Application for inclusion of an IVD category to the EDL

Applications for inclusion of diagnostic test categories in the EDL can be submitted by, or through, relevant department(s) within WHO, by WHO regional or country offices and by other stakeholders, such as academia, NGOs or member states, companies in the IVD industry and IVD industry associations.

As explained in detail in the process document, the application is a two-step process. The first step is a Screening Application which should only include the information requested in Sections 1, 2 and 3. Following review of this information by WHO, successful applicants will be invited to submit a Full Application with the information requested in Sections 4, 5, 6, 7, 8.

The full applications will be posted on WHO website under “Selection, access and use of in vitro diagnostics”

For more information, please refer to the following document: http://www.who.int/medical_devices/diagnostics/Procedure_to_update_EDL_20_07_2018.pdf

There are 19 questions in this survey

Applicant’s information

(This information will not be made public)

Please enter your contact information (primary contact)*

- Last name
- First name
- Email address (...@...)
- Phone number (+country code) phone number no spaces
Please enter secondary contact information *

- Last name
- First name
- Email address (...@....)
- Phone number (+country code) phone number no spaces

Please enter information on the main three institutions consulted and/or supporting the application (if applicable)

1. Name of the organization
   Contact person last and first name
   Contact email address

2. Name of the organization
   Contact person last and first name
   Contact email address

3. Name of the organization
   Contact person last and first name
   Contact email address
Organization submitting the application

Please note that applications will be published on WHO website and will be open for public review and comment.

Please provide the following information regarding the organization making the application. This information should be entered as you would like it to be disclosed on the application form.*

Please write your answer(s) here:

Name of the organization

Address

Department

Website

Phone number
**Disease or conditions addressed**

Please specify the disease(s) or conditions of the International Classification of Diseases (ICD) targeted by the IVD category * 

Please choose all that apply:

- 01 Certain infectious or parasitic diseases
- 02 Neoplasms
- 03 Diseases of the blood or blood-forming organs
- 04 Diseases of the immune system
- 05 Endocrine, nutritional or metabolic diseases
- 06 Mental, behavioural or neurodevelopmental disorders
- 07 Sleep-wake disorders
- 08 Diseases of the nervous system
- 09 Diseases of the visual system
- 10 Diseases of the ear or mastoid process
- 11 Diseases of the circulatory system
- 12 Diseases of the respiratory system
- 13 Diseases of the digestive system
- 14 Diseases of the skin
- 15 Diseases of the musculoskeletal system or connective tissue
- 16 Diseases of the genitourinary system
- 17 Conditions related to sexual health
- 18 Pregnancy, childbirth or the puerperium
- 19 Certain conditions originating in the perinatal period
- 20 Developmental anomalies
- Other:
Please enter information supporting WHO public health relevance and/or clinical benefit (epidemiological information on disease burden, assessment of use, testing gaps, target population)

Please write your answer here:

Please enter information on disease or condition: morbidity, mortality, impact on quality of life, economic impact. Please add references.

Please write your answer here:

Please enter information on how the IVD is used: single result or part of a diagnostic testing algorithm; reference to existing WHO and/or other clinical guidelines (when available). Please provide links.

Please write your answer here:
IVD category summary

Please indicate if you propose to: *

Please choose only one of the following:
- add a new test
- edit an existing test or characteristics of the test
- remove an existing test from EDL

This section summarizes basic information about IVD tests available in the diagnostic test category being proposed for the EDL. Below this table, you will be able to add any relevant information in a detailed way.

<table>
<thead>
<tr>
<th>Diagnostic Test (i.e. disease X antigen test)</th>
<th>Test Purpose (i.e. for the diagnosis of X infection)</th>
<th>Disease Specific? (yes/no)</th>
<th>Test Format (i.e. RDT, EIA)</th>
<th>Required Equipment (i.e. multiple basic automated instruments, simple hand held)</th>
<th>Regulatory status of available products (i.e. SRA)</th>
<th>Globally Available? (please indicate Broad (&gt; 100 countries incl LMIC's) vs. narrow)</th>
<th>List price of test (range in USD, i.e. 100-500)</th>
<th>List price of equipment (range in USD)</th>
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</thead>
<tbody>
<tr>
<td>Test 1</td>
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</table>
IVD category description

This section captures information about IVD tests available in the diagnostic test category being proposed for the EDL. Please specify the test you will provide comments on.

Please provide additional information related to “Diagnostic test”: Test for the detection or measurement of a marker for a specific disease/s or condition/s e.g. anti-HIV-1/2; glucose. There may be several different test formats for the marker.

Please write your answer here:

Please provide additional information on “Test purpose”: The reason the test is performed; diagnose, monitor, screen, other for the disease/s targeted.

Please write your answer here:

Please provide additional information on “Disease specific”: Is the test for a single disease or condition, or is the marker relevant in multiple diseases.

Please write your answer here:
Please provide additional information on “Required Equipment”: e.g. none required for an RDT, or sophisticated laboratory instrument as the case may require. Include all that apply.

Please write your answer here:

Please provide additional information on “Regulatory status”: Approved by a stringent regulatory authority (SRA), WHO prequalified (WHO PQ); WHO endorsed; none/unknown. Include all that apply.

Please write your answer here:

Please provide additional information on “Global distribution and availability”: Are there commercial products (give examples)? NOTE: This serves to clarify global distribution for the test category being requested only. Commercial products are not named in the list.

Please write your answer here:
Please provide additional information on “Approximate price”: Please provide price where available for all test formats within the IVD category. Please specify the markets and split the price components when possible.

Please write your answer here:

Please add up to five relevant documents supporting your application.

Please upload at most 5 files

Kindly attach the aforementioned documents along with the survey
Signature

Through the electronic signature below, I acknowledge that I have provided appropriate information to support this submission. I acknowledge that WHO reserves the right to format and select the information provided as necessary and agree that the information is publicly disclosed by WHO. *

Please write your answer(s) here:

Electronic Signature (type your full name to sign):

Date (yyyy-mm-dd):

Thank you for submitting your screening application.

If approved, you will receive a message to complete a full application.

Best

WHO EDL/SAGE IVD secretariat

edlsecretariat@who.int

Thank you for completing this survey.