



**World Health
Organization**

**Eligibility criteria for
WHO prequalification of in vitro diagnostics,
sixth edition**

Prequalification of in vitro diagnostics

Eligibility criteria for WHO prequalification of in vitro diagnostics, Prequalification of in vitro diagnostics, sixth edition
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Abbreviations

IVD in vitro diagnostic

UN United Nations

OEM original equipment manufacturer

G6PD glucose-6-phosphate dehydrogenase

1 Introduction

World Health Organization (WHO) prequalification of in vitro diagnostics (IVDs) is coordinated through the Regulation and Prequalification Department. Focus is placed on IVDs for priority diseases and their suitability for use in resource-limited settings.

WHO prequalification of IVDs is a comprehensive quality assessment of individual IVDs through a standardized procedure aimed at determining whether a product meets WHO prequalification requirements.

The full prequalification assessment process includes the following components:

- review of a full product dossier;
- performance evaluation, including operational characteristics;
- manufacturing site(s) inspection; and
- labelling review.

An abridged prequalification assessment includes the following components:

- review of an abridged product dossier;
- performance evaluation, including operational characteristics;
- manufacturing site(s) inspection; and
- labelling review.

Products submitted for prequalification assessment that meet, as determined by WHO, the WHO prequalification requirements are included in the WHO list of prequalified IVDs. The duration of the validity of the prequalification status of a product is dependent on the manufacturer's fulfilment, within the applicable deadlines, of its post-qualification obligations and requirements, including:

- prequalification commitments;
- annual reporting;
- reporting of changes;
- post-market surveillance obligations;
- undergoing routine inspections; and
- ongoing compliance with WHO prequalification technical specifications.

The findings of WHO prequalification¹ are used to assess the safety, quality and performance of commercially available IVDs for the purpose of providing guidance to interested United Nations (UN) agencies and WHO Member States in their procurement decisions.

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. It is recommended that manufacturers wishing

¹ Prequalification does not imply any approval by WHO of the product and manufacturing site(s). Moreover, prequalification does not constitute any endorsement or warranty by WHO of the fitness of any product for a particular purpose, including its safety, quality or performance.

to apply for WHO prequalification of their product(s) 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.²

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 prequalification, 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 exemptions must be agreed upon by WHO prior to the submission of the application for prequalification.

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
- Availability of prequalified products that are of a similar assay format and/or assay principle.

² 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/>

3.5 Eligibility criteria

The eligibility principles are applied using the following eligibility criteria: ³

- Products that are manufactured by original product manufacturers⁴;
- 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 products⁵.

The Prequalification team currently accepts the following applications:

Analyte/pathogen	Intended use	Technology
HIV-1 HIV-2	Diagnosis of infection	<ul style="list-style-type: none"> • Rapid diagnostic tests
		<ul style="list-style-type: none"> • Enzyme immunoassays • Nucleic acid tests
	Self testing	<ul style="list-style-type: none"> • Rapid diagnostic tests
	Monitoring of infection	<ul style="list-style-type: none"> • Flow cytometer for enumeration of lymphocyte subset including CD4+ T cells, or a technology that can be used at or near the patient • Nucleic acid tests for measuring viral load
Hepatitis C virus	Diagnosis of infection	<ul style="list-style-type: none"> • Rapid diagnostic tests • Enzyme immunoassays
	Aid to diagnosis of infection and monitoring of anti-viral therapy	<ul style="list-style-type: none"> • Nucleic acid tests
Hepatitis B virus	Diagnosis and monitoring of infection	<ul style="list-style-type: none"> • Rapid diagnostic tests • Enzyme immunoassays
	Monitoring of infection and anti-viral therapy	<ul style="list-style-type: none"> • Quantitative nucleic acid tests
Malaria parasites	Diagnosis of infection	<ul style="list-style-type: none"> • Rapid diagnostic tests

³ 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.

⁴ Re-branded products are not accepted for prequalification assessment

⁵ This document only applies to in vitro diagnostic medical devices. Male circumcision devices' assessment eligibility criteria are defined in a separate document.

Human papilloma virus	Diagnosis of infection (for cervical cancer prevention)	• Nucleic acid tests
Glucose-6-phosphate dehydrogenase (G6PD) enzyme	Enzyme deficiency detection	• Technologies/formats to be used at or near the patient
Toxigenic <i>Vibrio cholerae</i>	Detection of outbreaks or surveillance for the disease	• Rapid diagnostic tests
<i>Treponema pallidum</i> (Syphilis)	Screening and aid to diagnosis of infection	• Rapid diagnostic tests
Mycobacterium tuberculosis complex and resistance to first and/or second line anti-tuberculosis drugs	Diagnosis of infection	• Qualitative nucleic acid tests

Table 1: Products currently eligible for prequalification assessment

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

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

4 Relevant documents

The following documents provide information to guide the manufacturer through the requirements of the prequalification assessment:⁶

- Overview of the WHO Prequalification of in vitro diagnostics assessment: Document PQDx_007;
- Pre-Submission Form: Document PQDx_015;
- Instructions for the completion of the pre-submission form: Document PQDx_017.

5 Contact information

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

⁶ These documents are available through the following website: <https://extranet.who.int/pqweb/in-vitro-diagnostics>