations and updates for public consultation in the OIE Headquarters.

5.5.2. Obligations of individuals concerned

The Specialist Commission and Review Panel members and members of the OIE staff have a primary obligation to disclose at any time the existence of possible conflict of interests that may place the impartiality of the OIE at risk. The individual should state in particular the type and nature of interests, specifying whether they are general or relate to a specific product. If the conflict is product-related, prior involvement of the CRP and reviewer(s) in relation to competing products and past and current links with companies should be disclosed.

In the case of Members of the Specialist Commission and reviewers, the primary contact persons should be the OIE Headquarters.

Section 6 – Fees in the procedure for OIE registration of diagnostic kits

All diagnostic kits for diseases, including zoonoses, caused by pathogens (viruses, bacteria, prions and parasites) present in terrestrial and aquatic animals can be certified by the OIE and included in the OIE Register in the framework of this procedure.

6.1. Assessment fee

The applicant must pay an assessment fee of 4 500 € to initiate an evaluation of the data provided by a panel of experts. This is the case for the first assessment of the application and this might be the case when there is a change to a diagnostic kit currently included in the OIE Register or for the renewal of the registration (see Section 2).

6.2. Annual loyalty fee

Once a diagnostic kit is included in the OIE Register, the manufacturer or his authorised representative must pay an annual loyalty fee that consists in 0.1% of pre-tax annual cumulated turnover of the previous year gained from sale of the diagnostic kit registered by the OIE.

For the first year only, the annual loyalty fee is calculated for 7 months. This is because diagnostic kits are included in the OIE Register during the OIE General Session in May (after a vote by the World Assembly of Delegates).

Every year, between 1 and 15 January, the manufacturer or his authorised representative must pay the annual loyalty fee, based on a percentage of annual revenues and send a profit justification for the diagnostic kit.

If the fee is not received on time, the OIE will remove the diagnostic kit from the OIE website and the manufacturer or their authorised representative must no longer state that the diagnostic kit is validated, certified, and registered by the OIE. Any violation of this rule is liable to legal action by the OIE against the manufacturer.

6.3. Appeal fee

An administrative fee of 650 € must be paid by any applicant wishing to appeal a negative opinion of the relevant Specialist Commission (Biological Standards Commission or Aquatic Animal Health Standards Commission) within 10 days of receipt of the opinion.

6.4. Method of Payment

The applicant should pay by bank transfer to the OIE Account:

Crédit Industriel et Commercial
Bank Code 30066 – Branch Code 10141
Account Number: 00010308807– Key 38
Code BIC/SWIFT: CMCIFRPP
N° IBAN: FR76 3006 6101 4100 0103 0880 7 38

While effecting the bank transfer, kindly include the name of your country followed by the Code “007”.

Section 7 – OIE registration of a diagnostic kit as validated and certified - rules of recognition

The OIE logo is a part of the Organisation's intellectual property and may not be used without the explicit permission of the Director General of the OIE.

The OIE logo, name and abbreviation are also protected from being registered as a trade mark under article 6 of the Paris Convention for the Protection of Industrial Property.

The use of the OIE logo (marking) signifies the recognition and registration of a diagnostic kit by the OIE through the application registration process. The logo can only be used when the kit has been reviewed and accepted through the registration process. It could appear on any relevant device associated with the kit, on the instructions for use and on the sales packaging. For the device and sales packaging, it must be stated under the logo: "Validated and certified by the OIE as fit for the purposes defined in the <leaflet/kit insert/document> provided with this kit" [use appropriate term] and accompanied by the Registration number. For the instructions for use, it must be stated under the logo: "Validated and certified by the OIE as fit for the purposes defined in this <leaflet/kit insert/document>" [use appropriate term] and accompanied by the Registration number.

Within the main text (introduction) of the leaflet/kit insert/document, a more detailed paragraph should be provided, saying:

"The validation data for this kit have been certified by the OIE, based on expert review, as fit for the following purposes:

<give details of the certified purposes> (As stated in the resolution adopted by the OIE World Assembly of Delegates)."

The summary of the validation data (*Validation Studies Abstract*, Section 4 of the *Application Form*), will be posted on the OIE Register website in the *Validation Studies Abstract* section, and this information must also be included in this leaflet/kit insert/document.

The OIE registration will be withdrawn if the OIE considers that the aims and objectives of the certification no longer justify maintaining such registration.

The OIE validated and certified logo must consist of the initials OIE taking the following form (the OIE Secretariat for Registration of Diagnostic Kits will provide a jpg or ai file of the OIE logo on request):

Validated and certified by the OIE as fit for the purposes defined in [*this <leaflet/kit insert/document>*] or [*the <leaflet/kit insert/document> provided with this kit*]*

Register number: ___ ___ ___ ___ ___ ___ ___

If the logo is reduced or enlarged, the proportions must be respected.

* *As relevant*

APPENDIX I. DECLARATION FORMS

FORM A1. Confidentiality Undertaking for the experts of the Review Panel

Confidentiality Undertaking for the experts of the Review Panel, i.e. Chairpersons and Reviewers

In the course of discharging your functions as an expert adviser to OIE under the attached dossier (Standard Operating Procedure for OIE Registration of Diagnostic Kits), you will gain access to certain information that is proprietary to OIE or entities collaborating with OIE, including the manufacturers of the product(s) that need to be assessed as part of the procedure. You undertake to treat such information (hereinafter referred to as "the Information") as confidential and proprietary to OIE or the aforesaid parties collaborating with OIE. In this connection, you agree:

(a) not to use the Information for any other purpose than discharging your obligations under the above-mentioned procedure; and

(b) not to disclose or provide the Information to any person who is not bound by similar obligations of confidentiality and non-use as contained herein.

However, you will not be bound by any obligations of confidentiality and non-use if you are clearly able to demonstrate that any part of the Information:

- was known to you prior to any disclosure by or on behalf of OIE (including by the manufacturer[s]); or
- was in the public domain at the time of disclosure by or on behalf of OIE (including the manufacturer[s]); or
- becomes part of the public domain through no fault of your own; or
- becomes available to you from a third party not in breach of any legal obligations of confidentiality.

You also undertake not to communicate your deliberations and findings and/or those of the panel(s) of experts in which you will participate, as well as any resulting recommendations to, and/or decisions of, OIE to any third party, except as explicitly agreed by OIE.

I hereby accept and agree to the conditions and provisions contained in this document.

Signature

Name_____ Date_____

FORM A2. Confidentiality Undertaking for the staff of the OIE, and the Biological Standards Commission and Aquatic Animal Health Standards Commission members

The respect of confidentiality during the OIE Procedure for Registration of Diagnostic Kits is an essential part of the relationship between the OIE, industry and other parties. The OIE recognises that its staff, and the Biological Standards Commission (BSC) and Aquatic Animal Health Standards Commission (AAHSC) members could have access to confidential information related to intellectual property or of commercial concern. Staff and BSC/AAHSC members are required to respect their obligations of confidentiality in all cases, whether in the work place or in a public place.

Each member of the OIE and BSC/AAHSC participating in the procedure is conscious that he/she must exercise the utmost discretion in regard to all matters of confidential information to which he/she could have access during the process of this procedure. He/She must not communicate to any person unpublished information known to him/her by reason of his/her official position, except in the course of his/her duties or by authorisation of the Director General. These obligations remain binding after termination of his/her functions.

I hereby accept and agree to the conditions and provisions contained in this document.

Signature

Name_____ Date_____

FORM A3. Public Declaration of Interests of Relevant Staff Members of the OIE

Surname (family name):	Forenames:

Position:	Grade:

Please list below all interests in a Diagnostic Kit Manufacturer (DKM)[1] if any:

Employment in a DKM during the previous 5 years:

Financial interests in the capital of a DKM:

Name of company:	Share type:	No. of shares:

List the work that you have previously carried out including paid/unpaid traineeships on behalf of a DKM in the 5 preceding years:

Other interests or facts that you consider should be made known to the Agency and the Public including matters relating to members of your household[2]:

Declaration

I, _____

Do hereby declare on my honour that, to the best of my knowledge, the only direct or indirect interests I and my household members have in DKMs are those listed above.

I further declare that should any changes occur and should it appear that I have or acquire additional interests that should be made known to the OIE, I must forthwith declare them and complete a new public declaration of interests.

(Signature) _____ Date_____

1 If you have no interests, please indicate "none" in the relevant section.

2 Household members means spouse, partner and dependent children living at the same address as the staff member. The names of these persons need not be declared.

FORM A4. Public Declaration of Interests of the Members of Specialist Commissions and of the experts of the Review Panel involved in the Procedure

Surname (family name):	Forenames:

Qualifications:

Professional Address:

Please list below all interests in the diagnostic industry[1] if any:

Employment in a Diagnostic Kit Manufacturer (DKM) during the previous 5 years:

Financial interests in the capital of a DKM:

Name of company:	Share type:	No. of shares:

Work you previously carried out in return for payment including paid/unpaid traineeships on behalf of a DKM in the 5 preceding years:

Other interests or facts that you consider should be made known to the OIE and the Public including matters relating to members of your household[2]:

Declaration

I, _____ do hereby declare on my honour that, to the best of my knowledge, the only direct or indirect interests I or my household members have in DKMs are those listed above.

I further declare that should any changes occur and should it appear that I have or acquire additional interests that should be made known to the OIE, I must forthwith declare them and complete a new public declaration of interests.

Done at: _____

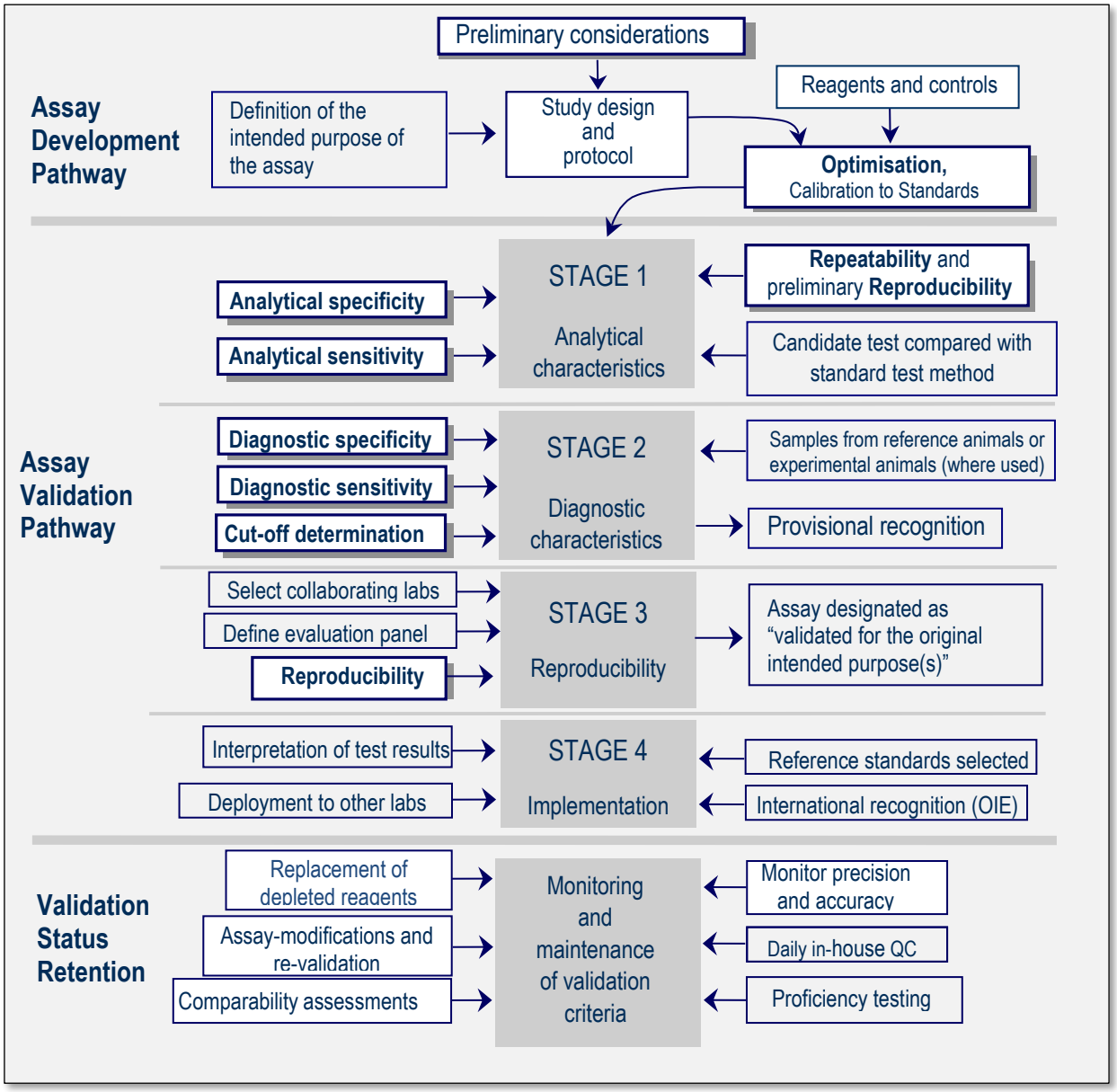
Signature_____Date_____

[1] If you have no interests, please indicate "none" in the relevant section. If you lack space on this form, please use and attach additional pages.

[2] Household members means spouse, partner and dependent children living at the same address as the committee member/reviewer. The names of these persons need not be declared.

APPENDIX II. DIAGNOSTIC KIT ASSAY DEVELOPMENT AND VALIDATION PATHWAY

Figure 1. Diagnostic kit assay development and validation pathway*.



*Reference: OIE *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals, Chapter1.1.6. Principles and Methods of Validation of Diagnostic Assays for Infectious Diseases.*

https://www.oie.int/fileadmin/Home/eng/Health_standards/tahm/1.01.06_VALIDATION.pdf

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