



Request for Proposals: Evaluation of Automated Rapid Plasma Reagin (RPR) Systems for the Diagnosis of Syphilis

Revised: September 10, 2019

Application Due Date: October 9, 2019

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Summary

The Association of Public Health Laboratories (APHL), in cooperation with the Centers for Disease Control and Prevention's (CDC) Division of STD Prevention (DSTDP), is seeking to identify three public health laboratories to participate in an evaluation of automated rapid plasma reagin (RPR) systems compared to manual RPR. Selected laboratories will perform testing using one of the three automated RPR systems commercially available in the US to collect performance data on a set of provided serum samples.

Background

Syphilis, caused by the spirochete bacterium *Treponema pallidum* subspecies *pallidum*, is an ongoing global and domestic public health concern, and is transmitted sexually or vertically from an infected mother to her child. Recent national surveillance reports from the Centers for Disease Control and Prevention (CDC) have shown continuing increases in syphilis rates among both sexes and most age groups across the United States, as well as the emergence of ocular syphilis in recent years.¹

Furthermore, syphilis and other STIs are one of several risk factors associated with an increased risk for HIV transmission, and treatment of STIs could reduce the incidence of HIV.² The diagnosis of syphilis is challenging in part due to overlapping and/or ambiguous clinical presentation particularly during early syphilis or infection(s) with other ulcerative STIs. Additionally, laboratory testing relies on indirect serologic detection of the pathogen causing the infection. Therefore, laboratory testing and clinical evaluation must be interpreted together to properly diagnose infection.

The laboratory diagnosis of syphilis primarily involves serology assays that detect nontreponemal and treponemal antibody responses. While direct detection methods including darkfield microscopy and PCR of syphilitic lesion exudate smears to detect treponemes is possible, this method is less common.^{3,4} Direct detection methods requires testing of a primary lesion which may no longer be present when a person presents for diagnosis. In contrast, there are several FDA-cleared syphilis serology assays and current testing recommendations involve a combination of both nontreponemal and treponemal tests using either the traditional or reverse sequence algorithm. Choice of algorithm and serology assay(s) depends on a number of factors that include incidence of disease, patient population, volume and frequency of tests, turnaround time, and cost. The advent of automated methods has facilitated higher throughput testing. In addition to a number of automated treponemal assays which have been available for a number of years, there are now three new FDA-cleared automated nontreponemal RPR assays: the ASI Evolution, AIX1000, and BioPlex 2200 Syphilis Total and RPR Assay. While these new technologies have the potential to contribute to rapid and accurate diagnosis of syphilis, information on the use and performance of these automated nontreponemal assays is limited due to their relatively nascent release, thus raising more questions in an already shifting field of syphilis diagnostics. Comprehensive evaluation of the practicality and performance of these systems is imperative for determining the

optimal approach for syphilis diagnosis in the United States, as nontreponemal assays are a key component of current testing algorithms.

In an effort to address the knowledge gap, APHL in collaboration with the CDC DSTDP is seeking to identify three laboratories to evaluate automated RPR systems. Selected laboratories would test serum panels consisting of syphilis reactive and non-reactive specimens provided by the CDC with the automated RPR assay their laboratory is currently utilizing. The same panels will also be evaluated at CDC DSTDP with manual RPR testing and the treponemal assay *Treponema pallidum* Particle Agglutination (TP-PA) as a reference standard for data acquired from participating laboratories.

This funding announcement is designed to identify laboratories to participate in an evaluation of all three FDA-cleared automated RPR systems using characterized serum panels consisting of syphilis reactive and non-reactive specimens provided by the CDC to better understand the performance of these newer automated RPR assays. The ideal study design will include each of the three automated RPR systems.

Eligibility

APHL is looking to identify three laboratories, including all member public health laboratories and hospital and academic laboratories that have unrestricted access to one of the three FDA-cleared automated RPR systems and meet the specific expectations regarding methodologies to be used by the awardees are outlined in [Appendix A: Expectations for Automated RPR Evaluation](#). All applicants are required to agree to the minimum requirements as outlined in [Appendix B](#) and detailed below:

- Established experience and competency with syphilis testing.
- Established and demonstrated competency and capacity using one of the following automated RPR systems : ASI Evolution, AIX1000 or BioPlex 2200 Syphilis Total and RPR Assay
- Sufficient and unrestricted access to the equipment and laboratory supplies, laboratory space and workforce capacity for the proposed number of specimens to be tested.

Anticipated RFP Schedule

August 28, 2019	–	RFP Issued
September 9, 2019	–	Informational Teleconference (Q&A)
September 13, 2019	–	Letter of Intent Due to APHL (see below)
October 9, 2019	–	RFP Responses Due
October 24, 2019	–	Proposal review completed
October 25& 28, 2019	–	If needed, follow-up interviews and updated proposals due
October 31, 2019	–	Final review completed and awardees selected

November 1, 2019 – Draft contracts submitted to APHL Legal Dept. for final internal review

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

Response Submittal

Confirmation of Intent to Respond

APHL requests that prospective applicants submit a brief email statement indicating an intent to submit a proposal. APHL must receive this email by no later than **5:00pm EST on Friday, September 13, 2019**

Final Response

APHL must receive complete responses by **5:00 pm EST on Wednesday, October 9, 2019**. 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

APHL will send an email acknowledging the receipt of your application; if you do not receive an acknowledgement within 48 hours, please email the RFP points of contact above to confirm receipt.

Award

APHL will select up to three laboratories depending on the strength of the applications, funding requested and funds available. The evaluation has a budget of \$80,000 which will be divided amongst the awarded sites based on the proposed budget and project needs. APHL will distribute the award via a contract administered with APHL.

Term of Project

The project term will be from the date of notification through June 30, 2020. The expected contract term will cover the period from November 1, 2019 through June 30, 2020. APHL anticipates that from the date of notification to the start date of the contract, the selected sites will work with APHL and the CDC work group to review the statement of work, and ensure mechanisms are in place for specimen and data transfer between the participating laboratory and the CDC.

Evaluation Team

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

A team of three subject matter experts (SMEs) from CDC DSTDP and a panel of three APHL members selected from non-applicant public health laboratories will review complete proposals. APHL will identify

and select SMEs from CDC based on their familiarity with laboratory techniques and project requirements. APHL member experts will be identified from among the non-applicant PHLs by the APHL HHST Program Manager. They will have expertise in the laboratory testing methods described in this RFP. 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** in order to disclose any real or perceived conflict of interest prior to the start of the evaluation process. Reviewers will have to affirm that they have no conflict of interest that would preclude an unbiased and objective review of the proposals received. A copy of the disclosure statement and the related Fiduciary Responsibility and Conflict of Interest Policy is attached as [Appendix D: Conflict of Interest Disclosure Statement and Policy](#). APHL will not select reviewers with a perceived or potential conflict of interest. **Applicants do not fill out Appendix D 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 C](#).

The evaluation team will give preference to PHLs, laboratories with extensive experience with the test methods, ability to handle high number of serum specimens, ability to comply with expectations laid out in [Appendix A](#), and the ability to meet the minimum expectations outlined in [Appendix B](#). If laboratories score similarly, preference will be given to diversify instrumentation.

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 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 the name of the selected applicant is posted.

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

Conditions of Award Acceptance

The eligible laboratory must be able to contract directly with APHL or have an existing relationship with a third-party organization that can contract directly with APHL on behalf of the laboratory. Laboratories must agree to comply with expectations outlined in [Appendix A](#).

Prior to making the official award, a group of individuals from CDC and APHL will be entitled to tour the facilities to assess compliance with requirements for testing and/or have a teleconference with applicant laboratories. Post award, APHL may conduct site visits to include an assessment of continued compliance as necessary.

Request for Proposal – Required Submissions

In order to be considered for selection, an interested laboratory must submit a proposal that responds to the following questions. Responses should be limited to no more than four double-spaced pages (font size \geq 11pt and page margins of \geq 1 inch) and must comply with submission requirements set out in the [Additional Information and Deadlines for Application Submission](#) below.

- 1. Please describe your laboratory's current syphilis testing practices and experience addressing the following points:**
 - a. What algorithm(s) do you use?
 - b. What specific syphilis assays are used in your laboratory?
 - c. What specific instruments are used in your laboratory?
 - d. How frequently is testing performed per method?
 - e. What is your overall testing volume for syphilis?
 - f. Describe how many years syphilis testing has been performed in your laboratory, the number of staff trained in testing and the amount of experience they have in the methods described above (years, training, and consistency of performing testing).
 - g. Describe storage conditions for specimens; include details on storage upon receipt, between testing methods (if applicable) and after testing is completed.

2. Please describe your laboratory's automated RPR platform and address the following points:

- a. Describe which automated RPR instrument (ASI Evolution, AIX1000, or BioPlex 2200 Syphilis Total and RPR Assay) is in use.
- b. How long (months, years) has the assay been in use in your laboratory?
- c. Briefly describe how your laboratory validated the automated RPR method
- d. How often testing is performed on the instrument (times per day/week)?
- e. How often is repeat testing indicated?
- f. Describe laboratory staff experience with the instrument (years, training, and consistency performing method).
- g. Describe the specimen volume required for qualitative and quantitative testing including approximate volumes needed for a dilution protocol in case an RPR reactive specimen has a titer greater than the instrument can perform automatically. Please also clearly describe the dead volume to ensure sufficient specimen volume is provided.

3. Please describe existing laboratory resources available to perform the proposed work?

- a. Describe how your laboratory will incorporate qualitative testing of up to 850 specimens and quantitative testing of up to 15 specimens (10 repeats each) into your laboratory workflow
- b. Describe the availability of primary and supplementary equipment, supplies, reagents, kits, laboratory space, and workforce capacity for the proposed work.

4. Please provide an overall budget for the project that is based on a per specimen cost. Please outline, at minimum, the costs associated with testing the following: reagents, kits, staff time and any other charges or overhead based on the **maximum estimates of specimens (qualitative RPR: 850 samples, quantitative RPR: 50 specimens titered to end-point and 15 specimens titered to end-point with up to 10 replicates.)**

5. Include a completed and signed copy of [Appendix B](#) as an attachment.

Additional Information and Deadlines for Application Submission

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

[Revised 9.10.19] Please send the Letter of Intent (Due 9/13/19) and completed application (Due 10/9/19) to Anne Gaynor, anne.gaynor@aphl.org

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

APHL will hold an optional teleconference on Monday, September 9, 2019 at 3:00pm 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.

Teleconference Call-in Information is below, or please contact anne.gaynor@aphl.org or infectious.diseases@aphl.org no later than 5:00pm ET on Friday, September 6, 2019 to be sent the calendar invitation.

Join Zoom Meeting

<https://aphl.zoom.us/j/349006653>

Call-in Information

+1-646-876-9923, or

+1-669-900-6833,

Meeting ID: 349 006 653

APHL must receive applications, attention Anne Gaynor by close of business (5:00pm ET) Wednesday, October 9, 2019. Either electronic or physical submission is acceptable. APHL will send an email acknowledging the receipt of each application; if you do not receive an acknowledgement within 48 hours, call 240-485-2739 to confirm receipt.

References

- 1 Centers for Disease Control and Prevention. Sexually Transmitted Disease Surveillance 2017. Atlanta: U.S. Department of Health and Human Services; 2018.
https://www.cdc.gov/std/stats17/2017-STD-Surveillance-Report_CDC-clearance-9.10.18.pdf (2017).
- 2 Ward, H. & Ronn, M. Contribution of sexually transmitted infections to the sexual transmission of HIV. *Curr Opin HIV AIDS* **5**, 305-310, doi:10.1097/COH.0b013e32833a8844 (2010).
- 3 Morshed, M. G. & Singh, A. E. Recent trends in the serologic diagnosis of syphilis. *Clin Vaccine Immunol* **22**, 137-147, doi:10.1128/CVI.00681-14 (2015).
- 4 Ratnam, S. The laboratory diagnosis of syphilis. *Can J Infect Dis Med Microbiol* **16**, 45-51 (2005).

Appendix A: Expectations for Automated RPR Evaluation

Methods

Applicants must be well equipped with relevant instruments, supplies, and laboratory space and workforce capacity for the proposed work. APHL will not provide equipment, supplies, kits and reagents.

Specimens

1. Specimens for qualitative (maximum of 850 specimens) and reproducibility/end-point titer (up to 15 specimens-up to 10 repeats) testing will be provided (≥ 500 μ l aliquot per specimen or more, depending on instrument requirements) by CDC, with each vial being labeled with a CDC-issued specimen barcode. Specimen inquiries and results reporting during the project period should reference these barcodes. CDC will provide an Excel spreadsheet containing specimen inventory.
2. Specimens will be shipped frozen on dry ice by CDC DSTDP at no cost to the participating laboratory, and should be stored at -20 degrees Celsius to -80 degrees Celsius upon receipt at the selected laboratory until testing can be performed.
 - a. APHL will provide the schedule for disbursement of samples prior to the start of the project.
3. Freeze-thaw cycles of samples must be kept to a minimum (≤ 2 cycles) and should be consistent across batches.
4. Upon thawing, specimens should be immediately tested or can be stored at 4 degrees Celsius until testing for no longer than 7 days. Instrument manufacturer's instructions on specimen handling/storage should also be followed. If any unanticipated delays occur during testing that may warrant longer storage at 4 degrees Celsius, please indicate as such to APHL and on line listed reports.
5. At the conclusion of the project (June 30, 2020) any residual specimen(s) remaining after completion of all automated RPR testing should be returned frozen on dry ice to CDC no later than July 15, 2020 or as directed by APHL. A CDC FedEx account number will be provided for specimen returns.

Testing

1. All specimens must be tested using the automated RPR system (ASI Evolution, AIX1000, or BioPlex 2200 Syphilis Total and RPR Assay) specific to the applicant's laboratory, according to the instrument manufacturer's protocols and the laboratory's standard operating protocol/workflow. CDC will provide feedback regarding supplied specimens and other technical assistance via email and/or teleconference but will not provide any training.

2. Each selected laboratory will perform qualitative testing for a maximum of 850 specimens that include both syphilis reactive and nonreactive sera.
 - a. Specimens should be run only once on the laboratory's automated RPR platform. Additional/repeat testing, e.g. in the event of inconclusive results or run/instrument error(s) should only be performed per the manufacturer's instructions for use or upon consultation with APHL/CDC. Participants should include a note next to results for any repeated runs to provide reason(s) for repetition.
 - b. Specimens should be tested in batches, and information pertaining to the number of batches, the number of specimens per batch, and batch testing schedule will be provided by APHL/CDC after laboratories have been selected, and amended as needed to derive a mutually agreed upon schedule. Specimens provided by CDC should be run separately from any clinical specimens.
 - c. From this group of specimens, a small subset of specimens (maximum of 50 specimens) will be selected by APHL/CDC for each selected laboratory to perform quantitative testing to determine the specimens' titers. Information pertaining to the number of batches, the number of specimens per batch, and batch testing schedule will be provided by APHL/CDC after laboratories have been selected, and amended as needed to derive a mutually agreed upon schedule.
3. Each selected laboratory will perform reproducibility/end-point titer testing for a minimum of 10 and maximum of 15 reactive serum specimens during the project period.
 - a. Specimens will include non-reactive samples and up to 15 blinded samples with RPR titers ranging from 1:1 through 1:256 or potentially higher, depending upon availability.
 - b. Selected laboratories will test each specimen up to ten times using the automated RPR assay to determine reproducibility. A defined testing schedule will be provided by APHL/CDC after laboratories have been selected, and amended as needed to derive a mutually agreed upon schedule.
4. Selected laboratories must agree to provide all data to APHL and CDC within agreed time frames prior to the end of the project period using a standardized collection form that will be provided.

Procurement

The cost of reagents should be incorporated into the per specimen reimbursement. No financial support is available for the procurement of equipment. Supplies, kits and reagents can be procured using the funding awarded for this project. Funds allocation is at the discretion of the awarded sites.

Turnaround Time

Automated RPR results for each batch of specimens provided for qualitative and quantitative testing should be provided to APHL and CDC within 1 month of test completion or as determined with the sites.

Data Management

APHL will provide a template for data collection which would include categories such as: specimen details, test kit name, lot number and expiration date, laboratorian operating the assay, QC data and results to the selected laboratories. Instrument-generated raw data files (original instrument read-outs of results for each batch of specimens) should also be provided by the selected laboratories. Data will be sent to APHL and CDC as defined in the schedule to be provided.

Performance Management and Evaluation

Performance will be monitored by timeliness of responses to APHL requests and successful completion of testing and reporting.

Reports

The laboratory will send completed data collection tables after each batch of testing to APHL and CDC. APHL and CDC will prepare a final report outlining the performance of the automated instruments compared to the manual testing conducted at CDC. If a manuscript is developed, each awarded laboratory will be offered to add one co-author to the manuscript

Site visits and teleconferences

APHL, CDC and the awardee laboratories will participate in a kick-off teleconference and monthly teleconferences to discuss project progress and address any anticipated or ongoing challenges, mitigation plans and resolutions.

Appendix B: Minimum Requirements for the Automated RPR Evaluation

YES	NO	MINIMUM REQUIREMENT
		Does your laboratory have experience and competency with syphilis testing?
		Does your laboratory have unrestricted access to an FDA-cleared automated RPR instrument?
		Does your laboratory have sufficient supplies, reagents, laboratory space and workforce capacity for the proposed work?

Signature: _____
Printed Name:

Date: _____

Appendix C: Automated RPR Evaluation 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 have sufficient capacity and experience in syphilis testing?</p> <p><i>Consider prior and current experience of the laboratory with syphilis diagnosis, and training and experience of existing staff.</i></p> <p><i>Excellent: Perform syphilis testing 5-6 days per week, process at least 2,000 specimens per week, and have 2 or more staff with appropriate experience (16-20 points)</i></p> <p><i>High: Perform syphilis testing 3-4 times per week, process at least 1,000 specimens per week and have 2 or more staff with experience (11-15 points)</i></p> <p><i>Moderate: Perform syphilis testing 2-3 times per week, process at least 250 specimens per week and have at least 1 staff with experience (6-10 points)</i></p> <p><i>Limited: Perform syphilis testing 1-2 times per week, process at least 100 specimens per week and have at least 1 staff with experience (1-5 points)</i></p> <p><i>Insufficient capacity or no experience (0 points)</i></p>	20		Type comments here. (REQUIRED)
<p>2. Does the applicant have sufficient competency and experience performing automated RPR testing to comply with the requirements described in Appendix A of the RFP?</p> <p><i>Evaluate proposed methodology and workflow for automated RPR testing. Consider training and experience of existing staff in automated methods and automated RPR instruments.</i></p> <p><i>Excellent: >18 months experience (>100,000 specimens tested), has approved protocols, trained staff and completed validation and have 2 or more staff with appropriate experience (41-50 points)</i></p> <p><i>High; 12- 18 months experience (50,000-100,000 specimens tested), has approved protocols and completed validation and have 2 or more staff with appropriate experience (31-40 points)</i></p> <p><i>Moderate: 6-12 months experience 25,000-49,999 specimens tested), has approved protocols and completed validation and have at least 1 staff with experience (21-30 points)</i></p> <p><i>Fair: 6-12 months experience (<25,000 specimens tested), validation plan and at least 1 staff member with experience (11-20 points)</i></p>	50		Type comments here. (REQUIRED)

<p><i>Limited: ≤ 6 months experience (1,000 specimens tested); is finalizing protocols and completing validation (1-10 points)</i> <i>No experience (0 points)</i></p>			
<p>3. Does the laboratory have workspace, workforce capacity, and sufficient supplementary supplies, reagents and kits for the proposed work?</p> <p><i>Excellent: Laboratory has dedicated work space and ancillary equipment; lab currently uses the appropriate supplies and reagents, and has approved procedures needed to perform the proposed work, lab has appropriate staffing to perform testing for the RFP (16-20 points)</i> <i>High: Laboratory has an established work space and maintains ancillary equipment; lab currently uses the appropriate supplies and reagents, and has approved procedures needed to perform the proposed work, lab has appropriate staffing to perform testing for the RFP (11-15 points)</i> <i>Moderate: Laboratory has access to shared work space and shared ancillary equipment; lab will purchase appropriate supplies and reagents to perform proposed work, lab has some staffing to perform testing for the RFP (6-10 points)</i> <i>Limited: Laboratory has limited access to shared work space and shared ancillary equipment; lab will purchase appropriate supplies and reagents to perform proposed work, lab has staffing but with limited experience (1-5 points)</i> <i>Insufficient equipment, supplies, reagents, space, or workforce: (0 points)</i></p>	20		Type comments here. (REQUIRED)
<p>4. Has the applicant provided an appropriate budget and per specimen cost for the proposed work?</p> <p><i>Appropriate budget for proposed work (8-10 points)</i> <i>Budget lacks some detail or reservations about proposed budget (4-7 points)</i> <i>Major concerns with budget (1-3 points)</i> <i>Insufficient or inappropriate budget(0 points)</i></p>	10		Type comments here. (REQUIRED)
TOTAL SCORE	100		

Appendix D: Conflict of Interest Disclosure Statement and Policy

Association of Public Health Laboratories
Conflict of Interest Disclosure Statement

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

APHL will keep your completed disclosure statement in the corporate records of the association.

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

2. Do you, or does any family member, currently serve as an officer, director, committee member, or other volunteer (or work as an employee of or a paid consultant to) any organization serving the interest of laboratory science or public health laboratories other than APHL or your state or local laboratory?

Yes No

If yes, please list the organization(s) and provide detail on your or your family member's interest or position in the organization(s).

3. Do you, or any family member, have an existing or potential interest in, or compensation arrangement with, any third party providing goods or services to APHL, or with which APHL is currently negotiating?

Yes No

APHL Conflict of Interest Disclosure Statement

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.

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.

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.