

Request for Proposals (RFP): Legionella Reference Center(s)

Application Due date: November 18, 2022

Submit to: Liz Toure, Senior Specialist, Respiratory Diseases
(elizabeth.toure@aphl.org)

Table of Contents

- Table of Contents 1
- Summary 2
- Background 2
- Eligibility 3
- Anticipated RFP Schedule 3
- Response Submittal 4
- Award 4
- Term of Project 4
- Evaluation Team 4
- Evaluation Criteria..... 5
- Evaluation Process 5
- Post-Evaluation Procedures 5
- Conditions of Award Acceptance 6
- Proposal – Required Submissions 6
- Additional Information and Deadlines for Application Submission..... 7
- Appendix A: Expectations for Legionella Reference Center(s) 8
- Appendix B: Minimum Requirements for the *Legionella* Reference Center RFP 12
- Appendix C: Application 13
- Appendix D: Score Card (For Completion by Reviewers Only – Applicants Do Not Need to Complete).... 16
- Appendix E: Conflict of Interest Disclosure Statement and Policy (For Completion by Reviewers Only – Applicants Do Not Need to Complete) 20
- Appendix: F – APHL Fiduciary Responsibility and Conflict of Interest Policy (For Completion by Reviewers Only – Applicants Do Not Need to Complete) 23

Summary

The Association of Public Health Laboratories (APHL), in cooperation with the Centers for Disease Control and Prevention (CDC) is seeking up to two (2) public health laboratories (PHLs) to provide testing in a flexible, shared services model that enhances *Legionella* case and outbreak investigation capacity to support CDC, state and local jurisdictions. The selected *Legionella* Reference Center(s) (LRCs) will provide a variety of testing services related to *Legionella* outbreak response including clinical and environmental spread-plate culture, molecular detection (real-time PCR) and next generation sequencing (NGS).

Background

Legionnaires' disease cases and outbreaks have historically been sporadic, seasonal and regional. This combined with the specialized testing required to identify and characterize *Legionella* species in support of source identification have made it challenging to for many PHLs to maintain testing capabilities. CDC often aids jurisdictions that do not have the capability to detect or characterize *Legionella* themselves, or who are experiencing a large outbreak for which testing needs exceeds their capacity. As the incidence of Legionnaires' disease and number of *Legionella* outbreaks appears to be increasing, assuring access to high quality testing is essential.

The establishment of the LRC(s) will build redundancy into the national system ensuring adequate resources for high-quality, *Legionella* testing for case detection and outbreak response. The primary purpose of the LRCs(s) is to provide a flexible, shared service model that enhances access to high-quality laboratory support for *Legionella* case and outbreak investigations to aid CDC, state and local jurisdictions. The LRC(s) will provide spread-plate culture, molecular detection and NGS for clinical and environmental samples and molecular detection and NGS for isolates submitted by state and local PHLs. The LRC(s) will only support testing for case detection and outbreak response, not routine environmental testing for water management plans or surveillance. The LRC(s) will also serve as a valuable source of expertise, technical assistance and surge capacity for the PHL community and will increase the overall national capacity for identifying and characterizing *Legionella* cases and outbreaks which will ultimately result in improved public health.

Eligibility

Eligible laboratories include all PHLs with the following capabilities and facilities in place. Specific expectations regarding methodologies to be used by the awardees are outlined in [Appendix A](#). All applicants are required to agree to the minimum requirements (as outlined in [Appendix B](#)).

1. Applicants must meet the following eligibility requirements:

- a. Currently an Environmental Legionella Isolation Techniques Evaluation (ELITE) Program member laboratory for isolation *Legionella* from environmental specimens
- b. Currently perform real-time PCR on bacterial isolates in compliance with CLIA requirements
- c. Currently conducting next generation sequencing on bacterial isolates
- d. In possession of the major equipment and space required to conduct the *Legionella* testing described in [Appendix A](#)
- e. Willing to alter or amend existing testing protocols or workflows at the request of APHL and CDC
- f. Willing to provide technical assistance, training and SOPs to other jurisdictions to improve testing capacity
- g. Has a Laboratory Information Management System (LIMS) in place to meet clinical testing workflows and reporting requirements
- h. Ability to provide consultations to submitters around sample submission and result interpretation
- i. Willingness and ability to respond to Freedom of Information Act (FOIA) requests related to *Legionella* testing
- j. Ability to contract with APHL or has an existing relationship with a third party that can contract directly with APHL on behalf of the laboratory

Anticipated RFP Schedule

October 10, 2022	–	RFP Issued
October 27, 2022	–	Informational Teleconference at 2:00 pm ET (optional)
November 11, 2022	–	Letter of Intent Due to APHL by 5:00 pm ET
*NOTE: THIS DEADLINE HAS BEEN EXTENDED FROM THE ORIGINAL DATE (NOVEMBER 4)		
November 18, 2022	–	RFP Responses Due to APHL by 5:00 pm ET
December 9, 2022	–	Proposal review completed
December 12 – 15, 2022	–	As needed, follow-up interviews
December 16, 2022	–	Final review completed and awardees selected
February 6, 2023	–	Anticipated Contract Start Date
Spring 2023	–	Establish submission and result reporting processes, validation of assays and training activities, as needed
April 1, 2023	–	LRC(s) begin accepting samples/specimens/isolates from submitting laboratories

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 PHLs.

Response Submittal

Confirmation of Intent to Respond

APHL requires that prospective applicants submit a brief email statement indicating an intent to submit a proposal. APHL has extended the deadline to submit a letter of intent. The new deadline by which APHL must receive this email is by **5:00pm ET on November 11, 2022**. 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 ET on November 18, 2022**. Please see the [Proposal-Required Submissions](#) section for items that must be included in the completed proposal. Applicants should send proposals via email to elizabeth.toure@aphl.org.

APHL will send an email acknowledging the receipt of your application; if you do not receive an acknowledgement within 48 hours, please call Liz Toure at (240) 485-3860 to confirm receipt.

Award

APHL will select up to two PHL awardees. The selected applicant(s) will be eligible for an initial award of up to \$165,000. The initial award will run from approximately February 6, 2023 through June 30, 2023 and cover the establishment of the submission and result reporting processes, validation of assays, training activities and the launch of testing in Spring 2023. APHL will distribute the award via a contract administered with APHL.

APHL will provide general technical assistance and travel to CDC (or other relevant location) for training if necessary. Other expenses will be the responsibility of the awarded laboratory.

Term of Project

The initial project term will be from February 6, 2023 through June 30, 2023. The potential for annual renewals (with each additional funding year running from July 1 to June 30) may be considered by APHL based on availability of funds and performance of the awardee(s) for a maximum of two 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. The awardee will be notified in advance of any modification to the anticipated scope of work in a future funding year.

Evaluation Team

APHL staff members will conduct an initial review of all proposals for completeness. Incomplete proposals will not receive a formal evaluation.

Complete proposals will be reviewed by a team of three subject matter experts (SMEs) from CDC and a panel of three APHL members selected from non-applicant PHLs. SMEs from CDC will be identified and selected by the Associate Director of Laboratory Science (ADLS) in the CDC National Center for Immunization and Respiratory Diseases (NCIRD) 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 other APHL reference centers.

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 F](#).

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 D](#).

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, ability to comply with expectations laid out in [Appendix A](#), and the ability to meet the minimum requirements 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. 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 PHL(s).

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 PHL(s) within ten business days of the completion of the evaluation and will post the name(s) of the recipient(s) to APHL's procurement website, www.aphl.org/rfp, within three business days of the laboratories' acceptance of the award. Unsuccessful applicants will receive notification of these results by e-mail or by US mail within 30 days of the date the name of the selected applicant is posted.

All applicants 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 APHL's procurement website.

Conditions of Award Acceptance

The selected PHL(s) 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 PHL. The PHL(s) must agree to comply with expectations outlined in [Appendix A](#). The awarded PHL(s) must be able to receive samples and report results to all submitters and CDC via a mutually accepted system. Post award, APHL and/or CDC may conduct site visits to include an assessment of continued compliance as necessary. The acceptance of award by the eligible PHL(s) indicates that the PHL agrees with the terms laid out in the RFP.

Proposal – Required Submissions

To be considered for selection, an interested PHL must submit a letter of intent to apply (due 11/04/2022) and a proposal (due 11/18/2022) with the following items:

- A completed and signed copy of [Appendix B](#)
- A completed response to the application questions, found in [Appendix C](#)
- Proposed budgets
 - Provide a start-up budget outlining at least the following line items: method validation expenses, supply and equipment purchases or upgrades and LIMS enhancements needed based on the method requirements outlined in [Appendix A](#). Note: Procurement of sequencing platforms will not be considered, however incubators, centrifuges, vacuum manifolds, thermocyclers and other equipment will be considered. Please include a 1-2 sentence justification on all equipment requests describing why the equipment is needed to fulfill the obligations of the project. The start-up budget should not exceed \$100,000.
 - Provide a proposed per specimen/sample/isolate cost for each test method based on the applicant's proposed testing algorithm. The per specimen/sample/isolate budget should include the cost of test reagents, ancillary reagents, staff time, fringe/overhead and any other charges. This budget may be estimated based on an anticipated quarterly volume of 10 clinical specimens, 10 clinical isolates and 40 environmental samples, assuming 25% of environmental samples are positive for *Legionella*.
 - Provide proposed costs for any staff time required to respond to FOIA requests or other inquiries, provide consultation on
- A letter of support from Information Technology and/or Informatics leadership staff responsible for overseeing the work related to result messaging. 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.
- A biosketch or curriculum vitae (CV) for the Principal Investigator (not included in ten-page response limit)

Responses should be limited to **no more than ten double-spaced pages**. 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 the APHL Senior Specialist, Respiratory Diseases, Liz Toure (elizabeth.toure@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 Liz Toure at APHL (elizabeth.toure@aphl.org) no later than **5:00 pm ET on Friday, November 11, 2022**.

Applications should be submitted to Liz Toure at APHL (elizabeth.toure@aphl.org) no later than **5:00 pm ET on Friday, November 18, 2022**. APHL will send an email acknowledging the receipt of your application; if you do not receive an acknowledgement within two business days, call Liz Toure at 240-485-3860 to confirm receipt.

APHL will hold an optional teleconference on **Thursday, October 27, 2022 at 2:00 pm ET**. The purpose of this call will be to provide a brief overview of the project and to allow potential applicants to ask CDC and APHL questions. Please come with questions prepared.

Teleconference call-in information is below. Please contact elizabeth.toure@aphl.org or infectious.diseases@aphl.org no later than 12:00 pm ET on Monday, October 24, 2022 if you would like to be sent the calendar invitation.

Join Zoom Meeting

<https://aphl.zoom.us/j/87046244056?pwd=UDRnVUpMajRWVzNjaEJaTlFvU2piZz09>

Call-in Information

+13017158592 US (Washington DC)
+13126266799 US (Chicago)

Meeting ID: 870 4624 4056
Passcode: 821830

Appendix A: Expectations for Legionella Reference Center(s)

Biosafety

- The LRC is expected to follow best practices for biosafety and biosecurity according to their own institution's policies. If requested, these policies should be shared with CDC and APHL as they relate to *Legionella* activities and processing/handling of *Legionella* suspect specimens and samples and *Legionella* isolates.

Site visits and teleconferences

- If needed, CDC and APHL will conduct a site visit for training on *Legionella* identification and characterization procedures. Additional visits may be routine or may be indicated based on data review, ongoing challenges or new procedures. Site visits could include general program review, review of data, workflow, quality management systems (QMS), quality control (QC) and procedural observation.
- APHL, in collaboration with CDC, will host a regular teleconference which must be attended by the LRC to provide status updates and discuss any ongoing challenges and potential solutions.

Data Management/Informatics

APHL and CDC require the LRC to retain the human and technical resources to carry out the following data exchange and results reporting activities. Your letter of IT/Informatics support should consider these requirements.

- The LRC must have a Laboratory Information Management System (LIMS) in place to meet clinical *Legionella* testing algorithms, workflows, and reporting requirements. Additionally, the laboratory must have a way to enhance or modify the LIMS to address changes in reporting requirements or addition of new methods. The LRC must have and describe a well-established, and sustainable method for storing, tracking and reporting data on environmental samples and tests.

Mechanism for reporting results to submitter

- The LRC will report clinical test results as soon as possible to the submitting PHL via secure fax, secure email or Secure File Transfer Protocol (SFTP) initially. Environmental test results should be reported as soon as possible to the submitting PHL via email. In the future, the LRC will be required to comply with data modernization standards of practice.

Mechanism for reporting results to CDC

- The LRC will report clinical and environmental test results to CDC via an agreed upon method within 24 hours of reporting results to the submitter. In the future, the LRC will be required to comply with data modernization standards of practice for electronic reporting to CDC.

Project Evolution

- The LRC will need to have flexibility to meet the project requirements as national testing needs evolve over time. Any deviations in the scope of work, including potential updates to standard operating procedures (SOPs) or workflow, will be reviewed on a periodic basis and, after training and completion of any necessary validations, the LRC will adopt all changes within a mutually agreed implementation period.

- In the event of a local outbreak or local surge response, the LRC is expected to maintain reference center operations and fulfill the obligation to national testing. If any disruption in services is anticipated, the LRC will notify APHL and CDC immediately to develop a contingency plan and prioritize incoming clinical specimens and environmental samples.
- Other test methods may be added as public health needs arise and as are identified by CDC and APHL.

Requirements

Sample Types and Algorithm

- Sample collection will be the responsibility of the submitting PHL, not the LRC.
- A limited number of PHLs will be eligible to routinely submit specimens and samples to the LRC based on eligibility criteria defined by APHL and CDC. Eligible submitters will likely be those with an annual Legionnaires' Disease incidence below a to be determined threshold, among other factors. All public health laboratories will be eligible to utilize the LRC for outbreak and surge support as resources allow.
- Samples/ should be shipped and stored in accordance with the LRC's validated time and temperature ranges.
- The LRC should accept all appropriate clinical and environmental sample types, including but not limited to: sputum, bronchial alveolar lavage, fresh lung tissue, bulk water, swabs and filter material. Acceptable sample types will be explicitly defined based on the LRC's validated SOPs. Additional specimen types may require validation.
- Clinical specimens submitted to the LRC must originate from an individual with signs and symptoms [clinically compatible](#) with legionellosis or have an epidemiological link to a setting with suspected or confirmed cases or sources of *Legionella*.
- Environmental samples submitted to the LRC must be collected as part of an active outbreak investigation and require pre-approval.
- The exact testing algorithm will be determined in coordination with CDC and the LRC.

Real-time PCR

- The LRC will conduct multiplex real-time PCR for detection and discrimination between *Legionella* species, *Legionella pneumophila*, and *Legionella pneumophila* Serogroup 1 on clinical specimens and clinical or environmental isolates submitted to or recovered by the LRC for *Legionella* case detection and outbreak response.
- Testing of clinical specimens must be performed in compliance with CLIA regulations.
- The LRC will establish quality control and proficiency testing test procedures.
- The LRC must follow validated standard operating procedures (SOPs); protocol modifications and deviations must be communicated to CDC and APHL for approval.

Culture

- The LRC will conduct the necessary sample processing steps such as liquification, concentration, filtration, acid wash or heat treatment based on the sample type received. In some cases, processing by multiple methods may be necessary.
- The LRC will perform spread plate culture on clinical specimens and environmental samples.
- If an isolate is not obtained from a clinical specimen, but *Legionella pneumophila* is identified by real-time PCR the LRC will transfer the specimen to CDC for nested sequence-based typing (SBT).
- If an isolate is identified as non-*pneumophila Legionella*, it may be transferred to CDC for species identification.

- Testing of clinical specimens and isolates must be performed in compliance with CLIA regulations.
- The LRC will maintain its status as an ELITE member laboratory.
- The LRC will maintain a ready supply of appropriate culture media on-hand. Unused media will be discarded after expiration.
- The LRC must follow validated standard operating procedures (SOPs); protocol modifications and deviations must be communicated to CDC and APHL for approval.

NGS

- The LRC must be capable of conducting NGS for molecular characterization on bacterial isolates.
- NGS does not need to currently be performed in accordance with CLIA regulations; it can be performed for surveillance purposes.
- Isolates received for NGS testing only will be subcultured and *Legionella* genus verified via multiplex real-time PCR for detection and discrimination between *Legionella* species, *Legionella pneumophila*, and *Legionella pneumophila* Serogroup 1 prior to NGS.
- The LRC must follow well-vetted standard operating procedures (SOPs); protocol modifications and deviations must be communicated to CDC and APHL for approval.

General Testing Requirements

- The LRC will provide testing services as described above to eligible PHLs and submitting laboratories temporarily assigned by APHL or CDC as a consequence of emergency situations, federal or state government shutdowns, or increased testing burden.
- In the case of requests for assay updates or additions that are initiated by CDC, changes will be discussed and prioritized by APHL, CDC and the reference centers and a timeline for implementation will be agreed upon. Any changes initiated by the reference center to validated protocols must be submitted in writing to APHL and CDC for signed approval prior to implementation.
- APHL, CDC and the selected LRC will establish reasonable expected turnaround times for each sample and test type.

Specimen Repository

- The LRC will act as a repository and will maintain an inventory of clinical and environmental *Legionella* samples and isolates using an agreed upon line listing template. Specimens and isolates must be stored frozen for a minimum of two years. The LRC will make residual clinical material available to CDC and other collaborators as approved by CDC. A detailed storage and retention schedule will be developed with the LRC in coordination with CDC and APHL.
- The LRC will be required to participate in biannual review calls of the repository samples.

Consultation and Coordination

- The LRC will review and approve or reject clinical testing requests. The CDC Respiratory Diseases Branch Legionella Team will review and approve or reject environmental testing requests in consultation with the LRC and APHL. Some submissions may require further consultation with the CDC Respiratory Diseases Branch Legionella Team.
- The LRC testing staff will consult with the submitting laboratory and CDC SMEs (including laboratorians, epidemiologists and environmental health staff) as necessary, to discuss test results.
- The LRC will be responsible for maintaining all necessary testing documentation and responding to FOIA requests, as applicable.

Participation in Special Studies & Evaluation of New Platforms

- The LRC may be asked by APHL/CDC to participate in special studies and evaluations of new processes, methodologies and technologies. These activities will be supported under the LRC contractual agreement, with additional funding provided, as needed.
- The LRC could serve as an evaluation site for new testing platforms. Opportunities for evaluation will be explored with the LRC and CDC to determine sufficient facilities, personnel, and time resources. Evaluation of new platforms should in no way negatively impact service provision under the statement of work (SOW).

Training and Technical Assistance for Other Public Health Laboratories

- The LRC may provide *Legionella* testing training for other PHLs , if resources allow.
- The LRC may also provide SOPs and technical consultation to PHLs interested in developing in-house testing capacity.

Performance Monitoring and Evaluation

- APHL in collaboration with the CDC Pneumonia Response and Surveillance Laboratory will implement procedures for routine monitoring of the testing services, which may include, but is not limited to the following:
 - Number of clinical specimens received and tested
 - Number of clinical specimens rejected
 - Reasons for specimen rejection
 - Number of environmental samples received and tested
 - Number of isolates received and tested
 - Number of cluster investigations supported
 - Number of specimens/isolates referred to CDC for additional testing
 - Average turn-around time for results reporting
 - Proficiency testing and/or alternative performance evaluation (i.e., ELITE) results (CDC may provide LRC with test samples and specimens to evaluate performance)
 - Number of pre-submission requests received and number of pre-submission requests accepted
 - Number of result consults provided
- Monthly, quarterly, and annual reporting requirements will be determined in collaboration with APHL, CDC and the selected LRC(s).
- APHL will be responsible for tracking testing and service costs, the number of submitters utilizing LRC testing services and may conduct periodic customer satisfaction surveys that includes key informant interviews with select submitters to assess satisfaction with service, turnaround time, reporting format, expert consultation, and continued use of the LRC.

Appendix B: Minimum Requirements for the *Legionella* Reference Center RFP

Please complete each section.

YES	NO	MINIMUM REQUIREMENT
<input type="checkbox"/>	<input type="checkbox"/>	Is your laboratory currently an ELITE member laboratory for environmental <i>Legionella</i> testing?
<input type="checkbox"/>	<input type="checkbox"/>	Does your laboratory currently perform real-time PCR on bacterial isolates in compliance with CLIA regulations?
<input type="checkbox"/>	<input type="checkbox"/>	Is your laboratory capable of conducting next generation sequencing on bacterial isolates?
<input type="checkbox"/>	<input type="checkbox"/>	Does your laboratory possess the major equipment and space required to conduct the <i>Legionella</i> testing described in Appendix A ?
<input type="checkbox"/>	<input type="checkbox"/>	Would your laboratory be willing to alter or amend existing testing protocols or workflows at the request of APHL and/or CDC?
<input type="checkbox"/>	<input type="checkbox"/>	Is your laboratory willing to provide technical assistance, training and SOPs to other jurisdictions to improve <i>Legionella</i> testing capacity?
<input type="checkbox"/>	<input type="checkbox"/>	Does your laboratory have a Laboratory Information Management System (LIMS) in place to meet clinical testing workflows and reporting requirements?
<input type="checkbox"/>	<input type="checkbox"/>	Does your laboratory have the capacity to provide consultations to submitters around sample submission and result interpretation?
<input type="checkbox"/>	<input type="checkbox"/>	Is your laboratory willing and able to respond to FOIA requests related to <i>Legionella</i> testing?
<input type="checkbox"/>	<input type="checkbox"/>	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?

Signature: _____

Date: _____

Appendix C: Application

To submit a proposal for consideration, please respond to the following questions:

Application:

Testing Environment (Question 1) (10 points)

1. Describe the equipment and physical space available for performing all LRC testing, including ancillary equipment (incubators, refrigerators, etc.). Describe the organizational structure of your laboratory, particularly if environmental testing, clinical testing and NGS occur in different laboratory sections. Describe the approximate monthly volume your laboratory could routinely accommodate and your approach to surge testing.

Laboratory Workforce (Questions 2-4) (10 points)

2. Briefly describe your laboratory's overall experience with similar projects including investigating large outbreaks or testing specimens from outside your jurisdiction, including serving as a reference center for other pathogens.
3. Please fill in the table below for each person who would be involved in LRC activities (including the Principal Investigator). Include personnel from specimen accessioning through each methodology and reporting. Add additional rows as necessary.

Name	Title	Relevant experience	Planned role in the project	Authorized to perform any CLIA procedures? (Yes/No)	Cross-training	Comments

4. Describe your capability/capacity to continue *Legionella* reference center work during state or local outbreaks including those of other pathogens? How would in-state responses affect staff assigned to *Legionella* work and how would *Legionella* work be prioritized? How would you approach staffing to accommodate unpredictable testing volumes? Is there sufficient cross-training and capacity to support work during periods of increased testing demand?

Testing Algorithm and Methodology Adoption (Questions 5-7) (15 points)

5. Please describe your laboratory’s current *Legionella* testing algorithm. What is the proposed algorithm you would use for this project, if different from your existing algorithm? If environmental and clinical testing are performed by different laboratory sections, how will they coordinate?
6. Which test methods would you need to validate or receive additional training on, if any, to meet the LRC testing requirements?
7. Please describe the approach your laboratory would take to validate any LRC methods that are not already in place. Include information on numbers of specimens, approximate timeline, etc.

Legionella & Other Bacteria Testing Capabilities (Questions 8-10) (30 points)

8. Please fill in the table below with the pathogens tested, estimated test volume and average turnaround time for environmental *Legionella* culture, clinical *Legionella* culture (if applicable), real-time PCR on clinical specimens and bacterial isolates, and next generation sequencing on bacterial isolates.

Test Type	Pathogens Tested	Estimated Volume	Average Turnaround Time	Number of staff trained in this methodology	Comments
Legionella Environmental Culture	<i>Legionella</i>	Typical per month: Max capacity per month:			
Legionella Clinical Culture	<i>Legionella</i>	Typical per month: Max capacity per month:			
Real-time PCR Clinical specimens		Typical per week: Max capacity per week:			
Real-time PCR Bacterial isolates (clinical or environmental)		Typical per week: Max capacity per week:			
NGS Bacterial isolates		Typical per month: Max capacity per month:			

9. Please briefly describe your workflow and methods for the following:
- Legionella* environmental culture and clinical culture, if applicable
 - Real-time PCR with clinical specimens
 - Real-time PCR with bacterial isolates
 - Next generation sequencing with bacterial isolates
 - Please also describe your current bioinformatics infrastructure, current bioinformatics analysis capabilities, types of outputs provided to submitters and whether your laboratory currently runs NGS for any pathogens in compliance with CLIA regulations.
10. If applicable, please highlight any experience with *Legionella* clinical or environmental testing methods not listed here. Please include methodology, volume and typical turnaround time.

Outbreak Response (Question 11) (10 points)

11. Please describe your experience with *Legionella* or similar outbreak investigations. Describe coordination among laboratory, epidemiology and environmental health sections to respond to complex outbreaks. Include any experience providing consultation to submitters around sample submission and result interpretation. Please describe any experience communicating results to facilities.

Specimen Repository (Question 12) (5 points)

12. Please describe your specimen and isolate storage capacity and your approach to data tracking for managing an inventory of submitted samples/isolates for future sharing with CDC or other collaborators. Please describe your process for sharing samples/isolates with CDC or other collaborators.

Information Technology & Reporting (Questions 13-16) (15 points)

13. Please describe the human and technical resources available to carry out the data management, data exchange and reporting requirements that would be required of the LRC.
14. Please describe your laboratory's current data management infrastructure including how data on clinical and environmental specimens and samples are stored and managed (e.g., in a LIMS, a spreadsheet or in some other manner).
15. Please describe your laboratory's ability to modify the test menu in the LIMS and resources required should the test menu need to be modified. Do changes to your LIMS need to be made by the vendor or are laboratory staff able to make changes? How do you go about validating your LIMS if you add a new test? Is it feasible to add environmental testing to your LIMS, if applicable?
16. Please describe your laboratory's capabilities in terms of reporting results to CDC and how you would propose to report *Legionella* clinical and environmental test results to CDC and submitters.

Additional Comments (Question 17) (5 points)

17. 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.)?

Appendix D: Score Card (For Completion by Reviewers Only – Applicants Do Not Need to Complete)

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

Category/Question	Maximum Value	Score	Comments (REQUIRED)
<p>Testing Environment (Question 1)</p> <p>1. Rate the equipment and physical space available for performing all LRC testing, including equipment and space available to support surge testing.</p> <p>Ideal (6-10 points): Meets equipment and space requirements for all <i>Legionella</i> activities, including ancillary equipment, and has some redundancy in equipment and overflow space for handling large outbreaks.</p> <p>Adequate (1-5 points): Meets most equipment and space requirements but has limited equipment or space to support surge testing.</p> <p>Inadequate (0 points): Does not meet equipment requirements and has limited space.</p>	10		
<p>Workforce (Questions 2-4)</p> <p>2-4. Rate the suitability of the proposed workforce based on relevant experience and planned role to meet the project needs. Please consider the following:</p> <ul style="list-style-type: none"> • Does the applicant have sufficient dedicated personnel and experience to perform the methodologies described? • Is there sufficient staff cross-trained to perform the work? • Does the lab demonstrate capability/capacity to continue <i>Legionella</i> work during state or local outbreaks including those of other pathogens? • Does the lab describe a reasonable approach to balancing <i>Legionella</i> activities and state/local response needs? <p>Ideal (7-10 points): Sufficient staff with strong history of relevant experience, appropriate planned roles, strong cross-training/redundancy to ensure continuity of operations. Demonstrated ability to continue <i>Legionella</i> testing during increased testing volume or outbreaks and solid approach to balancing <i>Legionella</i> activities and local response needs.</p> <p>Adequate (4-6 points): Good workforce experience but will have a learning curve on a few areas or may be lacking in some redundancy; appropriate planned roles; could meet expectations but have some mild reservations regarding capability to complete work during increased testing volume or outbreaks. Adequate approach to balancing <i>Legionella</i> activities and local response needs.</p> <p>Possibly/Uncertain (1-3 points): Clear deficiencies in workforce experience and/or expertise; unrealistic planned roles; strong</p>	10		

<p>reservations about meeting expectations, especially during times of surge testing. Inadequate approach to balancing <i>Legionella</i> activities and local response needs</p> <p>Inadequate: (0 points).</p>			
<p>Testing Algorithm and Methodology Adoption (Questions 5-7) 5-7. Rate the laboratory’s proposed algorithm and its suitability for LRC activities. Will the laboratory need to validate or receive additional training? Is validation plan and timeline reasonable?</p> <p>Ideal (11-15 points): Describes a suitable and efficient flow of samples and specimens; is currently using all or most of the required methods; demonstrates clear understanding of testing timing. Minimal additional training and test validation needed.</p> <p>Adequate (6-10 points): May have to rearrange or adjust testing workflow to accommodate <i>Legionella</i> samples and specimens; has some deficiencies in their proposed flow of samples and specimens. Some training and/or test validation needed. Describes a reasonable approach and timeline for onboarding new methodology.</p> <p>Inadequate (0-5 points): Workflow will not suffice for <i>Legionella</i> activities, and/or does not demonstrate a clear understanding of requirements. Would need extensive training and test validation. Validation plan and/or timeline described is inadequate.</p>	15		
<p>Legionella Testing Capability (Questions 8-10) 8-9. Rate the applicant’s experience and capacity for:</p> <ul style="list-style-type: none"> • <i>Legionella</i> environmental and clinical culture • Real-time PCR • Next generation sequencing • Bioinformatic analysis <p>Ideal experience (18-25 points): extensive experience performing spread-plate <i>Legionella</i> culture on environmental samples and clinical specimens; extensive experience performing real-time PCR on <i>Legionella</i> specimens and isolates and next generation sequencing on bacterial isolates; some experience with bioinformatic analysis of NGS data, sufficient capacity for processing <i>Legionella</i> clinical specimens and environmental samples.</p> <p>Adequate experience (6-17 points): Some experience with <i>Legionella</i> culture on environmental samples; performs real-time PCR on bacterial isolates; limited or no experience with performing <i>Legionella</i> spread-plate culture on clinical specimens; limited or no experience with performing real-time PCR on clinical specimens; limited or no experience with next generation sequencing on bacterial isolates; limited or no experience with bioinformatic analysis of NGS data.</p> <p>Inadequate experience (0-5 points): little to no experience with <i>Legionella</i> environmental culture, real-time PCR or next generation sequencing or does not have the necessary capacity.</p>	30		

<p>10. Does the applicant have specific experience with other types of <i>Legionella</i> testing/characterization (e.g., clinical culture, direct fluorescent antibody, latex agglutination, etc.)?</p> <p>Ideal experience (4-5 points): strong experience in other <i>Legionella</i> testing types. Adequate experience (1-3 points): limited experience in other <i>Legionella</i> testing types Inadequate experience (0 points): no experience in other <i>Legionella</i> testing types</p>			
<p>Legionella Outbreak Response (Question 11)</p> <p>11. Does the applicant have experience coordinating with environmental health and epidemiology to respond to <i>Legionella</i> or similar outbreaks? Do the laboratory, epidemiology or environmental health sections have experience providing consultation to submitters around sample submission and results interpretation? Do they have experience communicating with facilities?</p> <p>Ideal experience (6-10 points): extensive experience coordinating with epidemiology and environmental health in response to <i>Legionella</i> or similar outbreaks; laboratory or epidemiology section has experience providing consultation to submitters on sample submission and result interpretation; laboratory or epidemiology section has some experience communicating with facilities. Adequate experience (1-5 points): some experience coordinating with either epidemiology or environmental health to respond to <i>Legionella</i> or similar outbreaks and/or laboratory or epidemiology section has some experience providing consultation to submitters on sample submission and results interpretation; laboratory and epidemiology section have minimal experience communicating with facilities. Inadequate experience (0 points): does not have experience coordinating with epidemiology and/or environmental health to respond to <i>Legionella</i> or similar outbreaks, consult on sample submission or communicate results; no experience communicating with facilities.</p>	10		
<p>Legionella Specimen Repository (Question 12)</p> <p>12. Does the applicant have experience storing, managing, and sharing specimens and bacterial isolates? Does the applicant have the ability to share specimens/isolates with CDC and other collaborators?</p> <p>Ideal experience (5 points): extensive experience with managing specimen and isolate repositories and sharing specimens and/or isolates. Adequate experience (1-4 points): routinely stores in-house specimens/isolates and has a system for managing inventory but, has not previously participated in a shared repository.</p>	5		

<p>Inadequate Experience (0 points): does not have experience with either in-house or shared repositories.</p>			
<p>Information Technology & Reporting (Questions 13-16) 13-16. Does the applicant have the infrastructure, human and technical resources in place to carry out the data exchange and results reporting necessary for the LRC? Does the applicant have a LIMS system that is easily adaptable? Does the applicant propose a reasonable reporting mechanism for reporting test results to CDC and submitters?</p> <p>Ideal (10-15 points): Laboratory has sufficient human and technical resources to carry out data management, data exchange and reporting requirements; already has a LIMS in place that can support the applicant’s proposed LRC testing algorithm, workflow and reporting requirements; the LIMS system can also be easily modified to meet new method needs; the proposed reporting mechanism is feasible and sufficient.</p> <p>Adequate (5-9 points): Laboratory has some human and technical resources to carry out data management, data exchange and reporting requirements; Laboratory has a LIMS in place that could be modified/updated to meet the applicant’s proposed LRC testing algorithm, workflow and reporting requirements; the proposed reporting mechanism is sufficient.</p> <p>Possibly/Uncertain (1-4 points): Laboratory lacks human and technical resources to carry out data management, data exchange and reporting requirements; clear deficiencies in LIMS that would make transmitting data difficult; the proposed reporting mechanism is has some deficiencies.</p> <p>Inadequate: (0 points): Laboratory lacks human and technical resources to carry out data management; does not have a LIMS in place that is adaptable for new test methodologies; the proposed reporting mechanism is not suitable.</p>	15		
<p>Additional Comments (Question 17) 17. Does the applicant have any unique aspects/services to contribute to the project (e.g., cutting edge technologies, high throughput, etc.)?</p> <p>Yes (1-5 points), No (0 points).</p>	5		
TOTAL SCORE	100		

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).

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: _____

Appendix: F – APHL Fiduciary Responsibility and Conflict of Interest Policy (For Completion by Reviewers Only – Applicants Do Not Need to Complete)

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.