World Health Organization

WHO Prequalification
of In Vitro Diagnostics Update

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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. One product was prequalified in this quarter.

Product name	Product code(s)	Manufacturer	Date of Prequalification
cobas HIV-1 Quantitative nucleic acid test for use on the cobas 4800 System	06979599190; 06979572190; 06979513190; 06979521190; 05235863190; 05235871190; 06979556190; 06979530190 ; 06979548190	Roche Diagnostics GmbH	24 September 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.

The status of each application is updated weekly on our webpage. Thus far, 65 expressions of interest for NAT assays, 41 for antibody detection assays and 53 for antigen detection RDTs have been received. To date 29 products have been listed as eligible for WHO procurement based on their compliance with WHO EUL requirements. 44 products were not accepted for WHO EUL listing. 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
30 September 2021	RADI COVID-19 Detection Kit	RV008	KH Medical Co., Ltd.
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) / 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.

3. WORKSHOPS HELD

A 5-day virtual workshop was held 5-9 July to provide manufacturers of IVDs based in India a comprehensive understanding of the WHO PQ programme for IVDs and the WHO resources available to attain PQ listing. The Workshop was organized and implemented by all three levels of WHO (Country Office, Regional Office and Headquarters) in collaboration with external partners in India. Over the week the workshop was attended by 194 industry participants representing 51 manufacturing enterprises.

Key staff from the PQ Team delivered presentations encompassing the following topics:

- Fundamentals of WHO Prequalification for IVDs
- Guidance documents available for manufacturers
- Compilation of manufacturer's evidence in the product dossier
- PQ performance evaluation
- Obtaining & maintaining PQ IVD listing

Technical experts as well as representatives from the manufacturing industry and national regulatory authority also contributed to the workshop programme through presentations and interactive Q&A sessions. There was strong engagement from participants during each session and positive feedback about the content shared. The PQ team at HQ would like to thank colleagues at SEARO for their support in delivering a successful workshop and we look forward to the knowledge gained translating into high quality IVD applications being submitted to WHO PQ in the near future.

4. PREQUALIFICATION OF TB IVDs

As communicated in previous Newsletters and broadcasted emails WHO haas initiated the preparatory work for the launch of prequalification assessments of TB IVDs. The WHO Global TB Programme and the Prequalification Unit have been working in close collaboration to design and implement an effective and efficient transition to PQ assessments of these critical products. This will be done in a step-wise approach with a progressive inclusion of specific product classes in prequalification.

The development of the PQ technical specifications for TB IVDs used for the qualitative detection of Mycobacterium tuberculosis complex (MTBC) with or without drug resistance has started and is planned to be completed by end of 2021. WHO should accept the first submissions for prequalification assessment in Q1 2022. The development of PQ specifications for other classes of TB IVDs will follow and the PQ eligibility will be expanded accordingly. WHO will keep stakeholders updated on the prioritization of product classes and timelines for specifications development.

WHO is working on an FAQ which will inform stakeholders on all major apsects related to the ongoing and future work on TB IVDs. The FAQ will answer the queries received by WHO.

5. ICDRA

The International Conference of Drug Regulatory Authorities (ICDRAs) has been held since 1980 and provides drug regulatory authorities of WHO Member States with a forum to meet and discuss ways to strengthen collaboration. As a platform established to develop international consensus, the ICDRA continues to be an important tool for WHO and drug regulatory authorities in their efforts to harmonize regulation.

An extraordinary (virtual) International Conference of Drug Regulatory Authorities was held on 20 to 24 September 2021. The theme of the extraordinary Conference was “Smart Regulation: Timely Delivery of Quality Assured Medical Products for All during the Global Pandemic”. A Programme overview can be found here. The conference included a session on Emergency Use Listing for medicines, vaccines and IVDs including inspections during the COVID-19 global pandemic where experiences and lessong learn were shared.

For more information on the ICDRA conference please refer to the dedicated webpage.

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