Request for Proposals: Facilitating Test Verification and/or Modification of Algorithms for Detection of Infection with Mycobacterium Tuberculosis with Interferon Gamma Release Assay (IGRA)

Application Due date: August 31, 2018
Submit to: Anne Gaynor, Manager of HIV, Viral Hepatitis, STD and TB (Anne.Gaynor@aphl.org)
Summary

The Association of Public Health Laboratories (APHL), in cooperation with the US Centers for Disease Control and Prevention (CDC) Division of Tuberculosis Elimination (DTBE), is seeking to award one-time funding for up to thirteen (13) state or local public health laboratories (PHLs) for the purpose of facilitating validation verification studies and/or modification of test algorithms for Interferon Gamma Release Assays (IGRA) to aid in diagnosis of Mycobacterium tuberculosis infection. Funds may be used to perform verification studies to newly implement IGRA or to replace an existing test with a newer generation IGRA such as the QuantiFERON-TB Gold Plus. Additionally, laboratories may choose to use funds to modify current testing algorithms (e.g., expand test population). Selected applicants may not use funds to contract with an outside facility to provide testing services. APHL will award funding to selected applicants through a contract.

Background

The prevalence of active tuberculosis (TB) in the United States continues to decline with a case rate of 2.8 cases per 100,000 persons reported as of 2017. Rapid identification of persons with active TB is required to prevent further transmission. It is estimated that up to 13 million individuals in the United States are latently infected with *Mycobacterium tuberculosis*. Without testing and treatment, latent TB infection (LTBI) could develop into active disease in approximately 5–10% of those infected, with some comorbidities (e.g., HIV and diabetes) increasing the risk of progression. Currently there are three FDA approved blood tests known as IGRAs for detection of TB: QuantiFERON-TB Gold In-Tube (no longer commercially available as of June 30, 2018), QuantiFERON-TB Gold Plus both by Qiagen, and T-SPOT.TB test (T-Spot) by Oxford Immunotec Limited. For full details of guidelines and considerations for using IGRAs, please refer to the CDC Guidelines updated in 2010, the ATS/IDSA/CDC Clinical Practice Guidelines from 2017 and the APHL TB Diagnostic Update from 2018.

Please note this is a one-time funding opportunity.

Eligibility

APHL is looking for eligible laboratories. All state or local member public health laboratories are eligible to apply. Laboratories should consult with their jurisdictional TB control program and indicate the joint planning as part of the application. Potential scenarios for applicants include the following:

**Option 1**: The public health laboratory in a given jurisdiction currently does not perform IGRA, but with programmatic input it would like to implement in-house testing capability.

**Option 2**: The public health laboratory performs IGRA but would like to perform verification studies for a replacement test to be offered in-house.

**Option 3**: The public health laboratory in a given jurisdiction would like to modify the current testing algorithm with programmatic input.
Anticipated RFP Schedule

<table>
<thead>
<tr>
<th>Date</th>
<th>Event</th>
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<tbody>
<tr>
<td>August 2, 2018</td>
<td>RFP Issued</td>
</tr>
<tr>
<td>August 13, 2018</td>
<td>Letter of Intent Due to APHL (see below)</td>
</tr>
<tr>
<td>August 31, 2018</td>
<td>RFP Responses Due</td>
</tr>
<tr>
<td>September 7, 2018</td>
<td>Proposal review completed</td>
</tr>
<tr>
<td>September 7-13, 2018</td>
<td>If needed, follow-up interviews and updated proposals due</td>
</tr>
<tr>
<td>September 14, 2018</td>
<td>Final review completed and awardees selected</td>
</tr>
<tr>
<td>September 21, 2018</td>
<td>Draft contracts submitted to APHL Legal Dept. for final internal review</td>
</tr>
<tr>
<td>November 1, 2018</td>
<td>Estimated Start of Contract/Work Begins</td>
</tr>
</tbody>
</table>

APHL will communicate any modification to this anticipated schedule on APHL’s procurement website (www.aphl.org/rfp) and via an email blast to applicants.

Response Submittal

Confirmation of Intent to Respond

APHL requests that prospective applicants submit a brief email statement indicating an intent to submit a proposal. APHL must receive this email by no later than 5:00pm EST on August 13, 2018.

Final Response

APHL must receive complete responses by 5:00 pm EST on August 31, 2018. Please see the Proposal-Required Submissions section for items that must be included in the completed proposal. Applicants may send proposals by the following methods:

- Via email to Anne.Gaynor@aphl.org
- Via Mail (USPS, FedEx, UPS) addressed to:
  Association of Public Health Laboratories
  Attn: ANNE GAYNOR
  8515 Georgia Avenue. Suite 700
  Silver Spring, MD 20910

APHL will send an email acknowledging the receipt of your application. If you do not receive an acknowledgement within 48 hours, please email the RFP points of contact above to confirm receipt.
Award
APHL will award up to $130,000 to various applicants to complete this project. APHL will select up to thirteen (13) laboratories depending on the strength of applications, funding requested and funds available. Each selected applicant will be eligible for an award of $10,000-$25,000 depending on the scope of the proposed project. APHL will distribute funding via a contract to the selected applicants.

Use of funds:
1. Purchasing instrumentation or equipment for the implementation of IGRA; including laboratory or collection site requirements;
2. Purchasing reagents to begin a testing program in-house or supplies for collection;
3. Performing verification studies to establish use of new technologies or methods;
4. In collaboration with TB Control, expanding patient populations in which IGRA is used;
5. Establishing infrastructure for collection sites to perform collection and remote incubation (if applicable);
6. Establishing or improving jurisdictional courier services to ensure timely transport of specimens; and
7. Providing training for laboratory or programmatic staff.

Term of Project
The project term will be from the date of notification through June 30, 2019. The expected contract term will cover the period from November 1, 2018 through June 30, 2019.

Evaluation Team
APHL staff, led by the HHST Program Manager, will conduct an initial review of all proposals for completeness. Any incomplete application on the proposal due date specified in the Anticipated RFP Schedule section above will not be considered and will not receive a formal evaluation.

A team of three subject matter experts (SMEs) from CDC DTBE and a panel of three APHL members selected from non-applicant public health laboratories will review complete proposals. APHL will identify and select SMEs from CDC based on their familiarity with laboratory techniques and project requirements. APHL member experts will be identified from among the non-applicant PHLs by the APHL HHST Program Manager. They will have expertise in the laboratory testing methods described in this RFP, and will have familiarity with collaborating with their TB control program. Once potential reviewers have been identified, APHL’s Director of Infectious Disease Programs will have final approval over the Evaluation Team’s composition.

Conflict of Interest
APHL will ask potential reviewers to complete and sign APHL’s Conflict of Interest Disclosure Statement in order to disclose any real or perceived conflict of interest prior to the start of the evaluation process. Reviewers will have to affirm that they have no conflict of interest that would preclude an unbiased and
objective review of the proposals received. A copy of the disclosure statement and the related Fiduciary Responsibility and Conflict of Interest Policy is attached as Appendix C: Conflict of Interest Disclosure Statement and Policy. APHL will not select reviewers with a perceived or potential conflict of interest.

**Evaluation Criteria**

The evaluation team will evaluate proposals based on responses to the questions in the Proposal – Required Submissions section. They will give a numeric score of up to 100 maximum points based on the scorecard template in Appendix B. Applicants will be given preference based on strong demonstration of programmatic/laboratory collaboration on the proposal, a strong evaluation plan, and a plan addressing sustainability.

**Evaluation Process**

The evaluation team will conduct the review via a combination of email communication between APHL’s HHST Program Manager and the members of the evaluation team, or among the evaluation team members and teleconference and/or webinar evaluation sessions. APHL’s HHST Program Manager will coordinate the review process and the evaluation sessions.

Reviewers may request follow-up interviews with all or some of the applicant laboratories and, following these interviews, may request supplemental information on an applicant’s proposal. The evaluation team will use these interviews and any supplemental information to clarify a laboratory’s capacity or experience in one or more of the evaluation criteria, or to explain other information contained in an applicant’s proposal.

There will be no formal evaluation performed by a member of APHL staff. In cases where all other evaluation criteria are substantially similar, APHL will have the ability to advise the evaluation team on selections that would provide geographical spread or otherwise diversify APHL’s funding allocations. APHL may provide the evaluation team with documentation on an applicant’s past performance in other capacities as part of the evaluation criteria.

**Post-Evaluation Procedures**

APHL staff will notify the selected laboratories within ten business days of the completion of the evaluation and will post the names of the recipient(s) to APHL’s procurement website, [www.aphl.org/rfp](http://www.aphl.org/rfp) on the same day. Unsuccessful applicants will receive notification of these results by e-mail or by U.S. mail within 30 days of the date that APHL posts the names of the selected applicants.

All applicant laboratories are 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 eligible laboratory 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 behalf of the laboratory. Laboratories must agree to comply with budgetary expectations outlined in Appendix A.
Proposal – Required Submissions

To submit a proposal for this one-time funding opportunity, please outline the collaborative approach between the PHL and the jurisdictional TB control program for implementation, verification, or changes to existing test algorithms for IGRA. Responses should be a minimum of three (3) and a maximum of six (6) double spaced pages (font size ≥11 pt. and page margins ≥1 inches), address the following questions, and must comply with submission requirements set out in the Additional Information and Deadlines for Application Submission below.

All Applicants Must Address the Following:

A detailed description of how the applicant and/or program intends to use the funds. This should include up to three measurable, specific objectives that describe the intended impact of the additional funding on laboratory services and addresses sustainability given the one-time funding. Suggested uses for the funds are detailed in the bulleted list in the Award Section.

1. A detailed description of how the laboratory and program plan to evaluate the impact of the award in their jurisdiction and the steps they will take to measure progress towards meeting each stated objective.
   a. Evaluations might include, but are not limited to, test performance, monitoring turnaround times (TAT), assessing the number of requests, identifying new submitters utilizing services, analyzing the positivity rate, and/or improving competency among laboratorians performing the testing.

2. A brief description of the laboratory and jurisdictional TB control program plan to determine and monitor the impact of improvements made by this award.
   a. Describe how the prioritization of specimens accepted for IGRA will be determined and how the applicant will report and use results in accord with the state or local TB control plan (laboratories are encouraged to work with their TB control program to develop these plans).

3. Provide a budget reflecting the requested funding amount as outlined in the Award above. The applicant should divide the budget into the line items outlined in Appendix A of the application package.

4. Provide a letter of support from the applicant’s jurisdictional TB Control Program.

Option 1 Applicants Only:

5. Since testing is not currently performed in-house but will be implemented as part of this funding opportunity, please answer the following based on proposed plans.
   a. Include information on the programmatic need for IGRA and what specific populations will be tested.
   b. Describe the implementation plan including specimen collection (who will be collecting and how will they be trained), remote incubation (if applicable), specimen transport, verification plans, as well as how laboratory and programmatic staff will be trained, how often testing will be performed, and estimated annual and maximum volume.
c. Describe how necessary training will be provided to laboratorians and program staff to enable them to provide guidance and interpretation of IGRA results.

d. Describe any previous experience using IGRA results.

Option 2 and 3 Applicants Only:

6. Please describe the laboratory’s existing IGRA testing service if currently performed in-house.
   a. Describe the programmatic need for IGRA and what populations are currently being tested.
   b. Describe how long the methodology has been in use, how often it is performed, annual and maximum volume, populations tested, and amount of experience laboratory staff has in using the methodology. If the applicant uses remote incubation, please also describe how that fits into the laboratory testing methods.
   c. Does your laboratory and/or program staff have subject matter expertise to provide guidance and interpretation of IGRA results and basic quality control interpretation of results? Please describe qualifications and experience of these staff members.

Additional Information and Deadlines for Application Submission

Applicants must direct all questions to Anne Gaynor at anne.gaynor@aphl.org. APHL will post questions received from interested PHLs, together with the answers provided by APHL or CDC staff to APHL’s procurement website (www.aphl.org/rfp).

Applicants must submit applications to Anne Gaynor at APHL (Anne.Gaynor@aphl.org; 8515 Georgia Ave Suite 700, Silver Spring, MD, 20910; telephone: 240-485-2739; fax: 240-485-2700) with a copy to Nicholas Ancona (Nicholas.ancona@aphl.org).

APHL must receive applications, attention Anne Gaynor by close of business (5:00pm ET) August 31, 2018. Either electronic or physical submission is acceptable. APHL will send an email acknowledging the receipt of each application. If you do not receive an acknowledgement within 48 hours, call 240-485-2739 to confirm receipt.
Appendix A: Expectations for Applicants

Budget
Applicants must prepare budgets to reflect costs through June 30, 2019. Applicants should divide the budgets into the line items shown below. A guideline for each line item is described for preparation of the budget and justifications. It is not appropriate to include staff time on this one time funding award. Please contact Anne Gaynor if special exceptions are needed in order to accept funding.

Equipment/Instrumentation
Applicants should list equipment/instrumentation in priority order, with the first item being of highest priority. The applicant must provide justification for the use of each item and describe how the item will be used to meet the project objectives. Applicants must show maintenance costs for equipment in the “Other” category.

Supplies
Provide a total supply budget and list each item included in that budget. Listing the cost of individual items is not required. Provide justification for each item and describe how it will be used to implement or expand IGRA. General laboratory or safety supplies not specifically used for IGRA, such as gloves, pipettes, lab coats, etc., are not appropriate for inclusion in this funding. However, purchase of items for blood collection (gloves, needles, vacutainers etc.) at collection sites can be included if needed specifically for this study.

Other
This category contains items not included in the previous budget categories. Appropriate items for inclusion include, but are not limited to relevant IT expenses, maintenance contracts, training costs, and courier expenses. Individually list each item and the amount requested and provide appropriate justification for how the item will be used to implement or expand IGRA.

Additional Costs Budget (optional)
Laboratories may include an additional costs budget reflecting additional funds needed (above the anticipated amount of this award) to fully implement or expand IGRA testing in their laboratory and or jurisdiction, in order to meet jurisdictional needs. In the budget, the applicant should also include a brief description of how they will use the funds. Applicants should prepare this using the instructions found in the above sections. This information will assist APHL and DTBE in determining the allocation of additional funds IF they become available.

Performance Management and Evaluation

APHL will measure performance by timeliness of responses to CDC and APHL requests, as well as successful completion of the proposed project.
Reports

The laboratory will submit to APHL and CDC a final report following the project. APHL will provide a template for submitting data from the project during the project period and at least three months prior to the due date.
### Option 1 Score Card:

<table>
<thead>
<tr>
<th>Category</th>
<th>Maximum Value</th>
<th>Score</th>
<th>Comments (REQUIRED)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Does the applicant demonstrate the ability to implement testing, verify testing, or modify testing algorithms?</td>
<td>30</td>
<td>Type comments here. (REQUIRED)</td>
<td></td>
</tr>
<tr>
<td>Sound plan, no issues or concerns = 18-30; Some Issues or reservations with plan: 10-17; Major reservations about ability to execute plan=1-9; No ability to execute plan= 0</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>2. Does the applicant provide sufficient information and an appropriate approach to implement or expand IGRA testing including up to 3 measurable objectives and has an appropriate sustainability plan?</td>
<td>30</td>
<td>Type comments here. (REQUIRED)</td>
<td></td>
</tr>
<tr>
<td>Appropriate approaches and Sufficient Plans = 18-30; Some Issues or reservations with plan: 10-17; Major reservations about ability to execute plans=1-9; No ability to execute plan= 0</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>3. Does the applicant provide sufficient information and an appropriate method for evaluation and monitoring of their outlined objectives?</td>
<td>30</td>
<td>Type comments here. (REQUIRED)</td>
<td></td>
</tr>
<tr>
<td>Appropriate approaches and Sufficient Plans = 18-30; Some Issues or reservations with plan: 10-17; Major reservations about ability to execute plans=1-9; No ability to execute plan= 0</td>
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<td></td>
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<tr>
<td>4. Does the applicant provide an appropriate budget for the requested funding?</td>
<td>10</td>
<td>Type comments here. (REQUIRED)</td>
<td></td>
</tr>
<tr>
<td>Appropriate Budget = 8-10 points; Some issues/reservations with Budget = 4-7; Budget not appropriate for proposal = 0-3</td>
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**TOTAL SCORE** 100
Appendix C: Conflict of Interest Disclosure Statement and Policy

Association of Public Health Laboratories
Conflict of Interest Disclosure Statement

Applicability: Disclosure of the following information is required of all Officers, Directors, committee members, staff members and other volunteers who have been designated and who have accepted responsibility to act on behalf of APHL ("APHL Personnel"). Please answer the following questions and, where indicated, include the same information for your immediate family members (your parents, your spouse or partner, your children and your spouse/partner's parents).
APHL will keep your completed disclosure statement in the corporate records of the association.

1. Please list the name, address, phone number, email address and type of business of your current employer. If you are self-employed, please note that below and provide us with the address, phone number, email address and type of business you operate.

2. Do you, or does any family member, currently serve as an officer, director, committee member, or other volunteer (or work as an employee of or a paid consultant to) any organization serving the interest of laboratory science or public health laboratories other than APHL or your state or local laboratory?
   ☐ Yes ☐ No
   If yes, please list the organization(s) and provide detail on your or your family member’s interest or position in the organization(s).

3. Do you, or any family member, have an existing or potential interest in, or compensation arrangement with, any third party providing goods or services to APHL, or with which APHL is currently negotiating?
   ☐ Yes ☐ No
   If the answer is yes, please provide the name of the organization below and describe in detail the nature of the position held.
4. Please note any other financial or business interest you may have with any organization serving the interests of public health laboratories.

If you have none, please check this box: ☐

5. Do you, or does any family member, have any other interest or affiliation that is likely to compromise your ability to provide unbiased and undivided loyalty to APHL, or that could come in conflict with your official duties as an Officer, Director, committee member, staff member or other volunteer who has been designated and who has accepted responsibility to act on behalf of APHL?

☐ Yes ☐ No

If you answered yes, please describe in detail below the nature of each such interest or affiliation.
6. If you are currently aware of any actual or possible conflict of interest that might otherwise hamper your ability to serve APHL to your best ability and with the highest degree of care, loyalty and obedience – including any potential conflict you or a family member may have with one or more of the RFP applicants – please describe them in detail below.

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

7. Do you agree that so long as you are an Officer, Director, committee member, staff member or other volunteer who has been designated and who has accepted responsibility to act on behalf of APHL you will immediately disclose to the other Directors and/or Officers or, for staff members, the Executive Director and/or General Counsel the nature of any interest or affiliation which you may hereafter acquire, which is in or is likely to become in conflict with your official duties with APHL?

☐ Yes    ☐ No

YOU MUST READ THIS SECTION AND THEN SIGN BELOW

I acknowledge that I have received and read APHL’s Fiduciary Responsibility and Conflict of Interest Policy (the Policy). I have listed all my relevant fiduciary responsibilities and affiliations, and I have identified any actual or potential conflict of interest on this Disclosure Statement and I agree to abide by the Policy. I understand that it is my responsibility to inform APHL in writing of any change in circumstances relating to the Policy and this Disclosure Statement.

Signature: ___________________________________________ Date: __________________

Printed Name: _______________________________________
APHL Fiduciary Responsibility and Conflict of Interest Policy

1. Policy Statement and Purpose

The members of the APHL Board of Directors understand the importance of serving APHL to the best of their ability and with the highest degree of obedience, loyalty and care. Accordingly, the Board adopts the following policy for APHL Officers and Directors, all staff, committee members, and other volunteers who have been designated and who have accepted responsibility to act on behalf of APHL ("APHL Personnel").

2. Individual Duty and Annual Disclosure

APHL Personnel will avoid any conflict of interest with APHL. APHL Personnel will not profit personally from their affiliation with APHL, or favor the interests of themselves, relatives, friends or other affiliated organizations over the interests of APHL. As used in this Policy, “Conflict of interest” includes any actual, apparent, and potential conflict of interest.

Upon commencing service with APHL, each APHL Personnel will file with the Board an annual statement disclosing all material business, financial, and organizational interests and affiliations they or persons close to them have which could be construed as related to the interests of APHL or the profession of public health laboratory science. Each APHL Personnel has an obligation to make an additional disclosure if a conflict of interest arises in the course of the individual’s service to APHL, whether arising out of his/her employment, consulting, investments, or any other activity. These disclosures will be documented promptly in writing and recorded in the Board minutes and corporate records.

3. Procedure

Whenever APHL considers a matter, which presents an actual, apparent, or potential conflict of interest for APHL Personnel, the interested individual will fully disclose his/her interest in the matter, including the nature, type, and extent of the transaction or situation and the interest of the individual or that individual’s relatives, friends or other affiliated organizations. The Board, after consultation with counsel as appropriate, will determine whether an actual and material conflict exists and, if so, what is the appropriate course of action under this policy and the Board vote will be recorded in the minutes.

Any Board member having a conflict of interest must either (i) voluntarily abstain from and be disqualified from participation in all deliberation and voting on all Board actions relating to the situation or matter that gives rise to the conflict of interest, or (ii) ask the Board to determine whether an apparent or potential conflict of interest is considered by the Board to be an actual and material conflict. In the event that the Board member in question requests that the Board evaluate the apparent or potential conflict, that Board member will abstain and be disqualified from participating in (and voting on) the determination of whether the issue presents an actual and material conflict. If the Board determines that an actual and material conflict exists, the Board member in question will abstain from all voting on, and will be disqualified from participation in all deliberation concerning all Board actions relating to the conflict of interest. The vote will be recorded in the minutes.

These procedures will neither prevent the interested individual from briefly stating his/her position on the matter, nor preclude him/her from answering pertinent questions of Board members, since his/her knowledge may be of assistance to the Board’s deliberations.

APHL Personnel must be cautious and protective of the assets of APHL and insure that they are used in the pursuit of the mission of APHL. The association’s policy requires APHL Personnel to avoid transactions in which APHL personnel may have a significant financial interest in any property which
APHL purchases, or a direct or indirect interest in a supplier, contractor, consultant, or other entity with which APHL does business. The Board, after consultation with counsel as appropriate, will determine whether an actual and material conflict exists and, if so, determine whether the transaction is nonetheless favorable to APHL before considering whether to approve it.

4. Other Duties and Obligations

Whenever any APHL Personnel discovers an opportunity for business advantage which is relevant to the activities of APHL, the opportunity belongs to APHL and the individual must present this opportunity to the Board. Only once the Board determines not to pursue the matter and relinquishes the opportunity may the individual consider it a matter of possible personal benefit.

APHL Personnel may not accept favors or gifts exceeding $75.00 from anyone who does business with APHL.

All APHL Personnel will keep confidential those APHL matters designated confidential. APHL Personnel are prohibited from disclosing information about APHL to those who do not have a need to know or whose interest may be adverse to APHL, either inside or outside APHL, and are prohibited from using in any way such information for personal advantage to the detriment of APHL.

All APHL Personnel who participate in APHL activities, including committee activities and international consultation activities, must be adequately prepared to fully participate as their position descriptions require and will do so in accordance with the applicable laws and regulations of their respective state or territory and APHL’s Articles of Incorporation, Bylaws, and corporate policies. The APHL Board will read and understand the association’s Articles of Incorporation, Bylaws, corporate policies and financial statements, and routinely verify that all state, federal, and local tax payments, registrations and reports have been filed in a timely and accurate manner.

Board members will never exercise authority on behalf of APHL except when acting in meetings with the full Board or the Executive Committee or as authorized by the Board. If any member of the Board has significant doubts about a course of action of the Board, he or she must clearly raise the concern with the Executive Director and the Board and, when appropriate, seek independent expert advice.