World Health Organization

WHO Prequalification of In Vitro Diagnostics Update

Issue 32
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IN THIS ISSUE:

1. PREQUALIFIED IVDs

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

Product name	Product code(s)	Manufacturer	Date of Prequalification
cobas HIV-1 Quantitative nucleic acid test for use on the cobas 6800/8800 Systems	07000995190	Roche Diagnostics GmbH	13 October 2020
MERISCREEN HIV 1-2 WB	HVWRPD-01 HVWRPD-02	Meril Diagnostics Pvt. Ltd	24 September 2020

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

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. The following IVDs are eligible for EUL submission:

- Assays for the detection of SARS-CoV-2 nucleic acid;
- Rapid diagnostic tests and enzyme immunoassays for the detection of IgM/IgG to SARS-CoV-2; and
- Rapid diagnostic tests for the detection of SARS-CoV-2 antigens.

Manufacturers interested in the EUL submission are invited to contact WHO at diagnostics@who.int and schedule a pre-submission call and consult our webpage for the most recent information. Update FAQs and requirements for nucleic acid tests and antigen detection RDTs will be published in December 2020.

The status of each application is updated weekly on our webpage. Thus far, 55 expressions of interest for NAT assays, 33 for antibody detection assays and 15 for antigen detection RDTs have been received. To date 21 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.

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

Rapid Antigen Tests

Date Listed	Product name	Product code(s)	Manufacturer
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

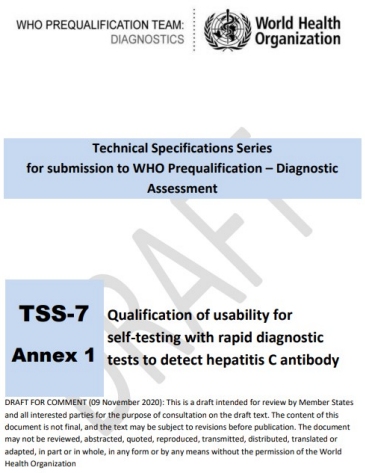
Date Listed	Product name	Product code(s)	Manufacturer
14 December 2020	Veri-Q PCR 316 Coronavirus disease 2019 (COVID-19) Detection System	QD-P100, 16TU-CV19, nCoV-QS and G2-16TU	MiCo BioMed Co Ltd
30 November 2020	Bio-Speedy SARS-CoV-2 (2019-nCoV) qPCR Detection Kit.	BS-SY-WCOR-304-100	Bioeksen R&D 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) / PGA4102P2 (lyophilized form)	Tellgen Corporation
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 GUIDANCE



New technical specifications for hepatitis C self-testing

New technical specifications for the "Qualification of usability for self-testing with rapid diagnostic tests to detect hepatitis C antibody" were published for public comment in Q4 after an online expert consultation.

The document is now being finalized and will be published in early 2021. This document once finalized will to added to the published Technical Specifications document "*TSS-7: Rapid diagnostic tests to detect hepatitis C antibody or antigen".*

Guidance for post-market surveillance and market surveillance of medical devices, including in vitro diagnostics

Post-market surveillance is a crucial tool to ensure that medical devices continue to be safe and well-performing and to ensure actions are undertaken if the risk of continued use of the medical device outweighs the benefit. New guidance for post-market surveillance has been published on our website and replaces the previous guidance published in 2015.

It describes the measures taken to ensure the ongoing compliance of medical devices with the requirements for safety, quality, and performance after they are placed on the market.

4. 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 NRAs and manufacturers to leverage 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.

WHO has partnered with the STAR initiative to conduct a series of workshops introducing the CRP to participating countries for registration of WHO prequalified HIV self tests. Customised, interactive workshops were held with Uganda in September, Mozambique in October and Cameroon in November. Participants were trained on the Prequalification assessment process with an emphasis on identification of key information in the dossier review, site inspection and performance evaluation reports. Strategies for effectively implementing the CRP into the regulatory structure and the development of an action plan were also discussed with each country during the workshops. Since the training both Uganda and Mozambique have committed to using the CRP for a HIV self test. In 2021 PQ/CRP workshops are planned with regulators from India and Indonesia.

National Regulatory Authorities and manufacturers interested in participating in the CRP for IVDs can contact us at diagnostics@who.int

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5. PERFORMANCE EVALUATION OF SYPHILIS RAPID TESTS

The first performance evaluation of a syphilis rapid test was conducted at the National Serology Reference Laboratory (NRL), Australia in Q3 2020. A clinical specimen panel comprising 270 anti-*Treponema pallidum* (Tp) positive specimens and 300 anti-Tp negative specimens was assembled at NRL for the evaluation of syphilis rapid tests. This clinical panel may be shared with other PQ evaluating laboratories (PEL) listed for the evaluation of syphilis rapid tests to ensure comparability of the evaluations across PELs.

The revised protocol for the performance evaluation of syphilis rapid tests for prequalification assessment, as well as other PQ performance evaluation protocols can be found on the following link:

https://extranet.who.int/pqweb/vitro-diagnostics/performance-evaluation

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6. TRANSITION TO ToC DOSSIER FORMAT EXTENDED UNTIL 2022

In April of this year WHO Prequalification of In Vitro Diagnostics commenced its transition to the International Medical Device Regulators Forum (IMDRF) Table of Contents (ToC) format for product dossier submissions. In doing so, WHO PQ is moving away from 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.

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.

A new, ToC-specific version of the WHO publication "PQDx_018 Instructions for Compilation of a Product Dossier" is now available at our website: https://extranet.who.int/pqweb/sites/default/files/documents/200324_draft_Instruction_for_compilation_of_a_product_dossier_pqdx_018_v4_toc_0.pdfThese instructions are open for public comment over the transition period. Any comments may be directed to diagnostics@who.int
In light of the Covid-19 pandemic, the transition period will extend to 2021.

For the remainder of 2020 and into 2021, WHO PQ will accept product dossiers in the new ToC format; alternatively, dossiers may still be submitted in STeD format. In 2022 dossiers will then be accepted in the ToC format.

WHO PQ will now also hold mandatory pre-submission meetings for *new* applicants of diagnostic products. Meetings may be either face-to-face or held as teleconferences and will allow both the new applicant and PQ 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.

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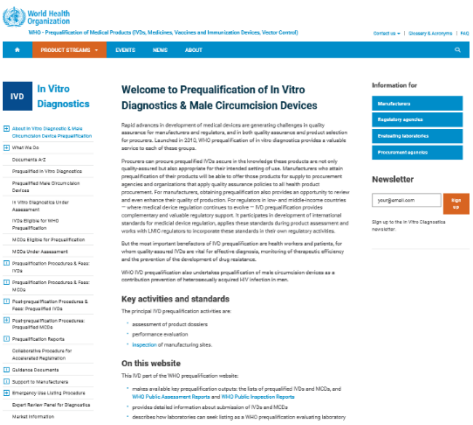
7. NEW WEBSITE



All information on Prequalification of in vitro diagnostics and male circumcision devices can be found on our new website https://extranet.who.int/pqweb/in-vitro-diagnostics

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8. ANNUAL UN MEETING WITH MANUFACTURERS

The 2020 Joint UNICEF–UNFPA–WHO Meeting with Manufacturers and Suppliers of Contraceptive Devices, In Vitro Diagnostics, Vaccines and Immunization Devices, Finished Pharmaceutical Products, Active Pharmaceutical Ingredients and Vector Control Products was held virtually from 30 November to 02 December 2020. The meeting gathered over 1000 stakeholders, including the UN family, manufacturers, experts, procurement agencies, and international donors.

Presentations and background documents are available on our webpages: https://extranet.who.int/pqweb/events/2020-joint-unicef-unfpa-who-virtual-meeting For any further information kindly contact diagnostics@who.int