QUESTIONS ON EMERGENCY USE LISTING (EUL) AND PREQUALIFICATION LISTING PROCESSES OF WHO

	Question	WHO Response
1	In some emergencies, National Regulatory Authorities may have declared state of emergency and subjected the products to a different assessment procedure. If WHO finds such assessment satisfactory then it seems to us that no performance test regarding the product will be asked and it will not even undergo the entirety of the multi-stage application process and will be finalised just with the QMS evaluation. Is that correct? Our products undergo a performance test via the Ministry of Health and registration procedure begins only after approval. Would WHO accept this procedure? Is the process going to be managed solely with QMS evaluation (e.g., COVID products)? a. If the answer to the question above is 'no': "PQDx_018 Instructions for compilation of a product dossier" has been removed from WHO website. We can procure it from sources without WHO extensions, however, we are not sure if those would be up-to-date. How can we find an up-to-date version?	The WHO EUL procedure for SARS-CoV-2 diagnostic tests is a seperate procedure from Prequalification. The EUL assessment consists of review of a product dossier and a desk-top QMS review. The information that must be provided by the manufacturer can be found in the document PQDX_347 on the WHO EUL website https://extranet.who.int/pqweb/vitro-diagnostics/coronavirus-disease-covid-19-pandemic-%E2%80%94-emergency-use-listing-procedure-eul-open . 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 EUL is not equivalent or an alternative to WHO prequalification, and should not be thought of as such. The main reason for not qualifying for prequalification is that the product concerned will, at the time of submission for EUL, not fall within the scope of prequalification. WHO Member States alone hold the authority to decide whether or not to allow the emergency use of in vitro diagnostics in their country.
2	If there is need for a meeting beforehand; what kind of a format would they like for product promotion? Should it contain a technical presentation or information regarding the product and its intended use? Is there a certain format in use (there are formats for pretty much every step, it is just that there does not seem to be a template just for this particular step)?	A manufacturer that would like to apply for EUL of a SARS-CoV-2 IVD must take part in a pre-submission meeting before an application will be accepted. We have allocated 30 minutes for a technical discussion of the product following a proposed agenda: • Short introduction of participants • Brief slide presentation of the assay • Slide presentation with a summary of clinical studies conducted to meet WHO requirements • study design (prospective/retrospective, blinding), specimen types claimed, populations claimed, PCR comparator, future planned studies

		• Availability of control material (if applicable) • Timeline for submission • Q&A • Next steps WHO will ask questions to understand if the manufacturer has performed sufficient validation and field studies to prepare a product dossier that will meet the requirements of PQDx_347.
3	According to WHO priority classification, our product falls under the Medium category. Does the 3-month duration apply anyway or could it take longer?	*Discussed during the Workshop.* The screening and assessment phase takes a minimum of six months for medium priority products, and also depends on the quality and completeness of the information submitted. Only for SARS-CoV-2 nucleic acid detection tests that have received US FDA Emergency Use Authorization, a shorter timeline might apply, as they are are eligible for an abridged assessment pathway.
4	Is it possible to provide information regarding the inclusion of non-COVID products in WHO listing?	*Discussed during the Workshop.* Information about the WHO Prequalification programme can be accessed from the website: https://extranet.who.int/pqweb/in-vitro-diagnostics Please send any specific questions to the IVD Assessment team using the email address: diagnostics@who.int
5	Which countries find the emergency use listing (EUL) sufficient for the marketing of the products?	There are 5 countries that have agreed to use the EUL-Facilitated Procedure, which is a reliance method to base market authorization decisions on the WHO EUL assessment. However, we make a public report available on the WHO website for each product that has completed EUL assessment and countries may use this information as part of their regulatory decision. We do not have information on how many countries are relying completely on EUL for market approval of IVDs at this time.
6	Some countries request for the registry of products to national databases like DIMDI, BfArM, NHS etc. before marketing of the products. Are these still necessary after WHO EUL?	Obtaining EUL does not automatically exempt that product from country-specific requirements. However, UN procurement decisions are based only on WHO EUL.
7	For European market, what are the differences between CE via notified body and WHO EUL? Or, for US market, what is different than FDA EUA?	*Discussed during the Workshop.* Regulatory requirements imposed by the EU and USA are specific to their markets. Some requirements overlap with those of the WHO-EUL programme. However, the EUL requirements have been developed with consideration of IVD performance,

		safety and stability in the wide range of Member States. Importantly, under the IVDD 98/79/EC IVD directive (IVDD), manufacturers of the majoirity of SARS-CoV-2 IVDs can self-declare conformity with relevant essential requirements of the IVDD to obtain CE marking; a conformity assessment via a Notified Body is not required. (This will change in future under the new IVD Regulation 2017/746 (IVDR))
8	How long does it take for product listing after submission of the application?	*Discussed during the Workshop.* For EUL there is a big variation, from 3-4 months to over a year. Applications for high-priority products will be assessed first. The assessment of applications that meet the requirements described in PQDx_347 will be the most efficient as there is less need to send request for further information to the manufacturer.
9	What is the process for molecular diagnostics kits that already has CE-IVD mark?	The EUL process for these products is no different than for products without CE-IVD marking. This is because for SARS-CoV-2 IVDs CE-IVD marking is a self-declaration process that does not include and independent product dossier review.
10	How much time do we have between the submission of the letter of agreement and submission of the product dossier?	It is preferred that the dossier is received within 1 month of the LoA being signed. Short extensions may be granted depending on the circumstances. Any request for an extension must be made to WHO in writing.
11	During the submission process, can we consult the WHO for more information or will we be informed in case of any missing necessary dossier?	When the application is received by WHO the product dossier will undergo screening to ensure the dossier is complete before it undergoes assessment. If there is any information missing the manufacturer will be notified in writing by WHO and will have 7 days to provide the missing information. A request for extension can be made in writing. If the manufacturer is unable to provide a complete dossier the application will be closed and the manufacturer may re-apply in the future if they are able to prepare a product dossier the meets the requirements of PQDx_347.
12	Do we need a certified translator in the process of making the product dossier?	Yes, an official document attesting to the accuracy of the translation and details on the credentials of the translator are also required.
13	General information about payments.	There are no fees associated with WHO-EUL assessment.