

# Invitation to Manufacturers

20th September 2021

## 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-20/09-2021

Diagnostic products for MTB complex species identification using rapid chromatographic immunoassay technology for the qualitative detection of *Mycobacterium tuberculosis* complex (MTbc) antigen

### 01 Background

The Global Fund to Fight AIDS, Tuberculosis and Malaria (the “Global Fund”) is one of the major funder of diagnostic products and related laboratory items for the diagnosis and management of HIV/AIDS, tuberculosis and malaria. Unitaid and the Global Fund support the procurement of large amounts of these products. In March 2011, the Global Fund established the Global Fund Quality Assurance Policy for Diagnostic Products (“the QA Policy”). The Global Fund revised its QA Policy for Diagnostic Products in May 2017 to reflect new WHO recommendations or guidelines and the Global Fund policy on co-infection and co-morbidities<sup>1</sup>.

While molecular methods are being made available, there is still use of mycobacterial culture in Drug Susceptibility Testing (DST) in order to monitor response to treatment for MDR-TB, as well as to determine whether there is susceptibility to second-line anti-TB agents. Mycobacteria can be cultured in specific solid or liquid media. Bacterial growth can be identified visually (that is, by identifying specific characteristics) or by automated detection of its metabolism. All positive mycobacterial cultures must be tested to confirm the

<sup>1</sup> Available at: <https://www.theglobalfund.org/board-decisions/b37-dp12/>

identification of *M. tuberculosis* complex (MTBC). Differentiation of species with the MTBC can be achieved using either phenotypic and/ or genotypic methods. The use of rapid immunochromatographic assays (or strip tests for speciation) to identify cultured isolates is recommended by WHO Global TB program because they provide definitive identification of all members of the MTBC (including *M. bovis*) in 15 minutes.<sup>2</sup>

The operationalization of WHO recommendations for the diagnosis of TB<sup>3</sup> requires a sufficient expansion in the number of quality-assured products meeting the Global Fund and Unitaïd quality assurance policies to improve access to TB diagnostics and finding missing cases (roughly 36% of people with active TB are missed each year). Access to some of these diagnostic products is of critical importance, especially when market entry may be pending comprehensive reviews associated with stringent regulatory assessment, WHO GTB programme assessment or World Health Organization (WHO) prequalification. Consequently, the assessment by the Expert Review Panel for Diagnostics (ERPDP) has been put in place, as described in the QA Policy<sup>4</sup>.

## 02 The Expert Review Panel for Diagnostic products (ERPDP)

The ERPDP is a **mechanism to review the risks and benefits associated with procurement and use of diagnostic products that may have a high public health impact but is not yet recommended by the WHO GTB programme or 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)<sup>5</sup>** when stringently assessed (high-risk classification). The ERPDP is not intended to replace the WHO GTB programme recommendation, 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 ERPDP 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, Unitaïd 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 Unitaïd 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, recommended by the WHO GTB programme or authorized for use through a stringent regulatory review.

The ERPDP is hosted by WHO and operates in accordance with its Terms of Reference. The ERPDP then advises the Global Fund, Unitaïd and other partners, as relevant, on the use of grant funds for procurement of such diagnostic products for a time-limited period and under specific conditions.

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 ERPDP review and the subsequent communication of the results to the manufacturers by the Global Fund - takes a maximum of six months.

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<sup>2</sup> Available at: <https://apps.who.int/iris/handle/10665/162712>

<sup>3</sup> Available at: <https://tbksp.org/guidance-books-solr>

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

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

### 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; and (3) which are not yet recommended by the WHO GTB programme.

### 04 Scope of the present invitation to submit an expression of interest

The present invitation focuses on diagnostic tests for TB testing. Any diagnostic test included in the expression of interest should meet the following:

- intended as MTB Species Identification test
- using lateral flow technologies for the qualitative detection of *Mycobacterium tuberculosis* complex (MTbc) antigen
- using a rapid test format

### 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, WHO GTB programme or is undergoing a stringent regulatory approval process;

OR

The aforementioned product has not yet been submitted to the WHO Prequalification, WHO GTB programme 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, (2) submit to the WHO GTB programme or (3) engage in a stringent regulatory approval process through one regulatory authorities of the Founding Members of the Global Harmonization Task Force (GHTF) after a successful ERPD review<sup>6</sup>;

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 (e.g. recognized certification body by a regulatory authorities of the Founding Members of the Global Harmonization Task Force (GHTF) or successfully assessed by WHO Prequalification);

### 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 product proposed for review:

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

- 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, WHO TB 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 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 website<sup>7</sup>.

## 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 this 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 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”).

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

There is no deadline for submission 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 of the ad-hoc will be published in the GF web pages 3 months in advance.

All submissions should be addressed with the reference number GF/ERPD/Adhoc-20/09-2021 and be sent by mail to the following address:

Dr René Becker-Burgos, PhD  
Quality Assurance Specialist, Diagnostic Products  
The Global Fund to Fight AIDS, Tuberculosis and Malaria  
Global Health Campus, Le Pommier 40  
CH-1218 Grand-Sacconnex  
Geneva, Switzerland

Should you have any further questions, you may contact Becker-Burgos at the following email address:  
[Rene.Becker-Burgos@theglobalfund.org](mailto:Rene.Becker-Burgos@theglobalfund.org)