Viral Load and Early Infant Diagnosis (EID) - Frequently Asked Questions

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QUESTION	ANSWER
What do I need to consider Viral Load and EID?	
Why do I need to consider Viral Load?	The 2013 WHO consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection recommend quantitative viral load testing as the preferred monitoring tool for diagnosing and confirming the failure of antiretroviral therapy (ART).
Why do I need to consider EID?	Qualitative viral load is the recommended approach to early infant diagnosis (EID) of HIV and can sometimes use the same platforms with different reagents to quantitative viral load.

<table>
<tr><th colspan="2">What was the scope and focus of the Request for Proposal (RFP)?</th></tr>
<tr><td>What was the prime focus of the RFP?</td><td>The prime focus of the RFP was to achieve simplified, transparent affordable pricing and optimal contracting models, whilst seeking commercial and market levers to impact other areas where possible.
Analysis by the Global Fund (and previously others) has indicated a wide variation in prices paid for tests, combined with a lack of understanding and transparency. In addition, a lack of utilisation of installed equipment, in some cases due to lack of maintenance / support was documented.
The availability of viral load testing early infant diagnosis in resource-limited settings has been constrained for a number of reasons including cost which is high and variable with an inconsistent range of (ex-factory) pricing of US$ 10–85 per test solely for reagents and most of the consumables. Through outright purchase, each lab-based analyzer can cost more than US$ 150,000.</td></tr>
<tr><td>Why was this the prime focus?</td><td>Stakeholders such as the Global Fund, UNITAID and others recognised one of the most important barriers to implementing viral load testing in resource-limited settings was the “current high cost of testing”, despite clinical and programmatic consensus on the importance of viral load testing
Hence the RFP sought to increase cost transparency, increase competition and reduce overall costs whilst doing this within the overall context of emphasising and incentivising the importance of ease of use; training, lab systems and supply chains.</td></tr>
<tr><td>What is the GF’s Procurement Strategy?</td><td>The Global Fund’s Procurement Strategy for Viral Load and Early Infant Diagnosis therefore focuses on both optimizing existing equipment and investments as well as supporting scale-up - and was developed within the context that expanding viral testing can be complex and requires, in addition to the investment in the products, significant investments in laboratory systems, sample transport networks and people.</td></tr>
<tr><td>What was the scope of the GF RFP?</td><td>The scope of the RFP included 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 systems; and both large lab-based/high through-put systems and low through-put/ “point of care” systems.
The following specifications supported the eligibility of the suppliers’ submissions:
<table>
<tr><td>Type of assay</td><td>Nucleic acid amplification or signal amplification</td></tr>
<tr><td>Output</td><td>Purified nucleic acids (RNA and DNA) or equivalent</td></tr>
<tr><td>Results</td><td>Quantitative/semi-quantitative VL and qualitative EID</td></tr>
<tr><td>Equipment required</td><td>Includes all pieces of equipment necessary to produce a test result</td></tr>
<tr><td>Reagent kits</td><td>Includes all reagents necessary to produce a test result</td></tr>
<tr><td>Consumables</td><td>Includes all the consumables necessary to produce a test result</td></tr>
<tr><td>Primary tube sampling</td><td>Possible</td></tr>
<tr><td>Procedure controls</td><td>Provided with the assay</td></tr>
<tr><td>Regulatory status</td><td>SRA approval/WHO pre-qualification/ERPD approval</td></tr>
<tr><td>Specimen type</td><td>Plasma or whole blood (DBS or primary tube)</td></tr>
</table></td></tr>
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		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
What are the QA requirements?	Only Bidders who are manufacturers of products in compliance with the Global Fund Quality Assurance Policy on Diagnostics are eligible to be on the Supplier Panel (www.theglobalfund.org/en/procurement/quality/diagnostics/).		
What will the RFP enable?	The RFP will enable: • Benchmarking both terms and pricing, for Principal Recipients to leverage in the selection and acquisition of these technologies and/or reagents • Providing Principal Recipients with transparent detailed technical and commercial information including on different contracting modalities to support informed decision-making across the various platforms and technical options. This includes providing clear cost-build-ups to the ex-factory price including freight and the national level add-ons such as distributor mark-ups, maintenance etc. leading to an itemised and optimised total cost of ownership where more than 50% can be added to the headline ex-factory price. • Supporting the introduction and up-take of new technologies for new manufacturers whose products are not yet qualified; new technologies including lower throughput or more "Point of Care" solutions; and improved sampling methods that enable testing of stable quality samples (e.g. Dried Blood Spot).		

What were the outcomes the RFP?	
What was the outcome of the RFP	Global Fund Principal Recipients (PRs) (and other eligible buyers) now have a range of credible, cost-effective, competitive options with more transparent pricing, costs and contracting for HIV Viral Load (VL) and Early Infant Diagnosis (EID) and simplified and shortened procurement. Specifically the evaluated tender results: • Enable volumes to be leveraged and promotes maximize up-time and testing throughput • Guide new selection and establish contracting modalities and templates • Benchmark existing arrangements with probable forward-applicability in many cases • Provide options of different acquisition models: purchase/lease; and Reagent Rental • Provide standardized costing applicable for most recipient countries enabling easier and more transparent decision-making • Provide clear cost build-up to Total Cost of Ownership available for first time enabling a more meaningful and fair comparison • Provide a "Reagent rental" option - now available from majority of suppliers that is comparable with the equivalent "all in" bottom up price – indicating no "premium" • Include two recent new entrants into the low-and-middle income market for lab-based systems • Include two further suppliers recently QA-eligible with attractive offerings for lower throughput/near-Point-of-Care offerings with clear pricing and costs (but limited scale-up capacity/coverage plans) • Establish process for new entrants, with a clear target for pricing and contracting • Identify various "added-value" solutions available • Enable better global visibility and performance management (rather than fragmented country-level) and sustained delivery • Deliver Framework contracts and transaction agreements agreed in principle with no major issues remaining or have been flagged • Include agreement to make key elements of this RFP "available" in the public domain including TCO calculations
What does "informed country choice to meet funded demand" mean?	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 to the RFP provide inputs into a defined and rational decision process to guide the competitive and transparent selection of viral load and EID technologies by PRs.

What are the key principles underpinning the arrangements between GF and the panel suppliers?	1) 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. 2) 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, 3) 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. 4) Closer collaboration between GF and the suppliers to improve efficiency and maximize utilization of installed equipment 5) A focus on value as well as affordability considering both commercial and technical factors.
What are the non-financial benefits of the RFP?	In addition to significant financial benefits, the non-financial benefits include: • More informed selection of the optimal technology selection for programs; • Alternative contracting mechanisms that better incentivize manufacturers to maximize asset utilization rates and tests performed; • Proposals for added-value solutions such as remote monitoring, lab systems design, and enhanced training; • Greater visibility and less fragmented contract management to drive improvements and exploit the GF's scale to hold manufacturers accountable; • Increased competition and options with two new suppliers for lab-based systems, and two new "new point of care" type solutions; and • Clear process for future new entrants. The RFP set the expectation and established a framework whereby the manufacturers will provide access to the outcomes of the RFP to other "public sector" and "donor funded" programs. This will provide further benefits and set a benchmark in the category.
Do the prices apply to legacy countries/ machines?	Yes. 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. The detailed transition arrangements will depend on any existing contracts in place between a supplier and PR.
Who else is eligible to leverage the contracts with suppliers?	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: a) Global Fund Grant principal recipients and sub-recipients;

	b) 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; c) United Nations-related organizations, non-governmental organizations and not-for-profit organizations; and d) 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.
What will happen with the new technical platforms expected to reach the market in the coming months/years?	A supplier with a newly available platform, eligible by GF quality assurance policy, can submit an offering at any time by the relevant contact person at The Global Fund (see web-site)

What are the different VL and EID technologies?	
What is the guidance regarding VL/EID testing?	Main direction was given by WHO: - Technical and Operational Considerations for Implementing HIV Viral Load Testing. 2014. WHO. : The Global Fund has developed some guidance: - "Programming of laboratory investments - with a focus on viral load testing: New Funding and Reprogramming: Version 1: 19 May 2014"
What is the difference between VL and Early Infant Diagnosis (EID)?	The measurement of HIV viral load can be quantitative (VL) to monitor the efficacy of the treatment and/or qualitative to diagnose HIV paediatric infection (EID)
How many types of technology should we have in one country	It is recommended to avoid a situation in which a country would have only one testing platform for the same level of lab facilities to foster competition between suppliers. This recommendation would not apply for small countries. Note that some standardization is also recommended to avoid having too many suppliers for the same test which complicate the management of the sup chain
What are the logistics arrangements needed for reagents?	Special attention should be paid to the shelf-life of the reagents and the requirements for transport and storage (temperature)
Do we need to buy consumables from the equipment manufacturer?	The current agreements are related to closed systems by which the consumables for a given test should be procured from the same supplier unless indicated differently
What are the implications for CD4 testing?	[WHO guidance] CD4 testing for treatment monitoring can be reduced except where viral load is not available. CD4 testing is still necessary to guide ART initiation.
Are POC tests available?	Point-of-care tests are progressively reaching the market. Two panel suppliers are offering a test for VL and another one for EID. More products are expected to be available in the coming months.
Are lab based tests and POC tests complementary?	Yes, each type of equipment and tests have complementary features and catchment capacities. A combination of the two types of platforms is likely to support the scale-up of VL testing programs
What are dry blood spots (DBS)?	DBS is an alternative way to collect blood samples allowing decentralization and safe conservation of the samples till their shipment to a centralized testing facility. Capillary blood is collected on specific filter paper, dried, packed and sent to a laboratory. As a reminder not all the VL equipment/tests are validated for the use of DBS for VL testing.

Do all the tests require controls, calibrators and consumables?	Each test has a specific list of components to add to the reagent kits. Not all the tests are built the same way, usually POC tests have everything included in their cartridges while lab-based tests require calibrator, controls and consumables for the test to be run. It is recommended to check with the supplier their requirements (type of additional components and quantities per reagent kit)

What are the commercial and contractual options available?	
What is the Framework Agreement and Transaction Agreement	The Framework Agreement provides the overall contractual and pricing framework. It sets 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. 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. 8) Each TA should contain, as a minimum :- • Description of Goods and/or Service to be provided • Responsibilities of parties • Volume conditionalities (for reagent rental arrangements) • Acceptance Criteria • Breakdown of costs • Stakeholders • Escalation process • Termination costs • Insurance provisions • Training requirements Maintenance schedule
What types of Transaction Agreements / commercial models will be available?	In broad terms, the Global Fund foresees two main types of TAs between the PRs and Suppliers: 1. Transaction Agreement Model-1: Standard purchase agreement, and associated support and maintenance arrangements 2. Transaction Agreement Model-2: Reagent rental agreement (to include the equipment, reagents, consumables, support and maintenance, and installation and training) In addition, agreements may contain options for turn-key arrangement, based on Transaction Agreement Model 1 or 2, but with specific value-added features offered to the program.
Do all PRs need to use the Framework	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.

Arrangements? Procure through the PPM mechanism?	Use of the PPM will follow current country choice and guidance
What is a standard purchase arrangement?	This is a standard way of purchasing each of the elements separately. Namely capital purchase of equipment; then separate purchasing of reagents, control, consumables, servicing
What is Reagent Rental?	A reagent rental agreement means a single price per test paid that includes reagents, controls, equipment and servicing, usually linked to planned volumes over a defined period.
Why should I choose a Reagent Rental deal?	In most cases a Reagent Rental option will be the Global Funds preferred acquisition approach as it incentivises maximum equipment use and reduces the risk of equipment maintenance and servicing being de-prioritised.
Which countries are eligible?	The majority of Global Fund PRs/ countries are eligible. The detailed list varies slightly by supplier and is available on request.
What is a price break?	A price break points is if a supplier has proposed price reductions once this point achieved. In general price break point is the number of tests when the global total number of future tests (all reagent types) procured through the GF Framework Contract under any channel during the term of the agreement. Please also see supplier specific variations.
What is a committed volume?	A supplier may propose committed volume price reductions if committed volume contracted based on volumes across 3 years of contracts (unless company-specific variation). All items procured within the committed volume will be at the same unit price. Please also supplier specific variations.
What happens if the country cannot meet the committed volume of tests?	The Transaction Agreement will set out the consequences if a country cannot meet the committed volumes within the agreed time-window. In general this will result in an increased price per test, and this may be applied retrospectively.
What a Total Cost of Ownership (TCO) include?	For the purposes of the RFP and GF guidance the TCO includes costs of reagents, controls, calibrators, consumables, equipment, installation, set-up, training, servicing, maintenance and logistics. The TCO is calculated as a cost per test performed. The facilitate fair comparison the TCO does not include “re-training” costs; upgrade costs; lab personnel time; lab facility costs; sample collection costs; opportunity costs around machine footprint; energy or other usage costs; end of life or recycling costs.
What length of contract?	The agreements with the panel suppliers will be set up on a 3 year period. However a longer time frame (5 or 7 years) can be considered depending on the country funding specific context.
What are the costs / implications from switching from one technology to another?	The detailed implications will depend on specific country context. In most GF countries it will be both commercially and technically viable to introduce and/or switch to an alternative technology. Key considerations to plan will be: • Training of lab staff.

	• The logistics of the sample collection and transportation. • Lab systems layout
What prices should we assume for logistics?	Suppliers have provided indicative costs. Specific prices will also depend on the procurement channel adopted – for example PPM or other.
What will the expansion of the use of virological load testing require?	The expansion of the use of virological load testing is recognised as complex and requires: 1) significant investments [planning, equipment, logistics and Quality Assurance (QA)]; 2) a well-functioning laboratory network, cross-cutting aspects such as human resources, information systems and infrastructure; and 3) harmonized efforts by the public health community - including HIV programmes, national governments, donors, industry, implementing partners, research institutions, healthcare workers and patients.
What Incoterms are relevant?	The main incoterms are described below: 1) EXW: EX -Works: The selling price reflects the price at the manufacturing site – the buyer is responsible for all insurance and freight costs. 2) FOB: Free on Board: The seller is responsible for transport to the port of shipment (in the exporting country); the buyer is responsible for international shipping and insurance. 3) FCA Free Carrier (named place of delivery): The seller to deliver goods to a named airport, terminal, or other place where the carrier operates. Costs for transportation and risk of loss transfer to the buyer after delivery to the carrier. 4) CIF: Cost, Insurance, and Freight: The seller is responsible for freight to the destination port and includes this cost in the selling price; the buyer is responsible for insurance once goods are loaded on the carrier and all costs after arrival in port. 5) DAP: Delivered at Place: The seller is responsible for insurance and freight to a named place of destination; the buyer assumes responsibility for insurance and transport, import duties.