



# Request for Proposals: Validation or Verification of New Culture Identification Methods for *Mycobacterium tuberculosis* complex (MTBC)

Application Due date: December 10, 2021

Submit to: Anne Gaynor, Manager of HIV, Viral Hepatitis, STD and TB  
(Anne.Gaynor@aphl.org)

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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 15 state or local public health laboratories (PHLs) for the purpose of validating or verifying a new method or expanding existing method(s) used for culture identification of *Mycobacterium tuberculosis* complex (MTBC) to replace Hologic® AccuProbe® due to anticipated discontinuation of the product in late 2022. Priority will be given to public health laboratories with no secondary identification methods currently available within their laboratories (Option 1) but applications from laboratories seeking to expand identification methods to include a secondary method are also welcomed (Options 2 and 3). Funding will be awarded via a contract with APHL.

## Background

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>.

Hologic® AccuProbe® has been used as a primary culture identification method for some nontuberculous mycobacteria (*M. avium*, *M. intracellulare*, *M. goodii*, and *M. kansasii*) and MTBC in laboratories for many years. The AccuProbe® culture identification test is a rapid DNA probe test which utilizes the technique of nucleic acid hybridization for the identification of mycobacteria isolated from culture. Hologic's recent letter to clients announcing the anticipated discontinuation of the AccuProbe line for MTBC has highlighted the need for many laboratories to select, evaluate, and implement a new primary identification method to replace AccuProbe® before the product is no longer available for purchase in late 2022. This funding mechanism provides an opportunity for public health laboratories to explore the potential to validate or verify culture identification methods. Please note this is a one-time funding opportunity.

## Eligibility

All state or local U.S. public health laboratories who perform testing in-house and are transitioning their *Mycobacterium tuberculosis* complex (MTBC) culture identification method from Hologic® AccuProbe® to another identification method (MALDI-TOF, real-time PCR, Cepheid GeneXpert) are eligible to apply. Potential scenarios include:

**Option 1:** Public health laboratories who currently perform Hologic® AccuProbe® as their primary identification method and do not currently have an available secondary culture identification method.

**Option 2:** Public health laboratories that are currently in the process of validating or verifying an identification method to replace AccuProbe® as a primary method.

**Option 3:** Public health laboratories that have already transitioned to a primary identification method other than AccuProbe® and would also like to expand the availability of alternative identification methods to include a secondary (back-up) method.

## Anticipated RFP Schedule

October 27, 2021	–	RFP Issued
<b>November 9, 2021</b>	–	<b>Required Letter of Intent Due to APHL (see below)</b>
<b>December 10, 2021</b>	–	<b>RFP Responses Due</b>
December 23, 2021	–	Proposal review completed
January 3-7, 2022	–	If needed, follow-up interviews and updated proposals due
January 14, 2022	–	Final review completed and awardees selected
February 1, 2022	–	Estimated contract start date

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

## Response Submittal

### Confirmation of Intent to Respond

APHL requires 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 November 9, 2021**. To allow for appropriate review process planning, **a letter of intent is required** for consideration.

### Final Response

APHL must receive complete responses by **5:00 pm EST on December 10, 2021**. Please see [Proposal-Required Submissions](#) section for items that must be included in the completed proposal. Applicants may send proposals via email to [Anne.Gaynor@aphl.org](mailto:Anne.Gaynor@aphl.org)

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 point of contact above to confirm receipt.

## Award

Funding will be distributed via a contract administered by APHL. APHL will select up to 15 laboratories, depending on strength of applications and funding requested and funds available. Award amounts will depend on the scope of the proposed project with the minimum award per site of \$10,000.

**Use of funds:** The awarded laboratory may use the funds for the following items.

1. Purchasing reagents or supplies for validation/verification of an MTBC identification method
  - Identification of MTBC is the primary focus of this funding opportunity; however, limited support for identification of nontuberculous mycobacteria may also be included.
2. Purchasing or leasing MTBC culture identification equipment
  - It is unlikely that the full amount of requested equipment purchases will be paid, but a portion of the budget could be requested for equipment.
3. Procuring MTBC or nontuberculous mycobacterial isolates for validation (if not available)
4. Providing training for laboratory staff
5. Updating PHL LIMS for reporting of new method test results

## Term of Project

The project term for each contract will be from February 1, 2022 through June 30, 2022.

## Evaluation Team

APHL staff, led by the HIV, Viral Hepatitis, STD and TB (HHST) Program Manager, 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 and familiarity with APHL Reference Center structure. 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 C: 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 [Appendix B](#)

## 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](http://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](#) and participation in a community of practice that would include all awardees and any other public health laboratories that are interested in sharing information on practices related to implementation of new culture identification methods for MTBC and NTM. 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 November 9, 2021**) and a proposal (**due December 10, 2021**). 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)**
  - Responses should be limited to no more than six (6) single spaced pages (font size  $\geq$  11pt,  $\geq$  1-inch margins)
  - The proposal should include responses to the questions below, including each aspect of the question. The proposal should clearly indicate what question is being answered.

## Response to Proposal Questions

**Please review carefully to ensure you respond to the correct questions for your application.**

For each option there is a unique initial question (Option 1 has a 1A and 1B). All applicants should then answer questions two, three, and four.

**Option 1: Proposals from PHLs who currently perform Hologic® AccuProbe® as their primary identification method and who do not currently have an available secondary culture identification method. Please answer the following questions (1A and 1B) and items 2-5 listed under “All Applicants” below.**

- 1A. Please describe the laboratory’s existing primary culture identification method.
  - a. Describe how long the methodology has been in use, how often it is performed, and annual volume.
- 1B. Please describe the laboratory’s plan to validate/verify and implement a new primary culture identification method to replace Hologic® AccuProbe®. Please also include the following:
  - a. Information on equipment that will be leveraged and/or if new equipment is required, please describe your ability to procure such equipment in a timely manner.
  - b. Describe where and how often this new primary culture identification method will be performed and how culture identification will be handled for multiple specimens from a single patient.
    - i. For example, if your new method requires an inactivation step be sure to address

this in your response.

- c. Describe the estimated timeline for implementation of the assay; consider time needed for validation plans, report approvals, LIMS modifications etc.
- d. Describe the subject matter expertise of your laboratory staff to evaluate a new culture identification method. Include qualifications and experience of staff members.
- e. Describe how necessary training will be provided to laboratorians to enable them to perform the test and provide interpretation of culture identification results.

**For Option 2: Proposals from PHLs that are currently in the process of validating or verifying a new primary identification method to replace Hologic® AccuProbe® as the primary method. Please answer the following question and items 2-5 listed under “All Applicants” below.**

Please describe the laboratory’s status of validation/verification and implementation of a new primary culture identification method to replace Hologic® AccuProbe®. Please also include the following:

- a. Information on equipment that will be leveraged and/or if new equipment is required, please describe your ability to procure such equipment in a timely manner.
- b. Describe where and how often this new primary culture identification method will be performed and how redundant testing for culture identification will be handled.
  - i. For example, if your new method requires an inactivation step be sure to address this in your response.
- c. Describe the estimated timeline for implementation of the assay; consider time needed for validation plans, report approvals, LIMS modifications etc.
- d. Describe the subject matter expertise of your laboratory staff to evaluate a new culture identification method. Include qualifications and experience of staff members.
- e. Describe how necessary training will be provided to laboratorians to enable them to perform the test and provide interpretation of culture identification results.

**For Option 3: Proposals from PHLs that have already transitioned to an identification method other than Hologic® AccuProbe® and would also like to expand the availability of alternative identification methods to include a secondary (back-up) method. Please respond to the following question and items 2-5 listed under “All Applicants” below.**

1. Please describe the laboratory plan to expand the availability of alternative identification methods to include a secondary (back-up) test method.
  - a. Describe the current primary identification method being performed to include test performed, testing algorithm, how often the test is performed, and turnaround time results.
  - b. Describe the PHLs need for a secondary identification method.
  - c. Describe the validation/verification plan for the secondary identification method and how this method will be used in relation to the primary identification method.

**ALL APPLICANTS (Option 1, 2, and 3)**

2. Please provide a brief explanation (3-5 sentences) of why these funds are needed to sustain or enhance MTBC identification capacity in your laboratory.

3. Provide a detailed description of how the laboratory intends to use the funds. This should include at least one and up to three specific, measurable objectives that describe the intended impact of the additional funding on laboratory services and addresses sustainability given the one-time funding.
4. Provide the proposed PHL testing algorithm for culture identification testing once all new methods are implemented.
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.

## Additional Information and Deadlines for Application Submission

Applicants must direct all questions to Anne Gaynor ([anne.gaynor@aphl.org](mailto: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 associated with the specific RFP ([www.aphl.org/rfp](http://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 Anne Gaynor at APHL ([anne.gaynor@aphl.org](mailto:anne.gaynor@aphl.org)) with a copy to Taylor Bethea ([taylor.bethea@aphl.org](mailto:taylor.bethea@aphl.org)) no later than **5:00 pm ET on Tuesday November 9, 2021**.

Applications are due to Anne Gaynor at APHL ([anne.gaynor@aphl.org](mailto:anne.gaynor@aphl.org)) with a copy to Taylor Bethea ([Taylor.Bethea@aphl.org](mailto:Taylor.Bethea@aphl.org)) by **5:00 pm ET on Friday December 10, 2021**. APHL will send an email acknowledging the receipt of your application. If you do not receive an acknowledgement within two (2) business days, call 240-485-2739 to confirm receipt.

## Appendix A: Budget Guidance

Budgets should be prepared to reflect costs through June 30, 2022. 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 ([anne.gaynor@aphl.org](mailto:anne.gaynor@aphl.org)) if special exceptions are needed 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 validate/implement or expand identification methods. 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 costs of a piece of equipment. However, we are open to payment for a portion of equipment, offsetting costs associated with leasing equipment and/or service agreements.
- Durable equipment that costs  $\geq$  \$5,000 must be reported to APHL as part of our cooperative agreement reporting.

### 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 validate/implement or expand identification methods. General laboratory or safety supplies not specifically used for identification methods, such as gloves, pipettes, lab coats, etc., are not appropriate for inclusion in this funding.

### 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 appropriate justification for how the item will be used to validate/implement or expand identification methods.

### Additional Costs Budget (optional)

Laboratories may include an additional costs budget reflecting additional funds needed (above the anticipated amount of this award) to fully validate/implement or expand identification 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 in the above sections.

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

## Appendix B: Scorecard

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)
<p>1. Does the applicant provide sufficient information and an appropriate approach to validate/verify or expand identification methods? (Questions 1-3)</p> <p><b>No issues or concerns</b>—Sufficient information and appropriate approach (15 points).  <b>Minor concerns</b>—Some information missing to fully assess and/or some minor concerns with the approach (11-14 points).  <b>Moderate concerns</b>—Information missing to fully assess plan and/or moderate concerns with the approach (6-10 points).  <b>Major concerns</b> —Significant information missing to fully assess plan and/or major concerns with the approach (1-5 points).  <b>Insufficient information to assess plan and/or inappropriate approach</b> (0 points).</p>	15		
<p>2. Does the applicant provide a clear explanation and justification for why these funds are needed to build, sustain, or enhance MTBC identification capacity in their jurisdiction? (Question 2)</p> <p><b>Applicant expresses significant need</b> – Jurisdiction has not made significant progress in transitioning from Accuprobe and/or may struggle to maintain MTBC identification capability without additional support (11-15 points).  <b>Applicant expresses moderate need</b> – Jurisdiction has made some progress in transitioning MTBC identification methods from Accuprobe but demonstrates how funds would enhance or accelerate the process (6-10 points).  <b>Applicant expresses minimal need</b> – Jurisdiction has an alternative MTBC identification method in place and will use the funds to implement an additional method to enhance capacity (1-5 points)</p>	15		

<p>2. Does the applicant demonstrate the capacity and capability to validate/verify or expand identification methods? (Question 1, 4)</p> <ul style="list-style-type: none"> <li>• <b>Option 1:</b> <i>Considering the proposed approach: does the applicant have appropriate staffing or mechanism to obtain additional assistance? Does the applicant have appropriate equipment and space, and/or the ability to obtain additional equipment and supplies to perform new primary identification method? Does the applicant provide a timeline for implementation of the new method that aligns with the project period?</i></li> <li>• <b>Option 2:</b> <i>Consider the status of the validation/verification/implementation a new primary identification method. Have equipment/supplies been purchased? Has space been allocated for the new test method? Is staffing appropriate (time and experience)? Is the timeline for implementation of the method aligns with the project period?</i></li> <li>• <b>Option 3:</b> <i>Consider the primary identification method already being performed. What is the justification/need for a secondary method? Has a validation/verification plan for this secondary method been developed and how will this method be used in conjunction with the primary identification method?</i></li> </ul> <p><b>No issues or concerns</b>—Applicant has capacity and capability to execute their proposed plans (30 points).  <b>Minor concerns</b>—There are minor concerns about the applicant’s capacity and capability to execute the proposal (23-29 points).  <b>Moderate concerns</b>— There are minor concerns about the applicant’s capacity and capability to execute the proposal (13-23 points).  <b>Major concerns</b> —There are major concerns about the applicant’s capacity and capability to execute the proposal (1-12 points).  <b>Objectives not provided and/or don’t address impact of project</b> (0 points).</p>	30		Type comments here. (REQUIRED)
<p>3. Does the applicant provide sufficient information and an appropriate method for evaluation and monitoring of their outlined objectives (Question 2)</p> <p><i>Consider whether applicant has included at least one specific, measurable objective(s) that will enable them to assess the impact of the funding. Consider whether the applicant addresses how this funding contributes to sustainable funding for the new method(s).</i></p>	20		

<p><b>No concerns</b> with objective(s), ability to use objectives as written to assess impact and sustainability (20 points).</p> <p><b>Minor concerns</b> with objective(s) and/or ability to use them to assess impact and/or sustainability (11-19 points).</p> <p><b>Major concerns</b> with objective(s) and/or ability to use them to assess impact and/or sustainability (1-10 points).</p> <p><b>Objective(s) not provided and/or don't address impact of project</b> (0 points).</p>			
<p>4. Does the applicant provide an understandable proposed testing algorithm for culture identification? (Question 3)</p> <p><b>No concerns with testing algorithm</b>—appropriate and clearly understandable testing algorithm (10 points).</p> <p><b>Minor concerns with testing algorithm</b>—appropriateness and/or clarity (5-9 points).</p> <p>Major concerns with testing algorithm—appropriateness and/or clarity (1-4 points).</p> <p><b>Testing algorithm not appropriate/not provided</b> (0 points).</p>	10		Type comments here. (REQUIRED)
<p>5. Does the applicant provide an appropriate budget for the requested funding? (Question 4)</p> <p><b>No concerns with budget</b> (10 points).</p> <p><b>Minor Concerns with budget</b> (5-9 points).</p> <p><b>Major Concerns with budget</b> (1-4 points).</p> <p><b>Budget not appropriate for proposal</b> (0 points).</p>	10		Type comments here. (REQUIRED)
<b>TOTAL SCORE</b>	<b>100</b>	<u>    </u>	

## Appendix C: 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.

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.

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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).

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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?

APHL Conflict of Interest Disclosure Statement

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.

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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:**

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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.

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APHL Conflict of Interest Disclosure Statement

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.

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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.