GLOBAL HEALTH SUPPLY CHAIN – QUALITY ASSURANCE

QA.APP.VLS-01.03

Viral Load: Vendor Technical Questionnaire

This questionnaire is used to collect information from offers of viral load tests and instruments. Additional documentation may be required and/or requested at the discretion of GHSC-QA.

INSTRUCTIONS

- Complete the fields in this questionnaire as applicable.
- Tick or place an X in any of the blocks that are true/applicable.
- Add rows to tables to include requested information. Alternatively, you may attach information in a separate sheet using the same format requested.
- PART II (Section 3 – 7) should be repeated if multiple platforms and products are submitted.
- PART III (Section 8 - 9) is required only once if all submitted platforms and products are manufactured at the same site. If the products are manufactured at the different manufacturing site, a separate questionnaire should be completed.
- **Submit your GHSC-QA Technical Questionnaire by 5pm ET on Apr 8**
- Refer to *Instructions for Creating a GHSC-QA Technical Questionnaire Submission* and *Instructions to Access and Upload Documentation to GHSC-QA SharePoint Site* to complete the submission.

Table of Contents

PART I. APPLICANT AND MANUFACTURER INFORMATION

1.0 APPLICANT INFORMATION

The information in this questionnaire can be shared confidentially between USAID and its implementing partners, WHO, UNFPA and The Global Fund for procurement purposes. If approved, the approval (including product identification, manufacturing sites, approved specifications and publicly available information) may also be shared with other procurement agencies. If applicant has any objections, mark an X in the box: ☐ **objection to sharing information between USAID and implementing partners, and/or other collaborating organizations.**

Request for Proposal Number	
Questionnaire Submission Date *(DD/MON/YYYY)*	
Company Name (Supplier) (*name of company submitting bid*)	
Physical address	
Postal address	
Telephone number	
Fax	
Website	
e-mail	
Organization capabilities	*(Select all that apply)* ☐ Marketing license holder ☐ Distributor ☐ Manufacturer ☐ Other (Specify):
Provide contact information for each of the following:	
Technical Specifications and Quality Assurance	Name: Telephone: Cell phone: E-mail:
Regulatory and Patent	Name: Telephone: Cell phone: E-mail:
General Inquiries	Name: Telephone: Cell phone: E-mail:

2.0 MANUFACTURER INFORMATION

2.1.1	Name of legal manufacturer		
2.1.2	Manufacturer physical address	Street Name and No.:	
		City:	
		Postcode:	Country:
2.1.3	Manufacturer postal address	Street Name and No.:	
		Postal Office Box No.:	
		City:	
		Postcode:	Country:
2.1.4	Manufacturer telephone		
2.1.5	Manufacturer e mail & web address		
2.1.6	Name of parent company		

PART II. PRODUCT AND REGULATORY INFORMATION

If the same manufacturer wishes to submit various products and/or platforms, then Part II (i.e. Sections 3 – 7) should be repeated for each product-platform combination.

3.0 PRODUCT INFORMATION – ASSAYS AND INSTRUMENT

3.1 Assays - Product name and product code/catalog number for GHSC-QA assessment

3.1.1 Product name:		
3.1.2 Provide the product code for each kit size submitted for GHSC RFP:		
Contents of the kit[1], including accessories *Insert name of one component per line.*	Number of tests per kit: *Product code:* ***Indicate** Xx vial/device/bottle (xx volume)*	Number of tests per kit: Product code: *if multiple kit sizes are available *Indicate Xx vial/device/bottle (xx volume)*
3.1.3 If reagents are supplied in more than one box, provide the reagent name, product code/catalogue number, and number of tests for each box of reagents		
Name of reagent for each box	Product code/catalogue number	Reagent box size (number of tests per kit)
3.1.4 Does this product require dedicated instrumentation? If so, please provide the instrument name, product code/catalogue number, and other relevant information in Section 3.3		
3.1.5 Is the regulatory version submitted to GHSC-QA assessment a WHO prequalified or approved by US FDA? (See Section 7 below)		☐ Yes Date product[2] was initially prequalified/approved:
		☐ No Product[3] expected to be prequalified/approved by:

[1] [**ATTACHMENT:** Attach photographs of all kit components (packaged and individually.]

[2,3] Refers to the product holding the regulatory version submitted for GHSC-QA assessment

3.1.6 Primary packaging label language ☐ English ☐ French ☐ Portuguese ☐ Spanish ☐ Other (Specify):
3.1.7 Secondary packaging label language ☐ English ☐ French ☐ Portuguese ☐ Spanish ☐ Other (Specify):
3.1.8 Instructions for use/Package Insert/Leaflet language ☐ English ☐ French ☐ Portuguese ☐ Spanish ☐ Other (Specify):
3.1.9 Patient Information Leaflet language ☐ English ☐ French ☐ Portuguese ☐ Spanish ☐ Other (Specify):

3.2 Assays - Transport, storage and operating temperatures

3.2.1 List transport, storage and operating temperatures and shelf life

Product name (If more than one box, provide the name for each reagent box)	Transport temperature range (min °C - max °C)	Storage temperature range (min °C - max °C)	Operating temperature range (min °C - max °C)	Shelf-life upon manufacture (months)

3.2.1 Describe any other storage conditions that are applicable to this product:

3.3 Instrument

If the instrument manufacturer is the same as the assay manufacturer, please complete 3.3.1 – 3.3.7 If the instrument manufacturer is NOT the same as the assay manufacturer, please complete 3.3.1 – 3.3.13			
3.3.1	Instrument name and product code	Instrument name: Product code/catalog number:	
		Instrument name: Product code/catalog number:	
		Instrument name: Product code/catalog number:	
3.3.2	The instrument platform	☐ Automated/semi-manual Point of Care	
		☐ Centralized laboratory testing	
3.3.3	Do you provide the training of instrument use to the end users?	☐ Yes	
		☐ No	
3.3.4	How do you handle the instrument software update?	Please describe or attach a separate document for the software update process (e.g., SOP)	
3.3.5	Do you provide the instrument maintenance and repair?	☐ Yes	
		☐ No If No, complete 3.3.6	
3.3.6	Do you contract a 3rd party (e.g. distributor or instrument service provider) for the instrument maintenance and repair?	☐ Yes If Yes, complete 8.1.12 – 8.1.16	
		☐ No If No, please describe the process of instrument maintenance and repair	
3.3.7	Do you allow lease rental of the instrument?	☐ Yes	
		☐ No	
Complete the following if the instrument manufacturer is NOT the assay manufacturer			
3.3.8	Instrument legal manufacturer		
3.3.9	Manufacturer physical address	Street Name and No.:	
		City:	
		Postcode:	Country:
3.3.10	Manufacturer postal address	Street Name and No.:	
		Postal Office Box No.:	
		City:	
		Postcode:	Country:

3.3.11 Manufacturer telephone	
3.3.12 Manufacturer email & web address	
3.3.13 Name of parent company (if applicable)	

4.0 PRODUCT - DISEASE CATEGORY, ANALYTE AND METHOD

4.1 HIV

4.1.1 Select HIV viral load assay methodology	
☐ HIV-1 RNA PCR	☐ Branched DNA
☐ Nucleic acid sequence-based amplification	☐ Reverse transcriptase
☐ Recombinant assays	
4.1.2 Identify HIV target selection (types and subtypes)	
☐HIV-1 • HIV1 subtypes -A, B, C, D, F, G, H, J and K ☐ A ☐ B ☐ C ☐ D ☐ F ☐ G ☐ H ☐ J ☐ K	☐ HIV-2

4.2 Specimen type

4.2.1 Select the specimen type(s) to be used with the product
☐ Plasma
☐ Capillary whole blood
☐ Dried blood spot
☐ Other: (Specify)

4.3 Product Stability Study

4.3.1 Stability studies		
Stability Study	Document Title and ID	Completion Status
Shelf-life stability study		
In-use stability study (if applicable)		
Transportation stability study (if applicable)		

4.3.2 Shelf-life and storage	
Shelf-life as it appears on the packaging	☐ 24 months ☐ 36 months ☐ 48 months ☐ Other *(Specify)*:
Storage conditions for this product as they appear on the packaging and based on stability studies	

4.4 Final Product Release Specification

[Describe functional characteristics and technical performance specifications for the device including as relevant, accuracy, sensitivity, specificity of measuring and other specifications including chemical, physical, mechanical, electrical and biological.]

Attach a copy of the release and shelf-life specifications for the final product

Attach a copy of Certificate of analysis of three (3) most recent batches released (whichever is greater)

Attach a copy of Certificate of Analysis of the most recent batch (1 batch) from the independent 3rd party testing facility (if applicable)

5.0 PRODUCT – OPERATION

5.1 Assay controls

5.1.1	For NAT assays, does the assay contain an internal (amplification) control?	☐ Yes ☐ No
5.1.2	Are control specimens (also called test-kit controls) such as positive, negative, low or high controls, supplied within the test kit or available separate of the test kit? If no answer is selected, no control specimens are assumed to be available.	☐ Within ☐ Separate

5.2 Product usage

5.2.1	How long does it take to obtain a test result (time required from specimen collection to the final result being read)?		Minutes
5.2.2	State the minimum and maximum number of specimens (excluding controls) that can be tested in a single run	Minimum	Maximum
5.2.3	If instrument-based, select the technology throughput per day		

☐ 0-20 tests/day per operator
☐ 20-50 tests/day per operator
☐ 50-100 tests/day per operator
☐ > 100 tests/day per operator

5.3 3rd Party services providers (Including assay manufacturer's affiliated companies, or another company under the same parent company)

Type of services	Service provider name and address	Contact information
Quality Incidents (Complaint handling)		
Instrument maintenance and repair		
Procurement logistics		
Other, please specify		

6.0 PRODUCT – PERFORMANCE CHARACTERISTICS

6.1 Specifications for virological technologies

6.1.1 Provide the manufacturer's performance specifications for this product	
Sensitivity % (95% confidence intervals)	**%** (**to** _____) **%**
Specificity % (95% confidence intervals)	**%** (**to**_____) **%**
Precision (CV%)	**%**
Bias (%)	**%**
Limit of detection (LOD)	
Dynamic range	
Invalid rate	**%**

7.0 REGULATORY AND COMMERCIAL STATUS OF THE PRODUCT

7.1.1 State the regulatory version of the product submitted for GHSC-QA Assessment (please tick and enter the approval period):
Provide copies of ticked approvals

Name of jurisdiction	Type of regulatory approval	Product name Product code Period of approval: Start (DD/MMM/YYYY) - Expiry (DD/MON/YYYY)
European Community (CE-mark) Directive 98/79/EC	☐ Self-declared CE-mark, Annex III	
	☐ Full quality assurance certificate, Annex IV.3	
	☐ Product design examination certificate, Annex IV.4	
	☐ Type examination certificate, Annex V	
	☐ Production quality assurance certificate, Annex VII	
WHO Prequalification	☐ Product is in the list of WHO prequalified products.	
	☐ Product submitted for WHO prequalification, but not yet prequalified. Date of Submission *(DD/MON/YYYY)*: WHO reference number:	

United States of America (FDA)	☐ Premarket Approval (PMA)	
	☐ 510(k) clearance	

7.1.2 Provide details of <u>any other</u> current regulatory approvals for this product (Do <u>not</u> include ISO 13485 certification details here. This is covered in question 8)		
Name of regulatory authority/jurisdiction	Type of regulatory approval	Product name Product code Period of approval: Start (DD/MON/YYYY) - Expiry (DD/MON/YYYY)

7.1.3 Provide a copy of the inspection certificate and/or inspection closing letter (when available) in the last 3 years by WHO or USFDA			
Type of Inspection	Authority	Inspection Dates	CAPA Status

PART III. QUALITY MANAGEMENT SYSTEM

Section 8 – 9 is required only once if all submitted platforms and products are manufactured at the same site. If the products are manufactured at the different manufacturing site, a separate questionnaire should be completed.

8.0 MANUFACTURER - QUALITY MANAGEMENT SYSTEM

Include a comment reference number, where applicable. Comments by reference should be provided in Section 10

8.1.1	Does the manufacturer have a quality management system in place for the design, development and production of this product?	☐ Yes	☐ No	☐ Comment #
8.1.2	Quality Management System ISO 13485 Medical devices — Quality management systems — Requirements for regulatory purposes *Attach a copy of the most recent valid certification*	☐ Yes	☐ No	☐ Comment #
8.1.3	Other Certifications or licenses issued by a regulatory authority *Attach a copy of the most recent valid certification*	☐ Yes	☐ No	☐ Comment #
8.1.4	Does the manufacturer have the procedures to provide the training of the testing to the end users? *Attach a copy of the procedures or training program*	☐ Yes	☐ No	☐ Comment #
8.1.5	Does the manufacturer provide installation and the training of the instrument to the end users?	☐ Yes	☐ No	☐ Comment #
8.1.6	Do you retain samples of product lots extending to or beyond the product expiration date? *Attach SOP for sample retention*	☐ Yes	☐ No	☐ Comment #
8.1.7	Do you outsource any product testing activities? *If yes, attach name and address of lab(s) and testing activities outsourced, and a copy of Certificate of Analysis as example.*	☐ Yes	☐ No	☐ Comment #
8.1.8	Do you have a procedure for receiving and managing customer complaints? *Attach SOP for handling complaints*	☐ Yes	☐ No	☐ Comment #
8.1.9	Do you have the procedure for recall/market withdrawal/safety alert activities? *Attach SOP for handling recalls/market withdrawal/safety alert activities*	☐ Yes	☐ No	☐ Comment #
8.1.10	Do you have the procedure for out-of-specification (OOS) investigation? *Attach SOP for handling OOS*	☐ Yes	☐ No	☐ Comment #
8.1.11	Do you have procedure for handling temperature excursion during the transportation? *Attach SOP for handing temperature excursion*	☐ Yes	☐ No	☐ Comment #

8.1.12	Do you have written procedure for 3rd party (e.g., instrument manufacturer, distributor, equipment maintenance/repair provider, etc.) service evaluation/re-evaluation process? *Attach the procedure of evaluation process*	☐ Yes	☐ No	☐ Comment #
8.1.13	Does QA participate in the 3rd party service evaluation/re-evaluation process?	☐ Yes	☐ No	☐ Comment #
8.1.14	Do you have Quality Agreement with 3rd party service providers? *Attach Quality Agreement or describe the elements in Quality Agreement especially the responsibility of the 3rd party service providers*	☐ Yes	☐ No	☐ Comment #
8.1.15	Does your staff or a contracted external inspection group perform audit of 3rd party service providers? *If yes, attach SOP for the audit of 3rd party service providers*	☐ Yes	☐ No	☐ Comment #
8.1.16	Do you have the procedure/agreement with 3rd party service providers in complaints handling? *If yes, attach SOP for the procedure or describe complaint handling with 3rd party service providers*	☐ Yes	☐ No	☐ Comment #

9.0 INSTRUMENT MANUFACTURER – QUALITY MANAGEMENT SYSTEM CERTIFICATION

Complete this section if Instrument Manufacturer is NOT the same as the Test Kit Manufacturer		
Type of QMS e.g. ISO 13485:2003 ISO 13485:2016	Name of certification body	Current period of certification Start (DD/MON/YYYY) - Expiry (DD/MON/YYYY)

10.0 MANUFACTURER COMMENTS

Use this section to include the comments referenced in above sections
Comment #_: Comment #_:

PART IV. MANUFACTURING INFORMATION

11.0 MANUFACTURER - SITES OF PRODUCT MANUFACTURE

11.1 Sites of manufacture

11.1.1 List all sites that are involved in the manufacture of this product. Include all stages of manufacture		
Description of the stage of manufacture	Name of site	Physical address of site
Assembly of device (list **all** sites from raw materials to components to finished product)		
Labelling		
Packaging		
Lot release QC		
Release for supply		
Other:		

11.2 Production

11.2.1 How many lots (of assay/test) do you manufacture per year?	Lot per year
11.2.2 What is the average size of a lot?	
11.2.3 How many assay/tests/devices in total do you manufacture per year?	assay/tests/devices per year
11.2.4 How many instruments in total do you manufacture per year?	instruments per year

PART V. MANUFACTURER AUTHORIZATION AND ATTESTATION

12.0 AUTHORIZATION FOR SHARING INFORMATION

☐ I, the undersigned [ENTER FULL NAME], confirm that the company has no objection to the information contained herein being shared with USAID and implementing partners, WHO, UNFPA and/or The Global Fund. If approved, the approval (including product identification, manufacturing sites, approved specifications and publicly available information) may also be shared with other procurement agencies. I, the undersigned, understand that any publicly available information may also be subject to disclosure by USAID under the Freedom of Information Act.

☐ I, the undersigned [ENTER FULL NAME], object to sharing the information contained herein with [SPECIFY]. However, I, the undersigned, understand that any publicly available information may also be subject to disclosure by USAID under the Freedom of Information Act.

Name	Signature	Date *(DD/MON/YYYY)*
Full title/Position	Company name	

13.0 MANUFACTURER ATTESTMENT

ATTESTMENT

I_____ (insert name) am authorized by (name of company) to provide the information requested in this application and certify that all information is correct and true and documentation is available upon request that will validate all responses.

Signature:	Date:
Print Name:	
Title and Position	
E-mail:	Phone