Request for Proposals (RFP): Re-compete for Vaccine Preventable Diseases Reference Centers

Application Due date: January 3, 2020

Submit to: Alisa Bochnowski, Senior Specialist, Respiratory Diseases (alisa.bochnowski@aphl.org)

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Summary

The Association of Public Health Laboratories (APHL), in cooperation with the Centers for Disease Control and Prevention (CDC) is seeking to re-compete four (4) laboratories to provide a flexible shared services model that enhances capacity for vaccine preventable disease (VPD) testing to support CDC and jurisdictions. The selected VPD Reference Centers (VPD-RCs) will provide a variety of testing services related to VPDs including molecular detection, genotyping/serotyping, bacterial serology and potentially viral serology and next generation sequencing. As needs arise, these reference centers may also provide testing for additional pathogens that require similar testing services to meet public health needs.

Background

In 2009, APHL was awarded funding through the American Recovery and Reinvestment Act of 2009 (ARRA) in a partnership with CDC to provide training programs and quality improvement activities for VPD testing in public health laboratories. As part of this effort, CDC and APHL sought to address the need for timely and accurate diagnosis of VPDs in order to identify and control outbreaks and to provide the information needed to improve vaccines and vaccination programs. As a result, in 2013, the APHL and CDC established the VPD-RCs, comprising of four PHLs to provide standardized testing for select VPDs to other jurisdictions. The original purpose was to provide "enhanced capacity for molecular and serologic testing to support CDC and public health laboratories in a shared service model." In 2019, APHL and CDC recognized that the epidemiology and laboratory capacity landscape around VPDs had shifted since the inception of the VPD-RCs, and these changes led to a revision of the original statement of purpose. APHL and CDC updated the new mission statement of the VPD-RCs to "provide a flexible shared services model that enhances capacity for VPD testing to support CDC and jurisdictions". This new statement of purpose encapsulates the dynamic nature of the VPD-RCs and their ability to adapt to the ever-changing landscape of VPD testing needs and capabilities.

Eligibility

Eligible laboratories include all public health laboratories with the following capabilities and facilities in place. Applicants may apply for: A) Option 1 Only, B) Options 1 and 2, C) Options 1, 2 **and** 3.

Possible Application Combinations	A	B	C
Option 1	✓		
Option 2	✓	✓	
Option 3	✓	✓	✓

Specific expectations regarding methodologies used by the awardees are outlined in Appendix A: Expectations for VPD Reference Centers. All applicants are required to agree to the minimum requirements (as outlined in Appendix B) for the option(s) they select.

1. **All Options: Regardless of which option a laboratory applies to it must meet the following eligibility requirements (required by all applicants):**
    a. Sufficient equipment, laboratory space and workforce capacity for the proposed work;
    b. Ability to electronically transmit data to CDC using HL7 messaging standards;
    c. Ability to report results back to submitters in a secure fashion (i.e., electronic portal or fax);
    d. Ability to meet published turn-around times;

e. Flexibility to add and modify testing services, implement protocol changes and adhere to CDC-provided protocols; and
f. Capability and capacity for next generation sequencing.

2. **Option 1 (Viral VPD-RC Services): VPD-RC to provide testing to submitting laboratories for measles, mumps, rubella, and varicella-zoster virus. (4 laboratories to be selected, required by all applicants)**
    a. Capacity for real-time PCR using CDC-approved assays for the identification and genotyping of measles, mumps, rubella and varicella-zoster virus; and
3. **Option 2 (Bacterial VPD-RC Services): VPD-RC to provide testing to submitting laboratories for *Bordetella pertussis*, *Neisseria meningitidis* and *Haemophilus influenzae* (2 laboratories to be selected; application optional)**
    a. Demonstrated competency and capacity for real-time PCR using CDC-approved assays for *Bordetella pertussis*, *Neisseria meningitidis* and *Haemophilus influenzae*; and
4. **Option 3 (Performance Evaluation Panels): Provide performance evaluation panel (PEP) program and/or validation panels for measles, mumps, rubella, varicella-zoster, bacterial meningitis and other pathogens as identified by APHL/CDC (1 laboratory to be selected; application optional)**
    a. Established system for enrolling panel participants;
    b. Demonstrated cell culture capability;
    c. Established standard operating procedures (SOPs) and a quality management system for manufacturing, tracking and reporting performance evaluation panels;
    d. Established system for receiving panel recipients reported results; and
    e. Established system for tracking data from enrollees and summarizing performance results in aggregate.

Anticipated RFP Schedule

November 12, 2019	–	RFP Issued
November 21, 2019	–	Informational Teleconference (optional)
December 6, 2019	**–**	**Letter of Intent Due to APHL (see below)**
January 3, 2020	–	**RFP Responses Due**
January 15, 2020	–	Proposal review completed
January 16-17, 2020	–	As needed, follow-up interviews/proposals due
January 22, 2020	–	Final review completed and awardees selected
March 1, 2020	–	Draft contracts submitted to APHL Legal Dept. for final internal review
Spring 2020	–	Training activities, as needed
July 1, 2020	–	First year project period start

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 requires that prospective applicants submit a brief email statement to alisa.bochnowski@aphl.org indicating an intent to submit a proposal. APHL must receive this email by no later than **5:00 pm EST on December 6, 2019. 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 January 3, 2020**. Please see Proposal-Required Submissions section for items that must be included in the completed proposal. Applicants may send proposals via email to alisa.bochnowski@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

APHL will select a total of four laboratories to serve as reference centers. All four of those labs will participate in Option 1, and two of those four laboratories will participate in Option 2. One of the Option 2 laboratories will participate in Option 3. The amount of each award will vary year to year based on testing performed and volume of specimens submitted. Reimbursement will be based on a mixed model consisting of a flat rate, upon ratification, of $60,000 to cover costs associated with maintaining informatics capabilities, shipping and in-state testing and per specimen reimbursement as outlined below.

Each selected applicant for Option 1 will be eligible for an award up to $150,000, which is inclusive of the $60,000 rate listed above. Laboratories selected for Option 2 are eligible to receive up to an additional $100,000 dependent on APHL funding. The laboratory selected for Option 3 will receive an additional $200,000 for performance evaluation panels and additional funding as agreed upon for validation panels, as needed. Additional funding may be provided by APHL as needed and available if max compensations are reached due to submission volumes. The number of submission volumes vary greatly. For example, from 2016 to 2019, the number of specimens received at reference centers performing viral and bacterial testing ranged from 295 to 1,269. For reference centers performing viral testing only, the number of specimens received ranged from 49 to 518.

Per specimen compensation applies only to specimens submitted from outside of the Reference Center's jurisdiction and other ELC funded jurisdictions within the Reference Center's jurisdiction. All other in-state testing is not eligible for per specimen reimbursement unless otherwise agreed upon by APHL and the Reference Center. Compensation rates for specimens submitted outside of the Reference Center's jurisdiction are outlined in Table 1 below. Specimens submitted from other ELC funded jurisdictions within the Reference Center's jurisdiction will be reimbursed at 50% of the rates described in Table 1.

Table 1: Testing compensation rates

Testing Service	Rate per specimen tested
Viral Identification by PCR	$225
Viral Genotyping	$275
Measles Vaccine Strain Identification by PCR	$70
Bacterial Identification by PCR	$225
Bacterial Serotyping/Serogrouping	$275
Bacterial Serology	$275

APHL will distribute the award via a contract administered with APHL. By accepting the award, laboratories agree to these rates for a 5-year time span barring substantive changes in scope or material expenses at APHL's discretion.

Please note that no additional funds will be available for method validation or informatics implementation to newly selected sites. APHL will provide general technical assistance and travel to another PHL for laboratory training but other expenses will be the responsibility of the awarded lab.

Term of Project

The project term will be from July 1, 2020 through June 30, 2021. For any non-incumbent laboratory selected, there may be some work including training, validation and data messaging proceeding the project term period; awardees are expected to work with APHL, CDC and other VPD-RCs to expedite the implementation and onboarding of VPD-RC services including testing validation to ensure there are no or minimal gaps in testing services due to site transitions.

APHL will consider the potential for annual renewals (with each additional funding year running from July 1 to June 30) on availability of funds and performance of the awardee for a maximum of four additional years (through June 2025). Each of the potential renewals 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 awardees in advance of any modification to the anticipated scope of work in a future funding year.

Evaluation Team

APHL staff, led by Alisa Bochnowski, Senior Specialist, Respiratory Diseases, 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 and a panel of three APHL members selected from non-applicant public health laboratories will review complete proposals. SMEs from CDC will be identified and selected by Associate Director of Laboratory Science (ADLS) in the CDC National Center for Immunization and Respiratory Disease 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 Respiratory Disease Manager and will have expertise in the laboratory testing methods described in this RFP and familiarity with APHL reference center structure. APHL will ask potential reviewers to complete and sign APHL's Conflict of Interest Disclosure Statement (Appendix E) in order to disclose any real or perceived conflict of interest prior to the start of the evaluation process and 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.

Once potential reviewers have been identified, APHL's Director of Infectious Disease Programs will have final approval over the review team's composition.

Evaluation Criteria

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.

Laboratories will be given preference based on more extensive experience with the test methods, ability to handle increased volume and meet turnaround time requirements, existing in-house subject matter expertise, experience and past performance serving as a reference center, 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 communication mechanisms (e.g., email, teleconference) between APHL's Senior Specialist, Respiratory Diseases and the members of the evaluation team. APHL's Senior Specialist, Respiratory Diseases 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 request documentation from APHL staff on an applicant's past performance in other capacities as part of the evaluation criteria.

Post-Evaluation Procedures

APHL staff will notify the selected laboratories within ten business days of the completion of the evaluation and will post the names of the recipient(s) to APHL's procurement website, www.aphl.org/rfp, within 3 business days of the laboratories' acceptance of the award. APHL will correspond with unsuccessful applicants by e-mail or by U.S. mail within 30 days of posting the name of the selected applicant.

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 awarded laboratory must be able to receive specimens and report results to all submitters and CDC.

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. The acceptance of award by the eligible laboratory indicates that the laboratory agrees with the compensation terms laid out in the RFP.

Proposal – Required Submissions

In order for consideration, an interested laboratory must submit a letter of intent to apply (due 12/06/2019) and a proposal (due 01/03/2020) with the following items:

- **A completed and signed copy of Appendix B.**
- **A completed response table Appendix C.**
- **A biosketch or CV for the Principal Investigator**
- **A letter of support from Information Technology and/or Informatics leadership staff responsible for overseeing the work related to the HL7 messaging feed. For incumbents, this can be a letter of continued support; for new applicants, it should include an acknowledgement of the efforts required by their team and plan for dedication of appropriate resources and long-term maintenance of the data feed.**

Responses should be limited to no more than eight double-spaced pages for option 1 only. If applying for option two, an additional four double-spaced pages are allowed and if applying for option three, an additional two double-spaced pages may be used (font size ≥ 11pt and page margins of ≥ 1 inch). All submissions must comply with the requirements set out in the Additional Information and Deadlines for Application Submission below.

Additional Information and Deadlines for Application Submission

Applicants must direct all questions to Alisa Bochnowski (alisa.bochnowski@aphl.org). APHL will post questions received, together with the answers provided by APHL or CDC staff to APHL's procurement website (www.aphl.org/rfp).

To allow for appropriate review process planning, a letter of intent is required for consideration. Letters should be submitted by email to Alisa Bochnowski at APHL (Alisa.bochnowski@aphl.org) no later than 5:00 pm EST on Friday, December 6, 2019.

Applications should be submitted to Alisa Bochnowski at APHL (alisa.bochnowski@aphl.org) **by close of business (5:00 pm EST) January 3, 2020.** APHL will send an email acknowledging the receipt of your application; if you do not receive an acknowledgement within two (2) business days, call 240-485-2758 to confirm receipt.

APHL will hold an optional teleconference on Thursday, November 21, 2019 at 2:00 pm EST. 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 alisa.bochnowski@aphl.org or infectious.diseases@aphl.org no later than 12:00 pm EST on Thursday, November 21, 2019 for a calendar invitation.

Join Zoom Meeting
https://aphl.zoom.us/j/814675478

Call-in Information
+16468769923,,814675478# US (New York)
+16699006833,,814675478# US (San Jose)

Meeting ID

814 675 478

Basic CDC protocols for the VPD methodologies will be made available by APHL to applicants who submit a letter of intent to apply. For NGS, there are no standard protocols in use but CDC can supply protocols to provide options for NGS.

Appendix A-Expectations for Vaccine Preventable Diseases Reference Centers

Requirements for all reference centers (Options 1, 2 and 3)

Biosafety

- CDC and APHL expect reference centers to follow best practices for biosafety and biosecurity according to their own institution's policies. Reference centers should provide these policies to CDC and APHL upon request as they relate to VPD activities and processing/handling of VPD specimens.

Site visits and teleconferences

- As needed, CDC and APHL will conduct a site visit for training new laboratories on VPD diagnostic procedures. CDC and APHL may conduct additional monitoring visits based on data review and any ongoing challenges mutually identified. Site visits could include data review, review of laboratory workflow, procedural observation, and QC information.
- APHL, in collaboration with CDC, will host a required bimonthly teleconference to provide status updates and discuss any ongoing challenges and potential solutions.

Data Management/Informatics

APHL and CDC require all reference center laboratories to retain the human and technical resources to carry out the following data exchange and results reporting activities (see VPD logical architecture document). An applicant's letter of IT/Informatics support should consider the following requirements:

- The reference center must have a Laboratory Information Management System (LIMS) in place to meet VPD testing algorithms, workflows, and reporting requirements. Additionally, the laboratory must have a way to enhance or modify the LIMS to meet potential new pathogen or method additions based on CDC and APHL direction.
- The reference center must be able to map local VPD LIMS data to the expected VPD vocabulary code sets. Mapping should conform to the agreed upon VPD data dictionary, this information can be found in the excel workbook entitled, *"VPD_Code Combination"* (also available as an Access database, as requested).
    - LOINC codes and PLT codes (when test codes are not available through LOINC) are the code systems used for VPD laboratory tests.
    - SNOMED CT codes and PLR codes (when result codes are not available through SNOMED CT) are the code systems used for VPD laboratory results as well as specimen information (type, source site and sometimes condition).
- The reference center must be able to capture and transmit properly coded VPD result data in a structured format using the VPD constrained version of the HL7 ELR 2.5.1 message specification. Applicants can find the rules governing the structure of these VPD messages in the document entitled, *"Business rules for Vaccine-Preventable Disease (VPD) Laboratory Messages by Reference Centers to CDC*".
- The reference center must transmit embedded files within the HL7 message as determined as directed by APHL and CDC. This includes the transmission of FASTA genotype data files and others as required currently or as needed based on updates to pathogen or method enhancements.

- The laboratory must be able to generate and transmit HL7 messages for all specimens submitted to the Reference Center, regardless of test result. This includes results for specimens where testing was not performed because they were deemed inadequate or unsatisfactory. An explanation of the process for sending such a message is in the specimen section of document entitled, *"Business rules for Vaccine-Preventable Disease (VPD) Laboratory Messages by Reference Centers to CDC"*.
- The laboratory must validate the full set of applicable test messages before transmitting result data to CDC. Reference centers will preferably validate these messages by using the General Validation Tool (GVT), developed based on the NIST validation tool. As needed and necessary, APHL will provide laboratories with validation technical assistance support.
- APHL and CDC expect the reference center to participate in the ongoing maintenance and enhancements of the HL7 2.5.1 VPD data feed to ensure timely and accurate data transmissions and maintain the overall integrity of the VPD production level dataset. This includes but may not be limited to:
    - Monitoring data feed and responding to any VPD Message Error Reports from CDC's Message Validation, Processing and Provisioning System (MVPS).
    - Participating in scheduled VPD Change Control Board meetings
    - Collaborating on data exchange issues and solutions with the APHL Informatics Technical Assistance Team, CDC VPD program leads and other VPD PHL reference center sites.
- The laboratory must establish and maintain data exchange transport mechanisms to CDC. Reference centers are required to use PHINMS, SFTP, or S3 to transport their messages. Laboratories who choose to use SFTP or S3, must use APHL Informatics Message Services (AIMS) Platform. Although not required, it is highly recommended that laboratories wishing to use PHINMS as a transport option route via the AIMS PHINMS instance since APHL will provide ongoing certificate management, and route maintenance and apply FISMA moderate security protocols for all data being transmitted over AIMS.
- The laboratory must submit electronic monthly reports to APHL. The laboratory will monitor and submit to APHL the number of specimens received, tested, and the turnaround times. At the end of the contract year, the laboratory will be required to submit a year-end report detailing total testing statistics, lessons learned and any challenges the laboratory faced performing their VPD testing activities.
- VPD-RCs will provide sequences and other test data generated to CDC. CDC will report data, including sequence data, and test results to appropriate databases (e.g., Genbank).

Project Evolution

- Successful laboratories will need to have flexibility to meet the project requirements as national surveillance and testing needs evolve over time. Any deviations in the scope of work, including updates to CDC SOPs, will be reviewed by CDC and APHL on an annual basis and, after a training period, laboratories will adopt all changes within a mutually agreed implementation period.
- VPD reference centers may be asked by CDC/APHL to participate in special studies and evaluations for new processes, methodologies and technologies. These studies will be supported under the VPD reference center contractual agreements.
- In the event of an outbreak or local surge response, the reference center is expected to maintain operations and fulfill the obligation to national surveillance. If the laboratory anticipates any disruption in services, the laboratory will notify APHL and CDC immediately to develop a contingency plan and prioritize incoming specimens.

- CDC and APHL may add additional pathogens and test methods as public health needs arise.

Option 1 Requirements

Viral VPD Reference Laboratories (required by all applicants)

Testing Capabilities

- The viral VPD reference center will be capable of providing molecular diagnostic and surveillance support, surge capacity during outbreaks and confirmation of vaccine adverse events when appropriate for measles, mumps, rubella and VZV. CDC and APHL may identify and add additional pathogens as public health needs arise. The viral VPD reference center should perform assays under CLIA compliant conditions.
- The laboratory will establish quality control and proficiency testing for molecular assays and genotyping for selected agents.
- The reference center will maintain the capacity to perform real-time PCR for each specimen type listed below for the viral VPDs. The laboratory must follow the protocols provided by CDC:

Virus	Specimen Type
measles	Throat swab (in viral transport medium); Nasopharyngeal swab (in viral transport medium); Combined Throat/Nasopharyngeal swab (in viral transport medium); Urine
mumps	Buccal swab (in viral transport medium); Nasopharyngeal swab (in viral transport medium); Throat swab (in viral transport medium)
rubella	Throat swab (in viral transport medium); Nasopharyngeal swab (in viral transport medium)
varicella-zoster virus	Skin lesion swab; Scab

- The reference center will maintain the capacity to perform genotyping for each specimen type listed below for the viral VPDs. The laboratory must follow the protocols provided by CDC:

Virus	Specimen Type
measles	Throat swab (in viral transport medium); Nasopharyngeal swab (in viral transport medium); Combined Throat/Nasopharyngeal swab (in viral transport medium); Urine; Nucleic acid extract; Viral isolate
mumps	Buccal swab (in viral transport medium); Nasopharyngeal swab (in viral transport medium); Throat swab (in viral transport medium); Nucleic acid extract; Viral isolate
rubella	Throat swab (in viral transport medium); Nasopharyngeal swab (in viral transport medium); Nucleic acid extract; Viral isolate
varicella-zoster virus	Skin lesion swab; Scab; Nucleic acid extract; Viral isolate

- Results for real-time PCR and genotyping testing will be reported to CDC and to the submitting laboratory according to the following table. Genotyping will be performed on all PCR positive specimens unless otherwise indicated as part of a larger outbreak:

Viral Diseases	Real-time PCR	Genotyping
measles	2 business days	10 business days
measles vaccine strain	3 business days	N/A
mumps	2 business days	10 business days
rubella	2 business days	10 business days
varicella-zoster virus	2 business days	10 business days

- The reference center will be available to provide testing services as described above to submitting laboratories temporarily assigned by APHL or CDC in cases of emergencies, federal government shutdowns, or other times of increased testing needs.
- In the case of requests for protocol or assay updates or additions initiated by CDC, APHL and the reference centers will discuss and prioritize these changes and develop an agreed upon timeline for implementation. The reference center must communicate any changes, in writing, to CDC and APHL for approval.
- If indicated by CDC, the laboratory must have the ability to perform viral serology (commercial or in-house) for measles, mumps and rubella. This is not a current test service but is under consideration as a future service.
- Capability to perform or implement NGS for viral pathogens for further characterization. This is not currently a routine testing service but is under consideration as a future service.
- If indicated by APHL and CDC, the laboratory must have the ability to perform diagnostic or surveillance testing for additional pathogens as the need arises. Compensation, protocols, turn-around-times and other requirements will be agreed upon by all parties in writing prior to testing implementation.

Viral Specimen Repository

- The VPD reference center will act as a specimen repository and will maintain an inventory of specimens using an agreed upon specimen line listing template. The laboratory will make viral specimens available to CDC, other VPD-RCs and other collaborators as approved by CDC; the reference center will submit selected specimens to CDC or to other reference centers as mutually agreed upon.
- The laboratory will be required to participate in biannual review calls of the specimen repository samples.

Option 2 Requirements

Bacterial VPD Reference Laboratories (optional)

Testing Capabilities

- The laboratory will establish quality control and performance evaluation panel testing for molecular assays, serology and serotyping/serogrouping for selected agents.
- The reference center will maintain the capacity to perform real time PCR for each specimen type listed below for the bacterial VPDs. The laboratory must follow the protocols provided by CDC; they will need to be run on the ABI 7500 Fast Dx Real-Time PCR Instrument:

Bacteria	Specimen Type
B. pertussis	Nasopharyngeal swab or isolate
N. meningitidis	CSF or isolate
H. influenzae	CSF or isolate

- The bacterial VPD reference center will be capable of performing serology (IgG anti pertussis toxin) for *B. pertussis*, molecular serogrouping for *N. meningitidis*, and molecular serotyping for *H. influenzae.*
- The reference center must be able to perform the following tests on each of the specimen types listed. Due to low testing demand at the current time, it is likely only one VPD-RC will be requested to perform *B. pertussis* testing, but the second Option 2 laboratory must be able to implement rapidly should demand increase. The laboratory must follow the following protocols provided by CDC:

Bacteria/assay	Specimen Type	Serology	Serotyping/grouping
B. pertussis serology	serum	X	
N. meningitidis serogrouping	CSF or isolate		X
H. influenzae serotyping	CSF or isolate		X

- The laboratory will report results for real time PCR, serology and serogrouping/serotyping testing and to the submitting laboratory according to the following table. Serology or molecular serotyping/serogrouping will be performed on all PCR positive specimens unless otherwise indicated as part of a larger outbreak:

Bacteria	Maximum Turnaround Times
N. meningitidis	PCR: 2 business days Serology: 5 business days Serotyping/grouping: 5 business days
H. influenzae	
B. pertussis	

- The laboratory will also be capable of performing diagnostic and surveillance support and surge capacity in the event of an outbreak. The reference center will perform all assays under CLIA compliant conditions where applicable.
- The reference center will be available to provide testing services as described above to submitting laboratories temporarily assigned by CDC in cases of emergencies, federal government shutdowns, or other times of increased testing needs.
- In the case of requests for protocol or assay updates or additions initiated by CDC, APHL and the reference center will discuss and prioritize changes and develop an agreed upon timeline for implementation. The reference center will submit, in writing, any changes initiated by the reference center to APHL and CDC for signed approval.
- If indicated by APHL and CDC, the laboratory must have the ability to perform diagnostic testing for additional pathogens as the need arises. APHL and CDC must agree upon any changes to compensation, protocols, turn-around-times and other requirements in writing prior to testing implementation.

Bacterial Specimen Repository

- The VPD reference center will make bacterial isolates available for performance evaluation panel development and other activities as approved by CDC; the reference center will submit selected isolates to CDC or to other reference centers as mutually agreed upon.

Option 3 Requirements

Performance Evaluation and Validation Panel Testing Program (optional)

Performance Evaluation Panel Testing Program

- The laboratory must have an established system for enrolling panel participants, established standard operating procedures (SOPs) and a quality management system for manufacturing, tracking and reporting performance evaluation panels.
- The reference center must have an established system for allowing panel recipients to report results. All state and local public health laboratories in the US are eligible for enrollment in the testing program.
- The reference center will develop and distribute six performance evaluation panels per contract year according to the following schedule to any PHL (state or local) that enrolls:

Panel	Time of Distribution
S. pneumoniae/N. meningitidis/ H. influenzae	Fall
Measles/Mumps	
Rubella/Varicella-zoster	
S. pneumoniae/N. meningitidis/ H. influenzae	Spring
Measles/Mumps	
Rubella/Varicella-zoster	

- APHL will work with the laboratory to establish terms and a schedule in writing per panel. Following the distribution of each panel, the laboratory will provide APHL with one electronic copy of the panel report detailing the number of laboratories that participated in each of the testing panels and any major findings associated with them.

Validation Panel Testing Program

- The laboratory must have an established system for enrolling panel participants, established standard operating procedures (SOPs) and a quality management system for manufacturing, tracking and reporting performance evaluation panels.
- The reference center must have an established system for allowing panel recipients to report results.
- As indicated by APHL and CDC, the reference center will develop validation panels for any of the VPD pathogens.
- The laboratory will handle all logistics and distribution of the panels to participating PHLs.

The reference center will collate the panel results and report them to APHL and CDC within 60 days of receiving the results.

Appendix B: Minimum Requirements for the Vaccine Preventable Diseases Reference Center RFP

Please complete the following section for each the options for which you are submitting applications. If you are applying for Options 2 and 3, please complete those sections.

Option 1

YES	NO	MINIMUM REQUIREMENT
		Does your laboratory have experience with viral PCR or PCR using lab developed tests?
		Is your laboratory able to receive specimens from and report results to external jurisdictions in a CLIA compliant manner?
		Would your laboratory be willing to alter or amend existing testing protocols at the request of APHL and CDC?
		Is your laboratory able to contract with APHL or do you have an existing relationship with a third party that can contract directly with APHL on behalf of the laboratory?
		Does your laboratory have a robust LIMS that is compatible with CDC data sharing capabilities? Does your laboratory have a secure transport connection to CDC?

Option 2

N/A*	YES	NO	MINIMUM REQUIREMENT
			Does your laboratory have experience with bacterial PCR using lab developed tests?
			Is your laboratory able to receive specimens from and report results to external jurisdictions in a CLIA compliant manner?
			Would your laboratory be willing to alter or amend existing testing protocols at the request of APHL and CDC?
			Is your laboratory able to contract with APHL or do you have an existing relationship with a third party that can contract directly with APHL on behalf of the laboratory?
			Does your laboratory have a robust LIMS that is compatible with CDC data sharing capabilities? Does your laboratory have a secure transport connection to CDC?

*Select N/A if not applying for option 2

Option 3

N/A*	YES	NO	MINIMUM REQUIREMENT
			Does your laboratory have experience with performance evaluation panel production?
			Does your laboratory have experience with validation panel production?
			Does your laboratory have an established system for the logistical handling and distribution of performance evaluation panel and/or validation panels?

*Select N/A if not applying for option 3

Signature: _____ Date: _____

Appendix C:-Application Responses

To submit a proposal for consideration for **Options 1, 2 and 3**, please respond to the following questions using this table:

Applicant:

Testing Environment (Questions 1-2) (10 points)

1. **Describe the equipment available for performing all reference center work, including equipment available to support surge testing.**

2. **How often does your laboratory perform VPD testing? How will your laboratory adjust testing schedules to ensure the posted turnaround times for each pathogen/test? How will your laboratory handle viral genotyping (i.e., will your laboratory perform the testing in-house or send the specimens out)? Do you anticipate the approach to genotyping impacting the posted turnaround times?**

Laboratory Workforce (Questions 3-6) (20 points)

3. **Briefly describe the laboratory's overall experience with similar projects of this scale and scope, including any relevant reference center experience.**

4. **For each person who would be involved in VPD activities (including PI), please briefly describe their relevant experience and their planned role in the project. Please include personnel from specimen accessioning through each methodology and reporting. Multiple staff cross-trained and assigned to each project area is preferred.**

5. **Please describe cross-training and redundancy in the skill set of your laboratory. Is there sufficient cross-training and capacity that work can be supported during periods of increased testing demand? How would you approach staff support for unpredictable testing volumes?**

6. **Describe your capability/capacity to continue VPD work during state or local outbreaks of other pathogens, pandemic influenza, etc. How would in-state responses affect staff assigned to VPD work and how would VPD work be prioritized? Describe your laboratory's approach to maintaining specified turn-around-time.**

Information Technology (Question 7) *(15 points)*

7. **Please describe the human and technical resources available to carry out the data management, data exchange and CDC specimen reporting activities outlined in this RFP. If applicable, describe your plan and proposed timeline to implement requirements not yet in place (e.g. FASTA file transmission).**

Flexibility and Methodology Adoption (Question 8) *(5 points)*

8. **Please describe the approach your laboratory takes to incorporate new testing technologies or methodologies as they become available. Include information on your approach for validating laboratory developed tests (i.e. numbers of specimens, approximate timeline, etc.).**

Viral Testing Capabilities (Questions 9-11) *(30 points)*

9. **Please describe your viral PCR experience using lab developed tests, including the following information. If applicable, please highlight any experience using CDC protocols:**

- **Pathogens**
- **Volume (i.e., typical per week and max capacity per week)**
- **Typical turnaround time**

10. **Please describe your genotyping experience including the following information:**

- **Pathogens**
- **Methods**
- **Volume (i.e., typical per week and max capacity per week)**
- **Typical turnaround time (if you send out specimens for genotyping, how will this impact TAT)**

11. **If applicable, please highlight any experience with viral pathogen sequencing or viral serology, including methodology, pathogen and volume. Emphasize experience with measles, mumps or rubella serology and/or non-kit based serology assays.**

Viral Specimen Repository (Questions 12) *(5 points)*

12. **Please describe your specimen storage capacity and your approach to data tracking system for managing an inventory of submitted specimens for future sharing with CDC or other laboratories as approved by CDC and APHL.**

Additional Comments (Questions 13) *(5 points)*

13. **Describe any unique aspects of your laboratory you have not yet mentioned that you could bring to the project (e.g., cutting edge technologies, high throughput, etc.)? If applying for Options 2 and/or 3, you may address points relevant to those options in this question as well.**

To submit a proposal for consideration for **Option 2**, please respond to the following questions using this table. **If you are not submitting a proposal for consideration for Option 2, please select N/A** ☐

Bacterial Diagnostics (Questions 14-16) *(25 points)*

14. **Please describe your real-time PCR experience including the following information:**
- **Pathogens**
- **Volume (i.e., typical per week and max capacity per week)**
- **Typical turnaround time**

15. **Please describe your laboratory's serology experience that would be relevant to performing an ELISA for anti-Pertussis toxin IgG detection:**
- **Pathogens**
- **Volume (i.e., typical per week and max capacity per week)**
- **Typical turnaround time**

16. **Please describe your molecular serotyping/serogrouping experience including the following information:**
- **Pathogens**
- **Volume (i.e., typical per week and max capacity per week)**
- **Typical turnaround time**

Bacterial Specimen Repository (Questions 17) *(5 points)*

17. **Please describe your specimen and/or isolate storage capacity and your approach to data tracking system for managing an inventory of submitted specimens and/or isolates for future sharing with CDC or other laboratories as approved by CDC and APHL.**

To submit a proposal for consideration for **Option 3**, please respond to the following questions using this table. **If you are not submitting a proposal for consideration for Option 3, please select N/A** ☐

Performance Evaluation Panel Preparation and Distribution (Questions 18) *(15 points)*

18. **Describe your process for preparing and distributing performance evaluation panels. Please include details around:**

- **Logistical systems (i.e. system for enrolling panel participants, tracking data from enrollees, summarizing performance metrics, etc.)**
- **Number of panels produced per year, and the types of panels (i.e., pathogen, assay type).**
- **Cell culture capabilities**
- **Any established SOPs or quality management systems for manufacturing, tracking and reporting on panels**

Validation Panel Preparation and Distribution (Questions 19) *(5 points)*

19. **Describe your process for developing, preparing and distributing validation panels. Please include details around:**
    - **Logistical systems**
    - **Specimen source (i.e., contrived vs. original clinical material)**
        - **If using contrived specimens, please specify the approach**
    - **Number of panels produced per year, and the types of panels (i.e., pathogen, assay type)**
    - **Any established SOPs or quality management systems for developing or manufacturing a validation panel**

Appendix D: Score Card

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)
Testing Environment (Questions 1-2) 1-2. Rate the suitability of the laboratory equipment, including availability to support surge testing, frequency of testing, and ability to meet turnaround time specifications. **Ideal** (6-10 points): Meets equipment requirements for all VPD activities; describes a suitable and efficient flow of specimens; demonstrates clear understanding of testing timing and turn around constraints. **Adequate** (1-5 points): Meets most equipment requirements but may have to rearrange or adjust testing workflow to accommodate VPD specimens; has some deficiencies in their understanding and proposed flow of specimens. **Inadequate** (0 points): Does not meet equipment requirements, workflow will not suffice for VPD activities, and/or does not demonstrate a clear understanding of requirements.	10		Type comments here. (REQUIRED)
Workforce (Questions 3-6) 3-5. Rate the suitability of the proposed workforce based on relevant experience and appropriate allocation of percent effort to meet the project needs. Please consider the following: • Does the applicant have sufficient dedicated personnel and experience to perform the methodologies described, including redundancy in their workforce? • Is there sufficient staff cross-trained to perform the work? • Does the lab demonstrate capability/capacity to continue VPD work during outbreaks? **High** suitability (10-15 points): Staff with strong history of relevant experience, appropriate allocation of staff time, strong cross-training/redundancy to ensure continuity of operations.	20		Type comments here. (REQUIRED

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Demonstrated ability to continue VPD testing during increased testing volume or outbreaks. Solid description and past performance meeting published turn-around times. **Moderate** suitability (5-9 points): Good workforce experience but will have a learning curve on a few areas or may be lacking in some redundancy; appropriate allocation of staff time; could meet expectations but have some mild reservations regarding capability to complete work during increased testing volume or outbreaks **Possibly/Uncertain** (1-4 points): Clear deficiencies in workforce experience and/or expertise; unrealistic time allocations; strong reservations about meeting expectations, especially during times of surge testing **Not suitable:** (0 points) 6. Does the applicant describe a reasonable approach to balancing VPD activities and state/local response needs? **Ideal** (3-5 points), **Adequate** (1-2 point), **Inadequate** (0 points)			
Information Technology (Question 7) 7. Does the applicant have the infrastructure, human and technical resources in place to carry out the data exchange and results reporting necessary for the VPD RC? **High** suitability (10-15 points): Laboratory already has a LIMS in place that meets VPD testing algorithm, workflow and reporting requirements; the laboratory can modify the LIMS system to meet new pathogen or method needs. The laboratory already has the local VPD data code sets mapped and captured and transmits the coded data using HL7 ELR 2.5.1 and FASTA genotype data files. **Moderate** suitability (5-9 points): Laboratory has a LIMS in place that could be modified/updated to meet VPD testing algorithm, workflow and reporting requirements. The laboratory can update LIMS in order to map the local VPD data codes sets, capture and transmit the coded data using HL7 ELR 2.5.1, and transmit FASTA genotype data files. **Possibly/Uncertain** (1-4 points): Clear deficiencies in LIMS that would make transmitting data difficult **Not suitable:** (0 points)	15		

Flexibility (Questions 8) **8**. Does the laboratory demonstrate the ability to incorporate new technologies and methodologies? Rate on a scale of 0-5 points (5=strongest answer; 0=insufficient/weak answer)	5		Type comments here. (REQUIRED)
Viral Testing Capability (Questions 9-11) 9-10. What is the applicant's experience and capacity for: • viral PCR using lab developed tests • genotyping **High:** extensive experience with performing real-time PCR **and** genotyping on measles, mumps, rubella and VZV; sufficient capacity for processing specimens; extensive experience with CDC protocols (18-25 points); **Moderate:** performs either real-time PCR **or** genotyping on some viral VPD pathogens; some experience using CDC protocols for viral VPD pathogens (7-17 points); **Low Experience:** little to no experience with real-time PCR or genotyping or does not have the necessary capacity (0-6 points) 11. Do they have specific experience with viral pathogen sequencing and viral serology (NGS, viral EIAs, etc.)? Rate on a scale of 0-5 points (4-5=strong experience in viral pathogen sequencing and serology; 1-3 experience in either viral sequencing or viral serology or minimal experience with both; 0=no experience in either viral sequencing or serology)	30		
Viral Specimen Repository (Question 12) 12. Does the applicant have experience storing, managing, and sharing viral specimens? Does the applicant have the ability to share data with APHL/CDC and specimens with CDC? **High:** extensive experience with managing specimen repositories and previously participated in shared, multi-site repositories (3-5 points); **Moderate:** routinely stores in-house specimens but has not previously participated in a shared repository; (1-2 points); **No Experience:** does not have experience with either in-house or shared repositories (0 points)	5		

Additional Comments (Question 13) 13. Does the applicant have any unique aspects/services to contribute to the project? (e.g., cutting edge technologies, high throughput, etc.) **Yes** (1-5 points), **No** (0 points)	5		
Bacterial Testing Capacity (Questions 14-16) 14-16. What is the applicant's experience and capacity for bacterial real time PCR, serology and molecular serotyping/serogrouping? **High:** extensive experience with performing real-time PCR, serology and molecular serotyping/serogrouping on the appropriate bacterial pathogen (*H. influenzae, B. pertussis, and N. meningitidis)*; sufficient capacity for processing specimens; extensive experience with CDC protocols (17-25 points); **Moderate:** performs either real-time PCR or serology and molecular serotyping/serogrouping on the appropriate bacterial pathogen (*H. influenzae, B. pertussis, and N. meningitidis)* but not necessarily both, or unclear capacity; (7-16 points); **Low Experience:** little to no experience with real-time PCR, serology or molecular serotyping/serogrouping or does not have the necessary capacity (0-6 points)	25		
Bacterial Specimen Repository (Question 17) 17. Does the applicant have experience storing, managing, and sharing bacterial specimens and/or isolates? Does the applicant have the ability to share data with APHL/CDC and specimens with CDC? **High:** extensive experience with managing specimen repositories and previously participated in shared, multi-site repositories (3-5 points); **Moderate:** routinely stores in-house specimens but has not previously participated in a shared repository; (1-2 points); **No Experience:** does not have experience with either in-house or shared repositories (0 points)	5		
Performance Evaluation and Validation Panel Preparation and Distribution (Question 18-19) 18. Does the applicant have an established system for preparing panels, enrolling panel participants, tracking data from enrollees and summarizing performance metrics? Does the applicant have experience producing panels, including established SOPs and quality metrics as well as cell culture capabilities? **High:** extensive experience with preparing, distributing and managing all aspects of a national proficiency **and** validation	20		

panel program (10-15 points); **Moderate:** routinely participates in validation or proficiency panel programs but has not previously managed a panel distribution program; (5-9 points); **No Experience:** does not have experience with either managing validation or proficiency panels or participating in one (0 points) 19. Does the applicant have a process for developing, preparing and distributing validation panels? Do they fully explain their specimen source (contrived vs. original clinical material), logistical systems, etc.? **Yes** (1-5 points), **No** (0 points)			
TOTAL SCORE		____	

Appendix E – Conflict of Interest Disclosure Statement and Policy (For Completion by Reviewers Only – Applicants Do Not Need to Complete)

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).

_____

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Effective July 1, 2017

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.