World Health Organization

WHO Prequalification of In Vitro Diagnostics Update

Issue 33
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1. PREQUALIFIED IVDs

Despite the substantial workload and prioritization of EUL assessments the Prequalification Team continues to work hard on prequalification assessments. We are very pleased to announce the prequalification of the following products:

Product name	Product code(s)	Manufacturer	Date of Prequalification
cobas HCV (Quantitative nucleic acid test for use on cobas 6800/8800 Systems)	6997732190	Roche Diagnostics GmbH	09 March 2021
First Response Syphilis Anti-TP Card Test	PI08FRC25, PI08FRC50 PI08FRC100	Premier Medical Corporation Private Limited	13 January 2021

For a complete list of prequalified products, including product codes, click here.
For a list of products undergoing prequalification assessment, click here.

2. COVID-19 PANDEMIC AND EMERGENCY USE LISTING

Emergency Use Listing (EUL) for candidate in vitro diagnostics (IVDs) to detect SARS-CoV-2 remains ongoing. In order to manage the large number of applications during the COVID-19 pandemic, the prioritisation of EUL presubmission meetings and EOIs have been updated. **Read more about new prioritisation criteria in section** Error! Reference source not found. **below**.

The following IVDs are currently eligible for EUL submission:

- Rapid diagnostic tests for the detection of SARS-CoV-2 antigens; and
- Assays for the detection of SARS-CoV-2 nucleic acid.

Manufacturers interested in the EUL submission are invited to contact WHO at diagnostics@who.int and schedule a mandatory pre-submission call and consult our webpage for the most recent information.

In partnership with PAHO and AFRO & ASLM, the Prequalification team has delivered virtual workshops to regulators and reference laboratory staff on the WHO Emergency use Listing (EUL) process for SARS-CoV-2 IVDs, in each region. Presentations were provided by key staff on the following topics:

- The purpose and design of WHO EUL procedure
- The information assessed in the QMS and product dossier review
- The differences between WHO PQ and WHO EUL
- The type of IVDs eligible for EUL and how these decisions are made
- Accessing WHO recommendations and EUL information for SARS-CoV-2 testing
- NRA access to WHO EUL assessment documents to support in-country authorization

Over 100 participants attended each workshop. A question and answer session with participants provided the opportunity to address specific issues raised during the session. Further EUL Workshops in partnership with WHO regional offices are planned for Q2 2021. The slide sets are available on our COVID19 EUL webpage under "Further Information".

The status of each application is updated weekly on our webpage. Thus far, 60 expressions of interest for NAT assays, 41 for antibody detection assays and 32 for antigen detection RDTs have been received. To date 28 products have been listed as eligible for WHO procurement based on their compliance with WHO EUL requirements. The listing is time limited and is reviewed after 12 months, or earlier, if new information emerges which changes the risk/benefit assessment of the assay. In light of the continuing pandemic, we will contact manufacturers in the coming weeks/months regarding eligibility for renewal of their EUL listing.

The following products are currently listed under the WHO EUL procedure:

Rapid Antigen Tests

Date Listed	Product name	Product code(s)	Manufacturer
17 March 2021	Sure Status COVID-19 Antigen Card Test	SS03P25	Premier Medical Corporation Private Limited
19 November 2020	Panbio COVID-19 Ag Rapid Test Device (NASAL)	41FK19	Abbott Rapid Diagnostics Jena GmbH
02 October 2020	Panbio COVID-19 Ag Rapid Test Device (NASOPHARYNGEAL)	41FK10	Abbott Rapid Diagnostics Jena GmbH
22 September 2020	STANDARD Q COVID-19 Ag Test	09COV30D	SD Biosensor, Inc

Nucleic Acid Tests

Date Listed	Product name	Product code(s)	Manufacturer
14 December 2020	Veri-Q PCR 316 Coronavirus disease 2019 (COVID-19) Detection System	7K105 7K111	MiCo BioMed Co Ltd
30 November 2020	Bio-Speedy SARS-CoV-2 (2019-nCoV) qPCR Detection Kit.	BS-SY-WCOR-304-100	Bioeksen R&D Technologies Ltd
23 November 2020	3DMed 2019-nCoV RT-qPCR Detection Kit	3103010011	3D Biomedicine Science & Technology Co., Ltd.
15 September 2020	SARS-CoV-2 Nucleic acid detection kit based on Real-Time PCR platform	PGA4102P1 (liquid) /	Tellgen Corporation

		PGA4102P2 (lyophilized form)	
2 September 2020	Novel Coronavirus (2019-nCoV) RT-PCR Detection Kit (commercial name: Fosun 2019-nCoV qPCR)	PCSYHF	Shanghai Fosun Long March Medical Science Co., Ltd.
28 August 2020	SARS-CoV-2 Virus Detection Diagnostic Kit (RT-qPCR Method)	XC25073	Ningbo Health Gene Technologies Co., Ltd.
14 August 2020	TaqPath COVID-19 CE-IVD RT-PCR Kit	A48067	Thermo Fisher Scientific
14 August 2020	Wantai SARS-CoV-2 RT-PCR	WS-1248	Beijing Wantai Biological Pharmacy Enterprise Co., Ltd
9 July 2020	COVID-19 Coronavirus Real Time PCR Kit	JC10223-1NW-50T	Jiangsu Bioperfectus Technologies Co.,Ltd
6 July 2020	Simplexa COVID-19 Direct and Simplexa COVID-19 Positive control Pack	MOL4150, MOL4160	DiaSorin
23 June 2020	Xpert Xpress SARS-CoV-2	XPRSARS-COV2-10	Cepheid AB
15 June 2020	COVID-19 Real-Time PCR Kit	HBRT-COVID-19	Chaozhaou Hybribio Biochemistry Ltd.
11 June 2020	Novel Coronavirus 2019-nCoV Nucleic Acid Detection Kit (Real Time PCR)	GZ-D2RM25	Shanghai GeneoDx Biotechnology Co., Ltd
8 June 2020	Diagnostic kit for SARS-CoV-2 Nucleic acid (Real-time PCR)	KH-G-M-574-48	Shanghai Kehua Bio-engineering Co., Ltd.
22 May 2020	Novel Coronavirus (SARS-CoV-2) Real Time Multiplex RT-PCR Kit	RR-0485-02	Shanghai ZJ Bio-Tech Co., Ltd
21 May 2020	FTD SARS-CoV-2 (FTD-114-32)	11416300	Fast Track Diagnostics Luxembourg S.à r.l.
19 May 2020	Multiple Real-Time PCR Kit for Detection of 2019-nCoV	CT8233-48T	Beijing Applied Biological Technologies Co. Ltd., (XABT)
14 May 2020	Detection Kit for 2019 Novel Coronavirus (2019-nCoV) RNA (PCR-Fluorescence Probing)	DA0930, DA0931 and DA0932	Da An Gene Co., Ltd. Of Sun Yat-sen University
7 May 2020	Real-time fluorescent RT-PCR kit for detecting 2019-nCoV	MFG030011	BGI Europe A/S
24 April 2020	PerkinElmer SARS-CoV-2 Real-time RT-PCR Assay	SY580	PerkinElmer Inc.
9 April 2020	Abbott Realtime SARS-CoV-2	09N77-090 and 09N77-080	Abbott Molecular Inc.
7 April 2020	Primerdesign Ltd COVID-19 genesig Real-Time PCR assay	Z-Path-COVID-19-CE	Primerdesign Ltd.
3 April 2020	cobas SARS-CoV-2 Qualitative assay for use on the cobas 6800/8800 Systems	09175431190 and 09175440190	Roche Molecular Systems, Inc.

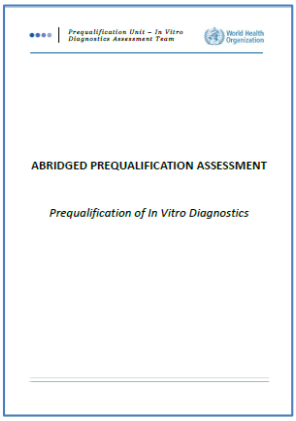
Antibody detection Assays

Date Listed	Product name	Product code(s)	Manufacturer
7 December 2020	Elecsys Anti-SARS-CoV-2 Qualitative assay for use on the cobas e 411/601/602/801 immunoanalyzers	09203095190, 09203079190 and 09216928190	Roche Diagnostics GmbH

3. NEW OVERVIEW DOCUMENT AND ABRIDGED ASSESSMENT GUIDANCE PUBLISHED

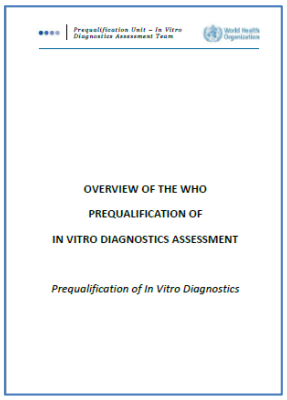
In January 2021 two updated PQDx documents have been published; the *Overview of the WHO prequalification of in vitro diagnostics assessment* and the *Abridged prequalification assessment*.

3.1. Abridged prequalification assessment



The aim of 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 eligibility for abridged prequalification assessment has been expanded to Class C and Class D in vitro diagnostics assessed and approved by the Singapore Health Sciences Authority. The updated abridged assessment procedure now includes the review of an abridged product dossier which replaces the review of documentary evidence during the site inspection. Finally, the recently implemented abridged assessment procedure allows WHO to better leverage Medical Device Single Audit Program (MDSAP) reports.

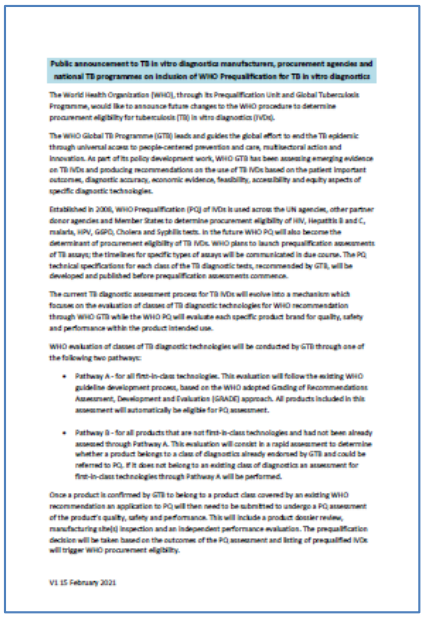
3.2. Overview of the WHO prequalification of in vitro diagnostics assessment



The updated *Overview of the WHO prequalification of in vitro diagnostics assessment* reflects the provisions of the amended *Abridged prequalification assessment guidance*. In addition, it introduces a new approach to the publication of prequalification public reports. The previously used Public Report has been split into the WHO Public Assessment Report (WHOPAR) and the WHO Public Inspection Report (WHOPIR). The WHOPAR summarizes the outcomes of the product dossier review, the Prequalification independent performance evaluation and labelling review. The WHOPIR reflects the outcomes of the prequalification site inspection.

Prequalification applications received since 4 January 2021 are subject to the provisions of the updated *Overview of the WHO prequalification of in vitro diagnostics assessment* and *Abridged prequalification assessment.*

4. PUBLIC ANNOUNCEMENT TO TUBERCULOSIS (TB) IN VITRO DIAGNOSTICS (IVDs) MANUFACTURERS, PROCUREMENT AGENCIES AND NATIONAL TB PROGRAMS ON INCLUSION OF WHO PREQUALIFICATION FOR TB IN VITRO DIAGNOSTICS



Public announcement to TB in vitro diagnostics manufacturers, procurement agencies and national TB programmes on inclusion of WHO Prequalification for TB in vitro diagnostics

The World Health Organization (WHO), through its Prequalification Unit and Global Tuberculosis Programme, would like to announce future changes to the WHO procedure to determine procurement eligibility for tuberculosis (TB) in vitro diagnostics (IVDs).

The WHO Global TB Programme (GTB) leads and guides the global effort to end the TB epidemic through universal access to people-centered prevention and care, multisectoral action and innovation. As part of its policy development work, WHO GTB has been assessing emerging evidence on TB IVDs and producing recommendations on the use of TB IVDs based on the patient important outcome, diagnostic accuracy, economic evidence, feasibility, accessibility and equity aspects of specific diagnostic technologies.

Established in 2008, WHO Prequalification (PQ) of IVDs is used across the UN agencies, other partner donor agencies and Member States to determine procurement eligibility of HIV, Hepatitis B and C, malaria, HPV, GBPD, Cholera and Syphilis tests. In the future WHO PQ will also become the determinant of procurement eligibility of TB IVDs. WHO plans to launch prequalification assessments of TB assays; the timelines for specific types of assays will be communicated in due course. The PQ technical specifications for each class of the TB diagnostic tests, recommended by GTB, will be developed and published before prequalification assessments commence.

The current TB diagnostic assessment process for TB IVDs will evolve into a mechanism which focuses on the evaluation of classes of TB diagnostic technologies for WHO recommendation through WHO GTB while the WHO PQ will evaluate each specific product brand for quality, safety and performance within the product intended use.

WHO evaluation of classes of TB diagnostic technologies will be conducted by GTB through one of the following two pathways:

- Pathway A - for all first-in-class technologies. This evaluation will follow the existing WHO guideline development process, based on the WHO adopted Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach. All products included in this assessment will automatically be eligible for PQ assessment.
- Pathway B - for all products that are not first-in-class technologies and had not been already assessed through Pathway A. This evaluation will consist in a rapid assessment to determine whether a product belongs to a class of diagnostics already endorsed by GTB and could be referred to PQ. If it does not belong to an existing class of diagnostics an assessment for first-in-class technologies through Pathway A will be performed.

Once a product is confirmed by GTB to belong to a product class covered by an existing WHO recommendation an application to PQ will then need to be submitted to undergo a PQ assessment of the product's quality, safety and performance. This will include a product dossier review, manufacturing site(s) inspection and an independent performance evaluation. The prequalification decision will be taker based on the outcomes of the PQ assessment and listing of prequalified IVDs will trigger WHO procurement eligibility.

V1 15 February 2021

On 8 March 2021 the WHO Prequalification Unit and Global Tuberculosis Programme published an announcement to inform stakeholders on future changes to the WHO procedure to determine procurement eligibility for tuberculosis (TB) in vitro diagnostics (IVDs). The current TB diagnostic assessment process for TB IVDs will evolve into a mechanism which focuses on the evaluation of classes of TB diagnostic technologies for WHO recommendation through WHO GTB while the WHO PQ will evaluate each specific product brand for quality, safety and performance within the product intended use.

The WHO/PQ and WHO/GTB are working together on a smooth transition from the current procurement eligibility mechanism to prequalification listing based WHO procurement eligibility.

The announcement is available at this link.

5. PRIORITY CATEGORIZATION OF PQ AND EUL APPLICATIONS

The prequalification team is committed to meeting the expectations and needs of Member States and UN procurement agencies. In order to manage the large number of application during the COVID-19 pandemic the following prioritization of incoming applications for prequalification and emergency use listing assessment was established. Please note that this is a temporary measure aiming at the most efficient use of limited resources and will be adjusted according to future public health needs. Please refer to our website for future updates.

The below types of applications are currently given priority:

High priority:

- EUL applications for SARS-CoV-2 antigen detection tests
- EUL applications for SARS-CoV-2 nucleic acid detection tests intended to be used at a point-of-care

Medium priority:

- PQ applications
- EUL applications for SARS-CoV-2 nucleic acid detection tests

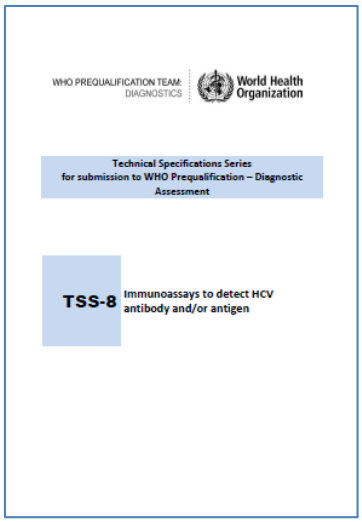
All other submissions/requests are currently of a lower priority. Change notifications are prioritized on a case-by-case basis.

Please also note that due to the current peak in applications under assessment the PQ team is only accepting EUL pre-submission calls and new EOIs for the above high and medium priority applications.

6. NEW GUIDANCE

The Technical Specifications document "*TSS-7: Rapid diagnostic tests to detect hepatitis C antibody or antigen*" has been updated in January 2021 to now include requirements for hepatitis C self testing. The new document is called ***"TSS.7: Hepatitis C rapid diagnostic tests for professional use and/or self-testing"*** and is available here.

The scope of prequalification will be broadened to include self-testing in the coming months based on WHO recommendations. In the meantime, manufacturers are welcome to contact the team to discuss these requirements.



7. COLLABORATIVE REGISTRATION PROCEDURE FOR IVDs

The Collaborative Registration Procedure (CRP) for WHO prequalified products aims to accelerate product registration by sharing information between WHO Prequalification and national regulatory authorities (NRAs). Applying the CRP can reduce duplicative efforts associated with in-country registration by forming an agreement between WHO, NRAs and manufacturers that enables leverage of WHO's PQ evidence of IVD quality, performance and safety while maintaining strict confidentiality. The target timeframe for a decision on country registration under the CRP is **90 days.**

Following on from CRP Workshops last year, Uganda and Mozambique are working towards registering their first IVD using the collaborative procedure. NAFDAC in Nigeria has successfully applied the CRP to register four IVDs and have two more applications under review.
Further information on the CRP for IVDs can be accessed via the WHO Prequalification website: https://extranet.who.int/pqweb/vitro-diagnostics/collaborative-procedure-accelerated-registration
National Regulatory Authorities and manufacturers interested in participating in the CRP for IVDs can contact us at diagnostics@who.int

8. PERFORMANCE EVALUATIONS

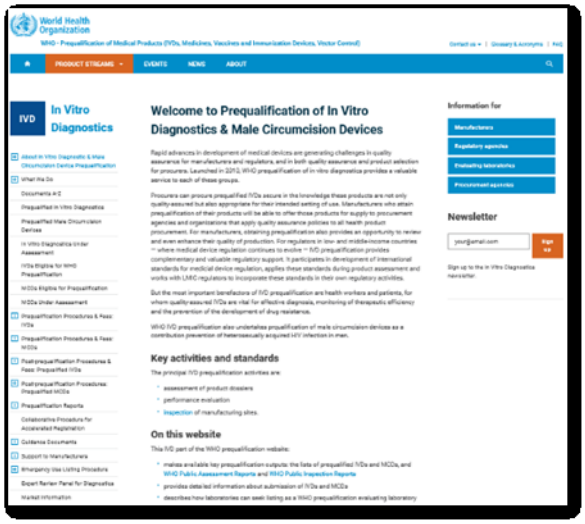
To ensure consistency and comparability of performance evaluation of HIV serology tests, a new panel of clinical specimens will be established. The prequalification evaluating laboratories and other collaborating centers will provide specimens, which will be centralized at the Institute of Tropical Medicine, Belgium, for characterization and storage. An aliquot of all 1200 specimens included in the panel will then be provided to the PQ evaluating laboratories upon request for a PQ performance evaluation of HIV serology tests.
The protocol for the collection of specimens is being finalized. It is expected that the specimen panel will be available for use in 2022.

9. ePQS PROJECT IMPLEMENTATION AND PREQUALIFICATION PORTAL

9.1. ePQS Project Implementation

The development of an IT platform to support the activities of the Prequalification Team and selected activities of the Regulatory Team is progressing. Final User Acceptance Testing (UAT) is taking place from 22 March to 14 April 2021. And tl tentative date for the Hard Launch is 31 May 2021.

9.2. Prequalification portal



The new PQ website was launched at the end of January 2021, as part of the streamlining efforts of all Prequalification streams. Below are the direct links to specific topics:

Prequalification of VDs:
https://extranet.who.int/pqweb/vitro-diagnostics/procedures-and-fees-prequalification

TSS Guidance documents:
https://extranet.who.int/pqweb/vitro-diagnostics/technical-specifications-series

WHO Emergency Use Listing Procedure (EUL) :
https://extranet.who.int/pqweb/vitro-diagnostics/emergency-use-listing-procedure

Prequalification of Male Circumcision Devices:
https://extranet.who.int/pqweb/vitro-diagnostics/assessment-male-circumcision-devices

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