



Request for Proposals (RFP): Strengthening Drug Susceptibility Testing for *Mycobacterium tuberculosis*

Application Due Date: October 13, 2023, 11:59PM EDT

Letter of Intent Due Date: September 15, 2023, 11:59PM EDT

Submit to: Sarah Buss, Manager of HIV, Viral Hepatitis, STD and TB
(sarah.buss@aphl.org) with a copy to infectious.diseases@aphl.org.

The development of this request for proposals application was supported by Cooperative Agreement Number NU60OE000104 (CFDA #93.322) from the Centers for the Disease Control and Prevention (CDC) of the Department of Health and Human Services. Its contents are solely the responsibility of the authors and do not necessarily represent the official views of the CDC.

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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 20 state or local public health laboratories (PHLs) for the purpose of enhancing capacity for drug susceptibility testing (DST) of *Mycobacterium tuberculosis* (MTB), specifically with respect to fluoroquinolones (FQ) and rifampin (RIF). Funding will be awarded via a contract with APHL.

Background

The recently recommended 4-month rifapentine-moxifloxacin treatment regimen can shorten duration for treatment of drug-susceptible *Mycobacterium tuberculosis* (MTB) by 2 months. Importantly, this new 4-month regimen has altered what could be considered first-line DST of MTB, with fluoroquinolone (FQ) testing now potentially a priority based on programmatic use of this regimen. [CDC's guidance document](#) for use of the 4-month regimen recommends testing MTB for susceptibility to isoniazid (INH), rifampin (RIF), pyrazinamide (PZA), and FQ (preferably moxifloxacin). Ideally, molecular drug susceptibility testing (mDST) for identification of mutations that affect susceptibility to INH, PZA, RIF, and FQ would be performed, followed by phenotypic drug susceptibility testing (pDST), as applicable, to RIF, INH, PZA, and moxifloxacin (MOX).

RIF is one of the most important anti-MTB drugs available today and is used as the surrogate rifamycin for rifapentine (RPT) testing related to use of the 4-month treatment regimen mentioned previously. In 2020, the World Health Organization (WHO) recommended [revised critical concentrations](#) (CC) for rifampin. The revision was based on a review of the published literature that demonstrated the epidemiological cutoff value for wild type MTB on Middlebrook 7H10 and BACTEC™ Mycobacterial Growth Indicator Tube™ 960 (MGIT) was lower than the previously recommended CC of 1.0 mg/L for rifampin. Consequently, the use of new CC may help resolve some discrepancies between mDST and pDST because strains possessing certain mutations that should be considered to confer resistance occasionally go undetected by pDST using the previous CC. The revisions apply to tests that employ 7H10 or MGIT and the updated CC for both media types is now 0.5 mg/L for rifampin.

Laboratories should update their protocols and test menus as the field advances to ensure offering relevant and quality services. To address the recommended changes to the rifampin CC and the potential need for FQ DST given programmatic use of the alternate 4-month RPT-MOX regimen, APHL with CDC-DTBE is excited to announce this one-time funding opportunity. The aim of this funding opportunity is to assist PHLs with evaluation of the new rifampin CC and / or evaluation of FQ susceptibility testing for MTB. This funding is being made available to support strengthening of phenotypic or molecular testing for these drugs, as applicable.

APHL is a non-profit, 501(c)(3) organization that works to safeguard the public's health by strengthening public health laboratories in the United States and globally. The Association's members include state and local laboratories, state environmental and agricultural laboratories, and other government laboratories that conduct testing of public health significance. To obtain more information about APHL, please visit <http://www.aphl.org>.

Eligibility

All state or local US public health laboratories that currently perform first-line pDST for MTB are eligible to apply for the one-time funding. Potential application scenarios include:

Option 1: Public health laboratories that currently perform pDST for rifampin using 7H10 Middlebrook and/or MGIT and would like to evaluate the updated WHO CC of 0.5 mg/L.

Option 2: Public health laboratories that currently perform first-line DST for MTB and would like to evaluate a FQ phenotypic or molecular susceptibility testing method(s) for MTB.

Note: Laboratories may apply for both Option 1 and Option 2, but each option will be evaluated separately.

Anticipated RFP Schedule

August 29, 2023	RFP Issued
September 6, 2023	Informational Teleconference
September 15, 2023	Required Letter of Intent Due to APHL (see below)
October 13, 2023	RFP Responses Due
October 27, 2023	Proposal Review Completed
November 1-3, 2023	Follow-Up Interviews and Updated Proposals Due (if needed)
November 10, 2023	Final Review Completed and Awardees Selected
December 1, 2023	Estimated Contract Start Date

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

Response Submittal

Confirmation of Intent to Respond

To allow for appropriate review process planning, a letter of intent is required for consideration. APHL requires that prospective applicants submit a brief email statement indicating an intent to submit a proposal to Sarah.Buss@aphl.org with a copy to infectious.diseases@aphl.org. APHL must receive this email by no later than **11:59pm EDT on September 15, 2023**.

Final Response

APHL must receive complete responses by **11:59 pm EDT on October 13, 2023**. Please see Proposal-Required Submissions section for items that must be included in the completed proposal. Applicants may send proposals via email to Sarah.buss@aphl.org with a copy to infectious.diseases@aphl.org.

APHL will send an email acknowledging the receipt of your application; if you do not receive an acknowledgement within two business days, please email the RFP point of contact above to confirm receipt.

Award

Funding will be distributed via a contract administered by APHL. Up to 20 laboratories, 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 an estimated award per site of \$10,000-\$25,000.

Use of funds: Funds may be used for activities contributing to evaluation of updated rifampin CC (0.5 mg/L) and / or phenotypic or molecular FQ susceptibility testing for MTB. Funds may not be used to contract with an outside facility to provide testing services. The activities listed below (singularly or in any combination) are examples of expenditures appropriate for the scope of the RFP. You may also propose other activities that are in-line with the scope of this funding opportunity.

1. Purchasing reagents or supplies for evaluation and potential validation or verification of:
 - a. new rifampin CC
 - b. a phenotypic FQ susceptibility test
 - c. a molecular FQ susceptibility test
2. Procuring isolates for evaluation of updated DST*
3. Updates to existing laboratory information management systems (LIMS) for electronic ordering and reporting of new laboratory orders and results, or instrument interfaced ordering and reporting
4. Providing training for laboratory staff

*APHL and the CDC are working to assemble a panel of MTB isolates that may be useful in these evaluations and will strive to make these panels available to awardees.

Term of Project

From date of contract signing (approximately December 1, 2023) through June 30, 2024. A final progress report will be required as a final deliverable. Up to 50% of the proposed amount will be made available at the start of the project and 50% upon completion.

Evaluation Team

APHL staff, led by the Manager of HIV, Viral Hepatitis, STD, and TB (HHST) Programs will conduct an initial review of all proposals for completeness. Any application that is incomplete as of 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 subject matter experts (SMEs) from CDC's Division of Tuberculosis Elimination and a panel of three APHL members selected from non-applicant public health laboratories. 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 laboratories by the APHL HHST Program Manager and will have expertise in the laboratory testing methods described in this RFP. Once potential reviewers have been identified, APHL's Director of Infectious Disease Programs will have final approval over the review team's composition.

Conflict of Interest

APHL will ask potential reviewers to complete and sign APHL's Conflict of Interest Disclosure Statement 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 E: Conflict of Interest Disclosure Statement and Policy. APHL will not select reviewers with a perceived or potential conflict of interest. This Conflict of Interest Disclosure Statement is provided in the RFP for Applicant review only. Applicants should not complete the Conflict of Interest Disclosure Statement unless instructed by APHL.

Evaluation Criteria

The evaluation team will evaluate proposals based on responses to the questions in the Proposal – Required Submissions section and will give a numeric score of up to 100 maximum points based on the scorecard template in Appendices B-D. **Note that when applying for both Option 1 and 2 (evaluate new RIF CC and a FQ testing method) each project will be separately evaluated and may be awarded differentially.**

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.

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. 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. In addition, the evaluation team may receive documentation from APHL staff 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, within three (3) business days of the laboratory's acceptance of the award. Unsuccessful applicants will receive notification of these results by e-mail within 30 days after the name of the selected awardee is 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 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. Acceptance of the award means agreement to the compensation structure and amounts agreed upon with the awardee and APHL.

* Laboratories must be legally able to contract within the United States and not disbarred or prohibited from contracting with businesses or the federal government.

Proposal – Required Submissions

An interested laboratory must submit both a letter of intent to apply (**due September 15, 2023**) and a proposal (**due October 13, 2023**). Applications must comply with submission requirements set out in the Additional Information and Deadlines for Application Submission below. A complete proposal will include the following items:

Responses to Questions (below)

o Responses should be limited to no more than six (6) single spaced pages (font size > 11pt, > 1-inch margins) inclusive of one (1) page for the budget.

o Proposal should include responses to the questions below, including each aspect of the question and should clearly indicate what question is being answered.

Response to Proposal Questions

Please review and respond to every question unless otherwise indicated. Note that Question 4 only needs to be answered if your proposal includes plans to evaluate Option 1 (updated RIF CC) and Question 5 only needs to be answered if your proposal involves evaluation of Option 2 (FQ DST). Answer both questions 4 and 5 if you intend to apply for both Option 1 and Option 2 (evaluate updated RIF CC and FQ DST).

- 1. Current Testing Capability:** Describe the laboratory's existing MTB testing (detection/identification and DST) capabilities to include physical space, test method(s) performed, testing algorithm, turnaround time for each method performed in algorithm and annual MTB DST volume.
- 2. Staffing:** Describe the qualifications and experience of existing laboratory staff trained to perform MTB DST (current methods and any methods you propose to evaluate) including familiarity with evaluation and validation of new test methods. Describe any relevant staff training that will be required to evaluate the new protocols or testing capacity.
- 3. Problem Statement:** Please provide a brief explanation (3-5 sentences) of why these one-time funds are needed and, if relevant, briefly document challenges you've encountered with the current RIF CC and/or lack of pDST or mDST for FQ, as applicable. Explain how evaluating updates to RIF CC and / or FQ DST will improve MTB DST and positively impact the TB program in your jurisdiction.
- 4. OPTION 1 ONLY: Detailed Description of Approach:** Provide a description of how your laboratory intends to use the one-time funding to evaluate the revised RIF CC. Please address:
 - a. Test Method:** Please describe the testing method(s) that will be evaluated for pDST of RIF, currently available equipment that will be leveraged and/or if new equipment is required and describe your ability to procure such equipment in a timely manner.
 - b. Evaluation Plans:** Please describe your plans for evaluation of the new CC (rifampin concentrations evaluated, reference/comparator method, how will discrepancies be resolved, etc.), and criteria that will be used to determine if the updated CC will be implemented in the laboratory. When estimating the timeline, please consider the time required for approvals and LIMS modifications, should the evaluation and validation be successful. Please indicate how stakeholders will be informed of any implemented changes.
 - c. Isolates:** Describe the types of MTB isolates you will use in these studies and how they will be obtained. Please consider that an isolate panel may be made available.
- 5. OPTION 2 ONLY: Detailed Description of Approach:** Provide a description of how your

laboratory intends to use the one-time funding to evaluate relevant FQ DST assays. Please ensure that you address all sub-parts of this question for each method you intend to evaluate (i.e., if proposing to evaluate both pDST and mDST for FQ, address both methods).

- a. **Test Method:** Please describe the testing method(s) that will be evaluated, currently available equipment/testing platforms that will be leveraged and/or if new equipment is required and describe your ability to procure such equipment in a timely manner.
 - b. **Evaluation Plans:** Please describe your plans for evaluation of the new assay including the estimated timeline, plans for validation (isolates and/or specimen types tested, reference/comparator method, how will discrepancies be resolved, etc.), and criteria that will be used to determine if the new assay will be implemented in the laboratory. When estimating the timeline, please consider the time required for approvals and LIMS modifications, should the evaluation and validation be successful. Please indicate how stakeholders will be informed of any implemented changes.
 - c. **Isolates:** Describe the types of MTB isolates you will use in these studies and how they will be obtained. Please consider that an isolate panel may be made available.
 - d. **DST Algorithm:** Assuming that the evaluation is successful, provide the updated DST testing algorithm for MTB once all new methods are implemented, to include the variety of test orders that would be available (i.e., would FQ tests be available by request only, or as part of an automated reflex or DST panel, what will you consider first-line testing, etc.) and estimated turnaround times.
 - e. **Sustainability:** Please provide a brief description of how these one-time funds will be leveraged to generate sustainable FQ DST testing capacity in your laboratory and be sure to address how testing will be funded in the future.
6. **Measuring Success:** Please describe at least one, and up to three, specific and measurable objectives that allow for assessment of impact and sustainability of the project.
 7. **Budget:** Provide a line-item budget reflecting the requested funding amount. Refer to Appendix A for more details. For each category of funding requested (supplies, travel, training materials, etc.), include a brief description of how the requested items support the proposed activities. If applying for both Option 1 and 2 (evaluate new RIF CC and a FQ testing method) please ensure that line items for each assay are distinct and indicate which assay/option each line item is needed for. Please limit your response to no more than one (1) single-spaced page.

Additional Information and Deadlines for Application Submission

Applicants must direct all questions to Sarah Buss at (sarah.buss@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 associated with the specific RFP (www.aphl.org/rfp). APHL will try to post responses on a rolling basis, within 1 business day of receipt of the question.

To allow for appropriate review process planning, a letter of intent is required for consideration. Applicants should submit letters by email to Sarah Buss at APHL (sarah.buss@aphl.org) with a copy to infectious.diseases@aphl.org no later than **11:59 pm EDT on Friday September 15, 2023**. Applications are due to Sarah Buss at APHL (sarah.buss@aphl.org) with a copy to infectious.diseases@aphl.org by **11:59 pm EDT on Friday October 13, 2023**. APHL will send an email acknowledging the receipt of your application. If you do not receive an acknowledgement within two (2) business days, call 240-485-3901 to confirm receipt.

Appendix A: Budget Guidance

Budgets should be prepared to reflect costs through June 30, 2024. Budgets should be divided into the line items shown below. When applying for both Option 1 and 2 (evaluate new RIF CC and a FQ testing method) please indicate which project/option each line item is needed for. If the same item is needed for both projects, please split it out or allocate a percentage. 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.

Supplies/Reagents

Provide a total supply budget and list each item included in that budget. Listing the cost of individual items is appreciated. Provide justification for each item and describe how it will be used to evaluate or expand drug susceptibility testing for MTB. General laboratory or safety supplies not specifically used for MTB testing, such as gloves, pipettes, lab coats, etc., are not appropriate for this award.

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 evaluate new rifampicin CC and / or FQ susceptibility testing. Maintenance costs for equipment should be shown in the “Other” category.

* Given the size of each award, it is unlikely we will be able to cover the total cost of a piece of equipment. However, we are open to providing funding for a portion of equipment, offsetting costs associated with leasing equipment and/or service agreements.

* If durable equipment that costs > \$5,000 is purchased using these funds, the cost must be reported to APHL as part of our cooperative agreement reporting.

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, shipping expenses for validation isolates, and training costs. Individually list each item and the amount requested and provide justification for how the item will be used to evaluate new rifampin CC and/or FQ DST.

Additional Costs Budget (optional)

Laboratories may include an additional costs budget reflecting additional funds needed (above the anticipated amount of this award) to fully evaluate or expand MTB DST methods in their laboratory and or jurisdiction, 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 above.

* This information will assist APHL and DTBE in determining the allocation of additional funds should they become available.

Appendix B: Scorecard for Option 1 (evaluation of RIF CC)

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

Category/Question	Maximum Value	Score	Comments (REQUIRED)
1. Considering the proposed approach (Question 4) --does the applicant demonstrate the capacity, capability (Question 1), and appropriate staffing (Question 2) to evaluate the new RIF CC and/or mechanisms to obtain additional resources to perform the testing? <i>Consider the following: Does the applicant have appropriate equipment, space, and expertise, and/or the ability to obtain additional equipment, supplies, or training required to perform the testing method? Does the applicant provide a timeline for evaluation of the new method that aligns with the project period?</i> No issues or concerns: Applicant has or will build capacity and capability to execute their proposed plans within established timelines (25 points). Minor concerns: There are minor concerns about the applicant's capacity and capability to execute the proposal within the proposed timeline (20-24 points). Moderate concerns: There is missing information and/or there are moderate concerns about the applicant's capacity and capability to execute the proposal within the proposed timeline (10-19 points). Major concerns: There are major concerns about the applicant's capacity and capability to execute the proposal within the proposed timeline (1-9 points). Applicant will not be able to evaluate plans based on the information provided (0 points).	25		

2. Does the applicant provide a sufficiently detailed and achievable plan for evaluation and validation of the updated RIF CC? (Question 4) No issues or concerns: Sufficient information and appropriate approach (30 points). Minor concerns: Some information missing to fully assess and/or some minor concerns with approach (20-29 points). Moderate concerns: Information missing to fully assess plan and/or moderate concerns with the approach (10-19 points). Major concerns: Significant information missing to fully assess plan and/or major concerns with the approach (1-9 points). Insufficient information to assess plan and/or inappropriate approach (0 points)	30		
3. Does the applicant provide a clear explanation and justification for how evaluating updates to RIF CC will improve MTB DST in their jurisdiction and positively impact their TB program? (Question 3) Applicant expresses significant and appropriate need: Jurisdiction has not evaluated updated RIF CC, demonstrates how funds would improve the testing program, and routinely performs MTB DST (20-25 points). Applicant expresses appropriate and moderate need: Jurisdiction demonstrates how funds would improve current MTB DST testing yet may have already evaluated new RIF CC using one method. Receives moderate MTB DST testing volume (11-19 points); reasonable request. Applicant expresses minimal need: Jurisdiction receives minimal MTB DST requests each year or fails to demonstrate why funds are needed to evaluate the new RIF CC but has reasonable request to utilize funds (1-10 points). Insufficient information to assess need (0 points).	25		

4. Does the applicant provide at least one and up to three specific, measurable objective(s) that will enable them to assess the impact of the funding (Question 6)? No concerns with stated objective(s): Objective(s) are appropriate, clear, specific, and measurable (10 points). Minor to moderate concerns with objective(s): Objective(s) may not be totally appropriate, clear, specific, or measurable but are generally acceptable to measure impact (5-9 points). Major concerns: Objective(s) are not entirely appropriate, clear, specific, or measurable and would be difficult to use for measuring success/impact (1-4 points). Objective(s) not provided and/or don't address impact (0 points).	10		
5. Does the applicant provide an appropriate budget for the requested funding? (Question 7) No concerns with budget (10 points). Minor to moderate concerns with budget (5-9 points). Major Concerns with budget (1-4 points). Budget not appropriate for proposal (0 points).	10		
TOTAL SCORE	100	_____	

Appendix C: Scorecard for Option 2 (evaluation of FQ DST)

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

Category/Question	Maximum Value	Score	Comments (REQUIRED)
1. Considering the proposed approach --does the applicant demonstrate the capacity and capability (Question 1) and appropriate staffing (Question 2) to validate/verify the indicated FQ DST method and/or obtain additional resources to perform the testing? Please ensure that you consider this question with respect to both pDST and mDST methods if both are being evaluated. <i>Consider the following: Does the applicant have appropriate equipment, space, and expertise, and/or the ability to obtain additional equipment, supplies, or training required to perform the new testing method? Does the applicant provide a timeline for evaluation of the new method that aligns with the project period?</i> No issues or concerns: Applicant has or will build capacity and capability to execute their proposed plans within established timelines (20 points). Minor concerns: There are minor concerns about the applicant's capacity and capability to execute the proposal within the proposed timeline (15-19 points). Moderate concerns: There is missing information and/or there are moderate concerns about the applicant's capacity and capability to execute the proposal within the proposed timeline (10-14 points). Major concerns: There are major concerns about the applicant's capacity and capability to execute the proposal within the proposed timeline (1-9 points). Applicant will not be able to evaluate plans based on the information provided (0 points).	20		

2. Does the applicant provide a sufficiently detailed and achievable plan for evaluation and validation of FQ DST test method(s)? (Question 5b and 5c). Please ensure that you consider this question with respect to both pDST and mDST methods if both are being evaluated. No issues or concerns: Sufficient information and appropriate approach is provided with respect to each test that will be evaluated (30 points). Minor concerns: Some information missing to fully assess and/or some minor concerns with approach (20-29 points). Moderate concerns: Information missing to fully assess plan and/or moderate concerns with the approach (10-19 points). Major concerns: Significant information missing to fully assess plan and/or major concerns with the approach (1-9 points). Insufficient information to assess plan and/or inappropriate approach (0 points)	30		
3. Does the applicant provide a clear explanation and justification for how these funds will be used to establish FQ DST, how adding FQ will improve MTB DST in their jurisdiction and the impact of adding FQ DST on their TB program? (Question 3) Applicant expresses significant and appropriate need: Jurisdiction has not evaluated either mDST or pDST for FQ, demonstrates how funds would improve the testing program, and receives substantial MTB DST testing volume each year (15-20 points). Applicant expresses appropriate and moderate need: Jurisdiction demonstrates how funds would improve current MTB DST testing but may already offer pDST for FQ. Receives adequate MTB DST testing volume (9-14 points). Applicant expresses minimal need: Jurisdiction receives a low number (< 20) of MTB DST requests each year but has reasonable request to utilize funds (1-8 points).	20		

Insufficient information to assess need (0 points).			
4. Does the applicant present a final algorithm consistent with achieving a clinically relevant turnaround time and discuss how testing via the algorithm would be sustained in the future? (Questions 5d and 5e) No issues or concerns. Proposed algorithm is appropriate and the applicant describes how testing will be sustained. (10 points). Minor to moderate concerns. There are minor to moderate concerns with the applicant's plans for flow of proposed testing algorithm and /or sustainability of testing (5-9 points). Major Concerns. There are major concerns with the applicant's flow of proposed testing algorithm or plans for sustainability of testing (1-4 points). Algorithm not appropriate or sustainable (0 points).	10		
5. Does the applicant provide at least one and up to three specific, measurable objective(s) that will enable them to assess the impact of the funding (Question 6)? No concerns with stated objective(s): Objective(s) are appropriate, clear, specific, and measurable (10 points). Minor to moderate concerns with objective(s): Objective(s) may not be totally appropriate, clear, specific, or measurable but are generally acceptable to measure impact (5-9 points). Major concerns: Objective(s) are not entirely appropriate, clear, specific, or measurable and would be difficult to use for measuring success/impact (1-4 points). Objective(s) not provided and/or don't address impact (0 points).	10		
6. Does the applicant provide an appropriate budget for the requested funding? (Question 7) No concerns with budget (10 points). Minor to moderate concerns with budget (5-9 points). Major Concerns with budget (1-4 points). Budget not appropriate for proposal (0 points).	10		

TOTAL SCORE	100	_____	
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Appendix E: Conflict of Interest Disclosure Statement and Policy (APPLICANTS NEED NOT COMPLETE UNLESS INSTRUCTED BY APHL)

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.

- 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.
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-
-

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.