

Request for Proposals: Expanded access to Interferon Gamma Release Assays (IGRA)

Application Due Date: December 11, 2015

Submit to: Anne Gaynor, Manager of HIV, Hepatitis, STD and TB Programs (HHST)
(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 twelve (12) state or local public health laboratories (PHLs) or their jurisdictionally-affiliated TB Control program for the purpose of expanding the use of Interferon Gamma Release Assays (IGRA) to aid in diagnosis of *Mycobacterium tuberculosis* infection. Funds may be used to implement, expand or improve access to IGRA in the PHL or for contracting with an outside facility to provide testing services. Funding will be awarded via a contract with APHL.

Background

The prevalence of active tuberculosis (TB) in the United States continues to decline with a case rate of 2.96 cases per 100,000 persons reported in 2014, down from 3.0 cases per 100,000 in 2013. However, this decline of 2.2 % is the smallest annual decline observed in more than a decade. Rapid identification of persons with active TB is required to prevent further transmission. It is estimated that the pool of latently infected individuals in the United States is more than 11 million. Without testing and treatment, latent TB infection (LTBI) develops into active disease in approximately 5–10% of those infected with some comorbidities (e.g., HIV and diabetes) increasing the risk of progression. Continuous advancement towards TB elimination requires directing efforts towards identification and treatment of individuals with LTBI. Before 2001, the tuberculin skin test (TST) was the only widely-available immunologic test for LTBI approved for use in the United States. Currently there are two FDA approved and commercially available blood tests known as IGRAs for detection of TB; QuantiFERON-TB Gold In-Tube by Qiagen, Chadstone, Victoria, Australia, and T-SPOT.TB test (T-Spot) by Oxford Immunotec Limited, Abingdon, United Kingdom. For full details of guidelines and considerations for using IGRAs, please refer to the CDC Guidelines updated in [2010](#).

This funding mechanism would provide an opportunity for the jurisdictional TB control program and their state or local public health laboratory to explore the potential to implement or expand access to IGRA. Please note this is a one-time funding opportunity.

Eligibility

All state or local US public health laboratories or TB Control programs are eligible to apply provided their proposal is written in collaboration with their jurisdictional counterpart. A letter must be submitted with all applications from both the laboratory and their jurisdictional TB control program that demonstrates a joint plan. Potential scenarios include:

Option 1: Public health laboratory in a given jurisdiction currently has some limited capacity to perform IGRA but with programmatic input would like to expand testing capability.

Option 2: Public health laboratory that does not currently perform IGRA but would like to implement IGRA as an in-house service based on a defined programmatic need.

Option 3: TB Control program in a jurisdiction where the public health laboratory is either not interested or not able to expand testing capability or to bring IGRA in-house but endorses the program contracting with an outside laboratory to perform testing.

Anticipated RFP Schedule

At this time, APHL anticipates the following schedule:

- October 30, 2015 – RFP issued
- November 10, 2015 – Informational teleconference for RFP questions and answers
- December 11, 2015 – RFP responses due**
- December 18, 2015 – Proposal review completed
- December 18-23, 2015 – If needed, follow-up interviews and updated proposals due
- December 23, 2015 – Final review and selection of awardees**
- January 30, 2016 – Contracts finalized and work begins**

Any modification to this anticipated schedule will be communicated on APHL's procurement website (www.aphl.org/rfp) and via an email blast to the public health laboratories (PHLs) and TB control programs.

Award

Funding will be distributed via a contract administered by APHL. Up to twelve (12) laboratories or programs, depending on strength of applications, funding requested and funds available, will be selected. Award amounts will depend on the scope of the proposed project with the minimum award per site of \$25,000.

Use of funds:

1. Purchasing instrumentation or equipment for the implementation of IGRA; including laboratory or collection site requirements
2. Purchasing reagents to begin or expand 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 contracts with a reference laboratory for provision of IGRA
6. Establishing infrastructure for collection sites to perform collection and remote incubation (if applicable)
7. Establishing or improving jurisdictional courier services to ensure timely transport of specimens
8. Providing training for laboratory or programmatic staff

Term of Project

From date of contract signing (Approximately February 1, 2016) through June 30, 2016.

Request for Proposals – Required Submissions

To submit a proposal for this **one-time** funding to expand access to IGRA, please outline the collaborative approach between the PHL and the jurisdictional TB control program for implementation, expansion or improved access to IGRA by responding to the following questions based on the Option applied for. 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).

For Option 1: Proposals from PHLs that want to expand current testing. Please answer the following question and items 2-5 listed under “All Applicants” below.

1. Please describe the laboratory’s existing IGRA testing service;
 - a. Describe the programmatic need for IGRA and what populations are currently being tested and what populations will be tested in this expansion.
 - 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 remote incubation is used please also describe how that fits into the laboratory testing methods.

- c. Does your laboratory and/or program staff that 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.

For Option 2: Proposals from PHLs that want to implement IGRA. Please answer the following question and items 2-5 listed under “All Applicants” below.

1. Please describe the laboratory’s plan to implement a testing service for IGRA;
 - 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.

For Option 3: TB Control Programs in a jurisdiction where the PHL either does not perform IGRA and/or does not wish to expand current testing but endorses the program contracting with an outside laboratory to perform testing. Please respond to the following question and items 2-5 listed under “All Applicants” below.

1. Please describe the programmatic plan to expand or implement testing via contracting with an outside laboratory;
 - a. Describe the programmatic need for IGRA, what populations are currently being tested (if applicable), what populations will be tested in this expansion, and that the public health laboratory endorses an outside contract.
 - b. Describe the implementation plan including specimen collection (who will be collecting and how will they be trained), remote incubation (if applicable), and specimen transport.
 - c. Describe how and what laboratory necessary testing services will be contracted with.
 - d. Describe any previous experience using IGRA results and/or how necessary training will be provided to program staff to enable them to provide guidance and interpretation of IGRA results.

All Applicants

2. A detailed description of how the laboratory and/or program intends to use the funds. This should include from three (3) to five (5) 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.
3. A detailed description of how the laboratory and program plan to evaluate the impact of the award in their jurisdiction and the steps that will be taken to measure progress towards meeting each stated objective.
 - a. Evaluation might include, but is not limited to, 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.
4. A 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 results will be reported and used in accord with the state or local TB control plan (laboratories are encouraged to work with their TB control program to develop these plans).
5. Provide a budget reflecting the requested funding amount as outlined in the Award above. The budget should be divided into the line items outlined in Appendix A of the application package.

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.

Complete proposals will be reviewed by a team of three (3) subject matter experts (SMEs) from CDC and a panel of three (3) reviewers, two (2) APHL members selected from non-applicant public health laboratories and one (1) representative from the National TB Controllers Association (NTCA). SMEs from CDC will be identified and selected by the Chief of the Laboratory Branch of the Division of Tuberculosis Elimination based on their familiarity with project requirements. APHL member experts will be identified from among the non-applicant PHLs by APHL's HHST Program Manager and will have expertise in the laboratory testing methods described in this RFP and 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 review team's composition.

Evaluation Criteria

Proposals will be evaluated based on responses to the questions above and will receive a numeric score of up to 100 maximum points based on the scorecard template in **Appendix B**. Laboratories

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 entire review will be conducted via a combination of email communication between APHL's HHST Program Manager and members of the evaluation team or among evaluation team members and teleconference and/or webinar evaluation sessions. APHL's HHST Program Manager will coordinate the review process and the evaluation sessions.

The 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. These interviews and any supplemental information would clarify a laboratory's capacity or experience in one or more of the evaluation criteria or 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. In addition, the evaluation team may receive documentation from APHL staff on an applicant's past performance in other capacities noted in this RFP as part of the evaluation criteria.

Post-Evaluation Procedures

The selected laboratories will be notified by APHL staff within ten (10) business days of the completion of the evaluation and the names of the recipients will be posted to APHL's procurement website, 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 the names of the winning recipients are posted.

All applicant laboratories 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 eligible laboratories 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**.
- Prior to making the official award, a group of individuals from CDC and APHL reserve the right to tour the facilities to assess compliance with requirements for testing and/or have a

teleconference with applicant laboratories. Post award, monitoring site visits may be conducted to include an assessment of continued compliance.

Additional Information and Deadlines for Application Submission

All questions should be directed to Anne Gaynor at anne.gaynor@aphl.org. Questions received from interested PHLs, together with the answers provided by APHL or CDC staff will be posted to APHL's procurement website (www.aphl.org/rfp).

Applications should be submitted 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). For electronic submission, copy Kelsey Vellente (Kelsey.Vellente@aphl.org). Applications must be received at APHL, attention Anne Gaynor by close of business (5:00pm ET) December 11, 2015. Either electronic or physical submission is acceptable. APHL will send an email acknowledging the receipt of your application; if you do not receive an acknowledgement within 48 hours, call 240.485.2739 to confirm receipt.

An optional informational teleconference will be held Tuesday November 10, 2015 at 1:00 pm ET.

The purpose of this call will be to provide a brief overview of the project and to allow potential applicants to ask CDC and APHL questions. Please come with questions prepared.

For the teleconference there are a limited number of lines, please use only one (1) line per laboratory.

Phone: 866.822.6061, Passcode: 858376#

Appendix A: Budget

Budgets should be prepared to reflect costs through June 30, 2016. The budgets should be divided 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

Equipment/Instrumentation should be listed in priority order, with the first item being of highest priority. Provide justification for the use of each item and describe how the item will be used to implement or expand IGRA. Maintenance costs for equipment should be shown 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. This budget should also include a brief description of how the funds would be used and should be prepared 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.

Appendix B: TB IGRA RFP Score Card

The following table is a copy of the score card that will be used to evaluate RFP responses.

Category	Maximum Value	Score	Comments (REQUIRED)
<p>1. Does the applicant demonstrate the ability to implement or expand testing (Question 1 for Option 1-3)?</p> <ul style="list-style-type: none"> • For Option 1: Consider the programmatic need and what populations will be tested, availability of existing staff, equipment and space, and the ability of the laboratory to purchase additional equipment, hire additional staff, and respond to increased testing. • For Option 2: Consider the programmatic need and what populations will be tested, the availability of existing staff, equipment and space, and the ability to purchase additional equipment, hire additional staff, and ensure training and quality control for the laboratory and program staff. • For Option 3: Consider the programmatic need and what populations will be tested, the ability to contract or obtain testing through a third party laboratory, and ability to provide the necessary training. <p>Excellent = 26-30; High= 18-25; Moderate =10-17; Low =1-9; No experience = 0</p>	30		Type comments here. (REQUIRED)

<p>2. Does the applicant provide sufficient information and an appropriate approach to implement or expand IGRA testing including 3-5 measureable objectives and has an appropriate sustainability plan? (Question 2)</p> <p>Excellent = 26-30; High= 18-25; Moderate =10-17; Low =1-9; No experience = 0</p>	<p>30</p>		<p>Type comments here. (REQUIRED)</p>
<p>3. Does the applicant provide sufficient information and an appropriate method for evaluation and monitoring of their outlined objectives? (Question 3 & 4)</p> <p>Excellent = 26-30; High= 18-25; Moderate =10-17; Low =1-9; No experience = 0</p>	<p>30</p>		<p>Type comments here. (REQUIRED)</p>
<p>4. Does the applicant provide an appropriate budget for the requested funding?</p> <p>Appropriate Budget = 8-10 points; Some issues/reservations with Budge = 4-7; Budget not appropriate for proposal = 0-3</p>	<p>10</p>		<p>Type comments here. (REQUIRED)</p>
<p>TOTAL SCORE</p>		<p>100</p>	