



Invitation to manufacturers of in vitro diagnostics for SARS-CoV-2 to submit an application for emergency use listing by WHO (updated 03 July 2020).

1 Introduction

The global spread of COVID-19 has dramatically increased the number of suspected cases and the geographic area where COVID-19 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). IVDs of assured quality, safety and performance are needed for e.g., screening suspect cases, diagnosis, case cluster finding or serosurveillance. Because this is a new strain of coronavirus that has not been previously identified in humans, there are several assays to detect SARS-CoV-2 now under development.

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.
- Immunoassays for the detection of SARS-CoV-2 specific antibodies.
- Immunochromatographic (lateral flow) or Immunofiltration (flow through) rapid diagnostic test (RDT) to detect SARS-CoV-2 antigens. (Other platforms to detect SARS-CoV-2 antigen will be considered on a case by case basis. Contact diagnostis@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 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 version 8 January 2020²)

The manufacturer is requested to submit an application letter to WHO's Director of Regulation and Prequalification Department (RPQ), Ms Emer Cooke (cookee@who.int), with a copy to the PQT/IVDs Assessment Team Lead, Ms Irena Prat (prati@who.int and diagnostics@who.int) and the SARS-CoV-2 IVD focal point, Dr Ute Ströher (stroheru@who.int) and the National Regulatory Authority (NRA) responsible for the regulatory oversight of the product.

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 or not the NRA³ 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.

Instructions on the essential data/validation requirements for IVDs to be submitted is available on the

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://www.who.int/diagnostics_laboratory/eual/200110_new_eul_procedure_final.pdf?ua=1

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

webpage: http://www.who.int/diagnostics_laboratory/EUL/en/index.html

The instructions are subject to change as more is learnt about COVID-19, its risk-benefit profile and pending target product profiles. Any updates will be published on our website as they become available.

The 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 submit an application is provided in the presubmission call.

6 Process for assessment

The assessment will take into account 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/manufacture) 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.

The validity of an emergency use listing in the context of a public health emergency will generally be for 12 months.

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 http://www.who.int/diagnostics_laboratory/postmarket/en/) are required. 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.

9 Contact information

Please refer to the EUL webpage http://www.who.int/diagnostics_laboratory/EUL/en/index.html

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