

Invitation to Manufacturers

10 October 2023 (update)

Manufacturers of Diagnostic Products Are Invited to Submit An Expression of Interest For Product Evaluation by the Global Fund Expert Review Panel for Diagnostic Products

Closing Date: Not applicable (open Call)
Reference Number: GF/ERPD/Adhoc-14/10-2019

Concerning Diagnostic Tests for:

- Syphilis (*Treponema pallidum*) infections
- Combined HIV, Hepatitis B and *Treponema pallidum* infections

01 Background

The Global Fund to Fight AIDS, Tuberculosis and Malaria (the “Global Fund”) and UNITAID support the procurement of large amounts of diagnostic products and related laboratory items for the diagnosis and management of HIV/AIDS, tuberculosis and malaria. In March 2011, the Global Fund established the Global Fund Quality Assurance Policy for Diagnostic Products (“the QA Policy”). The QA Policy applies to, among other products, HIV, TB and malaria Rapid Diagnostic Tests (RDTs). The Global Fund revised its QA Policy for Diagnostic Products in February 2014,¹ and in May 2017² including diagnostic tests for syphilis amongst others to reflect new WHO recommendations or guidelines and the Global Fund support on co-infection and co-morbidities³.

The available and recent information on syphilis Rapid Plasma Reagin (RPR), TPPA (*Treponema Pallidum* Particle Agglutination) and TPHA (*Treponema Pallidum* Hemagglutination) is rather scarce and regulatory certificates for this category of products are insufficient to provide evidence of current QA Policy requirements and to support any procurement decision by the Global Fund and its partners.

¹ Available at: <https://www.theglobalfund.org/en/board/meetings/31/>

² Available at: <https://www.theglobalfund.org/board-decisions/b37-dp12/>

³ Available at: <https://www.theglobalfund.org/board-decisions/b33-dp08/>

Access to these diagnostics products is of critical importance, especially when market entry may need additional time for a comprehensive review associated with licensing after stringent regulatory assessment or World Health Organization (WHO) prequalification. As a consequence, the assessment by the Expert Review Panel for Diagnostics (ERPD) has been put in place, as described in the QA Policy⁴.

02 The Expert Review Panel for Diagnostic products (ERPD)

The ERPD is a **mechanism to review the risks associated with procurement and use of diagnostic products that may have a high public health impact, but have not yet undergone a stringent regulatory assessment**, either by the WHO Prequalification of In-Vitro Diagnostics Programme or by **regulatory authorities of the Founding Members of the Global Harmonization Task Force (GHTF)**⁵ when stringently assessed (high-risk classification). The ERPD is not intended to replace the WHO prequalification programme or stringent regulatory assessment, but to provide an interim solution for a time-limited period, in anticipation of the completion of a stringent review process. Thus, the ERPD mechanism may help to expedite access to innovative diagnostic products, if the associated risks are deemed to be less than the potential benefits.

Among innovative diagnostic products of potential interest for the countries supported by the Global Fund, Unitaid and other stakeholders, the diagnostics products selected in the present invitation for an Expression of Interest have been identified as a priority.

The Global Fund and Unitaid are issuing this invitation for an Expression of Interest, inviting manufacturers of the selected category of diagnostic products to submit their product information (as specified in the product questionnaire) for review. Once a submission is accepted by the Global Fund, an independent panel of technical experts will conduct an analysis of the potential risks and benefits linked to the procurement and use of such diagnostic products which have not yet been prequalified by WHO or authorized for use through a stringent regulatory review.

The ERPD is hosted by WHO, and operates in accordance with its terms of reference. The ERPD then advises the Global Fund, Unitaid and other partners, as relevant, on the use of grant funds for procurement of such diagnostic products for a time-limited period.

The complete process - the invitation to submit an Expression of Interest, followed by the submission of the diagnostic product questionnaire by the manufacturers to the Global Fund, the ERPD review and the subsequent communication of the results to the manufacturers by the Global Fund - takes a maximum of six months.

03 Purpose of this invitation

The purpose of this invitation is to invite manufacturers to submit their product dossier to the ERPD to determine the acceptability for procurement and use of their diagnostic products as per the scope of product categories described in this document. This invitation applies only to diagnostic products (e.g. test reagent kits) that can (1) at least provide qualitative results at clinical decision points; and (2) which are not yet prequalified by WHO or authorized for use through a stringent regulatory review.

Note: Regulatory assessments by founding members of the Global Harmonization Task Force (GHTF), which are not undertaken in a stringent way, are not sufficient for Syphilis testing devices products for compliance to the Global Fund's QA Policy for Diagnostic Products.

⁴ Available at: <https://www.theglobalfund.org/en/sourcing-management/quality-assurance/diagnostic-products/>

⁵ The founding members of the Global Harmonization Task Force (GHTF) include U.S., Japan, EU, Canada, and Australia.

04 Scope of the present invitation to submit an Expression of Interest

The present invitation focuses on:

- 1) Rapid Plasma Reagin (RPR) Tests and TPPA (Treponema Pallidum Particle Agglutination) or TPHA (Treponema Pallidum Hemagglutination) for syphilis testing meeting the following specifications
 - a) using non-treponemal sensing technologies (RPR test) for manual and automated testing;
 - or
 - b) using treponemal sensing technologies (TPPA or TPHA tests) for manual and automated testing;
- 2) Syphilis rapid diagnostic tests (RDTs) (including TP/NTP, dual tests)
 - a) using rapid test format and/or technologies (eg lateral flow, immune-filtration assays) that can be used at or near to point-of-care; or
 - b) using rapid test format and/or technologies (eg lateral flow, immune-filtration assays) that can be used for Self-Testing;
- 3) Diagnostic Tests for Syphilis
 - a) using enzyme linked immunosorbent assay (ELISA) technologies (including chemiluminescence immunoassays)
- 4) Combinations of HIV, Hepatitis B and Syphilis in a rapid diagnostic tests (RDTs)
 - a) using rapid test format and/or technologies (eg lateral flow, immune-filtration assays) that can be used at or near to point-of-care; or
 - b) using rapid test format and/or technologies (eg lateral flow, immune-filtration assays) that can be used for Self-Testing;

05 Eligibility criteria

Manufacturers must meet the following criteria in order to be eligible for ERPD review.

- i. The diagnostic product has a dossier already under review by the WHO Prequalification of In-Vitro Diagnostics Programme or is undergoing a stringent regulatory approval process;

OR

The aforementioned product has not yet been submitted to the WHO Prequalification or has not yet been stringently assessed and approved by a regulatory authorities of the Founding Members of the Global Harmonization Task Force (GHTF) but the manufacturer can provide a signed “Letter of Commitment” either to (1) submit to the WHO Prequalification of In Vitro Diagnostics Programme or (2) engage in the stringent regulatory approval process through one regulatory authorities of the Founding Members of the Global Harmonization Task Force (GHTF) after a successful ERPD review.⁶

AND

- ii. The aforementioned product is manufactured at a site that is compliant with the requirements: ISO 13485:2016 or an equivalent quality management system (ISO 13485) recognized by an appropriate body, ie recognized certification body by a regulatory authorities of the Founding Members of the Global Harmonization Task Force (GHTF) (eg European Notified Bodies, MDSAP members, etc.) or successfully assessed by WHO Prequalification);

⁶ For example: Conformity assessments as of European Directive 98/79/EC article 9 paragraph 2

06 Submission of documents for ERPD review

All manufacturers interested in submitting applications for review by the ERPD are requested to submit the following information and material for each diagnostic products proposed for review:

- A cover letter expressing interest in submitting the product to the ERPD for review and indicating the authorized contact for the manufacturer;
- Where appropriate, a letter from the WHO Prequalification of In-Vitro Diagnostics Programme or a stringent regulatory authority confirming that the submission for the said diagnostic product is currently under review for the intended use or - in the absence of such a confirmation letter - a letter of commitment from the manufacturer;
- One of the following documents, substantiated by the most recent inspection reports:
 - i. An ISO 13485 certificate; or
 - ii. A certificate ensuring that the product (reagents and equipment) is manufactured at a site that is compliant with ISO 13485 requirements; or
 - iii. an equivalent quality management system certificate recognized by a regulatory authorities of the Founding Members of the Global Harmonization Task Force (GHTF); or
 - iv. a letter from WHO ensuring that the manufacturing site has been inspected by the WHO Prequalification of In-Vitro Diagnostics Programme and found compliant with WHO prequalification requirements.
- A completed product questionnaire, which can be found on the Global Fund website⁷.

07 Confidentiality

All information provided by manufacturers will be received by the Global Fund, kept confidential in accordance to the Global Fund's rules and shared with the ERPD members for the purpose of facilitating their review of the submission and provision of advice to the Global Fund under a confidentiality agreement with WHO as coordinating entity.

Review outcomes and advice provided by the ERPD, in connection with the Expression of Interest, will be shared with and used by the Global Fund, Unitaïd and the following partners as the basis for procurement decisions: Médecins sans Frontières (MSF), UNICEF and USAID.

08 Eligibility

The Global Fund Quality Assurance for Diagnostic Products will review all submissions for completeness. All the documents listed in section 6 and specifically detailed in the Diagnostic Product Questionnaire must be included by the applicant. Incomplete submissions will not be forwarded to the ERPD for review.

09 Instructions for submission

Submission should be submitted by electronic means (either via email or web based download service) together with a hard copy of the duly signed questionnaire, cover letter and letter of commitment (accompanied by an electronic copy on **CD or a USB key**). Files should be named to reflect their content as mentioned in this letter (e.g. "Cover letter.pdf", "annex A.pdf", "annex B.pdf").

⁷ Available at: <https://www.theglobalfund.org/en/sourcing-management/quality-assurance/expert-review-panel/>

There is no deadline for submitting an Expression of Interest as long as the invitation is published on the Global Fund website (submissions are accepted at any time until closure of this call). Information of the closing will be published on the Global Fund website 3 months in advance.

All submissions should be addressed with the reference number GF/ERPD/Adhoc-14/10-2019 and be sent by mail to the following address:

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The Global Fund to Fight AIDS, Tuberculosis and Malaria
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Should you have any further questions, you may contact Becker-Burgos at the following email address:
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