OIE Procedure for Registration of Diagnostic Kits

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Background of the initiative

- Two Consultants Meetings: one in 2002 and a second one in 2003 after the adoption of the Resolution No. XXIX, at the 71st General Session of the OIE, in May 2003

- The OIE Procedure was launched in May 2005
Aim and Scope of the Procedure

- Developed to meet the needs of OIE Member Countries, the aim of this procedure is:
  - to certify a kit as validated fit for specific purpose(s).
  - to produce an OIE register of recognised diagnostic kits.

- All diagnostic kits for animal diseases, including zoonosis, can be validated and certified by the OIE through the procedure.
Procedure in brief 1/3

- **Procedure based on the submission of a dossier** by a kit manufacturer wishing to have its kit certified by the OIE as validated fit for some specific purpose(s);
- Fees requested for the initial assessment and then annual fee if diagnostic kit included in the OIE Register;
- Reassessment of the validation data of the kit included in the OIE Register every 5 years;
- Dossier, that has to be filled in, downloadable from the OIE website;
- Dossier based on the OIE validation pathway.
Procedure in brief 2/3

- Submission of a dossier
- Panel of experts
- Relevant Specialist Commission
- Scientific evaluation
Procedure in brief 3/3

- The relevant Specialist Commission provide an opinion to propose or not the diagnostic kit for inclusion in the **Register** for some specific purposes to the vote of the World Assembly of Delegates:
  
  - **Favourable opinion:** the diagnostic kit will be proposed for adoption through a resolution to the vote of the World Assembly of Delegates by the OIE Director General;
  
  - **Unfavorable opinion:** the OIE Director General informs the applicant in writing that the application does not satisfy the criteria for inclusion of the kit in the OIE register, together with the reasons for rejection – Appeal procedure possible

- Vote of the World Assembly of Delegates (Assembly) during the next General Session
OIE Procedure for Registration of Diagnostic Kits

Outline of all the process

1. Applicant Contact
2. Dossier + Fees
3. Validation of content of the dossier
4. Appoint assessors
5. Assessment
6. Meeting of the BSC/AAHSC
7. Decision
8. Notification
9. Vote of the World Assembly of Delegates

ADDITIONAL INFORMATION

- Inclusion in the OIE Register
- Appeals procedure

OIE SECRETARIAT FOR THE PROCEDURE

30 d

FURTHER ASSESSMENT

135d
Renewal of registration

- Diagnostic kit registered by the OIE for a period of five years;
- Possibility for the renewal to extend the purposes for which the kit was included in the OIE Register, in this case new evaluation;
- For a renewal with the same purposes, OIE Headquarters in consultation with relevant Specialist Commission decide if a new evaluation is needed;
- Consultation also of the relevant OIE Reference Laboratories;
- Each renewal proposed for adoption to the Assembly.
Standard Operating Procedure 1/2

Our scientific expertise
Registration of diagnostic kits
Procedure for submission

Standard Operating Procedure (guidance document)

1. General outline

2. Guidance document

Guide and Administrative Forms (2012)
Our scientific expertise

Registration of diagnostic kits

Download application form

Download the Application form (for applicants)

This is the application form for the dossier containing the necessary information about a diagnostic kit to be submitted to the OIE for certification of “fitness for purpose”.

1. General Information

Before filling in the form and submitting an application, applicants should read “Standard Operating Procedure (SOP) for OIE Registration of Diagnostic Kits: Guide and Administrative Forms”.

The chapter 1.1.5., “Principles and methods of validation of diagnostic assays for infectious diseases” of the OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals should be also read (available on the OIE website at: http://www.oie.int/en/international-standard-setting/terrestrial-manual/access-online/). It deals with principles of validation and therefore could be helpful when filling in this dossier.

2. Application form (version 1.6., 2012)

Click on the link above and save this file in your local disk. Open it in MS Word, filling the necessary information in the required fields.

3. The applicant shall send the completed application form and the applicable fee to the OIE:

Director General
OIE procedure for validation and certification of the diagnostic assays
OIE
12, rue de Prony
75017 Paris
FRANCE

Contact OIESVCRDA
Dossier 3/3

Content

- Section 1: Guide for applicants
- Section 2: General information
- Section 3: Development & Validation
- Section 4: Performance summary
- Section 5: Additional data
- Section 6: References
Our scientific expertise

Registration of diagnostic kits

The register of diagnostic kit

OIE Register currently comprises 8 diagnostic kits (kits for AI, Bovine tuberculosis, BSE/TSE, Newcastle, Salmonella typing, and White Spot Disease)

20 application form submitted during the last 9 years
Resolution with the specific purposes certified by OIE

Summary of the validation data for the diagnostic kit

Diagnostic kit’s insert

<table>
<thead>
<tr>
<th>Disease</th>
<th>Name of the Diagnostic Kit</th>
<th>Name of the Manufacturer</th>
<th>Contact</th>
<th>Purpose(s) validated</th>
<th>Date and Number of Validation</th>
<th>Validation Results Abstract Sheet</th>
<th>Kit Insert</th>
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</thead>
<tbody>
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<td>BioChain AsiaInfluenza Antibody test kit</td>
<td>BioChain UK Ltd</td>
<td><a href="mailto:info@biochain.com">info@biochain.com</a></td>
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<td>May 2008 by the World Assembly of the OIE Delegates</td>
<td>S102223</td>
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<td>White spot disease</td>
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<td>Genethon Biotech Corp</td>
<td><a href="mailto:tkdes@geneathion.com">tkdes@geneathion.com</a></td>
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<td>manual</td>
</tr>
</tbody>
</table>
What is expected

- Communication with your national authority on the existence of this procedure

- Communication with kit manufacturers to encourage them to submit applications for their kits through this procedure

- Comments to improve the procedure are welcome
Future development of the procedure

- Interaction with countries having already a procedure in place

- More involvement from OIE Reference Centres
Thank you for your attention