

**Issue Date:** 22 December 2014  
**Closing Date:** 4 February 2015, 5:00 pm CET time  
**Subject:** REQUEST FOR PROPOSAL (RFP) TGF-14-063

## **HIV VIRAL LOAD AND EARLY INFANT DIAGNOSIS TECHNOLOGIES**

Through this Request for Proposal (“**RFP**”), the Global Fund to Fight AIDS, Tuberculosis and Malaria (the “**Global Fund**”) invites all potential Bidders to submit proposals to supply viral load and early infant diagnosis technologies for delivery to recipients of Global Fund financing, as fully described in this RFP.

The objective is to select a panel of suppliers to support programmes implement quality viral load testing with the optimal pricing and contracting modalities whilst at the same time maintaining a sustainable, competitive market that also encourages the introduction of new technologies.

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## 1. Introduction

### 1.1 Objectives

- 1) The purpose of this RFP is to select a panel of manufacturers with whom the Global Fund will enter into Framework Agreements (long-term agreements) to supply HIV Viral Load (VL) and Early Infant Diagnosis (EID) technologies to Global Fund Principal Recipients (PRs) both through the Pooled Procurement Mechanism (“PPM”), formerly referred to as Voluntary Pooled Procurement (VPP) and through other procurement channels of Global Fund grant recipients.
- 2) Whilst the choice of specific technologies will ultimately remain a country-led choice based on the needs of the programme, the responses on key elements of this RFP will provide inputs into a defined process to guide the competitive transparent selection of viral load technologies by PRs.
- 3) The commercial arrangements may include options for allocated or committed volumes based on aggregated forecast demand across Global Fund PRs. The term and level of any commitment will follow the Global Fund evaluation of submitted proposals and subsequent second stage review.

### 1.2 Structure of RFP and Award

- 1) The RFP and award process will take place in two Stages:
  - a. **Stage 1** involves the preparation, submission and opening of proposals, preliminary examination, screening and evaluation of proposals, and the invitation of selected individual Bidders that submitted responsive proposals (the “Qualified Bidders”) to participate in Stage 2. Invitations to Stage 2 will also include a list of specific priority topics for discussion.
  - b. **Stage 2** involves dialog and meeting(s) where the supplier has the opportunity to discuss more detailed information as directed by the Global Fund’s invitation and the Global Fund has the opportunity to clarify aspects of the overall proposal. Subsequent to the dialog, all Qualified Bidders will be invited to submit their Best and Final Offer (BAFO) and service level agreements (SLAs) for key support service elements for those countries where the manufacturer wishes to be considered.
- 2) Following Stage 2 the final decision will be made by the Global Fund and communicated to all Qualified Bidders based on the processes detailed in this RFP. Any agreement between the Global Fund and a Qualified Bidder shall be reflected in the terms and conditions of a definitive agreement with such Qualified Bidder.
- 3) The Global Fund encourages new entrants in the market and the same 2-stage process will be followed to consider new entrants for inclusion on the panel of suppliers after they meet the conditions for participation detailed in Section 1.4.

### 1.3 Timeline of RFP

- 1) Proposals must be submitted by 4 February 2015, 17.00hrs Geneva Time
- 2) The scheduled time of the key activities of this RFP are as follows, with all times Central European Time (Geneva):

Activity	Scheduled Time – Deadline
1. Request for Proposal issued	22 December 2014 17.00
2. Deadline for prospective Bidders to submit requests for clarification by email to the RFP and the proposal contract	13 January 2015 17.00
3. Last day for the Global Fund to issue responses to all requests for clarification to all prospective Bidders	20 January 2015 17.00
4. Deadline for electronic submission of proposals	4 February 2015 17.00
5. Stage 1 Examination and evaluation of proposals	5- 6 February 2015 17.00
6. Issuance of invitation for Stage 2 to Qualified Bidders	6 February 2015 17.00
7. Scheduled Dates for Stage 2	23-27 February 2015
8. Deadline for submission of BAFO	13 March 2015 17.00
9. Final evaluation	Mid-March 2015
10. Notification of Awards to Bidders	31 March 2015

### 1.4 Conditions for RFP Participation

- 1) Only Bidders who are manufacturers of products in compliance with the Global Fund Quality Assurance Policy on Diagnostics are eligible to participate in this RFP ([www.theglobalfund.org/en/procurement/quality/diagnostics/](http://www.theglobalfund.org/en/procurement/quality/diagnostics/)).
- 2) The offered product should be responsive in terms of specifications and performance to the most recent guidelines and technical updates published by WHO for the implementation of viral load testing.<sup>1</sup>
- 3) A Bidder must comply with the Global Fund's Code of Conduct for Suppliers (2009, as amended from time to time) and shall be subject to the Global Fund's Sanctions Procedures Relating to the Code of Conduct for Suppliers (2013, as amended from time to time), in order to be eligible as a supplier to the Global Fund. The Code of Conduct for Suppliers and the Sanctions Procedures Relating to the Code of Conduct for Suppliers are available on the Global Fund's website at the following link: <http://www.theglobalfund.org/en/librarydocuments/>.
- 4) Participation in this RFP is subject to the terms and conditions contained herein. This RFP shall not be construed as a contract or a commitment of any kind. This RFP in no way obligates the Global Fund to award a contract, nor does it commit the Global Fund to pay any cost incurred in the preparation and submission of the proposal(s).
- 5) All proposals must remain valid for a period of 120 calendar days from the deadline for the electronic submission of proposals.
- 6) A bid security is not required for proposals submitted under this RFP.
- 7) The Global Fund may, at its discretion, change the scheduled time of the key activities of this RFP, or revise this RFP and any of its Schedules, by issuing an amendment to this RFP. All Amendments to this RFP will be posted on the Global Fund website at <http://www.theglobalfund.org/en/business/solicitations/>. It is the Bidder's responsibility to

<sup>1</sup> Recent WHO Guidance at the time of issue of this RFP include

- WHO. June 2013 Consolidated Guidelines on the use of antiretroviral drugs for treating and preventing HIV infection. Recommendations for a public health approach
- WHO. March 2014 Supplement to the 2013 Consolidated Guidelines on the use of antiretroviral drugs for treating and preventing HIV infection. Recommendations for a public health approach.
- WHO. July 2014 Technical and operational considerations for implementing HIV viral load testing: interim technical update.

consult the Global Fund's website to ensure that it is aware of amendments to, and additional information for, this RFP.

- 8) The Global Fund may, at any stage of this RFP: (a) reject any or all proposals or price submissions; (b) accept for award a proposal or price submission other than the lowest cost proposal or price submission; (c) accept more than one proposal or price submission; (d) accept alternate proposals or price submissions; (e) accept part of a proposal or price submission; (f) waive informalities and minor irregularities in proposals or price submissions received; (g) cancel this RFP.
- 9) The Global Fund reserves the right to request supporting documentation to validate supplied information and to validate it through other sources. There will be a continuing obligation to keep the Global Fund updated of any changes in information provided throughout the duration of the contract period in a format to be advised by the Global Fund.
- 10) The Global Fund will be under no obligation to reveal, or discuss with any Bidder or supplier, how a proposal or price submission was assessed, or to provide any other information relative to the selection process. Bidders whose proposals are not selected will be notified in writing of this fact, and shall have no claim whatsoever for any kind of compensation.
- 11) Bidders shall be solely responsible for their own expenses, if any, in preparing and submitting a proposal in response to this RFP. This includes any costs incurred during functional demonstrations and subsequent meetings, workshops and negotiations.
- 12) By participating in this process, Bidders agree to the legal terms and conditions in Section 5.

## **2. Scope of the RFP**

### **2.1 Overall context for VL and EID Diagnosis Procurement Strategy**

- 1) The Global Fund has adopted a new model for procurement, the Procurement 4 Impact programme, based on the principles detailed in the Global Fund Strategic Framework 2012-2016 'Investing for Impact'<sup>2</sup>.
- 2) As part of this programme, the Global Fund, in collaboration with Presidents Emergency Fund for AIDS Relief (PEPFAR) and other partners, launched a collaborative exercise to: *"outline programmatic, financing and procurement strategies for operationalizing the rational scale-up of laboratory monitoring of HIV treatment and infant diagnosis recommended in the 2013 WHO Consolidated HIV Guidelines in the context of Global Fund and PEPFAR programmes."*
- 3) The expansion of the use of virological load testing is recognised as complex and requires:
  - a) significant investments [planning, equipment, logistics and Quality Assurance (QA)];
  - b) a well-functioning laboratory network, cross-cutting aspects such as human resources, information systems and infrastructure; and
  - c) harmonized efforts by the public health community - including HIV programmes, national governments, donors, industry, implementing partners, research institutions, healthcare workers and patients.
- 4) The following key principles were identified to optimize investments in HIV programs and recognize diagnostic pipeline:
  - a) Do no harm to existing programs;
  - b) Analyse the impact of scale-up on existing budgets;
  - c) Optimize existing equipment and investments;
  - d) Understand the current diagnostic marketplace;
  - e) Develop a quality assurance program that supports scale-up; and
  - f) Consider the context of the host country partner program as introduction and scale-up-takes place.

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<sup>2</sup> <http://www.theglobalfund.org/en/about/strategy/>; <http://www.theglobalfund.org/en/p4i/events/>

- 5) The Global Fund's procurement strategy for HIV diagnostics capability is thus within the context of the above wider joint initiative. Other actions include the provision of guidance to support recipients to prepare funding requests, prepare for grant implementation and better understand existing country data on the status of planning for the introduction of viral load.
- 6) The complete set of elements within the overall initiative are:
  - a) Clinical algorithm & linkages to care
  - b) Funded demand
  - c) Quality assurance policy
  - d) Optimal contracting models
  - e) Affordable pricing
  - f) Optimal selection & placement
  - g) Laboratory systems
  - h) Planning & forecasting
- 7) The prime focus of this RFP is to achieve simple, transparent affordable pricing and optimal contracting models, whilst seeking commercial and market levers to impact other areas where possible.
- 8) Against this background there are specifically a range of activities underway, including:
  - a) Implementation of the Global Fund's Quality Assurance Policy for Diagnostics including Expert Review Panel to expedite access to high public health impact products – for example, POC for CD4, Viral Load, Early Infant Diagnosis, molecular technologies using dried blood spots for viral load
  - b) Policies for the procurement of health products
    - i) Guidance for financing in Strategic Investment Notes for HIV and Health Systems Strengthening
  - c) Leveraging Global Diagnostics Working Group (GDWG) & African Society for Laboratory Medicine(ASLM) by supporting:
    - i) Quality assurance for product selection & testing implementation adopting a harmonized approach
    - ii) Optimal selection and use
    - iii) Strengthening laboratory systems
    - iv) Advocating for appropriate and affordable diagnostics

## 2.2 Objectives of strategy to support the scale-up of viral load and/or early infant diagnosis

- 1) The Global Fund has developed its diagnostics procurement strategy and associated objectives to address the challenges identified under the current arrangements and to meet the expected future needs of its PRs as they strive to implement WHO guidelines. The strategy is based on a combination of analysis of recent market dynamics data, and discussions with manufacturers, our recipients, donors and other technical agencies.
- 2) The key objective is to support programmes implement quality viral load testing with optimal pricing and contracting modalities whilst at the same time maintaining a sustainable, competitive market that also encourages the introduction of new technologies.
- 3) The ultimate desire is to maximise the number of people on antiretroviral therapy being monitored and hence optimally treated, maximising the total cost of ownership per test within the given funding envelope. The Global Fund's end-vision would be to move to an output-based mechanism where suppliers are rewarded for each patient correctly monitored and treated. The Fund recognises that neither countries nor indeed the industry are yet sufficiently mature to implement this type of "cost per reportable" mechanism however encourages respondents to propose "value added" approaches (within the attached response schedules) to move towards this ambition.

- 4) The key objective of the strategy has a number of sub-objectives:
- a) *“Support programmes implement”*:
    - i) Provision of detailed, quantified guidance technical and commercial information, and practical advice to support rational, informed and auditable decision-making by recipients across different technical options to meet the specific needs of country programmes.
    - ii) Increase ability to compare different proprietary closed systems, with different technical specifications and understand ability to switch technologies.
    - iii) Increase transparency and standardisation of product permutations and different regulatory versions whilst recognising country specific needs and contexts.
    - iv) Support and align with evolving normative guidelines
    - v) Link and reinforce required improvements in laboratory systems capacity and absorption ability
  - b) *“Quality viral load testing”*
    - i) QA requirements clear and understood by both PRs and suppliers
    - ii) Procurement of QA products
    - iii) Technologies and results appropriately used and acted upon by programmes
  - c) *“Optimal pricing and contracting modalities”* – simple, transparent and affordable pricing with different contracting modality options
    - i. Understand, coordinate, and where possible, standardize, funded demand across the portfolio of PRs enabling increased value through consolidated volumes both across a country, globally and over time
    - ii. Increased visibility through improved planning and forecasting, supporting longer term contracts
    - iii. Transparent cost-build-up, including visibility of any country-specific additions, leading to optimised total cost of ownership
    - iv. Significantly reduced variable pricing (often driven by in-country distribution model/ arrangements) with stability of contract term
    - v. Collaborative working to use supplier expertise, including identification of areas for increasing value / reducing waste especially in reducing supply chain risks
    - vi. Streamlined more efficient order processing and administrative processes.
    - vii. More consistent and optimal contracting modalities
    - viii. Reduce the linkage between procurement and financing cycles;
    - ix. Address challenges in financing of recurrent costs such as maintenance contracts
    - x. Improved on-time delivery performance with reduced and reliable lead times
    - xi. Mitigated supply risk
    - xii. Simplified supply logistic chains and distribution models – including explicit guidance on cold-chain requirements and improved shelf-life, and clear supply chain costs/ Incoterms
    - xiii. Optimised utilization of equipment and increased visibility of actual utilisation
  - d) *“A sustainable competitive marketplace that also encourages the introduction of new technologies”*
    - i. Continued supply of products – sustainable supply base and underlying technology
    - ii. Development of products encouraged with widespread country registration to reduce supply chain risks
    - iii. Maintaining sufficient supplier presence in the market by understanding and supporting adequate returns to enable forward investment and by encouraging new entrants who can demonstrate sufficient value add to the program.
    - iv. Selecting an appropriate mix of platforms for specific health care settings may enhance competitive pricing and avoid downtime related to one type of instrument”

- v. Support introduction and up-take of new technologies –new manufacturers (not yet qualified), new technologies (e.g. lower throughput / “Point of Care”) and new sampling methods (e.g. Dried Blood Spot).
  - vi. Close-to-launch technologies or technologies that do not yet have the quality accreditation that enables procurement with Global Fund funds will not proceed to Stage 2 at this time, however will be eligible for a similar Stage 2 process once accreditation is achieved.
- 5) The RFP includes the following key principles:
- a) The Global Fund will create and manage strategic relationships with key suppliers; where procurement for PRs is through the PPM, the Procurement Services Agent (PSA) may be responsible for transactional operations and physical logistics.
  - b) The Global Fund will hold manufacturers accountable for the performance of their agents and/or distributors. This will include ongoing performance measurement of delivery and quality. Performance in a country (cost, quality, time) will be a factor in future allocations and selection algorithms,
  - c) Longer term contracts that encourage maximal testing within country-specific algorithms and funding envelopes, and, where feasible and commercially advantageous, committed volumes for the appropriate period.
  - d) Closer collaboration to improve efficiency and maximize utilization of installed equipment
  - e) A focus on value as well as affordability considering both commercial and technical factors.
- 6) **In their responses to this RFP, suppliers must set out how their proposals will support achievement of the above objectives and principles.**

### 2.3 Informed country choice to meet funded demand

- 1) The Country Co-ordinating Mechanism (CCM) and PRs will set out their priorities as part of the HIV Concept Notes and grants. One consideration will be their plans for a rational scale up to meet the 2013 WHO guidelines on treating and preventing HIV infection (and subsequent updates on implementing HIV Viral Load testing). By the end of 2014, many priority countries will have submitted their initial concept notes, enabling the Global Fund to take to a more holistic views of potential funded demand for Viral Load testing.
- 2) Whilst the choice of specific technologies will ultimately remain a country-led choice based on the needs of the programme, the responses on key elements of this RFP will provide inputs into a defined process to guide the competitive transparent selection of viral load technologies by PRs. The factors to be included in the selection considerations may include (amongst others), the following elements
  - i. Costs: reagents, add-ons; total cost (total cost of ownership)
  - ii. Contractual offering and service level agreements including support, training, servicing
  - iii. Required throughput vs testing target
  - iv. Regulatory status (national & donor policies)
  - v. Routine or targeted testing frequency
  - vi. Existing VL & EID capacity in country
  - vii. Centralized vs decentralized approach
  - viii. Sample transportation; sample type
  - ix. Automated or manual
  - x. Logistics: cold chain, storage
  - xi. Platform polyvalence capability: TB, Hep C, others
- 3) Except in exceptional circumstances the Global Fund will expect all funded procurement of Viral Load diagnostics to leverage the framework arrangements put in place via this RFP.

- 4) Where achievable the Global Fund will seek to realise economies of scale to smooth global demand and extend planning horizons including the pooling of demand and risk in applicable reagent rental contracting models at the national, regional or global level. This may occur progressively over the course of the contract; as such the arrangements put in place must be able to exploit the value of increasing certainty with respect to funded demand and technology choices. For example, over the course of the contract, the Global Fund may be able to increasingly formally commit to global volumes of tests.

## 2.4 Product Specification

- 1) The scope of this RFP includes quantitative HIV viral load determination (VL) and qualitative HIV early infant diagnosis (EID) technologies (testing platforms and their corresponding reagent kits and consumables). It includes manufacturers offering closed or open systems; and both large lab-based/high through-put systems and low through-put/ “point of care” systems.

Type of assay	Nucleic acid amplification or signal amplification
Output	Purified nucleic acids (RNA and DNA) or equivalent
Results	Quantitative/semi-quantitative VL and qualitative EID
Equipment required	Includes all pieces of equipment necessary to produce a test result
Reagent kits	Includes all reagents necessary to produce a test result
Consumables	Includes all the consumables necessary to produce a test result
Primary tube sampling	Possible
Procedure controls	Provided with the assay
Regulatory status	SRA approval/WHO pre-qualification/ERPD approval
Specimen type	Plasma or whole blood (DBS or primary tube)
Throughput	From 10 specimen/day to 384 specimen/day
Level of automation	Fully automated to semi-manual
Maintenance requirements	Fully described
Servicing capacity	Included
Interface with LIS	Desirable
Training manual	Available
Training requirements	Fully described

## 2.5 Quality Assurance requirements

- 1) Products in compliance with the Global Fund Quality Assurance Policy on Diagnostics [www.theglobalfund.org/en/procurement/quality/diagnostics/](http://www.theglobalfund.org/en/procurement/quality/diagnostics/).

## 2.6 Product Volumes

- 1) Between 2014 and 2016 the grants for HIV total USD 7.8 billion across 105 countries. Based on historical evidence this is likely to translate into at least USD 3.4 billion on medicines and health products for HIV. Programmes and countries will undertake prioritisation of WHO-recommended HIV interventions including the rational scale up of HIV Viral Load as part of their overall programme and as part of their applications and grant making under the New Funding Model (NFM). Details on the NFM and its implementation can be found at <http://www.theglobalfund.org/en/fundingmodel/>.
- 2) The forecasted spend on HIV diagnostics in 2014 is \$119 million that translates to 82 million rapid tests, 500,000 viral load tests and 200,000 early infant diagnoses. It is expected that spend on viral load will increase by at least 50-100% per year in 2015 and 2016.
- 3) Total volumes for the pricing scenarios requested could range from 500,000 to 2,000,000 viral load tests and 200,000 – 750,000 early infant diagnoses per year across all technologies. In their submission, each Bidder should present scenarios related to their understanding of their potential market share within these global volumes.

## 2.7 Contracting

- 1) Following Stage 2 of the process described in this RFP the Global Fund intends to enter into Framework Agreements with certain suppliers, which will define the key commercial and contractual terms and conditions for the procurement of HIV Viral Load and EID technologies for a defined term, expected to be between three to seven years.
- 2) The Global Fund expects that Panel Suppliers will enter into agreements that have the same terms, conditions and pricing as the Framework Agreements with the following types of buyers: (i) Global Fund Grant principal recipients and sub-recipients; (ii) Governments of host countries (i.e. countries where Global Fund grants are being implemented), which includes ministries, agencies and governmental organizations or institutions, such as public hospitals and prison services in such host countries; (iii) United Nations-related organizations, non-governmental organizations and not-for-profit organizations; and (iv) development and/or public health financing mechanisms, such as PEPFAR and the United States Agency for International Development (USAID), including international agencies that are supporting in-country public health programs, like the United States Centers for Disease and Control. Such cases will be an exemption to any confidentiality obligation that may be provided in the Framework Agreements.
- 3) While the Framework Agreement will provide the contractual and pricing framework, it is envisaged that contractual commitments will be made between the PRs and Suppliers under individual Transaction Agreements (TAs) that will reflect specific requirements within the context of the overarching Framework Agreement. The precise arrangements may vary depending on whether PRs procure through the PPM or other arrangements.
- 4) In very broad terms, the Global Fund foresees two main types of TAs between the PRs and Suppliers:
  - a) TA Model 1: Standard purchase agreement, and associated support and maintenance arrangements
  - b) TA Model 2: Reagent rental agreement (to include the equipment, reagents, consumables, support and maintenance, and installation and training)
- 5) In addition, agreements may contain options for turn-key arrangement, based on TA Model 1 or 2, but with specific value-added features.
- 6) The Framework Agreement will set out an agreed approach to global operational governance (in a Governance Schedule) including the structure for operational management, maintenance, training, inventory management, infrastructure and environment (e.g. cold storage), logistics, technical and service delivery and the details relating to reviews and reporting.
- 7) The Governance Schedule will stipulate that regular review meetings will take place with key stakeholders and that appropriate performance against SLA's / KPI's should be supplied as specified in the TA's
- 8) Each TA should contain, as a minimum :-
  - i. Description of Goods and/or Service to be provided
  - ii. Responsibilities of parties
  - iii. Volumes / forecasts / commitments
  - iv. Acceptance Criteria
  - v. Breakdown of costs
  - vi. Stakeholders
  - vii. Escalation process
  - viii. Termination costs
  - ix. Insurance provisions
  - x. Training requirements
  - xi. Maintenance schedule

- 9) The Global Fund expects that each of the above models will reflect different risk and cost profiles and, as such, the applicability and appropriateness of each may vary per country.

## 2.8 Supplier Performance Management

- 1) The Global Fund will implement a Supplier Relationship Management process with all suppliers that have Framework Agreements, as set out in such Framework Agreements. This will include a periodic review of performance, including on-time delivery, quality, and equipment performance.
- 2) For the avoidance of doubt, the Global Fund expects suppliers to have global responsibility and accountability for the performance of their products supplied under each Framework Agreement, even if these are resold through an agent. **In their tender responses, suppliers must set out how they will achieve this.**
- 3) The Global Fund is interested in the installed performance of diagnostics equipment over the term of the contract and maximising the number of patient tests performed per machine. **Suppliers are invited in their responses to suggest how this could be monitored and achieved.**

## 2.9 Order Management

- 1) Transactional order management may be through the PPM, i.e. through the Global Fund's selected Procurement Services Agent (PSA), currently the IDA Foundation, or through an alternative mechanism.
- 2) **Suppliers are invited to highlight the value associated with any particular procurement channel, and any potential value that can be shared with the Global Fund.**
- 3) Where the PSA is used, the PSA will perform operational management of the procurement under the PPM pursuant to the Framework Agreements entered into between Panel Suppliers and the Global Fund, including the placement of purchase orders, monitoring of supplier performance, and tracking of any purchases that count towards the Global Fund's volume commitment or achievement of price breaks.

## 2.10 Pricing

- 1) As set out above, one of the main objectives of this RFP process is to bring increased transparency to all cost elements in order to achieve increased value for money and reduced price variability.
- 2) In order to be considered as a supplier under this RFP, suppliers must complete the attached templates in Schedule B. In some cases the requested cost element may be "included" in an overall charge – for example reagent rental – in this case suppliers must still clearly indicate the included cost and specify that it is included.
- 3) The Stage 2 process may include further clarification on pricing elements. The Global Fund will use the information provided to calculate a Total Cost of Ownership and equivalent cost per test.
- 4) As a key input into the defined process to guide the competitive transparent selection of viral load technologies by PRs described earlier, the Global Fund intends to publish pricing in a simplified total cost of ownership model. Suppliers may submit a proposed structure for this simplified model (which should be in line the cost templates in Schedule B) for the Global Funds consideration during Stage 1. Suppliers will be required to submit their pricing into the final simplified template determined by the Global Fund as part of their Stage 2 submission.
- 5) If, following an award under this contract, a supplier is aware that it is supplying a country, program or organization with products (equipment or reagents) funded by the Global Fund, then it must make the Global Fund aware of this.

- 6) Unless explicitly agreed otherwise in advance in writing,
  - a) Procurement of any viral load and EID products funded by the Global Fund will be under the commercial terms agreed in the relevant Framework Agreement.
  - b) The prices and contracting terms will also apply to “legacy countries or machines” where machines are already in place, whether previously procured, leased or placed.
  - c) Any applicable price breaks, discounts or rebates, will apply to total value procured using Global Fund funds, whatever the procurement channel (PSA or other), and whether supplied direct from supplier or via their agent or distributor.
- 7) The Global Fund intends to offer access to the base prices, i.e. without the discounts and other terms related to the framework agreements to non-PPM countries and other agencies. The access to these pricing will be subsequently agreed between parties and defined in the Framework Agreement.
- 8) The Framework Agreement will include a ‘most favoured customer’ clause for the benefit of the Global Fund (see Schedule C for more information).

### **3. Instructions to Bidders and RFP Process**

#### **3.1 Overall Process**

- 1) The RFP process will take place in two Stages, as indicated in Section 1.2 of this RFP.
- 2) The Global Fund shall not consider any proposal that is received by the Global Fund after the indicated deadline for electronic submission of proposals. Any proposal received by the Global Fund after the indicated deadline for electronic submission of proposals shall be declared late, rejected, and returned unopened to the Bidder concerned.
- 3) The selection and evaluation process will be conducted in line with the procurement principles of the Global Fund’s Procurement Policy (2008, as amended from time to time), as applicable (see Schedule E) and the Guide to Global Fund Policies on Procurement and Supply Management of Health Products (2012, as amended from time to time).
- 4) During the evaluation of proposals, the following definitions apply:
  - a) “Deviation” is a departure from the requirements specified in this RFP;
  - b) “Reservation” is the setting of limiting conditions or withholding from complete acceptance of the requirements specified in this RFP; and
  - c) “Omission” is the failure to submit part or all of the information or documentation required in this RFP

#### **3.2 Communications during the RFP**

- 1) This RFP is in two stages, (a) proposals submission and (b) face to face dialog meetings, with Stage 1 being managed electronically. Potential Bidders are required to submit their proposals by e-mail to [solicitation@theglobalfund.org](mailto:solicitation@theglobalfund.org), clearly indicating the supplier’s name and the RFP number in the subject line of the e-mail.
- 2) All communications with regard to this RFP, i.e. for both Stage 1 and 2 shall be through the following single point of contact at the Global Fund:

Mme. Anne-Sophie Salmon  
Sourcing Manager, Sourcing Department  
[anne-sophie.salmon@theglobalfund.org](mailto:anne-sophie.salmon@theglobalfund.org).
- 3) Any communication between a Bidder and the Global Fund regarding this RFP, made between the Issue Date and the Notification of award, which is not through the channel designated in this Section, shall invalidate the Bidder’s proposal to this RFP.
- 4) Any attempt by a Bidder to influence the Global Fund in the evaluation of proposals or ontract award decisions shall result in the rejection of its proposal.

### 3.3 Confidentiality

- 1) Information relating to the evaluation of proposals and recommendation of contract award shall not be disclosed to Bidders or any other persons not officially concerned with such process until information on contract award is communicated to all Bidders.
- 2) The Global Fund recognises that some of the information requested may be sensitive and the manufacturer may select to execute a confidentiality agreement in the form attached at Schedule D. The submission will remain confidential and will not be disclosed beyond a need-to-know basis to a limited group at the Global Fund and the United States Government.
- 3) Unless explicitly flagged and justified as Confidential Information, the Global Fund may explore with any Supplier as part of the Stage 2 process, potential sources of value identified as part of the Stage 1 submissions.

### 3.4 Stage 1: Preparation and Submission of Proposals

- 1) Each Bidder shall complete two templates, and each template (which comprises of a number of files including Word Documents and Excel sheets with accompanying notes).
  - Schedule B.1 and its annex Bi
  - Schedule B.2 Costing information
- 2) Each proposal template is an Excel workbook that contains general instructions on the first Worksheet and specific instructions for each question.
- 3) Bidders are expected to fully respond to all the questions or provide the relevant information as required. Failure to do so will be considered not fully responsiveness at the Stage 1 evaluation, and will be taken into account in the selection and/or the overall evaluation.
- 4) Note that Section 5 of Schedule B provides an opportunity to provide any inputs and/or comments that there may be on any of the sub-sections of the RFP document that need to be made or cannot be adequately expressed elsewhere.
- 5) Companies must substantiate their responses by reference to specific details at regional or country level with respect to their products support arrangements.
- 6) All Stage 1 proposals shall be submitted electronically using either the pre-formatted templates. All documents are to be submitted as separate files with each file not exceeding 8mb. Each proposal shall be submitted in both of the following formats to ensure no errors occur in the evaluation process:
  - a) A signed copy of all submissions in PDF format, where all copies shall be legible; and
  - b) A duplicate copy of all documents, in either Microsoft Word, Excel or PowerPoint format, as the case may be.
- 7) In the event of a conflict between the signed copy and the duplicate copy, the signed copy shall govern.
- 8) All proposals shall conform to the following conditions:
  - a) All proposals shall be written and submitted in the English language;
  - b) All prices shall be quoted in US Dollars; and
  - c) All product prices as required shall be quoted Ex-works (EXW - Incoterms 2010) where this is applicable.
- 9) Proposals shall include a completed Officer's Certificate of Conformance and Acknowledgement, as contained in Schedule A.
- 10) When submitting their proposals Bidders are requested to include in their covering email a complete list of the files submitted.

### 3.5 Stage 1: Examination, Screening and Preliminary Evaluation of Proposals

- 1) Upon receipt, the Global Fund will examine the proposals to determine whether they are substantially complete, whether the documents have been properly signed and whether the

proposals are generally in order. Any proposal found to be unsigned or signed by an unauthorized person, not meeting the minimum requirements in this RFP, or not providing the minimum information that is essential for the evaluation of the proposals, may be rejected by the Global Fund and not included for further consideration.

- 2) The overall process for Stage 1 shall be as follows:
  - a) Bidders shall submit the documents as defined in Section 3.4
  - b) The Global Fund will conduct a screening and preliminary evaluation and completeness assessment on Schedules.
  - c) The Global Fund will review both Commercial and Technical factors, but will not create a “weighted score” during Stage 1.
  - d) The Global Fund will identify, and subsequently notify, those Bidders that will be invited to participate in Stage 2. It will also define the further information required for confirmation, validation, clarification and negotiation.

Element	Criteria	Use
Company Information and Manufacturing locations		For information
Product Eligibility	<ul style="list-style-type: none"> <li>• Compliance with Global Fund QA Policy</li> </ul>	Mandatory requirement
Regulatory Approvals	<ul style="list-style-type: none"> <li>• Registration/ licencing status by country</li> </ul>	Evaluated
Product Information	<ul style="list-style-type: none"> <li>• Specimen type</li> <li>• Capacity, reliability, performance, degree of automation; ease of use</li> <li>• Shelf-life; storage requirements; controls and calibrators</li> <li>• Polyvalent platforms</li> </ul>	Evaluated
Innovation pipeline: development and regulatory	<ul style="list-style-type: none"> <li>• Specimen type</li> <li>• New products</li> </ul>	Evaluated
Sustainability of the product / technology	<ul style="list-style-type: none"> <li>• Including changes to platform technology, continued reagent availability, support arrangements, embedded IT and financial stability of supplier and/or distributor.</li> </ul>	Evaluated
Contracting models	<ul style="list-style-type: none"> <li>• Ability to offer different contracting models</li> <li>• Offering of different contracting models</li> </ul>	Evaluated
Country representation and support	<ul style="list-style-type: none"> <li>• Type of representation; geographic scope; scope of services offered; warranty offered</li> </ul>	Evaluated
Pricing	<ul style="list-style-type: none"> <li>• Cost per test result; value for money;</li> <li>• Simplicity, clarity and transparency of pricing</li> </ul>	Evaluated
Added value technology and services offered	<ul style="list-style-type: none"> <li>• To users, programmes and the Global Fund</li> </ul>	Evaluated
Discounts	<ul style="list-style-type: none"> <li>• Feasible proposals</li> </ul>	Evaluated
Innovative proposals to support implementation of WHO Guidelines on viral load monitoring and Global Fund end-state vision		Evaluated

### 3.6 Stage 2: Dialog and final evaluation

- 1) The Stage 2 process will be as follows:
  - a) The process will include at least one face to face dialog meeting. Such meeting will take place at the time and place and for the duration advised in the notification process. The Global Fund will advise attendees in advance.
  - b) Global Fund will also identify in advance the agenda and further information required for confirmation, validation, clarification and negotiation.
  - c) At the conclusion of the discussion both parties will confirm the points that have been agreed, and any further iterations required.
  - d) The Supplier will then re-submit their revised response and Best and Final Offer (BAFO) and other supplementary information in terms of SLAs and pricing into the simplified

total cost of ownership model template for publication determined by the Global Fund during Stage 1.

- e) Following these submissions, the Global Fund will conduct its final review and evaluation.

### 3.7 Volume Commitment

- 1) Following the Stage 2 process, the Global Fund may elect to allocate and commit volumes of tests to selected suppliers in the following instances:
  - a) Where there is identifiable funded demand based on country assessments for the products for which there is commitment
  - b) Where there is a commercial advantage of so-doing
  - c) Where this advantage out-weighs any risk associated with such a forward commitment

## 4. Notification on Selection

- 1) Upon and subject to successful completion of the RFP process, the Global Fund intends to notify selected Panel Suppliers and the proposed commercial arrangements by the date indicated in Section 1.3
- 2) A final agreement with any proposed Panel Supplier is subject to a definitive written agreement between that Supplier and the Global Fund. If the Global Fund and a proposed Panel Supplier do not come to a final written agreement, including due to protracted or unsuccessful contractual negotiations or material proposed amendments by the Supplier to the Form of Agreement provided by the Global Fund in this RFP, the Global Fund will take appropriate action at its discretion.

## 5. Legal Matters

By submitting a bid for this RFP, including the Officer's Certificate of Conformance and Acknowledgement contained in Schedule A, the Bidder agrees to the following:

- 1) The Global Fund makes no offer of a contract by posting this RFP or evaluating any proposals submitted in response to it, and there is no legal agreement or relationship, whether in contract (express, implied or collateral) or tort, created by this RFP process between the Global Fund and any Bidder, with the sole exception of the provisions of this Section. Other than the provisions of this Section, the only legal arrangement between the Global Fund and the Bidder will be through a definitive negotiated agreement after proposal evaluation and panel selection.
- 2) The Global Fund expressly reserves the right to amend, withdraw, or cancel this RFP process and/or its sourcing strategy, and to reject any or all bids, at any time and for any reason, without liability or penalty to any party.
- 3) Bidders shall be responsible for and bear their own costs, expenses, and liabilities arising in connection with the preparation and submission of a response to this RFP, as updated, amended or modified from time to time, and their involvement in the RFP process. In no circumstances whatsoever will the Global Fund be liable for any such costs incurred by Bidders, whether direct or indirect, irrespective of the outcome of the procurement process, nor if the procurement process is cancelled, altered or postponed for any reason.
- 4) There are no other arrangements or understandings between the Global Fund and any Bidder with respect to this RFP other than the text contained herein.
- 5) Any dispute, controversy, claim, or issue arising out of this RFP or surrounding this process or any other matter relating to procurement of HIV Viral Load and Early Infant Diagnostic Technologies (including investigatory findings) with Global Fund resources, including grant funds, shall be finally settled by arbitration conducted in accordance with the United Nations Commission on International Trade Law (UNCITRAL). The number of arbitrators shall be three, the place of arbitration shall be Geneva, Switzerland, and the language used at the arbitration shall be English.

- 6) The investigative, decision-making, and sanctions policies and processes of the Global Fund, including the activities of its Inspector General, the Global Fund's Code of Conduct for Suppliers, and consideration of any findings of fraud or abuse by the Global Fund Sanctions Panel, should the Global Fund in its sole discretion choose to refer the matter to the Sanctions Panel, can and will apply to: (i) this RFP; and (ii) any other matter relating to procurement of HIV Diagnostics with Global Fund resources; and these processes may include, without limitation, public disclosure at the Global Fund's full discretion of any findings and/or decisions.
- 7) The Global Fund has full discretion to investigate any potential fraud or abuse, whether occurring in the past, present or future, associated with the procurement of HIV Viral Load and Early Infant Diagnostic Technologies with Global Fund resources, and the Global Fund at its full discretion may publish the findings of such investigations; through participation in this RFP process, the Bidder acknowledges these processes and will not challenge in any setting the investigation by the Global Fund of potential fraud or abuse associated with procurement of HIV Viral Load and Early Infant Diagnostic Technologies with Global Fund resources, the dissemination of investigation findings and the responses undertaken by the Global Fund to findings of fraud or abuse, in all cases whether occurring in the past, present or future.
- 8) Nothing contained in this RFP may be construed as a waiver, express or implied, of the privileges and immunities accorded to the Global Fund.

**REQUEST FOR PROPOSAL****RFP No. TGF-14-063****HIV Viral Load and Early Infant Diagnosis Technologies**

**Schedule A: Officer's Certificate of Conformance and Acknowledgement** *Proposing Suppliers are required to complete this Certificate as part of their proposal, and to return a version of this Certificate in PDF format as part of their proposal submission **signed** by an Officer of their organization with the ability to obligate the organization, including by signing a Framework Agreement with the Global Fund pursuant to this RFP.*

As a duly authorized Officer of the organization listed below, I confirm, acknowledge, and agree, on behalf of that organization, that:

- 1) The product(s) offered in this RFP are in compliance with the Global Fund Quality Assurance Policy on Diagnostics ([www.theglobalfund.org/en/procurement/quality/diagnostics/](http://www.theglobalfund.org/en/procurement/quality/diagnostics/)) (state) as defined in Schedule B1  
.....

- 2) That there is no objection to the Global Fund validating the information with the Global Fund Quality Assurance Policy on Diagnostics designated in 1 above
- 3) To my knowledge, there are no contractual or legal issues preventing the organization from: (i) submitting this proposal; or (ii) supplying HIV Viral Load and Early Infant Diagnosis Technologies per the terms submitted in this proposal at a future date.
- 4) I have read and understand, and the organization will comply with: (i) the Global Fund's Code of Conduct for Suppliers, and (ii) to the terms contained in the RFP, including Section 5: Legal Matters. No conflict of interest exists or would arise in connection with the organization: (i) submitting this proposal; or (ii) becoming a panel supplier under this RFP.
- 5) If the organization is selected by the Global Fund as a panel supplier, it will be required to enter into a Framework Agreement with the Global Fund in order to supply HIV Viral Load and Early Infant Diagnosis Technologies per this RFP. That Framework Agreement will be based on one of the Forms of Framework Agreement included in the RFP documentation presented on the Global Fund's website. The organization agrees to enter into such an agreement, other than any exceptions to that document as presented in a marked/track changes version of the Proposed Form of Framework Agreement submitted by the organization as part of its proposal submission, and agrees that any material modifications to the Form of Framework Agreement in that marked/track changes version may lead the Global Fund to decline to enter into an agreement with the organization.
- 6) The organization is financially sound and is not subject to any activity, either initiated by itself or by any other organization, that may materially affect its ability to supply the products included in its proposal submission, including, but not limited to, a change of ownership.
- 7) The products proposed in the enclosed proposal submission have been priced according to the technical and packaging specifications as defined in the RFP document and accompanying templates.

[Note: If your organization has any reservations, clarifications, or other descriptive information in connection with this Certificate, you may provide that information in the box below, or, as necessary, on additional pages, and submit that supplemental information as part of the signed version of this Certificate. Please note that non-compliance with any of the provisions of this Certificate will be taken into account in the Global Fund's evaluation of your organization's bid submission.]

\_\_\_\_\_  
Signature of Official / Authorized Signatory

Name \_\_\_\_\_

Title \_\_\_\_\_

Date \_\_\_\_\_

Organization \_\_\_\_\_

**REQUEST FOR PROPOSAL**

**RFP No. TGF-14-063**

**Viral Load and Early Infant Diagnosis Technologies**

**Schedule B: Response Templates**

- Schedule B.1
  - Annex Bi (separate Excel file)
- Schedule B.2 Costing information (separate Excel file)

**SCHEDULE B1: RESPONSE TEMPLATE**

The content of this schedule and schedule Bi is largely identical to that issued as RFI TGF-14-014 on 14 April 2014 except removal of the previous section 3 if that RFI and addition of and a new section 4.

**1. Manufacturer and market information**

Company name			
Corporate headquarter address			
Point of contact: name, position, email address, telephone, mobile phone			
Description of company ownership/ structure/ number of employees: overall company, diagnostics, viral load, sales, regulatory, R&D etc. <i>[you may also provide supporting corporate presentations and/or web-link(s)]</i>			
What are your main product lines?			
Manufacturing site(s): <i>[confirm the type of product(s) manufactured at each site (e.g. testing platform, reagents, etc.)]</i>			
Geographical coverage: sales & technical support			<i>please complete within Schedule Bi (Excel file)</i>
Turnover	Company	2012	<i>Comment here if necessary</i>
		2013	<i>Comment here if necessary</i>
	Diagnostics	2012	<i>Comment here if necessary</i>
		2013	<i>Comment here if necessary</i>
	Viral load/Early Infant Diagnosis	2012	<i>Comment here if necessary</i>
		2013	<i>Comment here if necessary</i>
Do you have a corporate policy regarding resource limited low and middle income countries? Please provide information on your long-term commitment to this sector?			
What are your priority low- and middle income countries/target countries for viral load testing products (VL & EID)?			
Please provide a general description of your current country footprint, distribution network; and expectations for expansion			
Please provide details of your current country footprint and volume forecast (2014-19)			<i>please complete for all countries where you have provided or envisage providing products within Schedule Bi (Excel file)</i>
Please list your 5 largest customers and the number of tests anticipated for 2014			1   Country   Number of tests
			2   Country   Number of tests
			3   Country   Number of tests
			4   Country   Number of tests
			5   Country   Number of tests
Does your company have a pricing strategy for low and middle income countries? Please describe in detail including eligibilities.			<i>please complete within Schedule Bi (Excel file)</i>

## 2. Product Information

Manufacturers or manufacturers with different viral load products should complete separate templates for each product.

- a) Please provide in tabular format information on testing platform(s) and corresponding reagents; kits and other items as applicable (include catalogue number).
- b) Please provide any supporting product information electronically.
- c) Information on many of the viral load products is presented in the following public domain reports:

- Putting HIV treatment to the test; MSF Access Campaign, 2013; [http://www.msfacecess.org/sites/default/files/HIV\\_Report\\_VL\\_ENG\\_2013\\_o.pdf](http://www.msfacecess.org/sites/default/files/HIV_Report_VL_ENG_2013_o.pdf)
- HIV/AIDS Technology Landscape, UNITAID, 2013 (& updates); <http://www.unitaid.eu/en/resources/publications/technical-reports>

If your products are included in these reports please either confirm that this information is fully correct throughout the report (including appendices) or provide comments/corrections/updates as narrative or by annotation and submission of a scanned copy.

- d) Additional information – please complete the tables below

What type of assay controls are included?	Yes/No
internal controls	
low/high controls	
negative controls	

Validation & regulatory approval	Status	Volume Input
Use of plasma for VL		
Use of Plasma Dry Spot (DPS)		
Use of Dry Blood Spot (DBS) for VL		
Use of DBS for EID		
Limit of detection for VL testing using DBS		

On-going evaluations <i>add rows as necessary</i>		
Name of evaluation	Short description	Expected time line for completion & regulatory approval

Storage temperature & shelf-life of reagent kits <i>add rows as necessary</i>		
Product name	Storage temperature range (min°C- max°C)	Shelf-life at manufacture

<b>Reporting system potential</b> (assuming confidentiality concerns have been addressed)		
<b>Functions</b>	<b>Available (Yes/No)</b>	<b>Format</b>
Automated reporting of number of tests performed		
Automated reporting of results		
Remote trouble shooting		
GIS mapping		
Other possibilities/options		

<b>Product Performance Specifications</b>	<b>%</b>	<b>confidence interval %</b>
Sensitivity		
Specificity		

<b>Independent performance evaluations carried out in the last 5 years</b> <i>add rows as necessary</i>			
<b>Name of centre</b>	<b>Address</b>	<b>Year completed</b>	<b>Link to peer reviewed/papers</b> (or reference to separate submitted document)

<b>Ongoing independent performance evaluations</b> <i>add rows as necessary</i>			
<b>Name of centre</b>	<b>Address</b>	<b>Year expected for completion</b>	<b>Link to peer reviewed/papers</b> (or reference to separate submitted document)

<b>Details of all current regulatory approvals for this product</b> <i>add rows as necessary</i>				
<b>Name of regulatory mechanism</b>	<b>Date of submission</b>	<b>Type if regulatory approval</b>	<b>Period of Approval Start and end date (if applicable)</b>	<b>Comment</b>
WHO Prequalification				
Founding members of GHTF <i>(add name(s))</i>				
CE marking				
FDA				
CDC/US waiver list				
<i>List national approvals</i>				

**3. The future: pipeline products and what can be done differently**

**Do you have new products under development?** Please provide details including envisaged timelines

--

**What are the key obstacles in getting your technology to market and scaled up?**

--

**4. Additional information**

**Detail existing products or new products under development that can support laboratory integration across diseases (e.g. tuberculosis, hepatitis B and C) and the use of diagnostic platforms in a polyvalent manner.**

--

**Describe your distributor strategy, articulating how performance is managed and how the terms and conditions proposed will be affected through any distributors or agents.**

--

**Detail any pre-requisites for implementation - e.g. structural, technical, skills and proposals on how you may be able to support overcoming these**

--

**Detail any offerings or willingness to bundle proprietary and/or non-proprietary consumables to reduce supply chain complexity**

--

**Provide further details to Section 2 of Schedule B1 on reporting system options and potential for users, programme managers and a funders to maximise programme impact and maximise value for money**

--

**Detail proposals/ideas on how to maximise and/or incentivise the utilisation of existing capacity for viral load and/or early infant diagnosis**

--

**Detail any other value-added opportunities you are able to propose that support the achievement of the Global Funds objectives**

--

**Proposed simplified total cost of ownership costing structure (in line the cost templates in Schedule B - reference Section 2.10 of RFP)**

--

**Proposed Key Service Level Agreements (SLA) as described in Section 2.7**

--

## 5. Opportunity to provide further information and/or comments

Please provide any further inputs and/or comments that you may have in the table below outlined according to the sub-sections of the RFP document

For many sub-sections, please remark "noted" or "understood" if there are no specific comments.

For other sections, especially section 2.2, this is an opportunity to further articulate how your submission is responsive to the Global Funds objectives.

Additional materials can be submitted and considered, however these should be clearly cross-referenced in the table below

		Submission/comment
1. Introduction		
1.1 Objectives		
1.2 Structure of RFP and Award		
1.3 Timeline of RFP		
1.4 Conditions for RFP Participation		
2. Scope of the RFP		
2.1 Overall context for VL and EID Diagnosis Procurement Strategy		
2.2 Objectives of strategy		
2.3 Informed country choice to meet funded demand		
2.4 Product Specification		
2.5 Quality Assurance requirements		
2.6 Product Volumes		
2.7 Contracting		
2.8 Supplier Performance Management		
2.9 Order Management		
2.10 Pricing		
3. Instructions to Bidders and RFP Process		
3.1 Overall Process		
3.2 Communications during the RFP		
3.3 Confidentiality		
3.4 Stage 1: Preparation and Submission of Proposals		
3.5 Stage 1: Examination, Screening and Preliminary Evaluation of Proposals		
3.6 Stage 2: Dialog and final evaluation		
3.7 Volume Commitment		
4. Notification on Selection		
5. Legal Matters		
<b>Schedule A</b>	Officer's Certificate of Conformance and Acknowledgment	
<b>Schedule B</b>	Response Templates (including separate Excel Files and their individual "tabs")	
<b>Schedule C</b>	Framework Agreement and Transaction Agreement	
<b>Schedule D</b>	Form of Confidentiality Agreement	
<b>Schedule E</b>	Applicable Procurement Principles of the Global Fund's Procurement Policy	

**REQUEST FOR PROPOSAL**

**RFP No. TGF-14-063**

**VIRAL LOAD AND EARLY INFANT DIAGNOSIS TECHNOLOGIES**

**Schedule C: Framework Agreement and Transaction Agreement**

*Draft “Framework Agreements” and corresponding Draft “Transaction Agreement” will be provided separately on the Global Fund’s website for this RFP – we are currently scheduling to post these by Friday 9 January.*

**REQUEST FOR PROPOSAL  
RFP No. TGF 14-063  
VIRAL LOAD AND EARLY INFANT DIAGNOSIS TECHNOLOGIES**

**Schedule D: Form of Confidentiality Agreement**

This Confidentiality Agreement (the “**Agreement**”) entered into as of.....(the “**Effective Date**”) is made by and between the Global Fund to Fight AIDS, Tuberculosis and Malaria, Chemin de Blandonnet 8, 1214 Vernier, Geneva, Switzerland (the “**Global Fund**”) and.....  
(Collectively the “**Parties**”).

The Parties intend to provide certain confidential information to each other in connection with a potential transaction relating to the supply of Viral Load and Early Infant Diagnosis Technologies, as further described in Global Fund Request for Proposal No. TGF-14-063 (the “**Purpose**”).

In this Agreement, the term “**Disclosing Party**” means the party that is providing Confidential Information, and the term “**Receiving Party**” means the party that is receiving Confidential Information.

In consideration of the Parties’ sharing of Confidential Information (as defined in Section 1 below), and as a condition to such disclosure, the Parties agree to the following terms and conditions as specified below which shall be effective from the Effective Date.

1. In this Agreement, the term “**Confidential Information**” means any information disclosed by a Disclosing Party to a Receiving Party, either directly or indirectly, which is not generally available to the public, but excluding any information that may be disclosed in accordance with and 3.3 (2) of Global Fund Request for Proposal No. TGF-14-063. The fact that such information has been delivered to the Receiving Party is also considered Confidential Information. Confidential Information includes not only written information, but also information transferred orally, visually, electronically or by any other means. Information will not be considered Confidential Information if the Receiving Party can prove that:
  - a. it already lawfully possesses the information,
  - b. the information is lawfully made available to the Receiving Party by a third party that is under no obligation of confidentiality to the Disclosing Party,
  - c. it developed the information independently, or
  - d. the information is, or becomes, publicly available other than as a result of any action of the Receiving Party.
2. The Parties shall keep Confidential Information secret and confidential and shall not disclose it to any person except, on a need-to-know basis, to a limited group of their own, and their affiliates’, directors, officers or employees, outside professional advisors, and auditors. Each party assures that each individual to whom Confidential Information is being disclosed or made accessible according to the stipulations above is contractually and/or legally bound to hold such information in strict confidence.
3. The Receiving Party may disclose Confidential Information where disclosure has been ordered to be made as a result of a subpoena or other binding request from any competent judicial, administrative, legislative, or regulatory authority or body. In such an event the Receiving Party shall as far as reasonably possible provide the Disclosing Party with prior notice without undue delay so that the Disclosing Party may seek a protective order or other appropriate remedy and/or waive compliance with the provisions of this Agreement for the limited purpose of the required disclosure.
4. The Parties agree that, if the Purpose does not proceed or negotiations terminate for any reason, each will, unless otherwise requested by the other party or required by any applicable law, regulation, subpoena, or order from any competent judicial, administrative, legislative or regulatory authority or body, immediately return or, at the direction of the Disclosing Party, destroy all tangible documents and any copies and extracts made thereof and, to the extent feasible with reasonable effort, delete all electronically saved confidential information.

5. Nothing in this Agreement shall impose any obligation upon the Parties to enter into any negotiations or further agreement or to cooperate exclusively with respect to the Purpose.
6. The Parties acknowledge that this Agreement sets out the entire agreement and understanding between them in relation to the subject matter hereof and that it supersedes all previous agreements, arrangements and understandings between the Parties with regard hereto.
7. This Agreement covers all Confidential Information being exchanged on and after its Effective Date in connection with the Purpose and shall remain in effect for a period of three years from this day on irrespective of entering into any agreement in connection with the Purpose or its termination.
8. Nothing in this Agreement will create a relationship of partnership, agency, or joint venture between the Parties. Neither Party is authorized to act, or make any statement, representation, or warranty on behalf of the other Party.
9. Nothing contained in this Agreement will be construed as a waiver, express or implied, of the privileges and immunities accorded to the Global Fund under (i) international law, including international customary law, any international conventions, treaties or agreements, (ii) any national laws including but not limited to the United States of America's International Organizations Immunities Act (22 United States Code 288), or (iii) under the Headquarters Agreement between the Global Fund and the Swiss Federal Council dated 13 December 2004.

IN WITNESS WHEREOF, each of the Parties hereto has caused this Confidentiality Agreement to be duly executed and delivered by a duly authorized officer as of the Effective Date.

By: \_\_\_\_\_

Name: \_\_\_\_\_  
Title: \_\_\_\_\_

THE GLOBAL FUND TO FIGHT AIDS, TUBERCULOSIS AND MALARIA

By: \_\_\_\_\_

Name: \_\_\_\_\_  
Title: \_\_\_\_\_

.....

**REQUEST FOR PROPOSAL**  
**RFP No. TGF 14-063**  
**VIRAL LOAD AND EARLY INFANT DIAGNOSIS TECHNOLOGIES**

**Schedule E: Applicable Procurement Principles of the Global Fund's Procurement Policy (2008, as amended from time to time)**

**1. Value for Money**

Procurement shall be conducted with the aim of obtaining value for money (VFM). In determining what represents VFM, due consideration shall be given to factors such as:

- the direct and indirect costs of the goods/services over the whole procurement cycle;
- the quality and fitness for purpose of the goods/services to be procured;
- the proposed supply time-frame for the goods/services;
- the performance history of each prospective supplier and the strategic importance and/or risks of engaging particular suppliers;
- the appropriateness of contracting options (for example, contract extension options);
- the potential risks associated with the procurement of the goods/services.

**2. Competition**

Procurement shall be carried out on a competitive basis to the maximum practical extent.

**3. Efficient and Effective Procurement**

Procurement shall be conducted in a manner that maximises the efficient use of the Global Fund's resources and ensures that the goods and/or services procured effectively meet the requirements of the users.

**4. Impartiality, Transparency and Accountability**

Procurement shall be conducted in an impartial, transparent and accountable manner.

**5. Procurement Ethics**

The Global Fund shall endeavour to select and use suppliers that provide written contractual undertakings that they comply with the internationally recognized standards for human rights, labour, the environment and anti-corruption, as reflected in the Global Fund Code of Conduct for Suppliers.