

SECTION II – SCHEDULE OF REQUIREMENTS

Invitation to Bid (ITB) for the Establishment of Long-Term Agreement (LTA) with suppliers of Interferon Gamma Release Assay (IGRA) for the detection of latent TB infection.

e-Sourcing Ref. ITB/2024/52841

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SECTION 1: INTRODUCTION AND BACKGROUND

1.1 StopTB Partnership secretariat / Global Drug Facility (GDF) hosted by UNOPS

The **Stop TB Partnership** (hereinafter referred to as StopTB) is a global multi-stakeholder partnership that seeks to achieve a world without tuberculosis (TB) through facilitating, catalyzing and coordinating the work of its partners through the partnership's secretariat in Geneva.

United Nations Office for Project Services (hereinafter referred to as UNOPS), based in Geneva, Switzerland, provides management and financial/programmatic oversight of Global and Country specific Portfolios, Clusters and Operations Centers including hosting services, fund management, management advisory services, implementing projects, procuring goods and services and managing human resources. UNOPS has been hosting the Stop TB Partnership secretariat since 2015 and provides administrative services to the StopTB Partnership secretariat.

The **Global Drug Facility** (hereinafter referred to as "UNOPS/StopTB-GDF"), is a key initiative of the Stop TB Partnership established in 2001 to ensure access to quality-assured and affordable anti-TB medicines and related supplies required for treatment of TB, and medical devices, diagnostics and other health products required for screening and diagnosing TB (hereinafter referred to as "TB products"), by employing innovative business approaches, efficient knowledge management for evidence-driven leadership in market management, strategic procurement, and high-quality procurement and supply services to its clients in countries.

1.2 UNOPS/Stop TB - GDF's mission and role

The mission of GDF is to facilitate worldwide, equitable access to TB products which should help countries meet their targets set and adopted by world leaders at the United Nations High Level Meeting on Tuberculosis in 2018.

Today, GDF is the **largest supplier of quality-assured TB products** in the public sector worldwide. Since its inception, GDF has supported and increased access to critical quality-assured TB products to 164 countries.

The key added value of GDF is to offer a **full package of services** for ensuring market availability, affordability, and provision of quality-assured TB products to countries in need, as well as to offer country support for facilitating access to and uptake of new medicines and diagnostic tools. GDF's services include active market-shaping, strategic procurement solutions, innovative logistics approaches, a Strategic Rotating Stockpile for medicines, a quality monitoring program that incorporates pre-shipment inspection and quality control services, capacity-building and technical assistance.

As the largest public-sector purchaser, GDF is uniquely positioned to monitor and intervene in TB markets. Its market-monitoring and market-shaping work develops a transparent source of information to stakeholders and countries and provides downward pressure on the prices of TB products.

More information about GDF can be found at the following link

<https://www.stoptb.org/facilitate-access-to-tb-drugs-diagnostics/global-drug-facility-gdf>

1.3 Background of the Interferon Gamma Release Assays (IGRAs) for detection of latent TB infection

The programmatic management of latent tuberculosis infection (LTBI) in populations most at risk of developing TB remains a critical activity to disrupt transmission of *M. tuberculosis*, as identified in the End TB Strategy. LTBI is defined as a state of persistent immune response to stimulation by *M. tuberculosis* antigens with no evidence of clinically manifest active TB. Up to one third of the world's population is estimated to be infected with *M. tuberculosis*, and on average, 5–10% of those who are infected will develop active TB disease over their lifetime. The management of LTBI involves a comprehensive package of interventions, one of which is testing targeted individuals for LTBI. There is no gold standard method for diagnosing LTBI, but there are two available methods: use of the tuberculin skin test (TST) and use of Interferon Gamma Release Assays (IGRAs).

IGRAs are whole-blood tests that measure a person's immune reactivity to *M. tuberculosis*. White blood cells from most persons that have been infected with *M. tuberculosis* will release interferon gamma (IFN- γ) when mixed with antigens (substances that can produce an immune response) derived from *M. tuberculosis*. To conduct the tests, fresh blood samples are mixed with antigens and controls. The antigens, testing methods, and interpretation criteria for IGRAs differ between the available tests. IGRA interpretations are based on the amount of IFN- γ that is released or on the number of cells that release IFN- γ .

SECTION 2: OBJECTIVE OF THE ITB

Aware of the current availability on global market of various suppliers of Interferon Gamma Release Assays (IGRAs) for detection of latent TB infection, UNOPS/StopTB-GDF launches this ITB with the objective to select products with the best value for money for continuous access to countries of these essential products for the TB diagnostics via the GDF catalogue.

Bidders are invited to provide a technical and a financial Bid that will be evaluated by UNOPS/StopTB-GDF against defined criteria for award/s).

UNOPS/StopTB-GDF will then sign with awarded supplier/s three (3) years Long-Term Agreement/s (LTA/s) for the provision of the Interferon Gamma Release Assay (IGRA) for the detection of latent TB and with good performance of the supplier/s under LTA/s, the option to renew the LTA for two additional periods of one (1) year each under the same terms and conditions for a maximum of five (5) years.

This ITB is only opened to suppliers who are the manufacturers of IGRA tests. Therefore, distributors will not be considered.

SECTION 3: SPECIFIC INSTRUCTIONS FOR BIDDERS

For the general instructions to Bidders, please refer to the document **Section I: Instructions to Bidders**. This section 3 provides specific instructions to Bidders for this tender.

3.1. Description of Lots

The list of products/items requested/needed for this tender are divided into the following 2 lots:

Lot number and Description Items		
Lot 1 IGRA Enzyme-linked immunosorbent assay (ELISA) Test		
Item 1	a	IGRA Enzyme-linked immunosorbent assay (ELISA) Test kit
List of needed items supplied by Bidder	b	IGRA Enzyme-linked immunosorbent assay (ELISA) Specific accessories *, ** (as applicable)
Lot 2 IGRA Enzyme-linked immunospot (ELISPOT) Test		
Item 1	a	IGRA Enzyme-linked immunospot (ELISPOT) Test kit
List of needed items supplied by Bidder	b	IGRA Enzyme-linked immunospot (ELISPOT) Specific accessories *, ** (as applicable)

*** Accessories that ARE part of this tender:** Specific accessories, such as specific tubes, specific reagents, specific controls, separately supplied by the Bidder which are needed to run the offered IGRA test are part of this tender.

****Accessories that ARE NOT part of this tender:** General accessories, such as general laboratory apparatus, instruments, equipment, reagents, Personal, Protective Equipment (PPE) and other consumables readily available in a laboratory setting are not part of this tender.

The List of items requested/needed per Lot is described in the **Annex 1_Form C_Technical Bid Form_RFP52841**

3.2. Bids

- Bidder must bid for the requested IGRA test, and all specific accessories separately supplied by the Bidder (where applicable) to run the offered IGRA test per lot for their Bid to be considered.
- Failure to provide a Bid for a Lot with 100% of items required to run the requested IGRA test will lead to the Bid rejection for this Lot.
- If Bidder bid for specific accessories that are not part of this tender (see above), the Bid will not be rejected but the offered accessories will not be considered.
- The Bidder can submit a Bid for one or more lots.
- The Bidder can submit different packaging available for the list of items of the Lot 1 IGRA Enzyme-linked immunosorbent assay (ELISA) Test and Lot 2 IGRA Enzyme-linked immunospot (ELISPOT) Test where applicable, by adding a row in Annex 1_Form C_Technical Bid Form_RFP52841 and Annex 2_Form C_Financial Bid Form_RFP52841 accordingly

3.3 Quality assurance requirements for products offered.

UNOPS/StopTB-GDF QA requirements for products offered are defined as per clause 3 of the StopTB/GDF's Quality Assurance (QA) Policy which is accessible [here](#)

- a. Clause 3.1: Quality criteria for the manufacturer of the product/s
- b. Clause 3.3: Quality criteria for product/s offered (depending on the category of product/s).
 - a. For Product offered with a regulatory approval and marketing authorization issued by one of the former GHTF founding members now IMDRF (i.e., EU¹, USA, Canada, Australia, and Japan), the proof of regulatory compliance shall be as per the product's risk classification appropriate to the intended use.
 - b. The Declaration of conformity, for each product offered, shall clearly state all relevant international standards with which it is compliant.
- c. Clause 3.4: Additional requirements

3.4 Detailed technical specifications requirements for products requested/needed.

Detailed technical specifications requirements for each product to be procured for the 2 Lots are described in the ***Annex 1_Form C_Technical Bid Form_ITB52841*** with:

- a. Products technical specifications required for each item requested/needed.
- b. Logistic information requested for each item requested/needed.

3.5 Final destination

The ***Annex 3*** presents the list of countries to which GDF have made deliveries of TB diagnostics and medical products up to Q1 - 2024.

UNOPS/StopTB-GDF cannot provide forecasts or guarantee quantities to be purchased per product and country for the period of the LTA resulting of this ITB.

3.6 Submission of Bids by Bidders

Bidders shall complete, sign (where applicable), and submit the following forms (uploaded in "Documents" section of eSourcing platform) for the submission of their Bids:

- a. ***Annex 1_Form C_Technical_Bid Form_ ITB 52841***
For Lot 1 and 2, only Excel sheets corresponding to the Lot/s for which Bidders want to Bid shall be completed.
- b. ***Annex 2_Form D_Financial_Bid Form_ ITB52841***
For Lot 1 and 2, only Excel sheets corresponding to the Lot/s for which Bidders want to Bid shall be completed.

¹ The EU is implementing changes with regards to the medical device/IVD Regulatory Framework. As new regulations are adopted and implemented, GDF reserves the right to request information from suppliers on how they plan to transit and maintain compliance.

c. **Section III: Returnable bidding forms_ITB52841:**

Bidders shall submit the Section III: Returnable bidding Forms_ITB52841 completed and signed and provide all documents listed in Form H_Checklist as well as in “Checklist” section of the eSourcing platform.

d. **Questionnaire for Bidders:**

Bidders shall reply to the “Questionnaires” section of the eSourcing platform for this ITB.

e. **UNOPS DRIVE Supplier Sustainability Questionnaire**

Bidders shall complete and submit the Questionnaire.

Failure to provide requested documents and/or to respond to questionnaire/s may lead to the Bid rejection.

SECTION 4: ITB EVALUATION PROCESS

The ITB evaluation method is composed of the following 6 steps

4.1 Evaluation of Bidders Eligibility (Pass / Fail)

- a. Bidders’ eligibility will be evaluated applying a Pass / Fail methodology
- b. The criteria used for the evaluation are provided in the document ***Section IV Evaluation criteria ITB52841 - Section 1.***
- c. Non-eligible Bidder/s will be rejected from the ITB evaluation process.
- d. Only the Bidder/s that passed the eligibility evaluation will advance to the qualification evaluation.

4.2 Evaluation of Bidders Qualification (Pass / Fail)

- a. Bidders’ qualification will be evaluated applying a Pass / Fail methodology.
- b. The criteria used for evaluation are provided in the document ***Section IV Evaluation criteria ITB52841 - Section 3.***
- c. Non-qualified Bidder/s will be rejected from the ITB evaluation process.
- d. Only the Bidder/s that passed the qualification evaluation will advance to the technical evaluation.

4.3 Technical evaluation of Bids (Pass / Fail)

- a. Technical evaluation of the Bid will be done per Lot.
- b. The technical criteria used for the technical evaluation are presented in the document ***Section IV - Evaluation criteria ITB52841 – section 4.***
- c. Technical evaluation of the Bid will be conducted per Lot in 2 steps:
 - **Step 1** is the evaluation of the compliance of offered product/s for the Lot with UNOPS/Stop TB - GDF Quality Assurance (QA) requirements (refer to clause 3.2 above) applying a **Pass/Fail** methodology.

- A Bid is considered QA compliant if 100% of products offered for the Lot are compliant with UNOPS/Stop TB - GDF QA requirements.
- Only a Bid that pass Step 1 will advance to Step 2.
- A Bid that fails Step 1 will be rejected from the ITB evaluation process
- **Step 2** is the evaluation of the compliance of offered product/s for the Lot with UNOPS/Stop TB - GDF technical specifications requirements applying a **Pass/Fail** methodology.
 - A Bid is considered compliant with technical specifications if 100% of products offered for the Lot are compliant with UNOPS/Stop TB - GDF technical specifications requirements.
- d. At any time during the technical evaluation process UNOPS/StopTB-GDF may request clarifications or further information from the Bidder via the eSourcing platform to support the technical evaluation.
- e. A Bid for a Lot is considered **substantially compliant** if 100% of products offered for the Lot are compliant with UNOPS/Stop TB - GDF QA requirements and UNOPS/Stop TB - GDF Technical specifications requirements. Thus, if one of the product/s offered for the Lot does not pass the step 1 and the Step 2, the Bid will be rejected for the Lot.
- f. Only Bid substantially compliant will advance to the financial evaluation.

4.4. Financial Evaluation Bids

- a. The financial evaluation will be done at the level of a lot.
- b. Criteria used for the financial evaluation is provided in document ***Section IV Evaluation criteria ITB52841 – Section 5.***
- c. At any time during the financial evaluation process UNOPS/StopTB-GDF may request clarification or further information from Bidder via the eSourcing platform to support the financial evaluation. Please refer to Section I, Article 25.
- d. Bidders will be ranked based on the **price per test result**. Bidders shall explain the methodology of calculation used to determine the price per test result. The Bidder must consider for the calculation **ONLY** the items provided by the bidder to run the IGRA test.
- e. Bidder with the lowest price per test result is ranked in 1st position, the Bidder with the second lowest price per tests is ranked in 2nd position, and so on.

4.5 Award process

- a. The award process will be done at the level of a Lot.
- b. The award method is based on the ranking of Bidders. A Bidder ranked in the 1st position will be awarded the Lot.
- c. UNOPS/Stop TB - GDF may award more than one Bidder for each Lot depending on the number of products UNOPS/Stop TB - GDF want to include in the GDF catalogue. In this case and if there are Bidders ranked in 2nd position, 3rd position on so on, additional Bidders maybe also be awarded.

- d. UNOPS/StopTB-GDF reserves the right to cancel a Lot during the ITB evaluation process.

4.6 Notification of award to Bidders

- a. After completion of the ITB evaluation process, UNOPS/StopTB-GDF will notify Bidders whether or not they are awarded for a Lot and will issue the LTA with the awarded supplier/s.
- b. UNOPS/StopTB-GDF will then sign with awarded supplier/s three (3) years Long-Term Agreement/s (LTA/s) for the provision of the Interferon Gamma Release Assay (IGRA) for the detection of latent TB and with good performance of the supplier/s under LTA/s, the option to renew the LTA for two additional periods of one (1) year each under the same terms and conditions for a maximum of five (5) years.
- c. LTA/s in place will not be subjected to secondary bidding.