WHO Update

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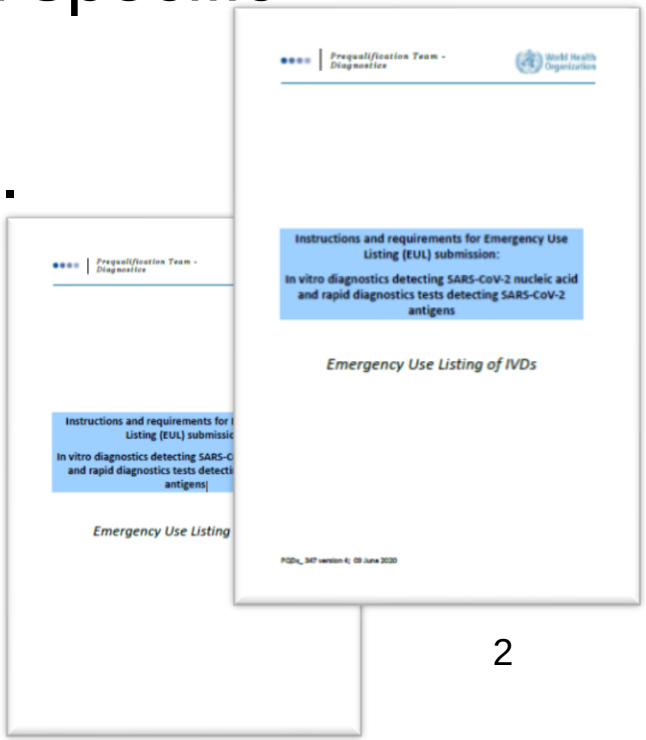
COVID-19 response

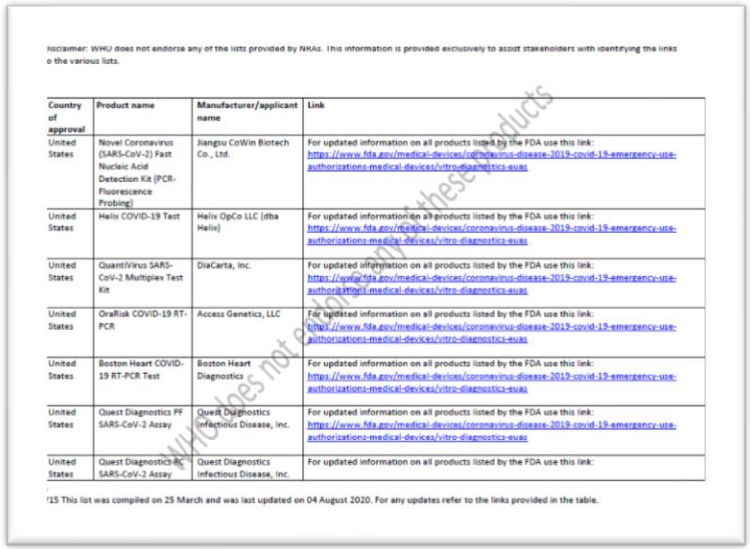
- WHO EUL scope:
  - Assays for the detection of SARS-CoV-2 nucleic acid;
  - Immunoassays for the detection of SARS-CoV-2 specific antibodies; and
  - RDTs for the detection of SARS-CoV-2 antigens.
- Instructions for manufacturers:
  - NAT and Ag detection IVDs;
  - Ab detection IVDs



https://www.who.int/diagnostics_laboratory/EUL/en/

COVID-19 response cont'd

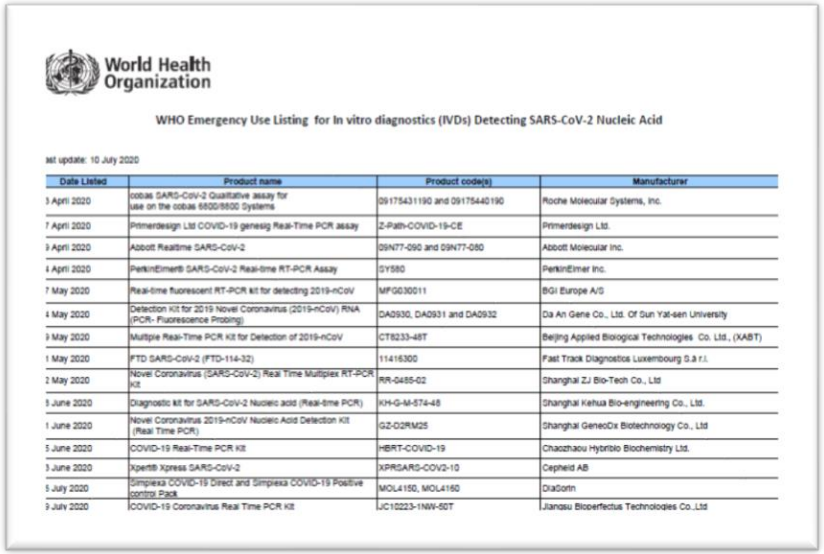
- Applications status publicly available
- 15 NAT assays listed as of 11 August
- Listings in IMDRF jurisdictions provided



Disclaimer: WHO does not endorse any of the lists provided by NRAs. This information is provided exclusively to assist stakeholders with identifying the links to the various lists.

Country of approval	Product name	Manufacturer/applicant name	Link
United States	Novel Coronavirus (SARS-CoV-2) Fast Nucleic Acid Detection Kit (PCR-Fluorescence Probing)	Jiangsu CoWin Biotech Co., Ltd.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Helix COVID-19 Test	Helix OpCo LLC (dba Helix)	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	QuantiVirus SARS-CoV-2 Multiplex Test Kit	DiaCarta, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	OraRisk COVID-19 RT-PCR	Access Genetics, LLC	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Boston Heart COVID-19 RT-PCR Test	Boston Heart Diagnostics	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Quest Diagnostics PF SARS-CoV-2 Assay	Quest Diagnostics Infectious Disease, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Quest Diagnostics RC SARS-CoV-2 Assay	Quest Diagnostics Infectious Disease, Inc.	For updated information on all products listed by the FDA use this link:

[15] This list was compiled on 25 March and was last updated on 04 August 2020. For any updates refer to the links provided in the table.



World Health Organization

WHO Emergency Use Listing for In vitro diagnostics (IVDs) Detecting SARS-CoV-2 Nucleic Acid

last update: 10 July 2020

Date Listed	Product name	Product code(s)	Manufacturer
3 April 2020	cobas SARS-CoV-2 Qualitative assay for use on the cobas 6800/8800 Systems	09175431190 and 09175440190	Roche Molecular Systems, Inc.
7 April 2020	Primerdesign Ltd COVID-19 genesig Real-Time PCR assay	Z-Path-COVID-19-CE	Primerdesign Ltd.
9 April 2020	Abbott Realtime SARS-CoV-2	09N77-090 and 09N77-080	Abbott Molecular Inc.
4 April 2020	PerkinElmer® SARS-CoV-2 Real-time RT-PCR Assay	DY580	PerkinElmer Inc.
7 May 2020	Real-time fluorescent RT-PCR kit for detecting 2019-nCoV	MFG030011	BGI Europe A/S
4 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
9 May 2020	Multiple Real-Time PCR Kit for Detection of 2019-nCoV	CTB233-48T	Beijing Applied Biological Technologies Co. Ltd., (XABT)
1 May 2020	FTD SARS-CoV-2 (FTD-114-32)	11416300	Fast Track Diagnostics Luxembourg S.à r.l.
2 May 2020	Novel Coronavirus (SARS-CoV-2) Real Time Multiplex RT-PCR kit	RR-0485-02	Shanghai ZJ Bio-Tech Co., Ltd
5 June 2020	Diagnostic kit for SARS-CoV-2 Nucleic acid (Real-time PCR)	KH-G-M-574-48	Shanghai Kehua Bio-engineering Co., Ltd.
1 June 2020	Novel Coronavirus 2019-nCoV Nucleic Acid Detection Kit (Real Time PCR)	GZ-02RM25	Shanghai GeneoDx Biotechnology Co., Ltd
5 June 2020	COVID-19 Real-Time PCR Kit	HBRT-COVID-19	Chaozhaou Hybriblo Biochemistry Ltd.
3 June 2020	Xpert® Xpress SARS-CoV-2	XPRSARS-COV2-10	Cepheid AB
5 July 2020	Simplexa COVID-19 Direct and Simplexa COVID-19 Positive control Pack	MOL4150, MOL4160	DiaSorin
9 July 2020	COVID-19 Coronavirus Real Time PCR Kit	UC10223-1NW-50T	Jiangsu Bioperfectus Technologies Co.,Ltd

PQDx IVD product dossiers – ToC format

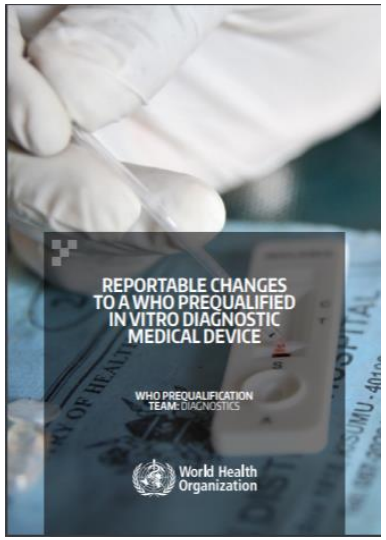
- For WHO PQ applications, product dossiers have been provided in, and reported against, **Summary Technical Documentation (STeD) format**
- In March 2020 WHO PQ Diagnostic Assessments began its transition to the **ToC format** for dossiers and review reports:
  - Dossier requirements, and dossier review documents have been updated to reflect ToC
  - Manufacturers are requested to provide product dossiers in either STeD or ToC format; dossier reviews will be reported using ToC report templates.
  - Training for assessors, and guidance for manufacturers will be provided.

Implementation, 2021:

  - All product dossiers to be submitted in ToC format.

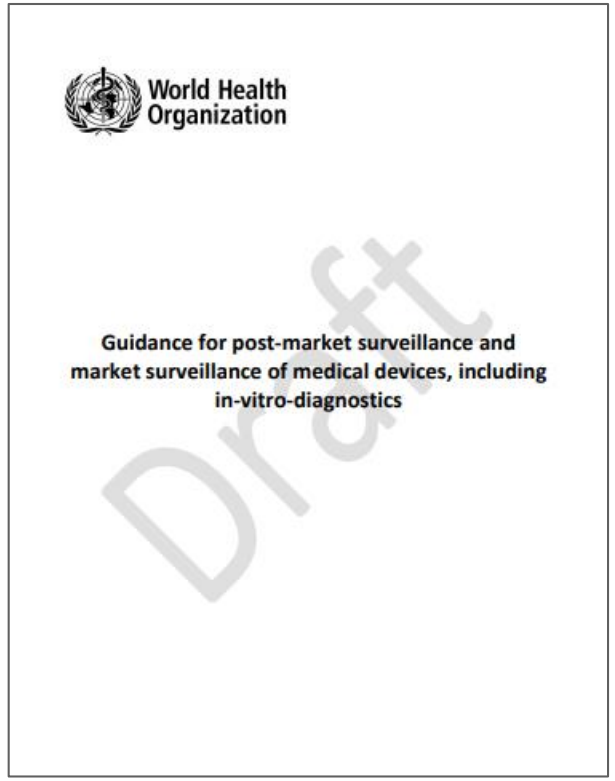
Inspections and changes

- Shifting from PR to WHOPAR and WHOPIR
- Regulatory flexibility: remote inspection SOP developed
- Update of internal Guideline documents to streamline process in line with MDSAP requirements
- Changes guidance update: Expected to be published for public comments by end of 2020



Updating WHO guidance on post-market and market surveillance of medical devices inc. IVDs

- Expected to be finalised - late 2020
- Encourages feedback from users to manufacturers
- Recommends IMDRF adverse event reporting terminology as foundation for manufacturers to report to NRAs
- Users/manufacturers can report to WHO in absence of adequate regulatory function
- Links to IMDRF UDI, and on-going efforts for WHO medical device nomenclature



New section of WHO website (health topic page for Substandard and Falsified Medical Products) that collates publicly available safety information for medical devices, including IVDs

Pilot CRP for IVDs: April 2019 – Dec 2019

- **Objective**

✓ Use the WHO-prequalification obtained for m-PIMA HIV-1/2 VL as a basis for country registrations.

✓ Assess feasibility of new WHO Collaborative Procedure including impact on registration timelines and requirements for additional country-specific studies.

- **Countries**

  Pilot was for 5 countries but only 4 countries participated and a 6th country joined later.

- **Outcome:** 3 registered the product (2 within 90 days and 1 in 179 days.
- **Lessons:**

✓ CRP for diagnostics has proved to be a great innovative mechanism that can accelerate registration of diagnostics and facilitate timely availability of IVDs. Benefits exhibited include; shorter regulatory approval times, reduced workload for NRA experts and reduced need for in-country evaluations based on acceptance of WHO PQ laboratory evaluation and related assessment reports

✓ Unclear registration pathways can hinder implementation of CRP.

✓ Delays in registration of products can be contributed by inadequate communication amongst key CRP stakeholders.

World Health Organization

EXPERT COMMITTEE ON BIOLOGICAL STANDARDIZATION
Geneva 19 to 23 October 2020

COLLABORATIVE PROCEDURE BETWEEN THE WORLD HEALTH ORGANIZATION (WHO) AND NATIONAL REGULATORY AUTHORITIES IN THE ASSESSMENT AND ACCELERATED NATIONAL REGISTRATION OF WHO-PREQUALIFIED IN VITRO DIAGNOSTICS (IVDS)

NOTE:

This document has been prepared for the purpose of inviting comments and suggestions on the proposals contained therein, which will then be considered by the Expert Committee on Biological Standardization (ECBS) and by the Expert Committee on Specifications for Pharmaceutical Preparations (ECSPP).

Publication of this draft is to provide information about the proposed *Guidelines for Collaborative Procedure between the World Health Organization (WHO) and National Regulatory Authorities in the assessment and accelerated National Registration of WHO-Prequalified In Vitro Diagnostics* to a broad audience and to improve transparency of the consultation process.

The text in its present form does not necessarily represent an agreed formulation of the ECBS. Written comments proposing modifications to this text MUST be received by 15 July 2020 using the Comment Form available separately and should be addressed to: Department of Health Products Policy and Standards (HPS), World Health Organization, 20 Avenue Appia, 1211 Geneva 27, Switzerland. Comments may also be submitted electronically to the Responsible Officer: gunlud@who.int.

The outcome of the deliberations of the ECBS and ECSPP will be published in the WHO Technical Report Series. The final agreed formulation of the document will be edited to be in conformity with the second edition of the *WHO style guide* (KMS/WHP/13.1).

Public consultation on the draft guideline – 2020

1st First public consultation (15 June to 15 July 2020

2nd Second public consultation (31 July to 30 September 2020)

Regional Initiatives for medical devices regulation

WHO is supporting:

- The African Medical Devices Forum (AMDF) through the Africa Medicines Regulatory Harmonization Initiative under the African Union to harmonize and strengthen regulation of medical devices in Africa

  - ✓ Development of guidance documents based on IMDRF recommendations for adoption by the MS.
  - ✓ Development of training modules for training of NRAs experts.
  - ✓ Platform for sharing information among NRAs experts.

WHO Global Benchmarking Tool Plus medical devices

- Integration of medical devices into the WHO GBT VI (GBT Plus medical devices)
- Finalization will involve regulatory authorities experts

- ✓ Discussions started in March 2020 but were postponed due to COVID 19 pandemic
- ✓ Expected to resume discussions from September 2020 until January 2021
- ✓ Piloting of the WHO GBT plus medical devices tool in selected countries is planned on Q2 of 2021

Thank you