Invitation to manufacturers of in vitro diagnostics for SARS-CoV-2 to submit an application for emergency use listing by WHO (date issued 28 February 2020)

1 Introduction
On 30 January 2020, the Director-General declared that the outbreak of COVID-19 caused by the 2019 novel coronavirus (SARS-CoV-2) constitutes a Public Health Emergency of International Concern (PHEIC). In vitro diagnostics (IVDs) of assured quality, safety and performance are needed to screen suspect cases and for diagnosis. 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 Emergency Use Listing (EUL) procedure for IVDs to detect SARS-CoV-2 was established 28 February 2020, to determine their eligibility for procurement by WHO and other partners.

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
- Assays for the detection of SARS-CoV-2 nucleic acid

4 Submission of applications
Applicants are highly encouraged to contact WHO as early as possible to discuss specifics of the application. 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 won’t 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 2020)

The manufacturer is requested to submit an application letter to WHO’s Director of Regulation and

1 https://www.who.int/diagnostics_laboratory/eual/200110_new_eul_procedure_final.pdf?ua=1
Prequalification Department (RPQ), Ms Emer Cooke (cooke@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 research only use product.

The application letter should include

- sites of manufacture,
- the presentations proposed for the product, and
- information on whether or not the NRA\(^2\) has issued an authorization for emergency use or equivalent.

WHO will acknowledge receipt of the application letter by e-mail, with a copy to the relevant NRA. The acceptance of an application will also be confirmed by email, with a copy to the NRA.

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

4.3 Essential data requirements for in vitro diagnostics EUL:

The EUL procedure includes the following:

- **Product Dossier Review**: assessment of the documentary evidence of safety and performance. This evaluation of limited scope is to verify critical analytical and performance characteristics.

Instructions on the essential data requirements for in vitro diagnostics to be submitted in the data submission is available on the webpage:


The EUL submission structure should follow the format prescribed in the 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

Interested manufacturers are encouraged to submit an application for IVDs to detect SARS-CoV-2 nucleic acid by sending the required documentation in hard copy and in electronic copy (CD or DVD) to the following address:

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\(^2\) The NRA of the country where the manufacturer is located.
6. **Process for Assessment**

The process for emergency quality assessment is described in the WHO document "Emergency Use Listing Procedure" version 8 January 2020. The assessment will take into account all evidence of the quality, safety and performance of IVDs that is made available to WHO for review.

5 **Process for Listing**

Upon making a decision whether or not to grant a recommendation (acceptance or nonacceptance) for emergency use listing of the evaluated 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.

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

6 **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.

7 Contact information


Any inquiries should be addressed to: [diagnostics@who.int](mailto:diagnostics@who.int)