

# Standard Operating Procedure for OIE Registration of Diagnostic Kits

Guide and Administrative Forms

2020



# 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.

Since the results of these diagnostic tests can have important implications for management of diseases, manufacturers and users of veterinary diagnostic kits continually strive to maintain and improve the quality of diagnostic kits to ensure that the tests correctly classify animal disease status and are fit for the intended purpose.

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 validated 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 supplying quality-controlled validation data following the OIE standards on validation published in the *Terrestrial Manual* and *Aquatic Manual* to demonstrate the fitness of the kit for a defined task or tasks.

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 who would like their kit to be

assessed for registration are required to submit 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 (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 compile 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. If approved, the applicants are notified, and the kit is entered into the OIE '*Register of Diagnostic Kits validated as fit for purpose*'. 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 an intended purpose. All diagnostic assays (laboratory and field assays) should be validated for the species and the system 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). The specific 'fitness for purpose' criteria are further explained in this document and the *Terrestrial Manual* chapters cited above.

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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/compartments/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 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 diagnostic kits 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 establish 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, all results of the validation of kits by the OIE are accessible on the OIE web site.

The “Application Form for Registration of Diagnostic Kits by OIE” must be used to apply for certification by the OIE of a diagnostic kit as 'fit for purpose'. The 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 such a level to show that the test's results can be interpreted to have a defined meaning in terms of diagnosis or another biological property being examined. It is no use reporting that a kit will detect antibodies to foot and mouth disease (FMD) or any other disease agent or that a polymerase chain reaction (PCR) can detect a genome to a particular analytical level. There must be proof for the purpose of the test in a diagnostic / detection setting. Enough information has to be given to show that this is a valid statement. There is a need to 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.

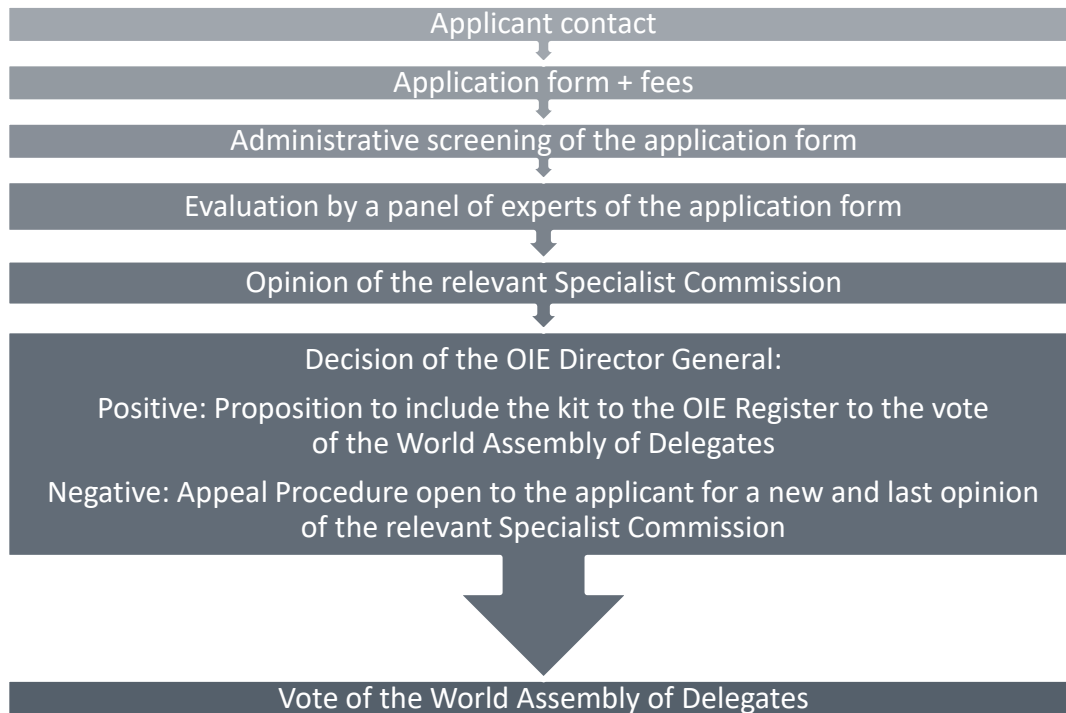
### **Examples:**

1. “To detect antibodies against non-structural proteins for FMD” is not specific enough as fitness for purpose.
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 specific as fitness for purpose.



## 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 for the Certification of Diagnostic Kits as Validated Fit for Specific Purposes (Application Form)*, duly completed and the applicable fee should be sent by the applicant to the OIE Director General, in one complete electronic copy and in one hard copy.

<p><b>Director General</b> OIE Procedure for registration of diagnostic kits OIE 12, rue de Prony 75017 Paris France Email: oie-srdk@oie.int</p>
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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

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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 OIESRDK 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**

The OIE Secretariat for Registration of Diagnostic Kits (OIESRDK) will operate under the Scientific and Technical Department.

The OIESRDK will be responsible for:

- Providing procedural guidance during the pre-submission phase;
- Monitoring regularly declarations and preliminary appraisals of compatibility of the interests declared by the individuals concerned;
- Co-ordinating the 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 (SC) 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 SC and the CRP;
- Preparing the scientific dossier (in English) for the SC;
- Co-ordinating with the President of the SC the preparation of the SC's opinion;
- Providing the necessary follow-up to the SC opinion (e.g. variations, post-marketing renewals, etc.), in consultation with the President of the SC 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 validated and certified diagnostic kits.

### **2.2.2. Submission of dossier**

The applicant must submit one complete electronic copy of the application (as email attachment, in a USB key or in a CD-ROM), and one hard copy to the OIE. The application must be completed in **English**.

The applicant must provide, as part of its 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 for the Certification of Diagnostic Kits as Validated Fit for Specific Purposes*(*Application Form*)).

The applicant must pay the full assessment fee in Euros, net of all bank charges, to the OIE. Applications are 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 with 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 SRDK**

The OIE Secretariat for Registration of Diagnostic Kits (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 receivable, the OIE Secretariat for Registration of Diagnostic Kits 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.

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 chairperson of the review panel (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, 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 CRP or reviewer(s), giving reason for such objection(s), within 10 days of receiving the email.

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

The OIESRDK, members of the SC 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 chairperson of the review panel (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 Secretariat for Registration of Diagnostic Kits (OIESRDK), 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 OIESRDK of subsequent changes to the timetable.

In summary, the opinion of the relevant Specialist Commission (SC) 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
<b>1</b>	The evaluation starts
<b>10</b>	Reviewer(s) provide a first report to the CRP
<b>15</b>	CRP submits to the OIE a preliminary assessment report and potential questions sent to the applicant. If there are questions, the clock stops until the answers from the applicant are provided to the reviewers
<b>16-59</b>	Exchanges with the applicant take place as necessary to clarify all pending technical matters
<b>60</b>	CRP submits a final assessment report through the OIESRDK to the Members of the SC
<b>61-119</b>	SC discusses the final assessment report
<b>120</b>	SC adopts its opinion and submits it to the OIE Director General
<b>135</b>	The OIE Director General informs the applicant of the SC 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 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)
<b>(May)</b>	At the General Session, the World Assembly of Delegates votes on a resolution for inclusion of the diagnostic kit(s) in the register. Within 14 days of the favourable vote of the World Assembly of Delegate, the OIE Register of Diagnostic Kits is updated
<b>(June-December)</b>	Mock-ups or specimens of the final outer and inner packages with labelling must be submitted to the OIE

(SC 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 the review panel submits its final report (from day 1 to 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 Secretariat for Registration of Diagnostic Kits (OIESRDK) as necessary.

The chairperson of the review panel may, in consultation with reviewers if necessary, send a list of questions to the OIESRDK, 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 2-month period, whichever earlier.

The applicant is expected to respond within 2 months from the date of receiving the questions. This is considered as reasonable amount of time to prepare answers to the questions. If the

applicant is unable to respond within 2 months, then it should consider withdrawing the application and resubmitting when the full information is available.

The review panel may take into consideration any evaluations and decisions from National Authorities on the diagnostic kits if there are any and 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. The OIE Secretariat for Registration of Diagnostic Kits may, however, recommend and request the testing of samples the diagnostic kit during the assessment of the application. In this case, the chairperson of the review panel and/or reviewer(s) will specify a test protocol in order to complete the relevant information not provided by the applicant. 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 will carry out the required testing. The cost of this testing will be charged to the applicant. Such information may be useful where a submission is regarded as bordering between the outlined validation stages or where there is disagreement about the fitness for purpose of a kit.

#### **2.3.5 Report of the Review Panel to the OIE SRDK and Specialist Commission**

The chairperson of the Review Panel (CRP) should prepare a report for the OIE SRDK and Specialist Commission (SC), summarising the Review Panel's conclusions regarding the fitness for purpose of the kit, and a recommendation from the Review Panel to the SC whether or not the kit should be included in the OIE *'Register of Diagnostic Kits validated as fit for purpose'*. The *Final Review Panel Report* for the SC 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 (SC) 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 SC's opinion, which may be favourable or unfavourable, is to be documented in the meeting report of the SC.

The SC 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 SC, the conclusion is drawn on the basis of a majority opinion of the SC members. Any minority views, if any, reasoning behind, and the count of votes cast are duly documented in the SC's report. In the absence of a majority position, the SC's opinion on the application is considered as negative.

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

The SC seeks to deliberate and adopt its position in a regular meeting to the extent possible but 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 (SC) 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 Director General for action:

- The proposal for inclusion in the register
- Category of the kit
- Fitness for purpose
- Conditions or restrictions regarding supply and use
- The SC report
- *Validation Studies Abstract*
- *Final Review Panel Report*

Following a favourable opinion from the SC, based on the conclusions and recommendations from the Review Panel and subsequent endorsement of the Review Panel report by the SC, the OIE Director General informs the applicant by writing that the diagnostic kit is proposed for inclusion in the 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 SC, 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 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 SC, 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 SC, 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 (SC) 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 Secretariat for Registration of Diagnostic Kits (OIESRDK) 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 SC 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 SC considers the report of the review panel at its following meeting and determines whether to maintain its previous opinion. The SC may decide to invite the applicant to make a short oral presentation and respond to questions from the SC if any.

The opinion of the SC is forwarded to the OIE Director General for action (see section 2.3.6.). If the SC is opinion is negative for the second time, further appeal is not possible.

## 2.5. Inclusion of the diagnostic kit in the 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 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 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 Secretariat for Registration of Diagnostic Kits 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, 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 of diagnostic kits certified as validated fit for purpose 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 requests to 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 Headquarters then forwards the reply received from the applicant to the relevant Specialist Commission (SC) 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 SC 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 SC 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 Secretariat for Registration of Diagnostic Kits 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 reflected in the 'Application Form for Registration of Diagnostic Kits by OIE'.

### 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, upper and lower control (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).

## 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)

- Rationale for statistical design
- Choice of populations, animals or animal models
- Numbers of animals used to generate confidence intervals for sensitivity and specificity

### 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.
- Relatedness to intended target population.
- Selection criteria including historical, epidemiological and/or clinical data.
- Pathognomonic and/or surrogate tests used to define status of animals 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.
- Relatedness to intended target population.
- Selection criteria including historical, epidemiological and/or clinical data.
- Pathognomonic and/or surrogate tests used to define status of animals or prevalence within population.
- Sampling plan and procedures.

### 3.2.4. Experimental animals/samples

- Complete description
  - Age, sex, breed, etc.
  - Immunological status.
  - Relatedness to 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, ROC, mean  $\pm$  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 in 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  $\pm 5\%$  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 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 confidentiality of 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 (BSC) and the Aquatic Animal Health Standards Commission (AAHSC) 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 Biological Standards Commission (BSC) and Aquatic Animal Health Standards Commission (AAHSC) members, chairperson of the review panel (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 BSC and AAHSC;
- 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<sup>1</sup>. 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<sup>2</sup> 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.

<sup>1</sup> Spouse or partner and dependent children living in the same household.

<sup>2</sup> 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<sup>3</sup>, 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 industry, whether associated with direct or indirect pecuniary or material benefits, including:

- Grants for study or research allocated by the 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 Secretariat for Registration of Diagnostic Kits [OIESRDK]) 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 BSC or AAHSC 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.

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<sup>3</sup> 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 CRP 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 BSC/AAHSC 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 OIESRDK**

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

- Remind all parties concerned of their obligation to declare their interests;
- Monitor regularly 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 OIESRDK 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 BSC/AAHSC 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 BSC/AAHSC 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 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 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 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 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 web site and the manufacturer or his authorised representative must no longer state that his diagnostic kit is validated and certified 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 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:
<input type="text"/>	<input type="text"/>

Position:	Grade:
<input type="text"/>	<input type="text"/>

Please list below all interests in a Diagnostic Kit Manufacturer (DKM)<sup>1</sup> 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:
<input type="text"/>	<input type="text"/>	<input type="text"/>

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<sup>2</sup>:

### 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 \_\_\_\_\_

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

<sup>2</sup> 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<sup>1</sup> 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<sup>2</sup>:

--

### 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 \_\_\_\_\_

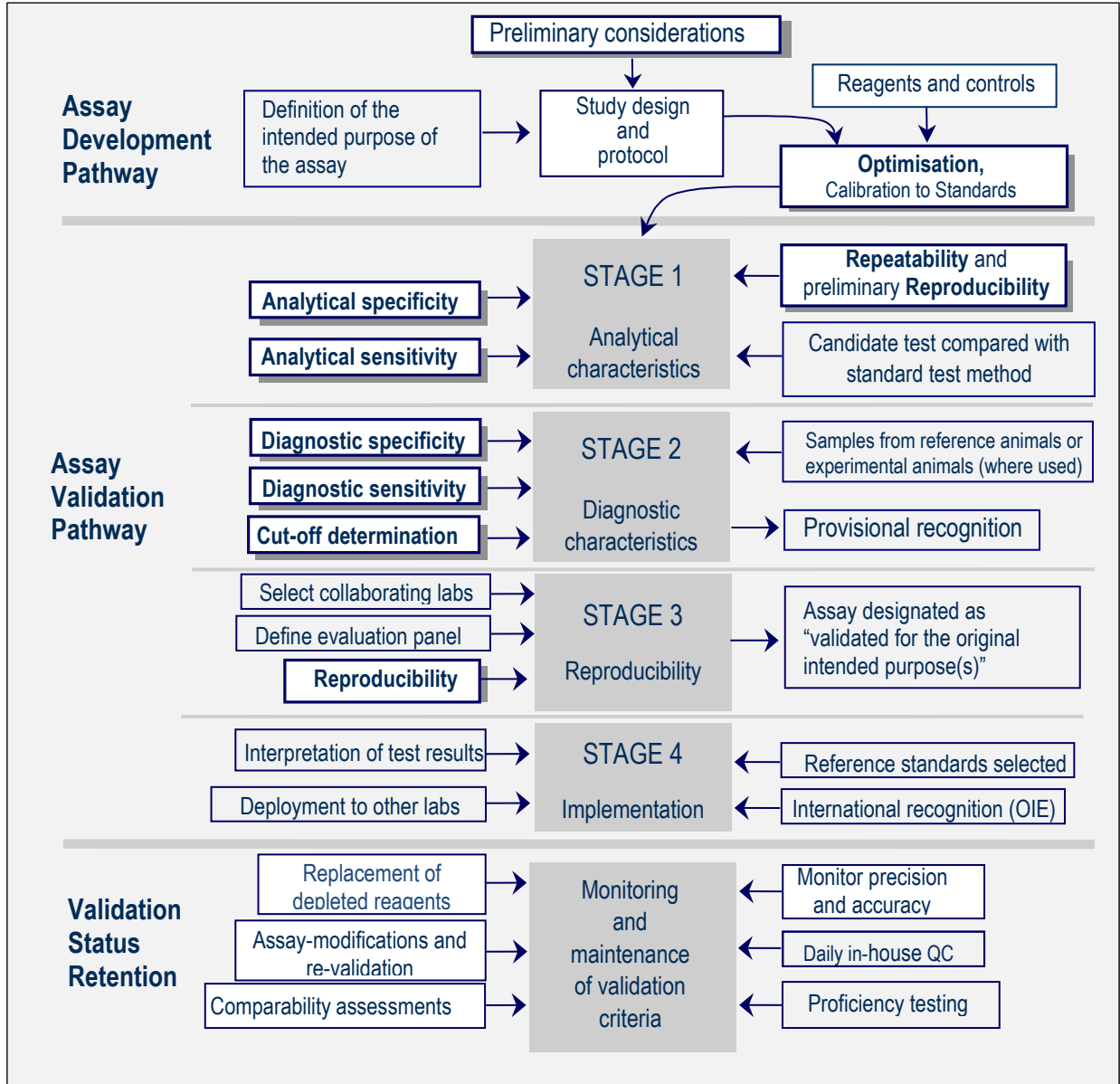
<sup>1</sup> If you have no interests, please indicate "none" in the relevant section. If you lack space on this form, please use and attach additional pages.

<sup>2</sup> 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, Chapter 1.1.6. 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](https://www.oie.int/fileadmin/Home/eng/Health_standards/tahm/1.01.06_VALIDATION.pdf)

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