ELIGIBILITY CRITERIA FOR
WHO PREQUALIFICATION OF
IN VITRO DIAGNOSTICS

WHO Prequalification of In Vitro Diagnostics
1. Introduction
The World Health Organization (WHO) Prequalification of In Vitro Diagnostics (IVDs) is coordinated through the department of Essential Medicines and Health Products. Focus is placed on IVDs for priority diseases and their suitability for use in resource-limited settings. This document outlines the criteria that manufacturers must fulfil in order to be eligible to submit an application for prequalification assessment.

2. Intended audience
This document has been prepared to provide manufacturers and other stakeholders with an overview of the eligibility criteria applied to products submitted for WHO prequalification assessment of IVDs. Manufacturers wishing to apply for WHO prequalification of their product(s) should read this document before applying for prequalification.

3. Eligibility for prequalification of IVDs

3.1 Original manufacturer
Applications for WHO prequalification of IVDs are accepted only from the legal manufacturer of the product.¹

3.2 Rebranded products
WHO is aware that several manufacturers purchase finalized products from other companies, and then "rebrand" and place these products on the market under their own name or brand. Such products are also known as original equipment manufacturer (OEM) products.

WHO considers a rebranded product to be one that is manufactured under identical conditions at the same manufacturing site(s) as the original product. In other words, a rebranded product is identical in every respect (including the intended use) to the product manufactured by the original manufacturer, except that the product is labelled with the rebranded product name and product code, and bears the rebrander's name or brand.

Rebranded products are outside the scope of the WHO prequalification of IVDs process, and hence are not accepted for prequalification assessment.

3.3 Commercial availability
Applications for WHO prequalification of IVDs are only accepted for products that are commercially available at the time of submission for prequalification assessment. Any exceptions to this requirement must be agreed upon in writing by WHO prior to the submission of the application for prequalification.

¹ The definition of a manufacturer is based on the definition used by the Global Harmonization Task Force (GHTF), and later adopted by the International Medical Device Regulators Forum (IMDRF). This internationally accepted approach has been adopted to ensure that there is a clear understanding of the term “manufacturer” across international markets. For further details see: http://www.imdrf.org/

3.4 Eligibility principles
To meet the needs of WHO Member States and UN agencies, the prequalification scope is defined according to the following prequalification eligibility principles:

- Need for IVDs for a particular disease or disease state;
- Appropriateness of the product for use in resource-limited settings;
- Requests from WHO Member States for particular IVDs;
- Recommendation in WHO disease specific testing guidelines; and/or
- Availability of prequalified products that are of a similar assay format and/or assay principle.

3.5. Eligibility criteria
The eligibility principles are applied using the following eligibility criteria:

- Products that are manufactured by original product manufacturers;
- Products that are commercially available when submitted for prequalification assessment;
- Products of interest to UN organizations and other procurement agencies;
- Product categories for which there exists few other prequalified products.

The eligibility criteria are reviewed and amended by WHO in consultation with WHO Member States, other UN agencies, WHO programmes and/or technical experts.

The prequalification pre-submission form and supportive documentation will be reviewed against the above criteria to determine whether the product is eligible for prequalification assessment. If the product meets the WHO prequalification eligibility criteria, WHO will instruct the manufacturer on the next steps to be followed depending on the type of prequalification assessment (full or abridged) applicable to the product.

3.5.1. Products of interest to UN organizations and other procurement agencies and product categories for which there exists few other prequalified products
Subject to the fulfilment of the other eligibility criteria, the WHO Prequalification of IVDs team currently accepts applications for the following types of products:

<table>
<thead>
<tr>
<th>Analyte/pathogen</th>
<th>Intended use</th>
<th>Assay format(s)/Technology</th>
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</table>
| Human Immunodeficiency virus | Diagnosis of infection | • Rapid diagnostic test (RDT)  
• Enzyme Immunoassays (EIA)  
• Nucleic Acid based Testing Technology (NAT)  
| HIV-1 | Self-testing | • Rapid diagnostic test (RDT)  |
| HIV-2 |

WHO reserves the right to apply other criteria dependent on changing global health needs, the particular needs of WHO Member States, and the emergence of new and relevant technologies.

Re-branded products are not accepted for prequalification assessment.

This document only applies to in vitro diagnostic medical devices. The eligibility criteria applicable to male circumcision devices is defined in a separate document.

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Monitoring of infection

- Flow cytometer for enumeration of lymphocyte subset including CD4+ T cells, or a technology that can be used at or near to point-of-care
- Nucleic Acid based Testing Technology (NAT) for measuring viral load

Hepatitis C virus (HCV)

- Diagnosis of infection
  - Rapid diagnostic test (RDT)
  - Enzyme Immunoassays (EIA)
- Monitoring of infection
  - Nucleic Acid based Testing Technology (NAT)

Hepatitis B surface antigen (HBsAg)

- Diagnosis and monitoring of infection
  - Rapid diagnostic test (RDT)
  - Enzyme Immunoassays (EIA)

Malaria parasites

- Diagnosis of infection
  - Rapid diagnostic test (RDT)

Human Papilloma virus (HPV)

- Diagnosis of infection (For cervical cancer prevention)
  - Nucleic Acid based Testing Technology (NAT)

G6PD enzyme

- Enzyme deficiency detection
  - Rapid diagnostic test (RDT)

| Table 1: Products eligible for prequalification assessment |

3. Relevant documents

The following documents provide information to guide the manufacturer through the requirements of the prequalification assessment:⁵

- Overview of the WHO Prequalification of in vitro diagnostics assessment: Document PQDx_007;
- Pre-Submission Form: Document PQDx_015;
- Instructions for Completion of the Prequalification of In-Vitro Diagnostics Pre-submission Form: Document PQDx_017.

4. Contact information

Any inquiries regarding WHO Prequalification of IVDs should be addressed to: diagnostcis@who.int

⁵ These documents are available through the following website: http://www.who.int/diagnostics_laboratory/evaluations/en/