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. No new products were prequalified in this quarter.

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. A new version of the following instructions document has been published on our website "Instructions and requirements for Emergency Use Listing (EUL) Submission: In vitro diagnostics detecting SARS-CoV-2 nucleic acid or antigen".

The status of each application is updated weekly on our webpage. Thus far, 64 expressions of interest for NAT assays, 41 for antibody detection assays and 43 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. 41 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
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.

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. PRIORITY CATEGORIZATION OF PQ AND EUL APPLICATIONS

The prequalification team continues to receive and review a large number of applications and change requests. A temporary measure aiming at the most efficient use of limited resources has been set up 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.

WHO understands that manufacturers may be in need of urgent reviews of specific submisisons. In such cases applicants are encouraged to contact the the In Vitro Diagnostics assessment Team at **diagnostics@who.int** to explain their needs and discuss options for assessment.

4. MANDATORY NOTIFICATION OF CHANGES TO THE IFU DURING THE PQ ASSESSMENT

It is not unexpected that an IVD will change in one way or another over the product lifespan. Changes may be minor (cosmetic changes to product housing; minor corrections to labelling; etc) or major (amending a product's intended use; modifying reagent formulation; adding/moving warehouses; etc).

It is a requirement of prequalification listing that manufacturers inform WHO in advance of any notifiable changes they propose to make to any of their listed products. Guidance as to what constitutes a reportable change can be found here: https://apps.who.int/iris/bitstream/handle/10665/251915/WHO-EMP-RHT-PQT-2016.01-eng.pdf;jsessionid=830C82950055325AF37A0A8302BE4623?sequence=1

WHO has become aware of several instances where changes appear to have a occurred to products while they are still going through prequalification assessment. This is particularly apparent with changes made to labelling, including the Instructions for Use (IFU), that must accompany a product. Depending on the nature of changes that are made to the IFU, there may be substantial impacts to the useful of the ongoing assessment; in extreme cases, it may be necessary to reconsider whether continuing with an assessment of a product remains feasible and appropriate.

It is fundamental to the quality of the assessment that underpins a product's listing that there be the utmost confidence that what has been listed as prequalified is the same as the product that was submitted for assessment.

As a consequence, WHO would like to underline how important it is that manufacturers communicate any product changes to WHO as soon as possible for any of their products that are under assessment.

This is particularly the case for product IFUs. It is not unexpected that version numbers and/or dates of these documents may change as a natural consequence of quality management procedures; however, they may also change to reflect substantial changes both the nature, and impact of which may not be readily apparent as a product goes through assessment.

For products that are still under assessment manufacturers must inform WHO of changes to its IFU. Depending on the nature of the change this should include at least:

- A summary of what is different between the new version of the IFU and that submitted to WHO for prequalification assessment - either as a table or list, or as a draft of the proposed IFU with changes highlighted.
- A description of what impact the change is likely to have on the performance of the product and how any differences between the new product and that already under assessment will be managed.

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5. EMERGENCY USE LISTING - FACILITATED PROCEDURE FOR IVDs

To facilitate timely access to reliable IVDs during public health emergencies a mechanism for accelerating national listing / authorization of WHO EUL IVDs has been developed. The WHO-EUL-Facilitated Procedure is based on similar principles to the WHO Collaborative Registration Procedure but is specifically for SARS-CoV-2 IVDs that have attained EUL. Information sessions to introduce the EUL-FP were held with manufacturers of EUL-listed IVDs on the 1st of July and with NRAs on the 15th of July. The webinar recording of the EUL-FP information session held with IVD manufacturers can be accessed under the "Further Information" tab on the webpage: https://extranet.who.int/pqweb/vitro-diagnostics/coronavirus-disease-covid-19-pandemic-%E2%80%94-emergency-use-listing-procedure-eul-open

Under the EUL-FP the manufacturer guarantees the same product assessed by WHO will be supplied and allows WHO to share confidential EUL assessment reports with participating NRAs. The NRA expedites the authorization process using the WHO EUL outcomes to support their decision. After receiving the information and documentation from WHO, the participating NRA is expected to issue a regulatory decision within 15 calendar

days. Participation in the EUL-FP is voluntary for manufacturers and NRAs and provides a clear pathway for NRAs to avoid duplication of effort and accelerate decision making for much needed SARS-CoV-2 IVDs that are EUL-listed. Details of the WHO EUL-FP can be found at: https://www.who.int/teams/regulation-prequalification/regulation-and-safety/facilitated-product-introduction

6. EMERGENCY USE LISTING WORKSHOP

In our ongoing collaboration with Regional Offices the Prequalification team has delivered a virtual workshop in partnership with the WHO office for Europe (WHO/EURO) to regulators and reference laboratory staff on the WHO Emergency use Listing (EUL) process for SARS-CoV-2 IVDs. Presentations from key staff covered 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

A question and answer session with participants from the European region provided the opportunity to address specific issues raised on the EUL process. The next EUL Workshop will be held in partnership with WHO South-East Asia (WHO SEARO) during Q3 2021.The slide sets from the workshop are available on our COVID19 EUL webpage under "Further Information".