World Health Organization

WHO - Prequalification of Medical Products (IVDs, Medicines, Vaccines and Immunization Devices, Vector Control)

Coronavirus disease (COVID-19) Pandemic — Emergency Use Listing Procedure (EUL) open for IVDs

On 30 January 2020, the Director-General declared that the outbreak of COVID-19 caused by SARS-CoV2 constitutes a Public Health Emergency of International Concern (PHEIC) and on 11 March 2020 it was characterized as a pandemic. In vitro diagnostics (IVDs) of assured quality, safety and performance are a critical component of an overall strategy to control the pandemic.

The WHO Emergency Use Listing procedure was developed to expedite the availability of IVDs needed in public health emergency situations. It is intended to assist procurement agencies and Member States with their decisions regarding the suitability for use of a specific IVD, based on a minimum set of available quality, safety, and performance data.

The procedure is currently open to candidate IVDs to detect SARS-CoV-2 (previously called 2019-nCoV).

Priority categorization of applications for prequalification and Emergency Use Listing (EUL) assessment of IVDs

Applications are currently prioritized as follows:

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:

- prequalification applications
- EUL applications for SARS-CoV-2 nucleic acid detection tests.

All other submissions/requests are currently assigned a lower priority.

Change notifications are prioritized on a case-by-case basis.

Please note that due to the current peak in applications under assessment that the Prequalification Unit is only accepting EUL pre-submission call requests and new expressions of interest in EUL assessment for the above high- and medium-priority applications.

IVDs eligible for EUL submission

Currently, the following IVDs are eligible for EUL submission:

- assays for the detection of SARS-CoV-2 nucleic acid (multiplex assays, detecting more than one viral target)
- rapid diagnostic tests for the detection of SARS-CoV-2 antigens; other platforms to detect SARS-CoV-2 antigen will be considered on a case-by-case basis. Please contact diagnostics@who.int for further information.

Instructions for manufacturers, detailing the technical documentation to be submitted, can be found below.

WHO procedure

WHO will review all documentation submitted in order to assess available evidence in support of the product's safety, quality and performance.

Currently, several performance evaluations of SARS-CoV-2 IVDs are being carried out by regulatory authorities, reference laboratories and other stakeholders in various regions. Manufacturers are strongly encouraged to participate in initiatives which generate evidence that can be used to support their EUL submission. However, participation in external evaluations does not replace the EUL submission, nor is participation in such studies mandatory for submission for WHO EUL.

INVITATION TO SUBMIT, SUBMISSION REQUIREMENTS & INSTRUCTIONS, Q&A

Invitation to manufacturers of in vitro diagnostics for SARS-CoV-2 to submit an application for Emergency Use Listing by WHO (updated 26 May 2021) [/pqweb/key-resources/documents/invitation-manufacturers-vitro-diagnostics-sars-cov-2-submit-application]

Instructions and requirements for Emergency Use Listing (EUL) submission: In vitro diagnostics detecting SARS-CoV-2 nucleic acid or antigen [/pqweb/key-resources/documents/instructions-and-requirements-emergency-use-listing-eul-submission-vitro]

Instructions and requirements for Emergency Use Listing (EUL) submission: In vitro diagnostics detecting antibodies to SARS-CoV-2 virus [/pqweb/key-resources/documents/instructions-and-requirements-emergency-use-listing-eul-submission-vitro-0]

FAQ: EUL assessment of IVD to detect SARS-CoV-2 or anti-SARS-CoV-2 antibodies [/pqweb/key-resources/documents/faq-eul-assessment-ivd-detect-sars-cov-2-or-anti-sars-cov-2-antibodies]

PUBLIC REPORTS AND IFUS FOR PRODUCTS ELIGIBLE FOR PROCUREMENT

Public reports

WHO EUL Public Report for SARS-CoV-2: Product: Ningbo Health Gene Technologies Co., Ltd (SARS-CoV-2 Virus Detection Diagnostic Kit (RT-qPCR Method)) EUL Number: EUL-0494-189-00 [/pqweb/key-resources/documents/who-eul-public-report-sars-cov-2-product-ningbo-health-gene-technologies-co]

WHO EUL Public Report for SARS-CoV-2: Product: Veri-Q PCR 316 Coronovirus disease 2019 (COVID-19) EUL Number: EUL-0495-188-00 [/pqweb/key-resources/documents/who-eul-public-report-sars-cov-2-product-veri-q-pcr-316-coronovirus-0]

WHO EUL Public Report for SARS-CoV-2: Product: Sure Status COVID-19 Antigen Card Test EUL Number: EUL-0590-010-00 [/pqweb/key-resources/documents/who-eul-public-report-sars-cov-2-product-sure-status-covid-19-antigen-card]

WHO EUL Public Report for SARS-CoV-2: Product: SARS-CoV-2 Nucleic acid detection kit based on Real-Time PCR platform EUL number: EUL-0517-204-00 [/pqweb/key-resources/documents/who-eual-public-report-sars-cov2-product-nucleic-acid-detection-kit-based]

WHO EUL Public Report for SARS-CoV-2: Product: COVID-19 Real-time PCR Kit EUL Number: EUL-0525-196-00 [/pqweb/key-resources/documents/who-eual-public-report-sars-cov2-product

WHO EUL Public Report for SARS-CoV-2: Product: cobas SARS-CoV-2 Qualitative assay for use on the cobas 6800/8800 Systems EUL Number: EUL 0504-046-00 [/pqweb/key-resources/documents/who-eual-public-report-sars-cov-2-product-cobas-sars-cov-2-qualitative-assay]

WHO EUL Public Report for SARS-CoV-2: Product: Primerdesign Ltd COVID-19 genesig Real-Time PCR Assay EUL Number: EUL-0489-185-00 [/pqweb/key-resources/documents/who-eual-public-report-sars-cov-2-product-primerdesign-ltd-covid-19-genesig]

WHO EUL Public Report for SARS-CoV-2: Product: Abbott RealTime SARS-CoV-2 Assay EUL Number: EUL-0503-027-00 [/pqweb/key-resources/documents/who-eual-public-report-sars-cov-2-product-abbott-realtime-sars-cov-2-assay]

WHO EUL Public Report for SARS-CoV-2: Product: PerkinElmer SARS-CoV-2 Real-time RT-PCR Assay EUL Number: EUL-0501-192-00 [/pqweb/key-resources/documents/who-eual-public-report-sars-cov-2-product-perkinelmer-sars-cov-2-real-time]

WHO EUL Public Report for SARS-CoV-2: Product: Real-time fluorescent RT-PCR kit for detecting 2019-nCoV EUL Number: EUL-0498-191-00 [/pqweb/key-resources/documents/who-eual-public-report-sars-cov-2-product-real-time-fluorescent-rt-pcr-kit]

WHO EUL Public Report for SARS-CoV-2: Product: Novel Coronavirus (SARS-CoV-2) Real-Time Multiplex RT-PCR Kit EUL Number: EUL-0486-139-00 [/pqweb/key-resources/documents/who-eual-public-report-sars-cov-2-product-novel-coronavirus-sars-cov-2-real]

WHO EUL Public Report for SARS-CoV-2: Product: Multiple Real-Time PCR Kit for Detection of 2019-CoV EUL Number: EUL-0491-187-00 [/pqweb/key-resources/documents/who-eual-public-report-sars-cov-2-product]

WHO EUL Public Report for SARS-CoV-2: Product: Novel Coronavirus 2019-nCoV Nucleic Acid Detection Kit (Real Time PCR) EUL Number: EUL-0513-200-00 [/pqweb/key-resources/documents/who-eual-public-report-sars-cov-2-product-novel-coronavirus-2019-ncov]

WHO EUL Public Report for SARS-CoV-2: Product: Diagnostic Kit for SARS-CoV-2 Nucleic Acid (Real-time PCR) EUL Number: EUL-0492-037-00 [/pqweb/key-resources/documents/who-eual-public-report-sars-cov-2-product-diagnostic-kit-sars-cov-2-nucleic]

WHO EUL Public Report for SARS-CoV-2: Product: Xpert Xpress SARS-CoV-2 EUL Number: EUL-0511-070-00 [/pqweb/key-resources/documents/who-eual-public-report-sars-cov-2-product-

WHO EUL Public Report for SARS-CoV-2: Product:Elecsys Anti-SARS-CoV-2 Qualitative assay for use on the cobas e 411/601/602/801 immuno analyzers EUL Number: EUL-0542-118-00 [/pqweb/key-resources/documents/who-eul-public-report-sars-cov-2-productelecsys-anti-sars-cov-2-qualitative]

WHO EUL Public Report for RADI COVID-19 Detection Kit EUL Number: EUL-0538-214-00 [/pqweb/key-resources/documents/who-eul-public-report-radi-covid-19-detection-kit-eul-number-eul-0538-214-00]

PUBLIC REPORTS FOR PRODUCTS NOT ELIGIBLE FOR PROCUREMENT

WHO EUL Public Report for SARS-CoV-2: Product: VivaDiag SARS-CoV-2 Ag Rapid Test EUL Number: EUL 0592-222-00 [/pqweb/key-resources/documents/who-eul-public-report-sars-cov-2-product-vivadiag-sars-cov-2-ag-rapid-test]

WHO EUL Public Report for SARS-CoV-2: Product: Humasis COVID-19 Ag Test EUL Number: EUL 0613-247-00 [/pqweb/key-resources/documents/who-eul-public-report-sars-cov-2-product-humasis-covid-19-ag-test-eul-number]

WHO EUL Public Report for SARS-CoV-2: 2019-Novel Coronavirus (2019-nCoV) Triplex RT-qPCR

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WHO EUL Public Report for SARS-CoV-2: Product:Novel Coronavirus (2019-nCoV) Antibody Rapid Test EUL Number: EUL 0552-219-00 [/pqweb/key-resources/documents/who-eul-public-report-sars-cov-2-productnovel-coronavirus-2019-ncov-antibody]

WHO EUL Public Report for SARS-CoV-2: Novel Coronavirus (2019-nCoV) IgM/IgG Antibody Rapid Test EUL Number: EUL 0553-219-00 [/pqweb/key-resources/documents/who-eul-public-report-sars-cov-2-novel-coronavirus-2019-ncov-igmigg-antibody]