

# Request for Proposals: Laboratory External Quality Assessment (EQA) Proficiency Testing Program in Kenya

*Issued: 1 March 2016*

*Responses due: **no later than 17:00 Eastern Standard Time (EST)/21:00 Coordinated Universal Time (UTC) 31 March 2016***

*Submit responses to:*

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## Background

The Association of Public Health Laboratories (APHL) through Cooperative Agreement U2GGH001097 (CFDA No. 93.067) with the U.S. Centers for Disease Control and Prevention (CDC), Division of Global HIV and AIDS Program is supporting the President's Emergency Plan for AIDS Relief (PEPFAR). APHL has worked with CDC as an implementing partner for the laboratory components of PEPFAR since the program was first established.

The procurement sought under this Request for Proposals (RFP) reflects one component of APHL's efforts to promote the overarching PEPFAR goal of strengthening health system capacity and services in Kenya. A complete description of PEPFAR may be found at <http://www.pepfar.gov/about/>.

Through this RFP APHL is soliciting proposals from proficiency test providers or suppliers (PT Providers) that have the capacity and experience to procure and deliver the proficiency testing (PT) items and panels that will be needed for the External Quality Assurance (EQA) programs administered by the Kenyan Ministry of Health (MoH) National Public Health Laboratory Service (NPHL).

Further information on the nature of the EQA programs and the PT procurement may be found in the [Overview of EQA and PT Program Structures](#) section of this RFP below. In addition, APHL has provided a list of the [Acronyms and Abbreviations](#) used in throughout this document, and some very basic background information regarding [EQA Terminology](#) in the final sections of this RFP.

## Eligibility

Any company or organization with the experience and capacity needed to deliver the goods and services discussed in this RFP and that meets the criteria specified in [Review Process – Phase 2](#) is eligible to apply.

APHL reserves the right to request that applicant PT Providers submit one or more reference letters from prior customers in order to show that the provider has the necessary experience and capacity. If APHL elects to require reference letter(s), the association will issue a public notice on APHL's procurement website ([www.aphl.org/rfp](http://www.aphl.org/rfp)) and will directly contact any PT Provider that submitted a completed application prior to the date of the public announcement.

## Anticipated RFP Schedule

At this time, APHL anticipates the following schedule:

01 March 2016	– RFP issued
31 March 2016	– RFP responses due
15 April 2016	– Phase 1 and Phase 2 review of responses complete
02 May 2016	– Phase 3 review presentations held in Nairobi, Kenya
15 May 2016	– Phase 3 review complete and selected PT Provider announced

Any modification to this RFP schedule will be communicated on APHL's procurement website.

## Term of Project; Projected Procurement and Implementation Schedule

This project will be funded on the Cooperative Agreement funding cycle, with each funding year starting on 01 April and ending on 31 March of the following year. APHL anticipates that this project will have an initial term of less than 12 months starting as soon as possible after APHL and selected PT Provider ratify the contract discussed below and ending on 31 March 2017, with a possibility of up to two (2) additional 12-month procurement periods (for a total of up to slightly less than three (3) years).

The specific terms and conditions related to the selected PT Provider's work on the project – including the project implementation and milestone schedule and the invoice and payment terms for a funding cycle – will be contained in a contract developed annually by APHL. The selected PT Provider will not be able to start its work in a funding cycle until it has reached agreement with APHL on the contract terms and the agreement for that funding cycle has been ratified.

The number of EQA program events in any annual funding cycle, and the amount of the PT materials and panels that the PT Provider will need to procure for a given event will likely vary depending on the level of Cooperative Agreement funding available and the needs of MoH NPHL's EQA programs. Accordingly, PT Providers responding to this RFP should include cost proposals based on one, two and three events per year in their response.

Once the PT materials and panels have been procured and distributed, the EQA program will train users on how to perform the proficiency testing and submit the PT reports to the PT Provider for analysis and feedback. Once a test event is complete, the PT Provider will review and analyze the test results and will prepare detailed reports as described below in [Appendix 2: Example of reporting requirements](#). The PT Provider will send these reports to participating NPHL laboratories and the NPHL Quality Assurance (QA) Office and will also transmit overall summary reports of test event performance to CDC and APHL. APHL

will require the PT Provider to closely collaborate with the NPHL QA Office to implement all of the PT programs and to develop any needed corrective action.

## RFP Response Submission Details

**The deadline for responses is 17:00 (U.S. Eastern Standard Time) on 31 March 2016. Proposals received after this time will not be considered and proposals that remain incomplete as of this time will not advance beyond Phase 1 of the evaluation described in [Review Process – Phase 1](#) below.**

A PT Provider's response must include the following material; responses that omit one or more of the required material will be considered incomplete and will not proceed to Phase 2 of the evaluation.

- Responses must include enough information to allow the reviewers to determine whether the respondent can competently provide all PT program services and fulfill all PT program requirements.
  - Competency will be determined based on the PT Provider's ability to meet the criteria set forth in ISO/IEC 17025 and/or ISO/IEC 17043.
  - The responses should include detailed descriptions of how the PT Provider will meet each of the points discussed in the [General Proficiency Test Program Requirements](#) and [Additional Considerations and Requirements](#) sections of this RFP below.
- Responses must contain the pricing and cost information requested on [Appendix I – PT Provider Cost Worksheet](#). All cost must be specified in US Dollars.
- Responses must include a separate section or separate document that provides the following information about the PT Provider:
  - Full legal name and place of incorporation or formation. In addition, if the PT Provider has a "doing business name" it must include its d/b/a name as well.
  - Authorized representative of the PT Provider for each of the following:
    - A programmatic representative for purposes of creating a detailed scope of work for each funding cycle and for questions or queries about procurement status or program items.
    - A financial or accounting representative for purposes of addressing concerns or questions on invoices or expense reimbursement requests.
    - A legal or operational representative for purposes of negotiation of the contract and addressing any contractual issue.
  - Telephone, fax and email address of a single, primary point of contact for communication between APHL and the PT Provider (it may be one of the authorized representatives discussed above or it may be another individual) and each person identified by the PT Provider as an authorized representative.
    - In addition, the PT Provider may provide contact information for additional individuals to whom the provider would like APHL to deliver a duplicate or informational copy of the information sent to the single point of contact.
  - A business mailing or postal address for the business.
  - Name and contact information of at least three previous customers of the PT Provider for whom they have provided similar services.

Responses may be sent to APHL using one of the following three methods: (1) by email as an attachment in MSWord or PDF format (electronic signatures accepted) to [LISproposal@aphl.org](mailto:LISproposal@aphl.org); (2) by fax to +1-240-485-2700 attention of Esther Gathinji, Specialist, Global Health Program, APHL; or (3) by courier/delivery service that has a tracking system or by U.S. Postal Service (USPS) Priority or Express Mail to Esther Gathinji, APHL, 8515 Georgia Avenue, Suite 700, Silver Spring, MD 20910 USA. Email and fax responses must be received at the APHL office by 17:00 EST/21:00 UTC on 31 March 2016. Courier and USPS responses must be postmarked or entered into a tracking system by 17:00 EST/21:00 UTC on 31 March 2016. APHL prefers that responses are sent as an attachment to email and encourages that submitting PT Providers use this delivery method if at all possible. Submitters should request a delivery receipt or read receipts for an email submission. In every case, submitters will receive a confirmation of receipt of their proposal from APHL. APHL may terminate or modify the RFP process at any time during the response period.

APHL will have no obligation to evaluate responses that are not fully received by the stated deadline and currently does not anticipate reviewing such responses, but APHL may, in its sole and absolute discretion, consider late proposals if their inclusion in the review process does not materially impact the evaluation process.

In addition, APHL may terminate this RFP at any time during the competitive bidding process by posting a notice on APHL's procurement website and by delivering written notice by email to the PT Providers who have submitted a completed submission prior to the termination date.

## General Proficiency Test Program Requirements

Submissions from PT Providers will be evaluated against the following requirements.

- The submitter must be able to accurately conduct inter-laboratory comparisons and have access to expertise with the types of PT test items provided.
- Strong preference will be given to a submitter that possesses a valid certificate of accreditation as a Proficiency Testing Scheme Provider using inter-laboratory comparisons in accordance with ISO/IEC 17043:2010-17043.
- If the submitter does not possess the valid certificate of accreditation noted above, the submitter must include evidence or provide sufficient information of capabilities, capacities and competencies, and contractual agreements with any accredited or qualified subcontractors.
  - The submitter may only subcontract planning of the scheme, the evaluation of performance or authorization of the final report to a third party that possesses a valid certificate of accreditation as a Proficiency Testing Scheme Provider using inter-laboratory comparisons in accordance with ISO/IEC 17043:2010-17043 and that third party will not be able to further subcontract work on any of these services.
  - In addition, the submitter must demonstrate the following abilities and experience:
    - Appropriate technical, statistical and administrative skills;
    - Ability to submit results online and generate online PT reports;
    - Competence of PT Provider's laboratory if not an accredited provider
    - Proposed testing methodologies and sample distribution logistics;
    - Proposed project reporting and follow up; and
    - Previous experience working with MoH or one or more PEPFAR funded organizations.
- If the submitter will utilize one or more third parties to provide a portion of the services to be rendered, each third party must possess a valid certificate of accreditation as a Proficiency

Testing Scheme Provider using inter-laboratory comparisons in accordance with ISO/IEC 17043:2010- 17043 and the submitter's proposal must specify the services that will be provided by each third party and must also detail the measures the submitter will take to ensure that each third party complies with applicable APHL contract terms.

- If two or more responses are substantially similar in overall qualifications and competencies, PT Providers with East Africa or Kenya registration will be preferred.
- The submitter must provide a detailed cost proposal for panels and the administrative, statistical analysis and management services related to the proficiency testing events.
- The PT Provider shall be willing to cooperate with participants and other customers in clarifying customers' requests and in monitoring the PT Provider's performance in relation to the work performed, provided that the PT Provider assures confidentiality to its participants.

## Evaluation Criteria and Review Process

Proposal submitted in response to this RFP will undergo a three-phase review process. Incomplete proposals will not advance to Phase 2 and only four (4) or fewer proposals will advance to Phase 3, as described below.

### Review Process – Phase 1

APHL Global Health Department staff will initially look through responses to determine whether or not a submission is complete. APHL will have the right to disqualify incomplete applications or applications from PT Providers who have violated the terms of this RFP (including the terms found in the [Additional Information and Designated Contact](#) section below). APHL staff may notify PT Providers that their application is incomplete, but no submission extension will be granted. The notified PT Provider will have until the response submissions deadline to provide any missing material.

### Review Process – Phase 2

During Phase 2 of the evaluation process, APHL will review all responses received by the submission deadline against the criteria set forth in the [RFP Response Submission Details](#) and [General Proficiency Test Program Requirements](#) sections above and the [Additional Considerations and Project Requirements](#) section below. A blank version of the evaluation form and scoring system that will be used during Phase 2 may be found in [Appendix 3: Review Process Phase 2 – Evaluation Form](#) of this RFP. Although not anticipated, APHL may post scoring guidance or other supplemental review information on [APHL's procurement website](#). APHL encourages all submitters to check the site periodically for updates.

Once the Phase 2 review team has completed their review, APHL will select up to four (4) proposals that the review committee determined were from submitters who satisfy the eligibility criteria and whose proposals best meet the RFP requirements. Only the selected proposals will be considered in a second part review.

### Review Process –Phase 3

The third and final phase of review will involve the top submissions (no more than four (4)), identified during Phase 2 of the review process. The selected providers will present their proposals to the Phase 3 review panel at an in-person meeting to be held in Nairobi, Kenya. The date(s) and location of this panel meeting will be determined by APHL in consultation with CDC and MoH. APHL staff will convey the meeting details to the qualifying PT Providers as soon as details are finalized.

The Phase 3 review panel will have its own evaluation criteria and form. APHL anticipates that it will distribute summaries of the Phase 3 review criteria, and a blank copy of any review form to the finalist PT Providers prior to the date of the in-person meeting.

During the Phase 3 review period, staff from APHL's Legal Department will conduct preliminary compliance checks on the finalist PT Providers. This compliance check will serve the following purposes:

- To validate that a PT Provider is neither excluded nor debarred from receiving funding from the U.S. Federal Government.
- To verify that a PT Providers does not appear on the Specially Designated Nationals List maintained by the Office of Foreign Asset Control of the U.S. Department of Treasury.
- To gather the information necessary (including a DUNS number for a vendor) to file any reports required under the Federal Funding Accountability and Transparency Act of 2006 (FFATA).

## Evaluation Team

APHL Global Health Department staff will verify whether or not a submission is complete. The Phase 2 review will be conducted by three (3) APHL member-consultants with technical expertise in implementing or improving EQA programs in the global health arena. The Phase 3 final bid selection stage will have up ten (10) reviewers comprised of key NPHL and CDC-Kenya representatives, with APHL staff coordinating and organizing the process.

APHL staff will ask potential reviewers to verify that they have no actual or potential conflict of interest that might inhibit their ability to make objective and unbiased decisions during the review. If an actual and verifiable conflict of interest is raised, the individual with the conflict will not be allowed to serve on the review committee. APHL may, in its sole discretion, also provide a code of review conduct to the reviewers.

Any change or modification to the expected structure of the evaluation teams will be posted on APHL's procurement website.

## Post-Evaluation Procedures

The selected PT Provider will be notified by APHL staff within ten (10) business days of the completion of the evaluation and the names of the winning provider will be posted to APHL's procurement website, [www.aphl.org/rfp](http://www.aphl.org/rfp) on the same day. Unsuccessful providers will receive notification of these results by e-mail or by standard international post within 45 days of the date the name of the winning vendor is posted.

All applicant PT Providers will be entitled to utilize APHL's RFP Appeals Process to formulate a protest regarding alleged irregularities or improprieties during the procurement process. Specific details of this policy are located on the procurement website.

## Conditions of Award Acceptance

- The selected PT Provider must be able to contract directly with APHL or have an existing relationship with a third-party organization that can contract directly with APHL on its behalf.
- Prior to issuing the initial contract, APHL will require the selected PT Provider to provide a final quotation for the offer. The final offer will permit inclusion of changes that may arise in

deliverables or conditions of the implementation during the negotiation that are approved by APHL.

## Additional Information and Designated Contact

APHL has identified the following individual is the designated point of contact for this RFP:

Esther Gathinji  
Specialist, Global Health  
Association of Public Health Laboratories  
8515 Georgia Avenue, Suite 700  
Silver Spring, MD 20910

Questions regarding general requirements or technical aspects of the application described in this RFP must be directed via email to Esther Gathinji at [LISproposals@aphl.org](mailto:LISproposals@aphl.org). Questions received from interested PT Providers, together with the answers provided by APHL staff will be posted to APHL's procurement website.

Interested PT Providers are prohibited from discussing or communicating about the content of this RFP with anyone other than the designated point of contact identified above. PT Providers may not communicate with any other employee of APHL an employee of MoH or CDC who is involved in the project, or any staff member at the NPHL laboratories, except as authorized in writing by the designated point of contact, during the period from the RFP's release until the name of the selected PT Provider has been listed on APHL's procurement website. Unauthorized contact concerning this RFP may disqualify the respondent from participating in the RFP process (and the respondent's proposal may not be considered in the review of respondents).

## Additional Considerations and Project Requirements

The following factors will also be considered during the review process and parties submitting a response are strongly encourage to provide evidence or information related to the following in their proposal.

- Produce and validate EQA PT materials and associated tools/forms
- Procurement, handling and distribution of proficiency panels.
  - The proficiency testing provider shall ensure that purchased supplies, equipment and consumable materials that affect the quality of proficiency testing schemes are not used until they have been inspected or otherwise verified as complying with specifications or requirements. Records of actions taken to check compliance shall be maintained.
  - The PT Provider should ensure that during packaging and distribution of specimen, quality of panels is not affected.
  - Shipments:
    - Provide information on specimen handling, preparation and storage before or during shipment and measures that will be taken in the event of lost or damaged proficiency test items.
    - Provide documentation of receipt and distribution of samples to participants.
- Training
  - Sensitization training to new facilities.

- Informatics training to new facilities/QA officers.
- Root cause analysis and corrective action training to National QA office personnel and participating facilities.
- Offer technical assistance to the national and county EQA coordination units in regards to the EQA PT test events.
- Data statistical analysis
  - The PT provider will provide information regarding comparison of results obtained by different test or measurement methods.
- Performance evaluation
  - Determination of results: Proficiency test results and scoring, and the outcome of the PT round sent to participants and NPHL QA office.
- Reporting
  - Types of reports: PT distribution and participation outcome report, test program performance reports, individual facility performance, comparison performance report for a year/ rounds for each program, summary by county of participation. Example of reporting requirements is shown in [Appendix 2: Example of reporting requirements.](#)
- Records
  - The PT Provider should retain records of all technical data from each PT round. Data should be readily retrievable and a retention time of records should be established.
  - The PT Provider must ensure that the identity of participants in the PT scheme and all information supplied by a participant be treated as confidential.
- Currently NPHL is in the process of developing its own integrated EQA PT database. Once this is finalized PT Provider will be required to share certain historical data based on the agreed data elements to be imported into this database. At this point in time we do not have specifics on the extracts and imports.

NOTE: Reports posted on the web will only be accessible by people with the correct permissions. Additionally, access to PT Provider online system/database MUST be given to MoH National QA officer

PT Provider may also provide the following information on performance reports:

- Possible sources of error
- Situations where certain factors made the evaluation of results impossible
- Advice and educational feedback to participants

### **Notification**

PT Provider will be expected to provide notification to all participating facilities during panels' dispatch/distribution, five days to closure of results entry and on the closing date of the online results entry.

### **Outcome reports**

The outcomes of the tests performed at a facility will be returned to the laboratory manager /designate responsible for the managing that test panel at the facility. This could be either through



- Email
- Posted on the website (and only accessible by the person configured)

### **User permission**

As noted in this document, there will be various individuals will role permissions;

Participants will need access to data entry screens for the programs they are enrolled. A participant should be able to see their own reports.

A national QA manager should have access to all the data for the public (MoH) laboratories. This person is designated by the Head NPHL.

## **Overview of EQA and PT Program Structures**

APHL in consultation with NPHL QA office and CDC will decide on PT test schemes to be offered for each participant. In the initial funding period APHL anticipates supporting up to 104 participants located throughout Kenya. The final level of support will depend on the funding made available to APHL. Once a PT Provider is selected, facility demographics will be provided.

The following is a list of test programs that may be offered as part of the EQA programs:

- **Core analytes**
  - HIV
    - HIV Rapid Test
    - ELISA
    - Viral load
    - EID PCR
  - Lymphocyte immunotyping
    - CD4 + (T helper cells) count
    - CD3 + count
  - Tuberculosis Laboratory
    - AFB Smear
    - GeneXpert
    - Drug Sensitivity
- **Other analytes**
  - Bacterial identification
    - Gram Stain
    - Culture Identification
    - Microbial Susceptibility Test
  - Malaria
    - Malaria Microscopy
  - Basic Biochemistry
    - Urea
    - Alkaline Phosphatase
    - Albumin

- Bilirubin-Total
- Bilirubin-Direct
- Calcium
- Chloride
- Chol-Total
- Chol-LDC
- Chol-HDL
- Creatine
- Glucose
- Gamma GT
- Potassium
- Protein total
- Sodium
- Uric acid
- TSH
- T3
- Basic Hematology
  - HB
  - WBC
  - RBC
  - MCV
  - Hematocrit
  - Platelets
  - RDW
  - MCH
  - MCHC
- Urinalysis
  - Crystal identification
  - HB
  - Protein
  - Urobilinogen
  - Specific gravity
  - Ph
  - Ketones
  - Bilirubin
  - Glucose
- Basic transfusion
  - ABO blood grouping
  - Rhesus (Rh) typing
- Blood parasite identification
- Treponema
- Brucella antigen test
- Rheumatoid factor
- Antigen pregnancy test

**NOTE:** PT Providers must consider the then-current World Health Organization (WHO) requirement on procedures and grading system where applicable when developing their methodology on results reporting.

## EQA Terminology

EQA and participating laboratories have a specialized language and often terms are used interchangeably and may have slightly different uses between countries or programs. PT Providers should refer to ISO/IEC 17043 for terms and definitions (a copy of which may be purchased at [http://www.iso.org/iso/catalogue\\_detail?csnumber=29366](http://www.iso.org/iso/catalogue_detail?csnumber=29366)).

## Acronyms and Abbreviations

APHL – Association of Public Health Laboratories

CDC – Centers for Disease Control and Prevention

EQA – External quality assurance

MoH – Ministry of Health

NPHL – National Public Health Laboratories

PEPFAR – United States President’s Emergency Plan for AIDS Relief

PT – Proficiency testing

PT Provider – Proficiency test provider or supplier

QA – Quality assurance

RFP – Request for Proposals

## APPENDICES

### Appendix I – PT Provider Cost Worksheet

#### Required Costs

As part of their proposal PT Providers must submit pricing for each of the following:

- Unit cost of sample
- Cost of sample per facility
- Cost of distribution to participants
- Shipping costs
- Service fees
- Other related cost fees (including any applicable training fees or costs)

Submitters must include pricing and costs based one, two and three PT events in an annual funding cycle.

#### Additional Costs

As detailed annual procurement requirements are developed by NPHL in collaboration with CDC and APHL, unanticipated or additional material or services may be needed. In these instances, APHL will expect the selected PT Provider to submit per unit costs to provide the materials or perform the services needed for the additional work outside of the requirements contemplated in this RFP.

## Appendix 2: Example of reporting requirements

These examples are only a guideline and the selected PT Provider will work with NPHL (and as needed APHL) to develop the specific reporting that will be required in connection with each PT event.

### A. Following Each Test Event

1. Summary of results for all PT specimens shipped in the event
  - a. Overall acceptable, unacceptable and results not evaluated for the test event
  - b. Details on results not evaluated for test event including reasons why results were not evaluated or evaluable.
  - c. Participation rate of all laboratories for the test event. If not 100% provide reason (s) for non-participation of missing facilities.
2. Overall Performance by Program
  - a. Performance by specialty, sub-specialty, test or analyte as appropriate (one chart for each class of test service that will be defined in the contract) e.g. hematology, Malaria, Biochemistry, CD4, etc.
3. Performance by test event for each Facility/Participant (This report goes to the facilities & MoH-NPHL QA office).
  - a. Overall performance
  - b. Acceptable, unacceptable and results not evaluated for test event by program.

### B. Following test event consequent test events

4. Include comparisons for previous test events as indicated above in 1a-c, 2 & 3.
5. Test Event comparison by Participant for each program

### Appendix 3: Review Process Phase 2 – Evaluation Form

## Laboratory External Quality Assessment Proficiency Testing (PT) Program

### Evaluation form for PT Providers

Name of the PT Provider being evaluated.....

Criteria	Maximum points	Given point	Comments
<b>Experience</b>			
<ul style="list-style-type: none"> <li>• History of providing PT panels (5)</li> <li>• Experience working with MoH (5)</li> <li>• Ability to demonstrate competency as PT provider/ valid accreditation certificate ISO 17043:2010 (15)</li> <li>• Capacity to provide training as contained in the RFP (5)</li> </ul>	30		
<b>PT Panels</b>			
<ul style="list-style-type: none"> <li>• Range of PT panels available (12)</li> <li>• Ability to obtain, store and distribute PT panels to participating laboratories (10)</li> <li>• Timely feedback of performance results (8) Follow up for poor performing facilities (8)</li> </ul>	38		
<b>Data Analysis and Report</b>			
<ul style="list-style-type: none"> <li>• Facilitate result reporting (paper based or web-based) (5)</li> <li>• If web-based does the system support: (5)               <ul style="list-style-type: none"> <li>○ multiple level login (users with different access rights)</li> </ul> </li> </ul>	20		

<ul style="list-style-type: none"> <li>○ Provision of web support when using the system?</li> <li>○ data security measures are in place for the system</li> <li>● capability to collate and analyze continuous data over time and generate summary EQA reports for the MoH (10)</li> </ul>			
<b>Project management plan</b>			
<ul style="list-style-type: none"> <li>● Provided an annual schedule for test events (4)</li> <li>● Provide a detailed logistics management plan for shipping, handling, distribution of panels (8)</li> <li>●</li> </ul>	12		
<b>Cost</b>			
<ul style="list-style-type: none"> <li>● Unit cost per panel/program</li> <li>● Annual program cost</li> </ul>			
<b>Total</b>	<b>100</b>		