

WHO Prequalification of In Vitro Diagnostics Update

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IN THIS ISSUE:

1. PREQUALIFIED IVDs
2. EXPANSION OF THE PREQUALIFICATION OF IN VITRO DIAGNOSTICS SCOPE
3. CALL FOR PUBLIC COMMENT: TECHNICAL SPECIFICATION SERIES
4. CALL FOR PUBLIC COMMENTS: ABRIDGED ASSESSMENT GUIDANCE
5. NEW DOSSIER FORMAT AND MANDATORY PRE-SUBMISSION MEETING FOR FIRST TIME APPLICANTS: UPCOMING CHANGES IN 2020
6. SECOND ANNUAL MEETING OF THE WHO PREQUALIFICATION EVALUATING LABORATORIES
7. THE UNICEF, UNFPA & WHO JOINT MEETING WITH MANUFACTURERS AND SUPPLIERS

1. PREQUALIFIED IVDs

We are very pleased to announce the prequalification of the following products:

Product name	Product code(s)	Manufacturer	Date of Prequalification
Abbott RealTime HCV	4J86-90 4J86-80 4J86-70	Abbott Molecular Inc	10 December 2019
SURE CHECK HIV Self-Test	60-9508-0	Chembio Diagnostic Systems, Inc	29 November 2019
Abbott RealTime High Risk HPV	02N09-092 02N09-080	Abbott GmbH & Co.KG	10 October 2019

For a complete list of prequalified products, click [here](#).

For a list of products undergoing prequalification assessment, [visit this page](#).

2. EXPANSION OF THE PREQUALIFICATION OF IN VITRO DIAGNOSTICS SCOPE



The WHO 5-year Strategic Plan (2019 – 2023) for WHO Regulatory Support Activities for Health Products outlines the maintenance and expansion of the prequalification service to help promote healthier populations as one of the strategic priorities. To that end, a consultation was organized to gather input from key stakeholders in order to determine the types of in vitro diagnostics for which

prequalification is most needed and for which it will have the greatest benefit. The input received during the consultation was compiled and assessed by independent consultants. SAGE-IVD also provided recommendations. The final list of new IVDs accepted for prequalification assessment was determined in collaboration with WHO programmes.

In vitro diagnostics for the analytes/diseases listed below were identified by stakeholders as priority for addition to the Prequalification of in vitro diagnostics pipeline:

- | | |
|---|---------------------------------|
| 1.Haemoglobin (point of care) | 8.Measles |
| 2.Glucose meters and test strips | 9.Rubella |
| 3.Tuberculosis | 10.Leishmaniasis |
| 4.Yellow Fever | 11.Schistosomiasis |
| 5.Dengue Fever | 12.Mycoplasma genitalium |
| 6.Gonorrhoea | 13.Onchocerciasis. |
| 7.Chlamydia | |

The WHO Prequalification Team will develop the Prequalification technical specifications and performance evaluations protocols and will identify dossier assessors and prequalification evaluating laboratories who will support prequalification assessments. It is expected that prequalification assessments will commence by the below timelines:

2020: Haemoglobin (point of care) and glucose meters and test strips
2021: Tuberculosis, yellow fever, dengue fever, gonorrhoea and chlamydia
2022: Measles, rubella, leishmaniasis and schistosomiasis
2023: Mycoplasma genitalium and onchocerciasis

The types of technologies for each infection/disease area listed above will be defined in consultation with WHO programmes and will be aligned with WHO testing guidelines.

IVDs for analytes/diseases currently eligible for prequalification assessment¹ will remain within the programme scope and the types of technologies regularly reviewed with WHO programmes and partner organizations. In addition, quality control materials intended to be used in combination with IVDs within the programme scope will become eligible for prequalification assessment.

¹ These include HIV-1 and HIV-2, HCV, HBsAg, malaria parasites, HPV, G6PD enzyme, toxigenic *Vibrio cholerae* and *Treponema pallidum* (Syphilis). For hepatitis B also refer to footnote 2.



3. CALL FOR PUBLIC COMMENTS: TECHNICAL SPECIFICATION SERIES

We would like to invite you to review the following draft documents posted on the WHO Prequalification – Diagnostic Assessment website under [Guidance and training](#) on 01 December for public comment.

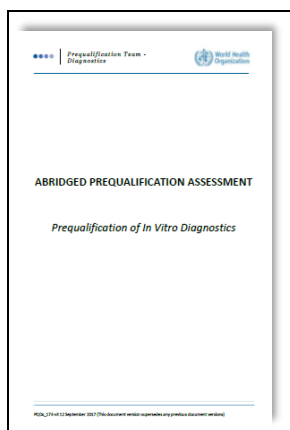
- TSS-13 Rapid diagnostic tests to detect hepatitis B surface antigen
- TSS-14 Immunoassays to detect hepatitis B virus surface antigen
- TSS-15 In vitro diagnostic medical devices used for the quantitative detection of hepatitis B nucleic acid²

The technical specification documents are developed for manufacturers of nucleic acid tests, rapid diagnostic tests and other immunoassays who are interested in applying for WHO prequalification assessment. These documents outline the minimum performance studies necessary to meet WHO Prequalification requirements.

The documents are available for public comment at the link https://www.who.int/diagnostics_laboratory/guidance/technical_specification_series/en/

Public comments must be received to diagnostics@who.int before **29 February 2020**, using the comments table, to be considered in the final version of the document.

4. CALL FOR PUBLIC COMMENTS: ABRIDGED ASSESSMENT GUIDANCE



The aim of an abridged prequalification assessment is to avoid duplication of effort and reduce the time taken to prequalify a product by focusing on aspects where WHO prequalification assessment brings added value. The abridged assessment procedure has been in place since 2014. A review has been undertaken to reflect changes to regulatory reviews leveraged under this procedure and to address comments received from applicants, including their call for further streamlining the abridged assessments through desk reviews and minimizing the time and frequency of manufacturing site inspections.

An updated Abridged prequalification assessment guidance is available for public comment [here](#). Please submit your comments and suggestions by using the comments table to diagnostics@who.int.

The main changes introduced by the new draft version of the abridged assessment procedure are:

- the updated list of acceptable evidence of stringent regulatory assessment;
- the addition of the Health Sciences Authority of Singapore to the list of regulatory authorities recognised for the purposes of the abridged assessment; and
- the introduction of an abridged product dossier.

² In vitro diagnostics intended for the quantitative detection of hepatitis B nucleic acids will become eligible for prequalification assessment in 2020.

The introduction of the abridged product dossier will allow WHO to assess a limited number of dossier sections which are critical to resource-limited settings through a desk review in lieu of the current review during the manufacturing site inspection.

5. NEW DOSSIER FORMAT AND MANDATORY PRE-SUBMISSION MEETING FOR FIRST TIME APPLICANTS: UPCOMING CHANGES IN 2020

In 2020 the WHO Prequalification Team, Diagnostics Assessment Group will implement the International Medical Device Regulators Forum (IMDRF) Table of Contents (ToC) format for its product dossier submissions. At present WHO PQ accepts product dossiers that use the Global Harmonization Task Force (GHTF) Summary Technical Documentation (STeD) format.

The ToC format seeks to harmonize both layout and content of documented evidence provided in support of regulatory (and for WHO purposes, prequalification) submissions. It uses a standardized folder structure that sets out globally-harmonized dossier requirements. At the same time it allows the flexibility for national regulatory authorities to include specific regional requirements. The ToC is also intended to be a single document template that can be used for all risk classifications of diagnostic devices.

WHO's implementation of the ToC dossier format will allow alignment with international best practice as uptake of the new format proceeds. It will also allow dossier reviews that will be compatible for use in those countries participating in WHO's Collaborative Registration Procedure.

In Q1 of 2020 a new, ToC-specific version of PQDx_018 Instructions for Compilation of a Product Dossier, will be published. Over a transition period of 12 months WHO PQ will accept product dossiers in either the current STeD format or using the new ToC format. In 2021 dossiers will be accepted in the ToC format only.

In 2020 WHO Prequalification will also introduce mandatory pre-submission meetings for *first time* applicants of in vitro diagnostic products. Meetings may be either face-to-face or held as teleconferences and will allow both the new applicant and prequalification team to better understand whether a product is ready to be submitted for prequalification assessment and what steps may need to be taken for the application to proceed. For existing applicants (those with products either under assessment or already listed), these meetings will not be mandatory, but may be requested at the applicant's discretion.

6. SECOND ANNUAL MEETING OF THE WHO PREQUALIFICATION EVALUATING LABORATORIES

WHO held the second meeting of WHO Prequalification Evaluating Laboratories (PEL) on 5-6 November 2019, bringing together 26 participants from 13 of the 14 PELs listed currently, as well as other partner laboratories.

The objectives of the meeting were:

- to follow up on action points raised during the first meeting;
- to discuss PELs experience with the organization of performance evaluations, including under the alternative performance evaluation mechanism and to improve the processes and support provided;
- to review and discuss proposed revisions of the performance evaluation protocols focusing on harmonization of methodology and data analysis across sites;
- to discuss the next steps for the creation of shared panels for evaluation of serological assays.

The revised prequalification performance protocols will be available on the website in Q1 2020. The current applicable versions of the performance evaluation protocols can be found [here](#).

The list of currently listed laboratories is available [here](#).

Laboratories interested in becoming a WHO Prequalification Evaluating Laboratory are encouraged to submit an expression of interest to WHO following instructions provided [here](#). WHO reserves the right to prioritize or decline applications based on the current availability of PELs in a given country/region or for specific analytes.

7. THE UNICEF, UNFPA & WHO JOINT MEETING WITH MANUFACTURERS AND SUPPLIERS



The meeting took place on **2-5 December 2019** at **UN City, Marmorvej 51, 2100 Copenhagen, Denmark** and gathered over 400 participants. The presentations are now available [here](#).

To subscribe or unsubscribe to the Prequalification of In Vitro Diagnostics mailing list, send an email to diagnostics@who.int with subscribe or unsubscribe in the subject. http://www.who.int/diagnostics_laboratory/evaluations/en/

