Request for Proposals: Evaluation of a Laboratory Developed Molecular Test for the Diagnosis of Genital Ulcer Disease (GUD)

Application Due date: June 15, 2018

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

Summary

The Association of Public Health Laboratories (APHL), in cooperation with the Centers for Disease Control and Prevention's (CDC) Division of STD Prevention (DSTDP), is seeking to enlist up to five state or local public health laboratories to assist with evaluation of a laboratory developed molecular test for detection of STD pathogens associated with genital ulcer disease (GUD), especially the causative agent of syphilis. Selected laboratories will participate in the validation of the CDC real-time multiplex PCR assay for the diagnosis of GUD (GUD M-PCR).

Background

Genital ulcer disease is a general term that refers to lesions resulting from specific sexually transmitted infections (STIs). *Treponema pallidum*, known to cause syphilis, and herpes simplex virus (HSV) types 1 and 2 are the predominant etiological agents of GUD. In the US, there were 27,814 primary and secondary (P&S) syphilis cases reported in 2016, which represents a 17% increase from 2015. HSV is among the most prevalent of sexually transmitted infections. However, HSV infection is not a notifiable disease in the US. *Haemophilus ducreyi*, which causes chancroid, is a known etiological agent of GUD but has rarely been detected in the US since 1996. In 2016, there were only 7 chancroid cases reported for the US. While HSV-2 is currently the leading cause of GUD in the US, the etiology of this disease can vary both temporally and geographically, and is strongly associated with behavioral, demographic, and socioeconomic factors, and the prevalence of HIV infection. It is recognized that not only is GUD associated with an increased risk for HIV transmission, but that treatment of STIs could reduce the incidence of HIV. Moreover, there are missed opportunities for laboratory diagnosis of syphilis in

patients with primary lesions because the most common current detection methods rely on an antibody response, which has not yet happened when the initial chancre appears.

There are a few testing options available for the direct detection of GUD from a lesion. These include culture and dark-field microscopy. However, the lack of expertise and capacity, long turnaround times, cost, and the lower test sensitivity and specificity of the above-mentioned methods result in GUD diagnosis often being based on clinical presentation. Due to the overlapping clinical presentation of syphilis and genital herpes, and possible coinfection, these diseases are often misdiagnosed in the absence of confirmatory laboratory testing.

In the past decade, nucleic acid amplification techniques such as PCR have been developed to identify the causative agents of GUD. PCR can be performed for each agent separately or by a multiplex assay. The advantages of a real-time multiplex PCR assay is that it allows for the simultaneous detection of multiple pathogens in a single assay with a relatively short turnaround time. Though studies have reported on the utility of real-time multiplex PCR for the diagnosis of GUD (GUD M-PCR), there has never been a commercially available assay, making validation and implementation of this type of assay challenging for laboratories serving STD clinics.

This funding announcement has two aspects. The first provides an opportunity to collect additional specimens from patients with GUD to aid in the evaluation and development of better tests. The second provides an opportunity for the evaluation of a TaqMan-based GUD M-PCR[1] test at state or local public health laboratories to better understand performance in a real-life setting and enable access to better laboratory diagnostic options, especially for P&S syphilis. Please note this is a one-time funding opportunity.

Eligibility

APHL is looking for eligible laboratories, including all member public health and academic laboratories with the following capabilities and facilities in place. Specific expectations regarding methodologies to be used by the awardees are outlined in Appendix A: Expectations for GUD M-PCR Evaluation. All applicants are required to agree to the minimum requirements (as outlined in Appendix B) for the option they are applying for. Applicants may apply for Option 1, Option 2, or both.

1. **Option 1: Collection and Submission of GUD Specimens to CDC for development/evaluation of novel diagnostic tests or genotyping assays.**

    a. Applicant must agree to provide 50-100 residual GUD specimens after routine HSV or syphilis testing and/or;
    b. Applicant must agree to collect an additional 30-50 syphilis specimens from patients presenting with moist/exudative primary or secondary syphilis genital lesions using Aptima Multitest Swab Specimen Collection Kit, which can be provided by CDC.

2. **Option 2: Evaluation of the GUD M-PCR[1] at the public health laboratory.**
    a. Applicant must agree to test a minimum of 40 GUD swabs during the project period from patients presenting suspected primary syphilis or HSV.

   i. Note that these specimens must be obtained by the public health laboratory performing the evaluation. CDC will not provide specimens.
b. Applicant must send half the volume or 1 mL (whichever is greater) of each residual sample after GUD M-PCR testing to CDC for quality assurance testing.
c. Applicant must have unrestricted access to a real-time PCR instrument (Rotor-Gene 6000/Q, ABI 7500 or similar instrument equipped with a minimum of 4 channel detection) and demonstrated competency and capacity using real-time PCR to perform bacterial and viral identification. The applicant must be well equipped and with sufficient laboratory space and workforce capacity for the proposed work.
d. Applicants must agree to conduct testing and provide all data to APHL/CDC prior to the end of project period.

Anticipated RFP Schedule

May 1, 2018	–	RFP Issued
May 16, 2018	–	Informational Teleconference (Q&A)
May 18, 2018	**–**	**Letter of Intent Due to APHL (see below)**
June 15, 2018	–	**RFP Responses Due**
July 2, 2018	–	Proposal review completed
July 2-9, 2018	–	If needed, follow-up interviews and updated proposals due
July 9, 2018	–	Final review completed and awardees selected
August 1, 2018	–	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 May 18, 2018.**

Final Response

APHL must receive complete responses by **5:00 pm EST on June 15 2017**. Please see Proposal-Required Submissions section for items that must be included in the completed proposal.
Applicants may send proposals by the following methods:

Via email to Anne.Gaynor@aphl.org or

Via Mail (USPS, FedEX, UPS) addressed to:
Association of Public Health Laboratories
Attn: ANNE GAYNOR
8515 Georgia Avenue. Suite 700
Silver Spring, MD 20910

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

Award

APHL will select up to four laboratories depending on the strength of applications. Each selected applicant will be eligible for an award of up to $8,750. 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, 2019. The expected contract term will cover the period from August 1, 2018 through June 30, 2019. APHL anticipates that from the date of notification to the start date of the contract, the selected site will work with APHL and the CDC work group to define the sample set, review the proposal, and ensure mechanisms are in place for specimen and data transfer between the participated laboratory and the CDC. APHL may consider the potential for annual renewal (with an additional funding year running from July 1 to June 30) based on availability of funds and the performance of the awardee(s). Potential renewal may involve some adjustment to the scope of work in order to address any change in the funding received by APHL and to accommodate CDC programmatic needs in that funding year. APHL will notify the selected applicant in advance of any modification to the anticipated scope of work in a future funding year.

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, and will be familiar 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** 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.

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 based on extensive experience with the test methods, ability to handle increased test volume for GUD, ability to comply with expectations laid out in Appendix A, and the ability to meet the minimum expectations outlined 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 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.

The eligible laboratory must be able to receive specimens and report results to all submitting partners in the proposal.

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.

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 ≥ 11pt and page margins of ≥ 1 inch) and must comply with submission requirements set out in the Additional Information and Deadlines for Application Submission below.

Option 1 requirements

1. **Please describe the laboratory's capability to obtain primary lesions swabs from patients presenting with GUD.**
    a. Describe how many specimens (per month) are collected from patients presenting with moist genital ulcers/lesions including HSV and P&S syphilis and what specimen transport media are used.
    b. What partnerships or arrangements are in place to ensure you will be able to meet the minimum sample request. Please provide a letter of support from your partner(s) clinics or organizations.
    c. Can additional swab(s) be collected from moist/exudative genital lesions of P&S syphilis and how long is local IRB approval anticipated to take?
2. **Include a completed and signed copy of Appendix B as an attachment.**

Option 2 requirements

1. **Please describe the laboratory's experience in testing for syphilis, HSV (1 and 2), and chancroid including tests used and methodologies.**

a. Provide a short description of testing methods and algorithms currently used to detect the above-mentioned pathogens and work up for GUD PCR, if applicable.

b. Please describe how many years each method has been in use, how many specimens are received for testing (per month), how often testing is performed (times per week), and amount of experience laboratory staff have in using the methodology (years, training, and consistency performing method).

2. **Please describe the volume of laboratory specimens submitted for HSV and syphilis testing. Alternatively, please describe how you would obtain the necessary specimens for the evaluation of the GUD M-PCR.**

    a. Describe how many specimens (per month) are collected from patients presenting with moist genital ulcers/lesions including HSV and P&S syphilis and what specimen transport media are used; or

    b. Describe how many specimens the laboratory can obtain from patients presenting with moist genital ulcers/lesions including HSV and P&S syphilis and what specimen transport media are used. Please also describe how the site will obtain them, including current partnerships or the development of a new partnership and letters of support.

3. **Please describe the laboratory's current real-time PCR testing practices including pathogens detected.**

    a. Describe how many years the real-time PCR instrument has been in use, which instrument is in use, how often testing is performed, specimen types, pathogens tested, and amount of experience laboratory staff have in using the methodology (years, training, and consistency performing method).

4. **Please describe the current laboratory resources available to perform real-time PCR.**

    a. Describe the availability of ancillary equipment, supplies, reagents, laboratory space, and workforce capacity for the proposed work.

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 PHLs, together with the answers provided by APHL or CDC staff to APHL's procurement website (www.aphl.org/rfp).

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

APHL will hold an optional teleconference on Thursday May 16 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.

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

Phone: 866.822.6061 Passcode: 858376#

APHL must receive applications, attention Anne Gaynor by close of business (5:00pm ET) June 15, 2018. Either electronic or physical submission is acceptable. APHL will send an email acknowledging the receipt of each application; if you do not receive an acknowledgement within 48 hours, call 240-485-2739 to confirm receipt.

References

1. Chen CY, Ballard RC. The Molecular Diagnosis of Sexually Transmitted Genital Ulcer Disease. In: MacKenzie C, Henrich B (eds). Diagnosis of Sexually Transmitted Diseases. Methods in Molecular Biology (Methods and Protocols). 2012 vol 903. Humana Press, Totowa, NJ.

2. Orle KA, Gates CA, Martin DH, Body BA, Weiss JB. Simultaneous PCR detection of Haemophilus ducreyi, Treponema pallidum, and herpes simplex virus types 1 and 2 from genital ulcers. J Clin Micro. 1996 Jan;34(1):49-54.

3.. Costa-Silva M, Coutinho D, Sobrinho-Simoes J, Azevedo F, Lisboa C. Cross-sectional study of Treponema pallidum PCR in diagnosis of primary and secondary syphilis. Int J Dermatol. 2018 Jan;57(1):46-49.

Appendix A: Expectations for the GUD M-PCR Evaluation

Methods

Selected laboratories will collaborate with CDC to:

a) **For Option 1a:** Applicants will work with their partnered STD clinics to collect 50-100 GUD specimens in transport media based on their routine management of GUD and will provide CDC with ≥ 1 mL of the residual volume (in the original collection tube) after routine HSV and/or syphilis testing. Specimens in transport medium stored at 4°C for 2 weeks (as part of routine HSV/syphilis testing procedures) or at -80°C if stored >2 weeks to 3 months will be accepted. **AND/OR;**

b) **For Option 1b:** Applicants will collect additional 30-50 moist/exudative primary and secondary ulcers/lesion specimens using the Aptima Multitest Swab Specimen Collection Kit (Hologic Inc.) and will send the entire volume to CDC. Specimens in transport medium stored at 4°C for 2 weeks (as part of routine HSV/syphilis testing procedures) or at -80°C if stored >2 weeks to 3 months will be accepted.

c) **For Option 2:** Applicants will perform GUD M-PCR[1] on a residual GUD specimens from local HSV and/or syphilis testing. Only remnant specimens with a volume ≥1 mL should be tested and must be obtained by the public health laboratory. CDC will not be providing specimens. Half of the specimen (≥500 ul) should be kept at the site for testing and the other half must be sent to CDC for quality control testing. Specimens in transport medium stored at 4°C for 2 weeks (as part of routine HSV/syphilis testing procedures) or at -80°C if stored >2 weeks to 3 months will be accepted. CDC will provide kits for DNA extraction, reagents and protocol for real-time M-PCR testing, sterile tubes for aliquoting specimens, barcode labels, and a FedEx Account number to ship specimens to CDC. Briefly, the GUD M-PCR protocol involves manual extraction of DNA from GUD specimens, preparation of PCR master mix, and operation of real-time PCR instrument[1]. Applicants will provide local HSV and/or syphilis testing and M-PCR results to APHL/CDC on a monthly basis.

d) Applicants should store all specimens being sent to CDC at -80°C (-20°C if -80°C freezer is not available) and shipped on dry ice. CDC will provide specimen collection kits for Option 1b and a FedEx Account number to ship specimens.

Procurement

Supplies, reagents and equipment can be procured using the funding for this project. APHL will fund labs that elect to participate in Option 1a up to $3,500. APHL will award labs collecting additional swab specimens (Option 1b) up to an additional $5,250. APHL will fund sites that participate in Option 2 up to $8,750. Funds allocation is at the discretion of the awarded sites.

Data Management

APHL will provide data collection sheets to the awardees. Data will be sent to CDC to analyze the results from the five laboratories.

Performance Management and Evaluation

Performance will be monitored by timeliness of responses to CDC and APHL requests and successful completion of testing the required number of GUD specimens.

Reports

The laboratory will submit to APHL and CDC comments on the M-PCR performance and results following testing. APHL and CDC will prepare a final report, and a manuscript may be published in a peer-reviewed journal. Each awardee 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 teleconferences to discuss specimen collection and selection, M-PCR testing, and address any barriers.

Appendix B: Minimum Requirements for the GUD Multiplex PCR Evaluation

Please complete the section for the options you are applying for. If you are applying for both, please complete both sections.

Option 1

YES	NO	MINIMUM REQUIREMENT
		1a. Does your laboratory routinely receive lesion specimens for HSV or syphilis testing or have the capacity to obtain additional lesion specimens for research purposes? **And/or**
		1b. Does your laboratory have the capacity to obtain additional lesion specimens for syphilis testing?
		1a & 1b. Does your laboratory have partnerships or arrangements in place to ensure you will be able to meet the minimum sample request? Please provide letters of support.

Option 2

YES	NO	MINIMUM REQUIREMENT
		Does your laboratory routinely receive lesion specimens for HSV or syphilis testing or have a plan to obtain specimens?
		Does your laboratory have partnerships or arrangements in place to ensure you will be able to meet the minimum sample request?
		Does your laboratory have demonstrated competence and capacity using real-time PCR for bacterial and viral identification?
		Does your laboratory have unrestricted access to a real-time PCR instrument?
		Does your laboratory have sufficient ancillary equipment, supplies, reagents, laboratory space, and workforce capacity for the proposed work?

Signature: _____ Date: _____

Printed Name:

Appendix C: Evaluation of the GUD M-PCR RFP Score Card

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

Option 1 Score Card:

Category	Maximum Value	Score	Comments (REQUIRED)
1. Does your laboratory routinely receive lesion specimens for HSV or syphilis testing? (1a) ***Excellent***:>50 specimens a month received for routine HSV or syphilis testing (31-40pts); ***High***: 30-50 specimens a month received for routine HSV or syphilis testing (21-30pts); ***Moderate***: 10-29 specimens a month received for routine HSV or syphilis testing (11-20pts); ***Limited***: <10 specimens a month specimens a month received for routine HSV or syphilis testing (1-10pts); ***Specimens are not routinely received*** = 0	40		Type comments here. (REQUIRED)
2. Does your laboratory have the capacity to obtain additional lesion specimens for syphilis testing? (1b) ***Excellent***: >30 specimens a month collected from patients presenting with moist genital ulcers including primary and secondary syphilis lesions (16-20pts); ***High***: 20-30 specimens a month collected from patients presenting with moist genital ulcers including primary and secondary syphilis lesions (11-15pts); ***Moderate***: 10-19 specimens a month collected from patients presenting with moist genital ulcers including primary and secondary syphilis lesions (6-10pts); ***Limited***: <10 specimens a month collected from patients presenting with moist genital ulcers including primary and secondary syphilis lesions (1-5pts); ***No capacity for specimen collection*** = 0	20		Type comments here. (REQUIRED)
3. Does your laboratory have partnerships or arrangements in place to ensure you will be able to meet the minimum sample request? (1a & 1b) **Excellent:** Partnerships and arrangements currently in place and provided letter(s) of support. No additional IRB or approvals needed or will require less than 2 months to obtain (31-40pts); **Good:** Partnerships and arrangements currently in place and able to provide letter(s) of support. Additional IRB or approvals are needed and will require greater than 2 months to obtain (21-30pts); **Moderate:** Able to establish partnerships and arrangements and provide letter(s) of support. Additional IRB or approvals are needed and will require greater than 2 months to obtain (11-20pts);	40		Type comments here. (REQUIRED)

Limited: Able to establish partnerships and arrangements and provide letter(s) of support. Additional IRB or approvals are needed and will require greater than 2 months to obtain (1-1opts). ***No partnerships or arrangements in place, unable to provide letter(s) of support*** = 0			
TOTAL SCORE	**100**	_____	

Option 2 Score Card:

Category	Maximum Value	Score	Comments (REQUIRED)
1. Does your laboratory routinely receive lesion specimens for HSV or syphilis testing? ***Excellent***: >50 specimens a month received for routine HSV or syphilis testing (16-20pts); ***High***: 30-50 specimens a month received for routine HSV or syphilis testing (11-15pts); ***Moderate***: 10-29 specimens a month received for routine HSV or syphilis testing (6-10pts); ***Limited***: <10 specimens a month specimens a month received for routine HSV or syphilis testing (1-5pts); ***Specimens are not routinely received*** = 0	20		Type comments here. (REQUIRED)
2. Does your laboratory have partnerships or arrangements in place to ensure you will be able to meet the minimum sample request? **Excellent:** Partnerships and arrangements currently in place and provided letter(s) of support. No additional IRB or approvals needed or will require less than 2 months to obtain (16-20pts); **Good:** Partnerships and arrangements currently in place and able to provide letter(s) of support. Additional IRB or approvals are needed and will require greater than 2 months to obtain (11-15pts); **Moderate:** Able to establish partnerships and arrangements and provide letter(s) of support. Additional IRB or approvals are needed and will require greater than 2 months to obtain (6-10pts); **Limited**: Able to establish partnerships and arrangements and provide letter(s) of support. Additional IRB or approvals are needed and will require greater than 2 months to obtain (1-5pts).	20		Type comments here. (REQUIRED)

No partnerships or arrangements in place, unable to provide letter(s) of support = 0			
3. Does your laboratory have demonstrated competence and capacity using real-time PCR for bacterial and viral identification? ***Excellent:*** Has performed real-time PCR for >3 years, performs real-time PCR 1x per week, all staff is highly experienced in method (16-20pts); ***High:*** Has performed real-time PCR for 1-3 years, and performs real-time PCR at least 1x per week, most staff is experienced in method, (11-15pts); ***Moderate*:** Has performed real-time PCR for 1-3 years, and performs real-time PCR less than 1x per week, some staff is experienced in method (6-10pts); ***Limited*:** has real-time PCR <1 year and/or performs real-time PCR less than 1x per week, staff has limited experience (1-5pts) ***No experience*** = 0	20		Type comments here. (REQUIRED)
4. Does your laboratory have unrestricted access to a real-time PCR instrument? ***Excellent:*** laboratory has > 1 real-time PCR instrument (16-20pts); ***High:*** laboratory has 1 real-time PCR instrument (11-15pts); ***Moderate*:** >1 real-time PCR instrument is available for use but is a shared resource (6-10pts) ***Moderate*:** a real-time PCR instrument is available for use but is a shared resource (1-5pts) ***No access*** = 0	20		Type comments here. (REQUIRED)
5. Does your laboratory have sufficient ancillary equipment, supplies, reagents, laboratory space, and workforce capacity for the proposed work? ***Excellent:*** laboratory has a unilateral workflow established and dedicated clean rooms, dirty rooms, ancillary equipment, supplies, reagents and workforce dedicated to run real-time PCR assays (16-20pts); ***High*:** laboratory has a unilateral workflow established with separated areas, ancillary equipment, supplies,	20		Type comments here. (REQUIRED)

reagents and workforce available to run real-time PCR assays (11-15pts); ***Moderate*:** laboratory has access to shared space with unilateral workflow established and ancillary equipment, supplies, reagents and workforce available to run real-time PCR assays (6-10pts); ***Limited*:** laboratory has limited access to shared space with unilateral workflow established and limited ancillary equipment, supplies, reagents and workforce available to run real-time PCR assays (1-5pts); ***Insufficient equipment, supplies, reagents, space, or workforce***= 0			
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**

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.