Invitation to manufacturers of in vitro diagnostics for SARS-CoV-2 to submit an application for emergency use listing by WHO (updated 11 March 2022).

1 Introduction

The global spread of COVID-19 has dramatically increased the number of suspected cases and the geographic area where SARS-CoV-2 testing is needed to identify infected individuals. In order to do this, in vitro diagnostics (IVDs) of assured quality, safety and performance are required.

On 30 January 2020, the Director-General declared that the outbreak of COVID-19 caused by SARS-CoV-2 constitutes a Public Health Emergency of International Concern (PHEIC) and on 11 March 2020 it was characterized as a pandemic. IVDs of assured quality, safety and performance are a critical component of an overall strategy to control the pandemic.

The World Health Organization (WHO) revised the Emergency Use Listing (EUL) Procedure (previously referred to as the Emergency Use Assessment and Listing Procedure (EUAL)) on 8 January 2020, to be used primarily during a PHEIC. The EUL process is based on an essential set of available quality, safety and performance data. The EUL procedure for IVDs to detect SARS-CoV-2 was established 28 February 2020, is intended to expedite the availability of IVDs needed in PHEIC situations and, in that context, to assist interested UN procurement agencies and Member States in determining the acceptability of using specific products for time limited procurement.

2 Purpose of this invitation for EOI

The purpose of this Expression of Interest (EOI) is to invite manufacturers to submit IVDs for SARS-CoV-2 for review by WHO through an emergency assessment mechanism.

3 Product categories included in this EOI

- IVDs for the detection of SARS-CoV-2 nucleic acid (multiplex assays, detecting more than one SARS-Cov-2 target)
- Rapid diagnostic tests for the detection of SARS-CoV-2 antigens intended for POC testing (other platforms to detect SARS-CoV-2 antigen will be considered on a case-by-case basis).
- Rapid diagnostic tests for the detection of SARS-CoV-2 antigens intended for self-testing.
- Contact diagnostics@who.int for further information.

4 Submission of applications

Applicants are strongly encouraged to contact WHO as early as possible to discuss specifics of the application. Applications are accepted **only** from legal manufacturers. Rebranded products are outside

the scope of EUL assessment and hence not accepted for assessment.[1] All manufacturers interested in submitting applications for review are requested to follow the steps below:

4.1 Pre-submission meeting

Manufacturers who are interested in an EUL submission are invited to contact diagnostics@who.int to arrange a pre-submission meeting/call. Please note that applications will not be accepted without prior consultation with WHO.

4.2 Application letter (see Annex 3 Application letter model in the Emergency Use Listing Procedure document[2])

The manufacturer is requested to submit an application letter to WHO's Director of Regulation and Prequalification Department (RPQ), Dr Rogerio Pinto de sá Gaspar (gasparr@who.int), with a copy to the PQT/IVDs Assessment A/Team Lead, Dr Susie Braniff (braniffs@who.int and diagnostics@who.int) and the SARS-CoV-2 IVD focal point, Dr Ute Ströher (stroheru@who.int).

The application letter should include

- The product name and product code,
- Name and address of the legal manufacturer,
- Title and name of the authorized contact for the EUL assessment,
- Sites of manufacture,
- Information on whether the National Regulatory Authority (NRA[3]) has issued an authorization for emergency use or equivalent.

WHO will acknowledge receipt of the application letter by e-mail; the acceptance of an application will also be confirmed by email.

Once the product has been accepted for review under the EUL procedure, a product dossier will be requested.

4.3 Essential data requirements for IVD EUL:

The EUL procedure includes the following:

- **Quality Management Systems Review and Plan for Post-Market Surveillance**: review of the manufacturer's Quality Management System documentation and specific manufacturing documents;
- **Product Dossier Review**: assessment of the documentary evidence of safety and performance.
- WHO reserves the right to conduct an **independent laboratory evaluation** of all EUL-listed IVDs or to require the manufacturers to participate in the blinded testing of their EUL-listed products via a performance panel. The same can also apply to products that are under EUL assessment.

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[1] A rebranded product is identical in every respect to the product manufactured by the original manufacturer, except that the product is labelled with the "rebranded" product name and product code and bears the rebrander's name. Such products are also known as original equipment manufacturer (OEM) products.

[2] https://extranet.who.int/pqweb/key-resources/documents/emergency-use-listing-procedure-eul

[3] The NRA of the country where the manufacturer is located.

Instructions on the essential data/validation requirements for IVDs to be submitted is available on the webpage: https://extranet.who.int/pqweb/vitro-diagnostics/coronavirus-disease-covid-19-pandemic-%E2%80%94-emergency-use-listing-procedure-eul-open. The instructions are subject to change as more is learnt about SARS-CoV-2 and COVID-19, and the risk-benefit profile of SARS-CoV-2 IVDs. Any updates will be published on our website as they become available. Furthermore, manufacturers are invited to consult the target product profiles that outline desirable and minimally acceptable profiles for different SARS-CoV-2 IVD categories. https://www.who.int/publications/m/item/covid-19-target-product-profiles-for-priority-diagnostics-to-support-response-to-the-covid-19-pandemic-v.0.1The EUL submission structure must follow the format prescribed in the respective instructions document.

4.4 Submission of updates

Manufacturers are required to inform WHO of any planned changes to the IVD and submit additional information on the development of the product, particularly if it may affect the product's benefit/risk assessment.

5 Submission

The information on how to apply is provided in the presubmission call.

6 Process for assessment

The assessment will consider all evidence of the quality, safety and performance of IVDs that is made available to WHO for review.

7 Process for listing

Upon making a decision whether or not to grant a recommendation (acceptance or nonacceptance) for emergency use listing of the assessed product, WHO will (without prejudice to any confidential information of the applicant/manufacturer) publish information about the product in a public report available on a dedicated portal of the WHO website. This may include negative assessment outcomes.

Subject to the protection of commercially sensitive confidential information, WHO will publish on the WHO website and make publicly available the following information in connection with the assessment process:

- the names of products and of manufacturers that have applied for EUL, the product code(s) submitted for EUL and the EUL status of each application;
- a WHO EUL public report summarizing the findings of the EUL assessment; and
- any negative outcomes of the EUL assessment.

In addition, WHO reserves the right to share full reports with the relevant authorities of any interested Member State of the Organization and interested United Nations agencies.

8 Post – listing activities

Subject to inclusion of the product in the WHO EUL list, any reportable changes to the product (as defined in the WHO guidance document PQDx_121 *"Reportable WHO Prequalified In Vitro Diagnostic Medical Device"*) must be reported to WHO. In addition, the listing status of the product may be reconsidered in light of a review by WHO of the change information. WHO reserves the right to ask for further information to support the change.

After a product has been listed, the manufacturer is required to also take into consideration the post-market surveillance activities (as defined by WHO guidance "*Post-market surveillance of in vitro diagnostics*" ISBN 978 92 4 150921 3 https://www.who.int/health-topics/substandard-and-falsified-medical-products/safety-info-medical-devices-in-vitro-diagnostics). In addition, the listing status of the product may be restricted or revoked by WHO in light of its review of post-market surveillance information.

WHO EUL listing in the context of a public health emergency is granted for a period of 12 months and may be renewed, upon request from the manufacturer, provided that the information requested by WHO is submitted within agreed timelines.

9 Contact information

Please refer to the EUL webpage https://extranet.who.int/pqweb/vitro-diagnostics/coronavirus-disease-covid-19-pandemic-%E2%80%94-emergency-use-listing-procedure-eul-open

Any inquiries should be addressed to: diagnostics@who.int