WHO's performance evaluation procedure for in vitro diagnostics

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Abbreviations

DOI	WHO's Declaration of Interest form
IVD	In vitro diagnostic
PE	WHO's performance evaluation of an IVD
PEL	Performance evaluation laboratory
PEPAR	WHO's Performance Evaluation Public Assessment Report
UN	United Nations
WHO	World Health Organization

1. Introduction

This document has been prepared by the World Health Organization (WHO) to provide an overview of WHO's performance evaluation procedure for in vitro diagnostic (IVD) medical devices (hereinafter each, an "IVD" or "product"). WHO's performance evaluation of IVDs is coordinated through WHO's Prequalification Unit.

Effective as of 1 January 2026, WHO's performance evaluation of an IVD pursuant to and in accordance with this procedure is a separate process from (as opposed to a component to), as well as a prerequisite to apply for assessment under, WHO's prequalification procedure for IVDs.

This procedure excludes medical devices other than IVDs.

Without prejudice to the requirements, terms and conditions set forth in WHO's prequalification procedure for IVDs[1], an application for WHO's prequalification assessment of an IVD will not be accepted by WHO unless and until a complete Expression of Interest for WHO's performance evaluation of the IVD (hereinafter, an "Expression of Interest") has first been received and accepted by WHO[2].

2. Intended audience

This document has been prepared to provide an overview of the procedure applicable to WHO's performance evaluation of an IVD, as a prerequisite for a manufacturer to separately apply for WHO's prequalification assessment of that IVD.[3] Manufacturers wishing to submit an Expression of Interest for their product(s) should read this document before doing so, in order to be prepared for WHO's performance evaluation process.

3. Definitions

As used in this procedure, the following terms have the following meanings:

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[1] Refer to document PQDx_007 *Overview of WHO's prequalification procedure for in vitro diagnostics*

[2] This requirement applies when WHO's performance evaluation of the product is required per document PQDx_459 *"Eligibility criteria for WHO's performance evaluation of in vitro diagnostics".*

[3] For the avoidance of doubt, WHO's prequalification assessment of IVDs (including, without limitation, any decisions by WHO on whether or not to accept a product for prequalification assessment and/or to grant prequalification listing to a product) will be carried out subject to and in accordance with document PQDx_007 "*Overview of WHO's prequalification procedure for in vitro diagnostics*".

Design lock-down	A formal milestone in the IVD, medical device, or system development lifecycle at which the design is considered finalized: all design inputs have been addressed, and verification and validation activities are complete. The design is placed under configuration control and formally released for manufacturing, regulatory submission, or subsequent development stages. From this point forward, any modifications are strictly managed through a documented design change control process, including risk management review, necessary validation and verification and—where applicable—regulatory notification or approval, in order to maintain a stable and traceable design baseline.[4]
In vitro diagnostic medical device or in vitro diagnostic or IVD or product	A medical device, whether used alone or in combination, intended by the manufacturer for the in vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes. *Note*: IVDs include reagents, calibrators, control materials, specimen receptacles, software, and related instruments or apparatus or other articles, and are used, for example, for the following test purposes: diagnosis, aid to diagnosis, screening, monitoring, predisposition, prognosis, prediction, determination of physiological status.
Manufacturer	Any natural or legal person with responsibility for design and/or manufacture of an IVD with the intention of making the IVD available for use, under his or her name, whether or not such an IVD is designed and/or manufactured by that person him- or herself or on his or her behalf by (an)other person(s). [5]
Performance evaluation laboratory	A laboratory that: (i) has been assessed and listed by WHO as a performance evaluation laboratory[6]; and (ii) is commissioned to and responsible for implementing WHO's performance evaluation of an IVD, subject to and in accordance with this procedure and WHO's performance evaluation protocol.
Performance evaluation public assessment report or PEPAR	A report written and published by WHO which summarizes the findings made during WHO's performance evaluation of the IVD in question, but which excludes confidential and proprietary information.
Rebranded product	Also known as original equipment manufacturer (OEM) products. WHO considers a rebranded product to be one that is manufactured under identical conditions at the same

[4] Changes that occur after a design lock-down must be documented and evaluated within the framework of change management.

[5] The definition of a manufacturer is based on the definition used by the Global Harmonization Task Force (GHTF), and later adopted by International Medical Device Regulators Forum (IMDRF). This internationally accepted approach has been adopted to ensure that there is a clear understanding of the term "manufacturer" across international markets.

[6] Such assessment and listing are made pursuant to and in accordance with the document PQDx_248 *"WHO's assessment procedure for Performance Evaluation Laboratories for in vitro diagnostics"* or any preceding and/or subsequent versions of the same.

	manufacturing site(s) as the original product. In other words, a rebranded product is identical in every respect (including the intended use) 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 or brand.
Rebrander	A manufacturer that purchases a finalized product from another company, rebrands that product and places the rebranded product on the market under the manufacturer's own name or brand.
WHO's performance evaluation	Evaluation of performance and operational characteristics of an IVD pursuant to and in accordance with the terms and conditions of WHO's performance evaluation procedure for IVDs, and as a prerequisite for the manufacturer of that IVD to separately apply for WHO's prequalification assessment of that product.

4. About WHO's performance evaluation of IVDs

The purpose and objective of WHO's performance evaluation procedure for IVDs are to independently assess the performance and operational characteristics of an IVD, including those that are considered essential for such IVD's use in resource-limited settings.

WHO's performance evaluation of an IVD is a prerequisite for that IVD to be submitted to and apply for WHO's prequalification assessment, pursuant to and in accordance with the separate application and procedure applicable to the latter.[7] The data, information, findings, analyses, results and reports arising and/or obtained from WHO's performance evaluation of an IVD will be used by WHO to inform its decision as to whether or not the IVD:

a) meets, to WHO's satisfaction, the technical requirements for WHO's performance evaluation in accordance with WHO's performance evaluation protocol; and/or
b) if applicable, can be accepted for assessment and/or granted listing under WHO's prequalification procedure for IVDs.

Before a manufacturer may separately apply for a product to be assessed under WHO's prequalification procedure for IVDs, an Expression of Interest for that product must first be submitted by the manufacturer to, and accepted by, WHO in accordance with the provisions set forth in this procedure. Without prejudice to the terms, conditions and/or other requirements set forth in WHO's prequalification procedure for IVDs, an application for WHO's prequalification assessment of an IVD will not be accepted by WHO unless and until, among other things, a complete Expression of Interest for that IVD has first been received and accepted by WHO[8].

WHO's performance evaluation must be carried out by a performance evaluation laboratory (PEL) in a manner that is subject to and in accordance with the terms and conditions of the following documents (collectively, the "PE Documents"):

i. WHO's performance evaluation procedure for IVDs;
ii. WHO's performance evaluation protocol and associated data entry and report templates, as provided by WHO;

[7] Refer to document PQDx_007 "*Overview of WHO's prequalification procedure for in vitro diagnostics"*
[8] This requirement applies when WHO's performance evaluation of the product is required per document PQDx_459 *"Eligibility criteria for WHO's performance evaluation of in vitro diagnostics".*

iii. the letter(s) of agreement and/or any other contractual document(s) relating to WHO's performance evaluation that are entered into between WHO, on the one hand, and the manufacturer or PEL, on the other hand;

iv. if Option A (as defined under Section 8 below) applies, the terms and conditions of the agreement and other contractual documents relating to WHO's performance evaluation that are entered into by the manufacturer and the PEL; provided, however that the manufacturer must ensure that the terms and conditions of any such agreements and/or documents are consistent, in all material respects, with the terms and conditions of the other PE Documents listed herein; and

v. any other documents and/or information determined by WHO.

For the avoidance of doubt, WHO's performance evaluation of IVDs and its procedure are separate from WHO's prequalification assessment of IVDs and its procedure. The fact that an IVD has been accepted for, is undergoing and/or has completed a WHO's performance evaluation does not mean or imply that such IVD will be accepted for WHO's prequalification assessment and/or be granted WHO's prequalification listing. For more information about WHO's prequalification assessment of IVDs and its procedure, please consult the *"Overview of WHO's prequalification procedure for in vitro diagnostics"* (document PQDx_007).

5. Eligibility for WHO's performance evaluation of IVDs

Expressions of Interest for WHO's performance evaluation of an IVD are accepted only for products that are found by WHO, in its discretion, to meet the eligibility principles and criteria set forth in "*Eligibility criteria for WHO's performance evaluation of in vitro diagnostics*" (document PQDx_459).

WHO will review the Expression of Interest against the abovementioned eligibility criteria and will inform the manufacturer, in writing, whether or not the product is accepted for WHO's performance evaluation according to the provisions of this procedure.

6. Parallel or sequential submissions for WHO's performance evaluation and WHO's prequalification assessment

It is the responsibility of the manufacturer to decide whether to submit an Expression of Interest for a product and, assuming that such Expression of Interest is accepted by WHO, to further decide whether to:

a) submit *in parallel* an application for WHO's prequalification assessment of that product; or

b) wait until WHO's performance evaluation of that product has first been completed, *before* submitting an application for WHO's prequalification assessment of that product.

Regardless of which of the two options above is chosen, the manufacturer's attention is drawn to the following points:

- WHO's performance evaluation and WHO's prequalification assessment are separate processes, with separate applicable procedures, forms and requirements;
- subject to WHO's acceptance of the Expression of Interest, the manufacturer commits to applying for WHO's prequalification assessment of the product within 60 days after WHO issues the final performance evaluation report for that product;
- the product submitted for WHO's performance evaluation must be identical to that which is submitted for WHO's prequalification assessment (and vice-versa), unless any changes made to the product have first been accepted by WHO in writing, pursuant to WHO's prequalification procedure for IVDs;

- the fact that an Expression of Interest for a product has been submitted to, is pending review by and/or has been accepted by WHO does not mean or imply that the application for WHO's prequalification assessment of that product will be accepted by WHO or that, if accepted, the product will be granted WHO's prequalification listing;
- the fact that WHO's performance evaluation of a product is in the process of being implemented and/or has been completed does not mean or imply that the application for WHO's prequalification assessment of that product will be accepted or that, if accepted, the product will be granted WHO's prequalification listing;
- WHO's decision (whether positive or negative) regarding WHO's performance evaluation of a product will be taken subject to and in accordance with the terms and conditions of this procedure; and
- WHO's decision (whether positive or negative) regarding WHO's prequalification assessment of a product—including whether or not to grant WHO's prequalification listing to that product—will be taken subject to and in accordance with the terms and conditions of WHO's prequalification procedure for IVDs.[9].

7. Applying for WHO's performance evaluation

7.1. Submission and review of Expressions of Interest

To ensure that WHO's performance evaluation is carried out as efficiently as possible, manufacturers should be fully prepared for WHO's performance evaluation process when they submit an Expression of Interest. Before submitting an Expression of Interest, manufacturers may contact WHO's Prequalification Unit (email: diagnostics@who.int) to commence discussions on WHO's performance evaluation processes and requirements. In addition, manufacturers should consult the relevant documents referenced under Section 15 below, as well as WHO's performance evaluation webpage (available at https://extranet.who.int/prequal/ivd-performance-evaluation), to prepare for WHO's performance evaluation.

As a first step in WHO's performance evaluation process, the manufacturer must complete and submit to WHO an Expression of Interest form (using document PQDx_460 "*Expression of interest form for WHO's performance evaluation of in vitro diagnostics*"), together with the necessary supporting documentation, to indicate the manufacturer's interest for an IVD to undergo WHO's performance evaluation. The Expression of Interest must be completed in accordance with the "*Instructions for completion of the Expression of Interest form for WHO's performance evaluation of in vitro diagnostics*" (document PQDx_461).

As part of the Expression of Interest form, the manufacturer must provide WHO with the names and contact information of two contacts who are duly and fully authorized and designated to act in the name and on behalf of the manufacturer in all respects and for all purposes in connection with WHO's performance evaluation of the IVD. In the event that, at any time during WHO's performance evaluation process, there is a change in the name(s) and/or contact information of any authorized contact(s), the manufacturer must promptly notify WHO, in writing, thereof and of the updated name(s) and contact information of the authorized contacts. Such notice must be given by official letter as described above, sent to WHO by email to diagnostics@who.int.

Once the complete Expression of Interest form and supporting documentation have been received by WHO, the Organization will review them against the applicable eligibility principles and criteria (see Section 5 above). If necessary, the manufacturer may receive a communication from WHO requesting additional information and/or clarifications, including to assist WHO in its eligibility

[9] Refer to *"Overview of WHO's prequalification procedure for in vitro diagnostics"* (PQDx_007)

decision. The manufacturer must provide WHO with the information and/or clarifications requested within the deadlines communicated by WHO. The manufacturer will be provided with two opportunities to correctly complete the Expression of Interest form with all requested information. If the manufacturer fails or delays to provide the necessary information after those two opportunities, the Expression of Interest will be rejected, and the product will not undergo WHO's performance evaluation.

WHO will determine and inform the manufacturer in writing whether or not the Expression of Interest is accepted (i.e., whether or not product is eligible for WHO's performance evaluation).

If the Expression of Interest is accepted (i.e., if the product is found by WHO to be eligible for WHO's performance evaluation), then:

- WHO will request the manufacturer to complete, sign and return to WHO a Letter of Agreement for WHO's performance evaluation of the product, using the document provided by WHO for this purpose (hereinafter, the "PE Letter of Agreement"). The PE Letter of Agreement will serve as: (i) an agreement between WHO and the manufacturer concerning WHO's performance evaluation of the product; and (ii) the manufacturer's acceptance of, and commitment to comply with, the terms and conditions of WHO's performance evaluation procedure for IVDs and of the PE Letter of Agreement;
- WHO will share with the manufacturer the relevant WHO's performance evaluation protocol(s) that will be used to assess the product's performance and operational characteristics;
- In the event that WHO's performance evaluation will be commissioned under Option A (see Section 8 below), then WHO will also request the manufacturer to ensure that a Declaration of Interest (DOI) form (using the document to be provided by WHO for that purpose) is completed, signed and returned to WHO by the selected PEL's principal investigator(s); and
- The manufacturer will be responsible for paying all WHO's performance evaluation fees (as defined in Section 10 below), and no liability or obligation shall attach to WHO in this regard.

If the Expression of Interest if not accepted (i.e., if the product is found by WHO *not* to be eligible for WHO's performance evaluation), then the Expression of Interest will be rejected, and the product will not be accepted for or undergo WHO's performance evaluation.

7.2. Conditions before WHO's performance evaluation may commence and proceed

If an Expression of Interest has been accepted, then before WHO's performance evaluation of a product may commence and proceed, the manufacturer must first ensure that all of the following conditions have been met:

i. the manufacturer has duly and fully signed, completed and returned to WHO the PE Letter of Agreement; and
ii. if WHO's performance evaluation will be commissioned under Option B: the manufacturer has paid in full all WHO's performance evaluation fees (including, but not limited to, WHO's coordination cost); or
iii. if WHO's performance evaluation will be commissioned under Option A:
   a) the manufacturer has ensured that the PEL's principal investigator(s) have duly and fully completed, signed and returned to WHO the DOI Form; and
   b) WHO has informed the manufacturer in writing that the relevant PEL and its principal investigator(s) may proceed to undertake WHO's performance evaluation of the product (see Section 12 below); and
   c) the manufacturer and the PEL have agreed to and signed a contract regarding the implementation of WHO's performance evaluation (including the payment of the fees

therefor), and such contract is consistent with and does not contradict the terms and conditions of this procedure and/or any other PE Documents.

WHO's performance evaluation of a product shall not commence or proceed unless and until all conditions mentioned in clauses (i), (ii) and (iii) above have first been met/completed.

For the avoidance of doubt, the issuance, receipt or signature of the PE Letter of Agreement, the payment of WHO's performance evaluation fees, and/or the commencement of WHO's performance evaluation process, do not mean or imply any decision by WHO (either positive or negative) on whether or not the product:

- meets, to WHO's satisfaction, the technical requirements for WHO's performance evaluation in accordance with WHO's performance evaluation protocol; or
- will be accepted for WHO's prequalification assessment pursuant to and in accordance with the separate procedure applicable thereto; or
- will be granted WHO's prequalification listing.

8. WHO's performance evaluation process

8.1. Commissioning options

When submitting the Expression of Interest, the manufacturer must choose one of the following two options for the commissioning of WHO's performance evaluation:

***Option A: WHO's performance evaluation commissioned by the manufacturer and carried out by a PEL selected by the manufacturer*.** If this option is chosen, the manufacturer will be responsible for: (a) commissioning and coordinating WHO's performance evaluation directly with the PEL selected by the manufacturer and approved by WHO pursuant to Section 12 below; and (b) directly paying (including, without limitation, to the PEL) all fees, costs and expenses in connection with WHO's performance evaluation of the product. See also Section 8.2 and Section 10 below.

Option B: WHO's performance evaluation commissioned by WHO and carried out by a PEL selected by WHO. If this option is chosen or otherwise applies (see the "Note" below), the manufacturer will be responsible for paying directly to WHO an amount equal to: (i) all fees, costs and expenses in connection with WHO's performance evaluation of the product, and (ii) the associated WHO coordination cost, as determined and communicated by WHO. Provided that the aforementioned amount has been fully paid by the manufacturer to and received by WHO, WHO will commission and coordinate WHO's performance evaluation of the product with the PEL selected by WHO. See also Section 8.2 and Section 10 below.

If the Expression of Interest for a product is accepted by WHO, WHO will confirm to the manufacturer in the PE Letter of Agreement whether Option A or Option B will apply for the commissioning of WHO's performance evaluation.

*Note: For specific product types and/or PELs, only Option B above (i.e., performance evaluation commissioned by WHO) may be available; in this case the manufacturer must use this option.

8.2. Product samples for WHO's performance evaluation

The manufacturer will be requested to send sufficient quantities from at least two different lots[10] of the product. Detailed shipping instructions (e.g. number of test kits and/or instruments, number of lots, etc.) will be communicated in due time to the manufacturer by the PEL.

[10] ISO 18113-1 :2022: In vitro diagnostic medical devices – Information supplied by the manufacturer (labelling) – Part 1 : Terms, definitions and general requirements: "The amount of material that is uniform in its properties and has been produced in one process or series of processes. The material can be either starting material, intermediate material or finished product.".

The manufacturer must send to the PEL the requisite quantities and lots of the product (test kits and/or instruments) , free-of-charge and "free domicile", in accordance with the aforementioned detailed shipping instructions. The manufacturer is responsible for shipping the kits under appropriate conditions, with a temperature log if required.

If necessary, special equipment needed to perform the assay must be made available by the manufacturer at no charge (i.e. customs declaration and payment of customs duties, transport, installation, training, etc., will be made by the manufacturer) to the PEL for the duration of the performance evaluation.

8.3. Conduct of WHO's performance evaluation

After conditions (i), (ii) and (iii) under Section 7.2 above have been completed, the manufacturer or WHO as applicable (i.e., depending on whether Option A or Option B applies), will proceed to commission WHO's performance evaluation directly with the selected PEL.

The party commissioning WHO's performance evaluation (i.e. the manufacturer under Option A or WHO under Option B) must ensure, and cause the PEL to ensure, that WHO's performance evaluation is carried out subject to and in accordance with this procedure and the other PE Documents, and that any data, information, findings, analyses, results and reports arising from or relating to WHO's performance evaluation of the product (collectively, "PE Results") are promptly, accurately and completely shared by the PEL directly with WHO.

Regardless of whether WHO's performance evaluation is commissioned under Option A or Option B, the manufacturer shall not, and shall ensure that any person or entity acting for or on behalf of the manufacturer does not, whether directly or indirectly, take any action or make any omission that does, or could be perceived as trying to, influence the objectivity, independence or assessment of any PEL or principal investigator and/or the conduct or results of the performance evaluation of the product.

While the performance evaluation is ongoing, upon request from WHO, the PEL must promptly share with WHO any PE Results available at that time. Once the performance evaluation has been completed, the PEL must promptly and timely share directly with WHO true, correct and complete copies of:

a) all PE Results;
b) all study data using the template spreadsheet provided by WHO; and
c) a draft report of the performance evaluation of the product using the template provided by WHO for that purpose (hereinafter, the "draft performance evaluation report").

For the avoidance of doubt, the PEL will not communicate directly to the manufacturer any of the items listed in the preceding clauses (a), (b) and (c) at any time during the performance evaluation or after its completion.

Upon receipt from the PEL, WHO will review and assess the PE Results and the draft performance evaluation report and, thereafter, will request the manufacturer to review and comment on the draft performance evaluation report. WHO will reasonably consider the manufacturer's comments to the draft performance evaluation report when preparing the final report; provided, however, that such comments have been received by WHO in writing within thirty (30) days after WHO sends the manufacturer the draft performance evaluation report. After such thirty-day period has expired, no comments to the draft performance evaluation report will be considered by WHO.

WHO will proceed to prepare, finalize and issue the final report of WHO's performance evaluation of the product (hereinafter, the "final performance evaluation report") in accordance with the relevant standard operating procedures and format established by WHO for that purpose, and after considering the manufacturer's comments (if any) that have been timely received during the

aforementioned thirty-day period. The final performance evaluation report will describe the results of WHO's performance evaluation of the product, and include any requests and recommendations (e.g. corrective actions) to the manufacturer.[11] A copy of the final performance evaluation report will be communicated in writing by WHO to the manufacturer and the PEL.

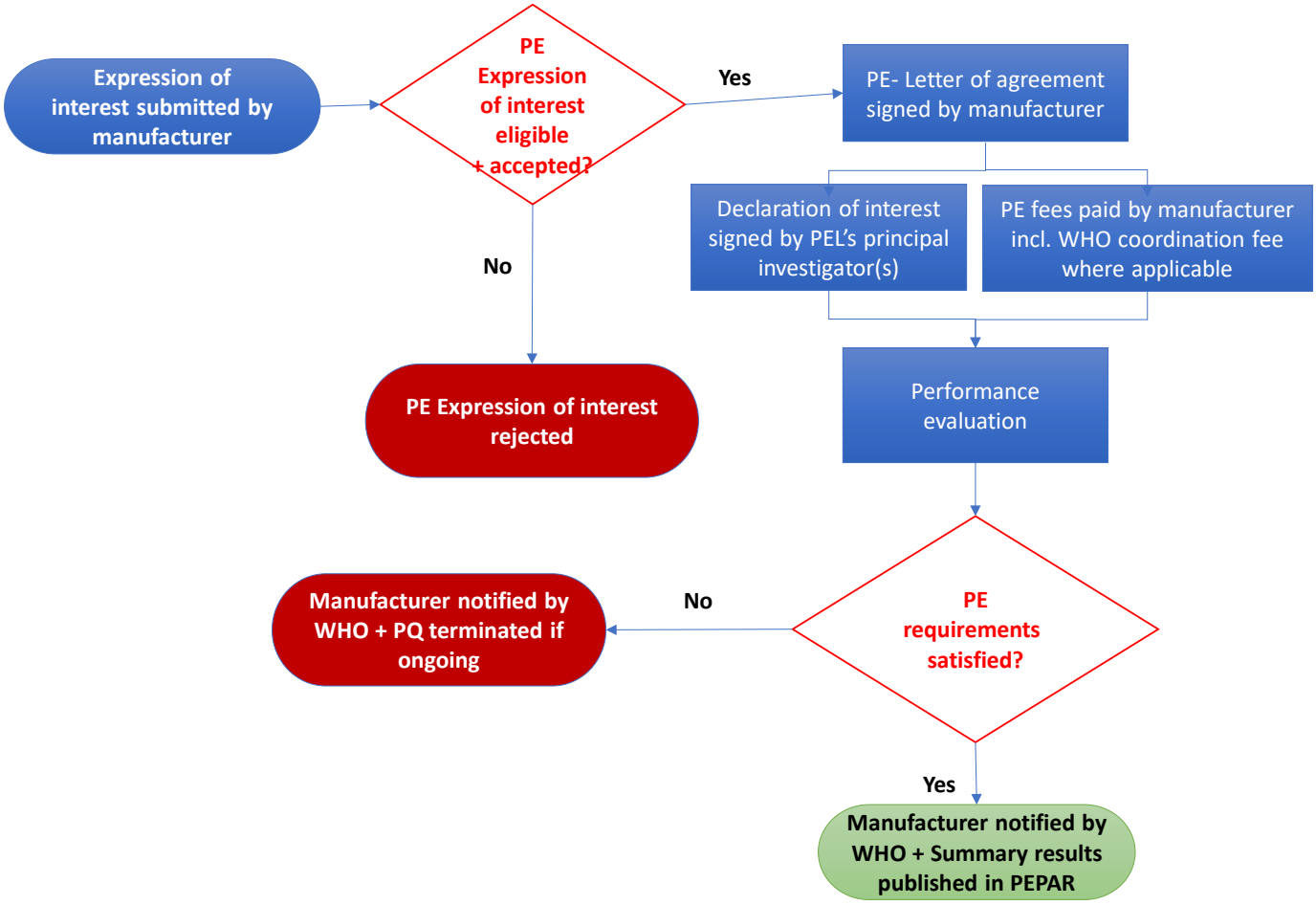
Once WHO's performance evaluation has been completed and the final performance evaluation report has been issued, WHO will decide whether or not the product meets, to WHO's satisfaction, the technical requirements for WHO's performance evaluation in accordance with WHO's performance evaluation protocol. As used in this procedure, the aforementioned technical requirements are in principle considered to be met if, among other things: (i) the results of WHO's performance evaluation are considered acceptable by WHO, in its discretion, taking into account the intended use of the product, the manufacturer's performance claims, and WHO's programmatic recommendations; and (ii) WHO finds that pre-defined acceptance criteria are met, where these acceptance criteria are stated in WHO's performance evaluation protocol.

Please refer to Section 9.4 below for more information about WHO's decision on whether or not the product has successfully completed WHO's performance evaluation.

Figure 1 provides a visual overview of WHO's performance evaluation process:

[11] Refer to section 9.4 of "Overview of WHO's prequalification procedure for in vitro diagnostics" (PQDx_007).

Figure 1 WHO's performance evaluation process



PE= Performance evaluation, PEPAR= Performance Evaluation Public Assessment Report PEL= Performance evaluation laboratory

9. Outcome of WHO's performance evaluation

9.1. Completion of WHO's performance evaluation as a prerequisite for WHO's prequalification decision

The successful completion of WHO's performance evaluation[12] is one of the pre-requisites for the product to be granted WHO's prequalification listing.

If WHO's performance evaluation is not completed or if the final performance evaluation report is not available by the time WHO's prequalification assessment components (i.e., product dossier review, manufacturing site inspection and labelling review) have been completed, a grace period of 60 days will be granted by WHO for the manufacturer to complete WHO's performance evaluation and obtain the final performance evaluation report.

If WHO's performance evaluation is not completed and/or the final performance evaluation report is not obtained within the 60 days grace period, then WHO's performance evaluation will be terminated early pursuant to Section 9.5 below, the prequalification application will be terminated pursuant to document PQDx_007 *"Overview of WHO's prequalification procedure for in vitro diagnostics"*, and the product will not be prequalified.

[12] As used in this procedure, the "successful completion of WHO's performance evaluation" means that WHO has found that the product meets, to WHO's satisfaction, the technical requirements for WHO's performance evaluation in accordance with WHO's performance evaluation protocol.

9.2. Ownership of WHO's performance evaluation results and reports

Taking into account that WHO's performance evaluation is a prerequisite to WHO's prequalification assessment of IVDs, and consistent with established WHO's prequalification procedures, the following apply:

The ownership of and all rights in and to any PE Results shall vest exclusively in WHO. However, as part of the PE Letter of Agreement, WHO will grant the manufacturer of that IVD a non-exclusive, worldwide, royalty-free license and right to use the PE Results subject to and in accordance with the terms and conditions set forth in the PE Letter of Agreement.

WHO will have and maintain full, exclusive and unfettered control over WHO's performance evaluation procedure and any reports, analyses, notices, publications and/or other materials (whether in draft or final form, and whether positive or negative) arising from or in connection with WHO's performance evaluation and/or any PE Results that are prepared by or on behalf of WHO and/or any PEL commissioned under Option A or B (all of the foregoing, collectively, "PE Reports"). The ownership of and all rights in and to any PE Reports shall vest exclusively with WHO.

Accordingly, and without limiting any other rights WHO may enjoy under this procedure or otherwise, WHO shall have the right to use, reproduce, display, distribute, share and publish any PE Results and/or any PE Reports in WHO's discretion, subject to the protection of any commercially sensitive confidential information of the manufacturer. As used in this procedure, the term "commercially sensitive confidential information" of the manufacturer means:

- confidential intellectual property, know-how and trade secrets (including, e.g. formulas, processes or information contained or embodied in a product, unpublished aspects of trademarks, patents, etc.); and
- commercial confidences (e.g. structures and development plans of a company).

9.3. Sharing of information and results of WHO's performance evaluation

As part of WHO's performance evaluation and/or WHO's prequalification assessment of a product, WHO may share the manufacturer's Expression of Interest, as well as any supporting documents and/or information submitted or obtained in connection therewith, with any interested regulatory authorities , subject to WHO entering into an appropriate confidentiality undertaking with each such regulatory authority.

As described under Section 8.3 above, WHO will provide the manufacturer with copies of the draft and final performance evaluation reports.

Subject to the protection of commercially sensitive confidential information of the manufacturer, WHO will publish on its website and make publicly available the following information in connection with WHO's performance evaluation process:

1. the names of manufacturers that have submitted an Expression of Interest, the names and product code(s) of IVDs for which an Expression of Interest has been submitted, and the status of each Expression of Interest; and
2. *if WHO's performance evaluation is successful*[13]: a summary of the results of WHO's performance evaluation of the product, as part of WHO's performance evaluation public assessment report (PEPAR) for that product.

[13] i.e., if WHO determines that a product meets, to WHO's satisfaction, the technical requirements for WHO's performance evaluation in accordance with WHO's performance evaluation protocol.

WHO reserves the right to remove the PEPAR from its website if the product to which such PEPAR relates is subsequently submitted for WHO's prequalification assessment and, for any reason, either WHO's prequalification assessment of the product is terminated or the product is withdrawn from WHO's prequalification assessment, or the product is delisted from WHO's list of prequalified IVDs.

Subject to the protection of commercially sensitive confidential information, and irrespective of the outcome of WHO's performance evaluation[14], WHO may decide to also publish on its website and make publicly available the following:

a) the results of WHO's performance evaluation of the product in a WHO composite report on the performance and operational characteristics of commercially available IVDs and/or in an article in a scientific journal; and
b) any negative outcomes of WHO's performance evaluation, including product alerts such as WHO information notices to end-users and/or WHO Notices of Concern.

Notwithstanding anything to the contrary contained in this procedure or elsewhere, and irrespective of the status (i.e., whether ongoing, completed or otherwise) and/or outcomes (i.e., whether positive or negative) of WHO's performance evaluation of a product, WHO shall have and hereby reserves the right to use, publish, issue, share with relevant regulatory and/or other authorities, with UN agencies, funds and programmes and/or with other relevant intergovernmental or international organizations, and/or make publicly available (in each case, in accordance with the provisions of this procedure, including provisions regarding the protection of any commercially sensitive confidential information of the manufacturer) any data, information, analyses, findings, outcomes, results, reports (including any PEPARs), notices (including any WHO Notices of Concern, WHO Notices of Suspension, WHO information notices and/or field safety notices), publications and/or other materials—whether in draft or final form, and whether positive or negative— arising from or relating to WHO's performance evaluation and including, without limitation, any confidential information to which WHO may gain access in the course of WHO's performance evaluation process. WHO's aforementioned rights shall be exercised in accordance with the provisions of this procedure including, but not limited to, those relating to the protection of commercially sensitive confidential information of the manufacturer.

9.4. Decision on whether or not the product has successfully completed WHO's performance evaluation

Once WHO's performance evaluation has been completed and the final performance evaluation report has been issued, WHO will decide whether or not the product meets, to WHO's satisfaction, the technical requirements for WHO's performance evaluation in accordance with WHO's performance evaluation protocol.

If WHO determines that the product meets, to WHO's satisfaction, the technical requirements for WHO's performance evaluation in accordance with WHO's performance evaluation protocol, then:

- WHO will inform the manufacturer in writing of the foregoing and that the product has successfully completed WHO's performance evaluation; and
- WHO will publish a summary of the results of WHO's performance evaluation in the PEPAR; and
- the PE Results and the final performance evaluation report will be used by WHO to inform, among other things, its decision on whether or not the IVD: (a) is accepted for assessment

[14] i.e., irrespective of whether WHO determine that the product does or does not meet, to WHO's satisfaction, the technical requirements for WHO's performance evaluation in accordance with WHO's performance evaluation protocol.

under WHO's prequalification procedure, and/or (b) if applicable, is granted WHO's prequalification listing thereunder[15].

If, on the other hand, WHO determines that the product does not meet, to WHO's satisfaction, the technical requirements for WHO's performance evaluation in accordance with WHO's performance evaluation protocol, or if based on an analysis of the overall outcomes and results of WHO's performance evaluation, WHO has concerns regarding the use of the IVD and its potential impact on public health; then:

- WHO will inform the manufacturer in writing of the foregoing and that the product has not successfully completed WHO's performance evaluation; and
- if the manufacturer already submitted an application for WHO's prequalification assessment of the product and that application has not yet been accepted by WHO, then the application for WHO's prequalification will be rejected and the manufacturer will be informed accordingly; and
- if the manufacturer has already submitted an application for WHO's prequalification assessment of the product and that application has been accepted by WHO, then the application will be terminated and the product will not be prequalified; and
- the manufacturer will not be allowed to re-submit an Expression of Interest for the product, unless and until all of the following conditions have been met:
    1. a design change in respect of the product and its performance is implemented by the manufacturer (the "Design Change"); and
    2. the manufacturer submits to WHO, for its review, the Design Change and any supporting documentation requested by WHO; and
    3. WHO reviews and, in its discretion, finds acceptable the submitted Design Change and supporting documentation; and
    4. WHO informs the manufacturer in writing that the product may be re-submitted for WHO's performance evaluation.

For the avoidance of doubt, the fact that a product has been found by WHO to meet the technical requirements for WHO's performance evaluation does not mean or imply that the product will be accepted for WHO's prequalification assessment and/or be granted WHO's prequalification listing.

9.5. Early termination of WHO's performance evaluation

WHO reserves the right to terminate early (upon providing written notice thereof to the manufacturer) WHO's performance evaluation of a product at any time or stage of the process/procedure if:

1. conditions (i), (ii) and (iii) under Section 7.2 of this procedure have not been fully met/completed within 60 days after the date on which WHO informs the manufacturer of WHO's acceptance of the Expression of Interest for the product; or
2. the manufacturer is not able to, or fails or unreasonably delays to, provide the kits and/or equipment necessary to perform the test(s); or
3. WHO becomes aware that the manufacturer, or any person or entity acting for or on behalf of the manufacturer, has taken any action or made any omission that does, or could be perceived as trying to, influence the objectivity, independence or assessment of any PEL or

[15] For the avoidance of doubt, the decision as to whether or not to accept a product for prequalification assessment and/or grant prequalification listing to a product will be taken by WHO subject to and in accordance with the *Overview of WHO's Prequalification procedure for in vitro diagnostics* (PQDx_007).

principal investigator and/or the conduct or results of the performance evaluation of the product; or

4. WHO determines, based on interim analysis of relevant data (e.g. the results of analytical part of WHO's performance evaluation), that the product will not meet, to WHO's satisfaction, the technical requirements for WHO's performance evaluation in accordance with WHO's performance evaluation protocol; or
5. WHO becomes aware of the implementation of any changes that may significantly affect the quality, safety and/or performance of the product while WHO's performance evaluation is ongoing; or
6. WHO's performance evaluation is not completed, and the final performance evaluation report is not obtained within the 60 days grace period granted to the manufacturer after completion of the WHO's prequalification assessment components;
7. For any reason WHO's prequalification assessment of the product is terminated, or the product is not granted WHO's prequalification listing, or the product is withdrawn from WHO's prequalification assessment.

9.6. Withdrawal from WHO's performance evaluation

The manufacturer may withdraw its Expression of Interest at any time or stage of WHO's performance evaluation, provided however that the manufacturer must provide WHO with prior written notice specifying the product(s) to be withdrawn from WHO's performance evaluation. The effective date of the withdrawal shall be the date on which WHO receives the aforementioned written notice, unless another effective date is mutually agreed in writing by WHO and the manufacturer.

If a product is withdrawn from WHO's performance evaluation, then:

- WHO's performance evaluation of the product(s) withdrawn will be terminated; and
- the manufacturer will not be allowed to resubmit an Expression of Interest for the product(s) withdrawn for a period of time determined by WHO, usually one year from effective date of the withdrawal, unless otherwise agreed in writing by WHO; and
- if the manufacturer already submitted an application for WHO's prequalification assessment of the product(s) withdrawn and that application has not yet been accepted by WHO, then the application for WHO's prequalification will be rejected; and
- if the manufacturer has already submitted an application for WHO's prequalification assessment of the product so withdrawn and that application has been accepted by WHO, then such application will be terminated and the product will not be prequalified; and
- the manufacturer will not be allowed to re-apply for WHO's prequalification assessment for the product(s) so withdrawn for a period of time determined by WHO, usually one year from effective date of the withdrawal, unless otherwise agreed in writing by WHO.

Without limiting the foregoing, if the Expression of Interest was withdrawn because the product does not meet or is unlikely to meet the technical requirements for WHO's performance evaluation in accordance with WHO's performance evaluation protocol, then the manufacturer will not be allowed to re-submit an Expression of Interest for the product, unless and until all of the following conditions have been met:

1. a design change in respect of the product and its performance is implemented by the manufacturer (the "Design Change"); and
2. the manufacturer submits to WHO, for its review, the Design Change and any supporting documentation requested by WHO; and

3. WHO reviews and, in its discretion, finds acceptable the submitted Design Change and supporting documentation; and
4. WHO informs the manufacturer in writing that the product may be re-submitted for WHO's performance evaluation.

9.7. Sharing of information or outcomes after early termination or withdrawal of WHO's performance evaluation

The termination of or withdrawal of an Expression of Interest and/or a product from WHO's performance evaluation at any time and for any reason will not prejudice, limit or otherwise affect WHO's rights set forth under Section 9.2 and/or Section 9.3 above. Such rights include, but are not limited to:

- WHO's right to use, reproduce, display, distribute, share and publish any PE Results and/or PE Reports; and
- WHO's right to use, publish, issue, share with relevant regulatory and other authorities, with UN agencies, funds and programmes and with other relevant intergovernmental or international organizations, and/or make publicly available (in each case, in accordance with the provisions of this procedure, including provisions regarding the protection of any commercially sensitive confidential information of the manufacturer) any data, information, analyses, findings, outcomes, reports, notices and/or results—whether in draft or final form, and whether positive or negative— arising from or relating to WHO's performance evaluation and including, without limitation, any confidential information to which WHO may gain access in the course of WHO's performance evaluation process.

10.WHO's performance evaluation fees

All fees, costs and expenses arising from or relating to any activities that are necessary for WHO's performance evaluation of a product including, but not limited to, the commissioning, implementation and, if necessary, WHO's coordination thereof (collectively, "WHO's performance evaluation fees") will be fully paid for and covered by the manufacturer, and no liability or obligation in connection with WHO's performance evaluation fees shall attach to WHO.

For the avoidance of doubt, WHO's performance evaluation fees are separate from and in addition to any fees, expenses or costs arising from or in connection with WHO's prequalification assessment.

The terms and conditions of document PQDx_462 *"WHO's performance evaluation fees*" apply to WHO's performance evaluation fees and their payment.

Payment of WHO's performance evaluation fees does not mean, imply or guarantee that the product will meet, to WHO's satisfaction, the technical requirements for WHO's performance evaluation in accordance with WHO's performance evaluation protocol, or that the product will be accepted for WHO's prequalification assessment, or that the product will be granted WHO's prequalification listing.

WHO's performance evaluation fees are non-refundable.

11.Confidentiality

In preparation or otherwise in connection with the conduct of WHO's performance evaluation, the manufacturer or WHO (acting as a "Disclosing Party") may disclose to other persons or entities including, but not limited to, PEL(s) and their principal investigator(s) (each, a "Receiving Party") certain information, data, documents and/or materials (including, without limitation, relating to a product and/or WHO's performance evaluation) which the Disclosing Party considers to be confidential, non-public and/or proprietary to the Disclosing Party and/or third parties collaborating with it (hereinafter, "confidential information").

Whenever a Disclosing Party provides or otherwise makes available any confidential information to a Receiving Party in connection with WHO's performance evaluation of a product, the Disclosing Party shall ensure that:

- any confidential information that is disclosed in written or other tangible form shall be clearly marked by the Disclosing Party as "confidential" at the time of its disclosure; and
- any confidential information that is disclosed in oral form shall be clearly stated by the Disclosing Party to be "confidential" at the time of its oral disclosure.

In addition to the foregoing, before the Disclosing Party provides or otherwise makes available any confidential information to a Receiving Party in connection with WHO's performance evaluation, the Disclosing Party shall first require the Receiving Party to be legally bound and abide by the following terms:

1. The Receiving Party will treat all confidential information as confidential and proprietary to Disclosing Party or third parties collaborating with it;
2. The Receiving Party shall use the confidential information solely for the following purposes (hereinafter, collectively, the "Purpose"): (a) enabling the Receiving Party to conduct any of its activities and/or obligations arising from or in connection with WHO's performance evaluation of the product, subject to and in accordance with the terms and conditions of this procedure and the PE Documents; and/or (b) enabling the Receiving Party to conduct any of its activities and/or obligations arising from or in connection with WHO's prequalification assessment of the product, subject to and in accordance with the terms and conditions of WHO's prequalification procedure for IVDs and other documentation applicable thereto.
3. The Receiving Party shall take all reasonable measures to ensure that confidential information shall not be used for any purpose(s) whatsoever other than the Purpose (as defined above), unless and until a further written agreement permitting such other use/purpose has first been executed by a duly authorized representative of the Disclosing Party.
4. The Receiving Party shall ensure that confidential information is not disclosed to any other person or entity, unless such other person or entity: (a) has a need to know the confidential information for the Purpose, and (b) is bound by similar obligations of confidentiality and restrictions on use as contained herein.

Notwithstanding the foregoing, the obligations of confidentiality and non-use stated above will not apply to any part of the confidential information that the Receiving Party is clearly able to demonstrate (as evidenced by written records or other competent proof):

a) was lawfully known to or in the possession of the Receiving Party prior to any disclosure by or on behalf of Disclosing Party; or

b) was in the public domain or the subject of public knowledge at the time of disclosure by or on behalf of the Disclosing Party; or

c) becomes part of the public domain or the subject of public knowledge through no fault of the Receiving Party; or

d) has become available to the Receiving Party from a third party not in breach of any legal obligations of confidentiality or restrictions on use; or

e) was subsequently and independently developed by or on behalf of the Receiving Party without access or reference to any confidential information; or

f) is required to be disclosed by the Receiving Party pursuant to law applicable thereto, provided that the Receiving Party shall in such case immediately notify the Disclosing Party in writing of such obligation and shall provide adequate opportunity to the Disclosing Party to object to or restrict such disclosure or request confidential treatment thereof; provided always, however, that nothing contained herein shall be construed as a waiver of any privileges and immunities enjoyed by WHO or any of its officials or experts and/or as submitting WHO or any of its officials or experts to the jurisdiction of any regional, national or subnational court or tribunal; see Section 14 below.

For the avoidance of doubt, nothing contained in this Section 11 shall: (i) prevent a Disclosing Party from disclosing any confidential information that is owned by the Disclosing Party to any third party for any purpose; or (ii) in any way limit, modify or prejudice any of WHO's other rights under this procedure or otherwise.

12.Conflict of interest

Before any PEL undertakes WHO's performance evaluation of a product, the manufacturer (if WHO's performance evaluation is commissioned under option A) or WHO (if WHO's performance evaluation is commissioned under option B) will require the PEL's principal investigator(s) to duly and fully complete, sign and submit to WHO a WHO Declaration of Interest form (a "DOI Form") according to which they are required to:

- disclose any circumstances that could represent a potential conflict of interest (i.e., any interest that may affect, or may reasonably be perceived to affect, the judgment, objectivity and/or independence of the PEL or any of its principal investigators);
- declare on their honour that the disclosed information is true and complete to the best of their knowledge; and
- promptly notify the responsible staff of WHO in writing should there be any change to the information declared in the DOI Form.

WHO will review and assess the DOI Form(s) submitted by the PEL's principal investigator(s).

If based on the DOI Form(s), WHO considers that a declared interest is insignificant or minimal and is unlikely to affect or be reasonably perceived to affect the principal investigator's judgment, then WHO will inform the manufacturer and the PEL that the PEL and its principal investigator(s) may proceed to undertake WHO's performance evaluation of the product in accordance with the terms of this procedure and the other PE Documents.

If based on the DOI Form(s), WHO considers that a declared interest is potentially significant and/or may give rise to a real or perceived conflict of interest, then the following will apply:

- WHO will inform the manufacturer and the PEL of the foregoing in writing; and
- another PEL must be selected by the manufacturer or WHO (as applicable, depending on whether option A or B applies) to conduct WHO's performance evaluation of the product; and
- the newly-selected PEL's principal investigator(s) will be required to complete, sign and return to WHO a DOI Form, and the process set forth under this section will apply and recommence.

13.Disclaimers

By submitting a product to WHO's performance evaluation, the manufacturer understands and agrees that: (a) it is not WHO's mandate to, and WHO does not, issue any approvals, certificates,

certifications, authorizations or licences for IVDs (such prerogative and responsibility lies with the national regulatory authority of each country); and (b) WHO does not, as a matter of policy, endorse, recommend or certify any specific commercial products, manufacturers and/or entities over any others.

The purpose of WHO's performance evaluation is to provide information to interested UN agencies, funds and programmes, WHO Member States and/or international or intergovernmental organizations to guide their procurement decisions. In this regard, the results of WHO's performance evaluation, the participation of the manufacturer and/or any product in WHO's performance evaluation process, WHO's decision (whether positive or negative) regarding WHO's performance evaluation of any product, and/or WHO's acronym, name and emblem may not be used by or on behalf of manufacturers or any other party for any commercial, marketing, advertising and/or promotional purposes.

Without limiting the foregoing, the manufacturer shall not, whether directly or indirectly, use or permit any other person or entity to use any PE Results, any PE Reports (whether in draft or final form) and/or the PEPAR in any manner that could suggest or imply that WHO has prequalified the product, except if and to the extent that WHO has first informed the manufacturer, in writing, that the product is listed on WHO's list of prequalified IVDs.

WHO will not accept any liability or responsibility whatsoever for any injury, death, loss, damage or other prejudice of any kind that may arise as a result of or in connection with the procurement, distribution and/or use of any product that has undergone WHO's performance evaluation and/or as to which WHO has published any reports, notices or other materials.

14.Disputes; privileges and immunities of WHO

In the event of any claims or disputes arising from or in connection with WHO's performance evaluation and/or this procedure including, but not limited to, their implementation, findings, outcomes and/or decisions (hereinafter, collectively, "Disputes"), such Dispute must be submitted in writing by the relevant manufacturer or other person or entity (hereinafter, the "Claimant") to WHO's Director of the Department of Regulation and Prequalification (RPQ), with a copy to the relevant Team Lead responsible for WHO's prequalification of in vitro diagnostics. Upon receipt of any Dispute, WHO's Director of RPQ, or one of his/her authorized representatives, will acknowledge receipt in writing and will conduct an investigation into the Dispute within 30 days. Following the investigation, WHO's Director of RPQ, or one of his/her authorized representatives, will provide a written response to the Claimant. If the Claimant is dissatisfied with the written response, then the Claimant must object in writing to WHO within 30 days of the date of WHO's response. In the event that the Claimant does not object to WHO in writing within such 30-day period, then the content of WHO's written response (including, without limitation, any findings or decisions contained therein) will be final and can no longer be challenged by the Claimant in any way. However, if the Claimant does object to WHO in writing within such 30-day period, then the Dispute will be referred to WHO's Director-General for his or her decision which will be final and binding on the parties.

By virtue of WHO's status as a Specialized Agency of the United Nations, WHO, its officials and experts performing missions for WHO enjoy privileges and immunities under national and international laws and conventions, including without limitation: (i) the Convention on the Privileges and Immunities of the Specialized Agencies, adopted by the General Assembly of the United Nations on 21 November 1947 (the "1947 Convention"); and (ii) the United States' International Organizations Immunities Act of 1945 and Executive Order 10025 relating thereto (collectively, the "IOIA"). Nothing contained in or relating to this procedure, any other PE Documents and/or any aspect of WHO's performance evaluation will constitute or be deemed as a waiver of any of the privileges or immunities which WHO, its officials and/or experts performing

missions for WHO enjoy pursuant to the 1947 Convention, the IOIA or otherwise under any national or international law, convention or agreement, and/or as submitting WHO, its officials and/or experts aforesaid to the jurisdiction of any regional, national or subnational court or tribunal.

15.Relevant documents

The following documents and webpages provide information to guide the manufacturer through WHO's performance evaluation process and are an integral part of this procedure.

- https://extranet.who.int/prequal/ivd-performance-evaluation
- Eligibility criteria for WHO's performance evaluation. Geneva: World Health Organization (PQDx_459)
- Expression of Interest form for WHO's performance evaluation of in vitro diagnostics. Geneva: World Health Organization (PQDx_460)
- Instructions for completion of the Expression of Interest form for WHO's performance evaluation of in vitro diagnostics. Geneva: World Health Organization (PQDx_461)
- WHO's performance evaluation fees. Geneva: World Health Organization (PQDx_462).
- WHO's performance evaluation webpage: https://extranet.who.int/prequal/ivd-performance-evaluation

16.Contact information

Any enquiries regarding WHO's performance evaluation of IVDs should be addressed to: diagnostics@who.int.