

Transitioning Emergency use listing for in vitro diagnostics to prequalification assessment

Questions and Answers document version 2

This document has been drafted by the prequalification of in vitro diagnostics team (PQT/IVD) to address questions related to the recent announcement that COVID-19 no longer constitutes a public health emergency of international concern (PHEIC), and the impact this has on the emergency use listing (EUL) procedure for IVDs to detect SARS-CoV-2.

These questions and answers are intended to provide clarity on the transition plan and the way forward to manufacturers and procurement stakeholders.

The document will be updated as more information is published and available.

1. How does the termination of the PHEIC impact the PQT-IVD assessment procedure for SARS-CoV-2 IVDs?

The EUL assessment procedure is temporary and remains only in effect for the duration of a PHEIC. The termination of the COVID-19 PHEIC has the following implications:

- No new applications will be accepted for EUL assessment
- The cancellation of ongoing EUL assessments (please also refer to Question 3).
- The launch of the transition plan for EUL-listed products from EUL assessment to prequalification assessment.

2. Will new applications for SARS-CoV-2 IVDs be accepted?

No, PQT-IVD is no longer accepting any new applications (or resubmissions) under the EUL procedure. Applications for prequalification assessment will be accepted in the near future (please refer to question 7 below). Please sign up to our Newsletter and/or check the website for timelines and additional information that will be provided once available.

3. My EUL application is still under review. What happens to my ongoing EUL application?

Ongoing assessments will be cancelled with the exception of products that are at an advanced stage in the QMS/dossier assessment process and fall in the high priority category. For those the assessment process will be extended until July 2023.

Applicants whose applications will be cancelled will receive an official communication from WHO informing them of the cancellation of their application.

4. My product is EUL listed. Can I still submit change requests for my current EUL listed product?

PQT-IVD are still reviewing changes to EUL listed products, and will continue during the transition period. Nonetheless PQT-IVD encourages you to consider submitting a prequalification application that will allow you to market beyond the end of the EUL termination.

5. Will the termination of the PHEIC impact procurement eligibility of SARS-CoV-2 IVDs?

All EUL-listed IVDs will remain eligible for procurement until 31 January 2024, provided that the manufacturer adheres to post-listing obligations (commitments, change notifications, post market surveillance), as per the EUL guidance documents and the signed Letter of Agreement.

To be eligible for procurement through UN agencies and WHO after this date, manufacturers are required to apply for prequalification assessment.

- **From 1 February 2024** only previously EUL-listed products that are undergoing prequalification assessment will be eligible for procurement. They will remain eligible for procurement until a PQ decision is taken.
- Any changes in the listing status will be made public on the WHO EUL/PQ IVD website.

6. Which SARS-CoV-2 IVDs will be eligible for prequalification assessment?

The following products will be within the scope of prequalification assessment:

- IVDs to detect SARS-CoV-2 nucleic acid (closed systems and open platforms); and
- Rapid diagnostic tests (RDTs) to detect SARS-CoV-2 antigen for professional use and/or self-testing.

The following products will not be eligible for prequalification assessment:

- NAT tests that detect only one single SARS-CoV-2 target
- IVDs for the detection of SARS-CoV-2 specific antibodies
- Multi-pathogen tests that detect additional pathogens other than SARS-CoV-2

7. When can I apply for Prequalification assessment of my SARS-CoV-2 IVD?

The prequalification assessment procedure is now open for SARS-CoV-2 IVDs. Please refer to our [website](#) for additional information.

8. What is the deadline to apply for Prequalification assessment of my SARS-CoV-2 IVD if I want my currently EUL listed product to remain eligible for procurement?

Manufacturers are expected to apply for PQ assessment no later than by 31 December 2023. Products not submitted for PQ assessment by 31 December 2023 will not be considered for procurement eligibility beyond 31 January 2024.

9. Do you have guidance documents to prepare a submission for prequalification assessment?

The WHO PQT-IVD Team has developed Technical specifications series (TSS) documents for SARS-CoV-2 antigen and nucleic acid IVDs. The TSS docs have been published on our website [here](#).

Manufacturers must submit a dossier for PQ assessment according to TSS requirements and prequalification dossier instructions “Instructions for compilation of a product dossier – IMDRF ToC (PQDx_018, v5 November 2022)”.

The PQT-IVD Team will organize a webinar for applicants to present the prequalification assessment procedure and the SARS-CoV-2 IVD TSS documents once finalized.

10. Can I submit my EUL dossier for prequalification assessment?

Our guidance documents for compiling and preparing a prequalification application are different to our recommendations to support an EUL application. Although certain studies from the EUL dossier can be leveraged and used in the application, we require the manufacturer to follow our guidance and recommendations for preparing a prequalification application. We will not accept the re-submission of the EUL dossier for prequalification assessment.

11. I am interested in applying for prequalification, are there any costs associated with an application?

A prequalification assessment fee is charged to a manufacturer once its application has been determined to be eligible for WHO prequalification assessment. For a product undergoing full assessment, US\$ 5000 is charged for dossier screening and US\$ 12,000 for product assessment.

12. What timeline should I expect for the review of my prequalification application?

Normal PQ timelines will apply ([Timelines | WHO - Prequalification of Medical Products \(IVDs, Medicines, Vaccines and Immunization Devices, Vector Control\)](#)). PQT-IVD strongly recommends that manufacturers start preparing their PQ application early in order to allow time to resolve any issues in

the dossier compilation. SARS-CoV-2 IVD applications will not be prioritised over prequalification applications for other products.

13. We have been asked to participate with our antigen RDT in the independent evaluation. Now that the PHEIC has been terminated, will this evaluation proceed?

Yes, the evaluation will go ahead. As listed product will remain eligible for procurement the data will still be useful for stakeholders and Member States.

14. What can we expect from PQ-IVD team in the coming weeks/months?

The following information will be available on our website in the coming weeks and months:

- Technical specifications series for prequalification assessment: SARS-CoV-2 antigen detection RDTs for professional use/self testing (published 10 July 2023)
- Technical specifications series for prequalification assessment: IVDs to detection SARS-CoV02 nucleic acid (published 10 July 2023)
- Webinar on the EUL to PQ transition plan.

15. Who can I contact if I have any additional questions?

For any further information please contact the PQT/IVD Team at diagnostics@who.int