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

Application Due date: January 17, 2025

Submit to: Liz Toure, Senior Specialist, Infectious Diseases (elizabeth.toure@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 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 culture, molecular detection (nucleic acid amplification) 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 LRC(s) builds 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 will provide culture and identification, molecular detection and NGS for clinical specimens, environmental samples and *Legionella* isolates submitted by state and local PHLs and environmental laboratories. The LRC(s) will only support testing for case detection and outbreak response, not routine environmental testing for water management programs or surveillance. The LRC(s) will also serve as a valuable source of expertise, technical assistance and surge capacity for PHLs and will increase national capacity for identifying and characterizing *Legionella* cases and outbreaks.

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 performing isolation of *Legionella* species from clinical specimens and environmental samples;
   b. Currently performing nucleic acid amplification testing (NAAT) for *Legionella* species, *Legionella pneumophila* (LP) and LP serogroup 1 (LP1) on clinical specimens and isolates in compliance with CLIA requirements;
   c. Currently conducting next generation sequencing on bacterial isolates and ability to have an NGS test for *Legionella* isolates by July 1, 2025;
   d. Sufficient equipment, laboratory space and workforce capacity for the proposed work 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 collection, sample submission and result interpretation;
   i. Willingness and ability to respond to Freedom of Information Act (FOIA) requests related to *Legionella* testing; and
   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

November 18, 2024	–	RFP Issued
December 5, 2024	–	Informational Teleconference at 2:00 pm ET (optional)
December 13, 2024	**–**	**Letter of Intent Due to APHL by 5:00 pm ET**
January 17, 2025	–	**RFP Responses Due to APHL by 5:00 pm ET**
February 3, 2025	–	Proposal review completed
February 4 – 16, 2025	–	As needed, follow-up interviews
February 17, 2025	–	Final review completed and awardees selected
Spring 2025	–	Establish submission and result reporting processes, validation of assays and training activities, as needed
July 1, 2025	–	Anticipated Contract Start Date
July 2025	–	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 to elizabeth.toure@aphl.org and infectious.diseases@aphl.org indicating an intent to submit a proposal. APHL must receive this email by no later than **5:00pm ET on December 13, 2024.** 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 January 17, 2025**. 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 and infectious.diseases@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 annual award of up to $200,000. The award will run from July 1, 2025 through June 30, 2030 and will cover testing services provided. APHL will distribute the award via an annual contract administered with APHL.

The award will include a monthly personnel stipend plus monthly compensation based on the number of samples/specimens tested following the rates outlined in the Table 1 below.

Table 1: Compensation Rates

Service	Fee
Monthly Personnel	$4,000 per month
Clinical specimen culture	$40 per clinical specimen
Environmental sample culture	$115 per environmental sample
Isolate subculture and identification	$50 per isolate (recovered or submitted)
NAAT	$125 per specimen/isolate
NGS	$185 per isolate

By accepting the award, the PHL(s) agrees to these rates for a 3-year time span barring substantive changes in scope or material expenses at APHL's discretion. After three years, the PHL(s) will have the opportunity to renegotiate rates if warranted.

Term of Project

The initial project term will be from July 1, 2025 through June 30, 2026 with annual renewals through June 30, 2030 provided the availability of funds and performance of the awardee(s). Renewals may include adjustments to the scope of work. Awardees will be notified of modifications in advance and modifications will be agreed to in writing.

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 Program Manager, Infectious Diseases and will have expertise in the laboratory testing methods described in this RFP and familiarity with other APHL reference centers.

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 Senior Director, Infectious Diseases 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 meeting the following criteria have preference in the evaluation:

a) Experience with the test methods;

b) Ability to handle anticipated LRC testing volume and meet turnaround time requirements;

c) Existing in-house subject matter expertise;

d) Experience and past performance serving as a Reference Center;

e) Ability to provide LRC services on July 1, 2025;

f) Existing system for onboarding submitters and releasing test results;

g) Ability to comply with expectations laid out in Appendix A; and

h) 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, Infectious Diseases and the members of the evaluation team. APHL's Senior Specialist, Infectious 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 12/13/2024) and a proposal (due 1/17/2025) with the following items:

- **A completed and signed copy of Appendix B.**
- **A completed response to the application questions, found in Appendix C.**
    - Appendix C responses should be limited to no more than 8 single-spaced pages (font size ≥ 11pt and page margins of ≥ 1 inch).
- **A letter of support from your Information Technology department.**
    - The letter 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.**

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, Infectious Diseases, Liz Toure (elizabeth.toure@aphl.org) and infectious.diseases@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 (elizabeth.toure@aphl.org) and infectious.diseases@aphl.org no later **than 5:00 pm ET on Friday, December 13, 2024**.

Applications should be submitted to Liz Toure at APHL (elizabeth.toure@aphl.org) and infectious.diseases@aphl.org no later than **5:00 pm ET on Friday, January 17, 2025.** 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, December 5, 2024 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 Wednesday, December 4, 2024 if you would like to be sent the calendar invitation.

Join Zoom Meeting
https://aphl.zoom.us/j/86418602478?pwd=t3HJWOkKkP5ndLSJwmAEnwC0hukuDM.1

Call-in Information

+ 1 301 715 8592	US (Washington DC)	Meeting ID: 864 1860 2478
+ 1 312 626 6799	US (Chicago)	Passcode: 232755

Appendix A: Expectations for the Legionella Reference Center(s)

Sample Types and Algorithm

- The LRC should accept all appropriate clinical and environmental sample types, including but not limited to: sputum, bronchial alveolar lavage, tracheal aspirate, bulk water, swabs and filter material. Acceptable sample types and acceptable storage times and temperatures will be explicitly defined based on the LRC's validated SOPs. Additional specimen types may require validation.
- Environmental samples submitted to the LRC must be collected as part of an active case or outbreak investigation and require pre-approval.
- The exact testing algorithm will be determined in coordination with CDC and the LRC.

NAAT

- The LRC will conduct NAAT 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 case detection and outbreak response.
- Testing of clinical specimens and clinical isolates 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 validated and communicated to CDC and APHL for approval prior to implementation.

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 conventional culture and identification on clinical specimens and environmental samples.
- If an isolate is not obtained from a clinical specimen, but *Legionella pneumophila* is identified by NAAT the LRC may be requested to transfer the specimen to CDC for culture-independent typing.
- 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 a ready supply of appropriate culture media. The LRC will notify APHL and CDC if a media shortage is anticipated.
- The LRC must follow validated standard operating procedures (SOPs); protocol modifications and deviations must be validated and communicated to CDC and APHL for approval prior to implementation.
- By July 1, 2025, the LRC environmental testing procedures must either be accredited by a recognized regional, national or international accrediting body according to a nationally or internationally recognized standard (e.g., ISO) or must be enrolled as a participant of the Environmental *Legionella* Isolation Techniques Evaluation (ELITE) Program).

NGS

- The LRC must be capable of conducting NGS for genetic characterization of bacterial isolates at the time of application with the expectation of having a validated *Legionella* NGS test available for the beginning of the award on July 1, 2025.
- NGS does not need to 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 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 prior to implementation.
- Sequences will be analyzed using CDC validated pipelines or equivalent, as agreed upon by all parties.
- Sequences must either be uploaded to NCBI or submitted to CDC within 1 year.

General Testing Requirements

- The LRC will provide testing services as described above to enrolled PHLs and 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 LRC and a timeline for implementation will be agreed upon. Any changes initiated by the LRC to validated protocols must be submitted in writing to APHL and CDC for signed approval prior to implementation.
- APHL, CDC and the LRC will establish reasonable expected turnaround times for each sample and test type.

Anticipated Volume and Turnaround Time Requirements

- The LRC should be able to accommodate an anticipated monthly testing volume of at least 40 environmental samples and at least 8 clinical specimens for reference center testing.
- The LRC should meet the following turnaround time requirements:
    - Culture: 16 days for clinical specimens and 18 days for environmental samples (positive results may be reported sooner).
    - NAAT: three days from receipt of a clinical specimen, or seven days of receipt or recovery of an isolate.
    - NGS: within 21 days of receipt or recovery of an isolate.

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, CDC *Legionella* Team and APHL will review and approve or reject environmental testing requests. Some requests may require further consultation with the requester.

- 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 and methods. Opportunities for evaluation will be explored with the LRC and CDC to determine sufficient facilities, personnel, and time resources. Evaluation of new platforms or methods 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 environmental test requests received and number of requests accepted
    - Number of result consults provided
- Monthly 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 include key informant interviews with select submitters to assess satisfaction with service, turnaround time, reporting format, expert consultation, and continued use of the LRC.

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

- CDC and APHL will conduct site visits if 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 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 a secure method (e.g., secure web portal, 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 web portal or email. In the future, the LRC will be required to comply with data modernization standards of practice.

Mechanism for reporting results to CDC

- TLRC will provide results at least weekly via API in a format compatible with ingestion into CDC Surveillance systems. More frequent reporting may be requested in some situations.

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.

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

Please complete each section.

YES	NO	MINIMUM REQUIREMENT
☐	☐	Does your laboratory currently perform isolation of *Legionella* species from clinical specimens and environmental samples?
☐	☐	Does your laboratory currently perform NAAT to detect *Legionella* species, LP and LP1 on clinical specimens and bacterial isolates in compliance with CLIA regulations?
☐	☐	Is your laboratory currently conducting NGS on bacterial isolates and is it currently or will it have an NGS test for *Legionella* isolates by July 1, 2025?
☐	☐	Does your laboratory possess sufficient equipment, space and workforce required to conduct the *Legionella* testing described in Appendix A?
☐	☐	Would your laboratory be willing to alter or amend existing testing protocols or workflows at the request of APHL and/or CDC?
☐	☐	Is your laboratory willing to provide technical assistance, training and SOPs to other jurisdictions to improve *Legionella* testing capacity?
☐	☐	Does your laboratory have a Laboratory Information Management System (LIMS) in place to meet clinical testing workflows and reporting requirements?
☐	☐	Does your laboratory have the capacity to provide consultations to submitters around sample collection, sample submission and result interpretation?
☐	☐	Is your laboratory willing and able to respond to FOIA requests related to *Legionella* testing?
☐	☐	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 for LRC testing and your approach to surge testing (the LRC is expected to be able to handle a testing volume of at least 40 environmental samples and at least 8 clinical specimens per month).

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 and 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?

Quality Management Systems (Questions 5-6) *(20 points)*

5. Please describe your quality management system for clinical *Legionella* testing including participation in any external or internal proficiency testing programs, any accreditations you hold and any other relevant information.
6. Please describe your quality management system for environmental *Legionella* testing including participation in any external or internal proficiency testing programs, any accreditations you hold and any other relevant information.

Testing Algorithm, Methodology, Capability and Capacity (Questions 7-10) *(30 points)*

7. 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?

8. Please describe your test methodology and level of experience for each of the following methods, including what equipment is used:
   a) *Legionella* environmental culture
   b) *Legionella* clinical culture
   c) *Legionella* NAAT on clinical specimens (please also include performance data of the NAAT)
   d) *Legionella* NAAT on bacterial isolates (please also include performance data of the NAAT)
   e) NGS on bacterial isolates (if *Legionella* NGS is not yet validated, please describe validation plan and timeline)

9. Please 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. Please also describe your willingness to use CDC's *Legionella* analysis pipelines or submit sequences to CDC for parallel analysis in order to generate standardized NGS results and reports.

10. Please fill in the table below with the estimated test volume that your laboratory could accommodate (current typical monthly volume and estimated maximum monthly capacity for LRC samples) and average turnaround time for environmental *Legionella* culture, clinical *Legionella* culture, NAAT on clinical specimens and bacterial isolates, and NGS bacterial isolates.

Test Type	Pathogens Tested	Estimated Volume	Average Turnaround Time	Number of staff trained in this methodology	Comments
Legionella **Environmental Culture**	*Legionella*	Typical per month: Estimated max capacity for LRC samples per month:			
Legionella **Clinical Culture**	*Legionella*	Typical per month: Estimated max capacity for LRC specimens per month:			
Legionella **NAAT** Clinical specimens	*Legionella sp. LP, LP1*	Typical per month: Estimated max capacity for LRC specimens per month:			
Legionella **NAAT** Bacterial isolates (clinical or environmental)	*Legionella sp. LP, LP1*	Typical per month: Estimated max capacity for LRC isolates per month:			
NGS Bacterial isolates	Any	Typical per month: Estimated max capacity for LRC isolates per month:			

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) *(10 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., experience with other *Legionella* test methods, 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)
Testing Environment (Question 1) 1. Rate the equipment and physical space available for performing all LRC testing, including equipment and space available to support surge testing. **Ideal** (6-10 points): Meets equipment and space requirements for all *Legionella* activities, including ancillary equipment, and has some redundancy in equipment and overflow space for handling large outbreaks. Can accommodate monthly LRC testing volume of at least 40 environmental samples and at least 8 clinical specimens. **Adequate** (1-5 points): Meets basic equipment and space requirements but has limited equipment or space to support surge testing. Can accommodate monthly LRC testing volume of at least 20 environmental samples and at least 4 clinical specimens. **Inadequate** (0 points): Does not meet equipment requirements and has limited space.	10		
Workforce (Questions 2-4) 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: • Does the applicant have sufficient 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 *Legionella* work during state or local outbreaks including those of other pathogens? • Does the lab describe a reasonable approach to balancing *Legionella* activities and state/local response needs? **Ideal** (5-10 points): Demonstrated experience with similar projects. Sufficient staff with strong history of relevant experience, appropriate planned roles, strong cross-training/redundancy to ensure continuity of operations. Demonstrated ability to continue *Legionella* testing during periods of increased testing volume or outbreaks and solid approach to balancing *Legionella* activities and local response needs. **Adequate** (2-4 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 *Legionella* activities and local response needs. **Inadequate** (0-1 point): Clear deficiencies in workforce experience and/or expertise; unrealistic planned roles; strong reservations about	10		

meeting expectations, especially during times of surge testing. Inadequate approach to balancing *Legionella* activities and local response needs			
Quality Management Systems (Questions 5-6) 5. Rate the applicant's clinical *Legionella* testing QMS. **Ideal** (5-10 points): *Legionella* clinical testing is currently performed in compliance with CLIA regulations; describes a robust QMS for clinical *Legionella* testing. **Adequate** (1-4 points): *Legionella* clinical testing is currently performed in compliance with CLIA regulations; describes an adequate QMS for clinical *Legionella* testing. **Inadequate** (0 points): *Legionella* clinical testing is not performed in compliance with CLIA regulations. 6. Rate the applicant's environmental *Legionella* testing QMS. **Ideal** (5-10 points): Currently participates in a performance evaluation program for environmental *Legionella* testing (e.g., ELITE) or holds an accreditation for environmental *Legionella* testing; describes a robust QMS for environmental *Legionella* testing. **Adequate** (1-4 points): Working towards or describes plans for participation in a performance evaluation program for environmental *Legionella* testing (e.g., ELITE) or working towards an accreditation for environmental *Legionella* testing; describes an adequate QMS for environmental *Legionella* testing. **Inadequate** (0 points): Does not participate in any environmental *Legionella* proficiency testing program nor working towards any accreditation for environmental *Legionella* testing.	20		
Testing Algorithm, Methodology, Capability and Capacity (Questions 7-10) 7. Rate the suitability of the applicant's proposed testing algorithm and coordination between laboratory sections/units. **Ideal** (4-5 points): Describes a suitable and efficient flow of samples and specimens; demonstrates clear understanding of testing timing; describes how lab sections coordinate testing. **Adequate** (1-3 points): May have to rearrange or adjust testing workflow to accommodate *Legionella* samples and specimens; has some deficiencies in their proposed flow of samples and specimens; unclear how lab sections coordinate. **Inadequate** (0 points): Workflow will not suffice for *Legionella* activities, and/or does not demonstrate a clear understanding of requirements; no coordination between lab sections. 8. Rate the applicant's test methodology and experience. **Ideal** (6-10 points): Extensive experience performing traditional *Legionella* culture on environmental samples and clinical specimens; extensive experience performing NAAT on *Legionella* clinical specimens and isolates, extensive experience performing NGS on bacterial isolates; ability to have NGS validated for *Legionella* isolates	30		

by July 1, 2025 if not already validated; describes suitable equipment for all test methods. **Adequate** (1-5 points): Some experience with *Legionella* culture on clinical and environmental samples; performs NAAT on *Legionella* isolates; limited experience with performing *Legionella* NAAT on clinical specimens; limited experience with NGS on bacterial isolates; ability to have NGS validated for *Legionella* isolates by July 1, 2025 if not already validated; describes suitable equipment for most test methods. **Inadequate** (0 points): Limited experience with *Legionella* environmental or clinical culture, NAAT or NGS; does not describe ability to have NGS validated for *Legionella* isolates by July 1, 2025; does not use suitable equipment for test methods. 9. Rate the applicant's bioinformatics experience and infrastructure. **Ideal** (4-5 points): Moderate or extensive experience with bioinformatic analysis of NGS data, sufficient bioinformatics infrastructure; willing to use CDC's *Legionella* analysis pipelines or submit sequences to CDC for parallel analysis; currently runs NGS for one or more pathogens in compliance with CLIA regulations. **Adequate** (1-3 points): Limited or no experience with bioinformatic analysis of NGS data; limited bioinformatics infrastructure; willingness to utilize CDC's *Legionella* NGS pipeline; does not run NGS on any pathogens in compliance with CLIA regulations. **Inadequate** (0 points): No experience with bioinformatic analysis of NGS data; unwillingness to utilize CDC's *Legionella* NGS pipeline. 10. Rate the applicant's monthly testing capacity and turnaround time. **Ideal** (6-10 points): Sufficient monthly maximum capacity for each testing type for LRC testing; reasonable turnaround time. **Adequate** (1-5 points): Adequate maximum monthly capacity for most testing types for LRC testing; slower turnaround time for some test types. **Inadequate** (0 points): Inadequate monthly maximum capacity for LRC testing; very slow turnaround time for most test types.			
***Legionella* Outbreak Response (Question 11)** 11. Does the applicant have experience coordinating with environmental health and epidemiology to respond to *Legionella* or similar outbreaks? Do the laboratory, epidemiology or environmental health sections have experience providing consultation to submitters around sample collection, submission and results interpretation? Do they have experience communicating with facilities? **Ideal** (6-10 points): extensive experience coordinating with epidemiology and environmental health in response to *Legionella* or similar outbreaks; laboratory or epidemiology section has experience providing consultation to submitters on sample collection, sample submission and result interpretation; laboratory or epidemiology	10		

section has some experience communicating with facilities. **Adequate** (1-5 points): some experience coordinating with and epidemiology or environmental health to respond to *Legionella* or similar outbreaks; laboratory or epidemiology section has some experience providing consultation to submitters on sample collection, submission and results interpretation; laboratory and epidemiology section have minimal experience communicating with facilities. **Inadequate** (0 points): does not have experience coordinating with epidemiology and/or environmental health to respond to *Legionella* or similar outbreaks, consult on sample submission or communicate results; no experience communicating with facilities.			
***Legionella* Specimen Repository (Question 12)** 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? **Ideal** (4-5 points): extensive experience with managing specimen and isolate repositories and sharing specimens and/or isolates. **Adequate** (1-3 points): routinely stores in-house specimens/isolates and has a system for managing inventory but has not previously participated in a shared repository. **Inadequate** (0 points): does not have experience with either in-house or shared repositories.	5		
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? **Ideal** (5-10 points): Laboratory has sufficient human and technical resources to carry out data management, data exchange and reporting requirements; has a LIMS in place that can support the applicant's proposed LRC testing algorithm, workflow and reporting requirements; the LIMS system can be easily modified to meet new method needs; the proposed reporting mechanism is feasible and sufficient. **Adequate** (1-4 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. **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 or has clear deficiencies in LIMS that would make transmitting data difficult; the proposed reporting mechanism is not suitable.	10		

Additional Comments (Question 17) 17. Does the applicant have any unique aspects/services to contribute to the project (e.g., experience with additional *Legionella* test methods, cutting edge technologies, high throughput, etc.)? **Yes** (1-5 points), **No** (0 points).	5		
TOTAL SCORE	100	___	