CITY OF NEW YORK
DEPARTMENT OF HEALTH AND MENTAL HYGIENE (DOHMH)
NEGOTIATED ACQUISITION FOR
LABORATORY TESTING SERVICES: LEGIONELLA
PIN: 17ET006900R0X00

Addendum #3
June 13, 2016

This Addendum contains revisions to Section I: General Information and Section II: Scope of Work. Also included in this Addendum are DOHMH responses to unduplicated vendor questions received on or before the Questions Due Date.

Except as otherwise stated below and by any prior or subsequent Addenda to the above-referenced Negotiated Acquisition, the Negotiated Acquisition remains unchanged.

I. **Revision to Minimum Qualification Requirements/Minimum Submission Requirements.** Section I(6) of the Negotiated Acquisition document is hereby amended to include New York State interim status for ELAP Certification for Legionella, with new language bolded:

6. Minimum Qualification Requirements/Minimum Submission Requirements

The following are the Minimum Submission Requirements of this solicitation. Applicants must provide proof that they meet all of these requirements at the time of application. Applicants that fail to meet these requirements will be rejected.

- Center for Disease Control and Prevention ("CDC") certification for Environmental Legionella Isolation Techniques Evaluation ("ELITE")
- At least one of the following:
  - Proof of certification from the National Environmental Laboratory Accreditation Program ("NELAP"), or
  - Proof of certification from the NYS Environmental Laboratory Approval Program (ELAP), or
  - Equivalent program overseen by another state. Applicant must provide proof of equivalent accreditation or approval.
- **Proof of interim ELAP Certified status for Legionella from the NYS Department of Health.**

II. **Revision to Section II(A)(1) – Specifications/Scope of Services.** Section II(A)(1) on page 8 of the Negotiated Acquisition document is amended to include the requirement for applicants to obtain interim ELAP Certification status for Legionella from New York State Department of Health. The selected vendor(s) must also maintain final, approved ELAP Certification for Legionella from New York State Department of Health as a requirement of the Agreement. The amended section is reproduced below with new language bolded:

A. SPECIFICATIONS/SCOPE OF SERVICES

1. OVERVIEW

Contractor shall perform laboratory tests and analyses of specimens when requested by the Department and as set forth in this Scope of Services.

Subject to the provisions of applicable NELAP, ELAP, and/or equivalent program overseen by another state, and the laboratory's reasonable protocols regarding the proper handling and maintaining of specimens, the Contractor shall provide laboratory testing services for DOHMH on a routine basis and in emergency or outbreak situations. Such laboratory services shall include but not be limited to the following: coordinating and communicating with DOHMH; providing sampling equipment and infrastructure in order to ship and receive samples gathered by DOHMH; adequately handling the samples once they arrive at the Contractor facility; analyzing collected samples; and providing timely reports to DOHMH. The Contractor must exercise laboratory analytical Quality Assurance/Quality Control (QA/QC) protocols to ensure the accuracy of the test results.

The Contractor is required to obtain interim ELAP Certified status for Legionella from New York State Department of Health and submit proof of this interim status with its initial application. The Contractor will be required to maintain its final, approved ELAP Certification for Legionella for the duration of the Agreement.

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III. **REVISED Attachment C: Acknowledgement of Addenda form (Annex A):** Attached is a REVISED Attachment C: Acknowledgement of Addenda form. Proposers are directed to sign this version of the form and submit it with their Expression of Interest and application package.

IV. **Vendor Questions and DOHMH Responses**: all vendor questions that were sent in writing and received on or before the Questions Due Date and DOHMH responses are included herein as **Annex B**.

REVISED ATTACHMENT C

PIN 17ET006900R0X00

ACKNOWLEDGEMENT OF ADDENDA

Directions: Complete Part I or Part II, whichever is applicable, and sign your name in Part III.

Part I

Listed below are the dates of issue for each Addendum received in connection with this Negotiated Acquisition:

Addendum # 1, Dated May 20, 2016

Addendum # 2, Dated June 6, 2016

Addendum # 3, Dated June 13, 2016

Addendum # 4, Dated _____, 20__

Addendum # 5, Dated _____, 20__

Addendum # 6, Dated _____, 20__

Part II

_____ No Addendum was received in connection with this Negotiated Acquisition.

Part III

Proposer's Name: _____ Date: _____

Signature of Authorized Representative: _____

Annex B

Answers to Questions received in writing by the Questions Due Date 5/12/16

NOTE: As deemed appropriate by DOHMH, similar/same questions have been consolidated and one response is provided.

1. **Question**: We are a CDC Elite and AIHA accredited Laboratory interested in performing your Legionella work. Is there a more specific scope for the chemical analysis as we may be able to team up with another Lab? We perform the culture method according to the CDC for Legionella.
   Answer: As indicated under Section I (1) on page 3, the Agency anticipates that there will be no subcontracting under the contracts that result from this solicitation.

2. **Question**: We do not go out and collect samples, we analyze samples collected by Environmental companies. Some of these companies do collect samples in NYC. Do you require any other certification for our laboratory to analyze samples from NYC?
   Answer: Samples will be collected by DOHMH and delivered (or shipped) to the contracted ELAP-certified lab. Refer to NYS for directives regarding ELAP certification for Legionella (http://www.wadsworth.org/regulatory/elap/legionella).

3. **Question**: Can you specify what specific activities involved for culture test for quantitative methods for Legionella? Does it mean to use specific culture method for Legionella to the counting of colonies or other technologies to count bacterial cells?
   Answer: Refer to published CDC guidelines for culture and enumeration of Legionella (http://www.cdc.gov/legionella/health-depts/inv-tools-cluster/lab-inv-tools/procedures-manual.html).

4. **Question**: For the culture test of serotyping for Legionella, Can we just run a test to identify group 1 or group 2-14 without specifying which group among 2-14?
   Answer: For processing most routine samples, running a test to identify group 1 or groups 2-14 without specifying which group among 2-14 will suffice. However, the lab must be able to identify all serogroups if specifically requested by DOHMH.

5. **Question:** If a Real-time PCR for *Legionella pneumophila* is run against a list of Legionella strains and other bacteria strains, do we still need a PCR test for serotyping?
   Answer: Yes.

6. **Question:** Is a prime contract lab required to perform all tasks? For example, if a lab may be just specialized in microbiological testing without doing the chemical testing, will it be qualified for a service contract for this project?
   Answer: As indicated under Section I.1 on page 3, the Agency anticipates that there will be no subcontracting under the contracts that result from this solicitation.

7. **Question:** For algal biomass, do you want the results expressed as dry mass, chlorophylls or bio-volume?
   Answer: Chlorophyll.

8. **Question**: may you be awarding 2 different contracts: One for the microbiological testing and one for the chemical testing?
   Answer: No. As indicated in Section I.1, DOHMH anticipates awarding up to three contracts for all services specified in the solicitation document, each to conduct both microbiological testing and chemical testing.

9. **Question**: Some of the chemical tests listed are best done in the field because of rapid changes that result when transporting samples to the lab e.g.; pH, conductivity, ORP, temperature. Will these field tests still be required for bidding purposes?
   Answer: The selected vendor(s) will not conduct field testing; any field testing will be handled by DOHMH personnel. However, DOHMH may request that these chemical tests be taken by the successful vendor(s) upon receipt of the samples for QA/QC purposes.

10. **Question**: NY State NELAP requires a strict 8 hour hold time for HPC. APHA Standard Methods 22nd edition specifies an 8 hour hold time but allows a 24 hour hold time if samples can't be processed in 8 Hours. Which will you require?
    Answer: 24 hour hold times.

11. **Question**: There are two types of agar that are traditionally used for HPC tests: Plate Count Agar and R2A agar. While R2A agar is recommended to be used with chlorinated or low nutrient samples, there is no clear direction which agar to use for cooling tower water or hot tub water samples which may or may not be chlorinated and are high nutrient samples. Will you be specifying which agar to use that is best suited to the sample collected or will that be the responsibility of the lab?
    Answer: Generally the water is halogenated with a variable nutrient load. The agar selection will be responsibility of the lab.

12. **Question**: For the chlorine test, do you want total chlorine or free residual chlorine?
    Answer: Total chlorine.

13. **Question**: We use a qualitative PCR test for determining the presence or absence of L. pneumophila 1 (Lp1) by identifying the mip gene. This is a method that was developed by EPA. After doing a literature search and discussions with CDC, we were not able to identify a validated qPCR method to quantitate Lp1. If you have a validated method and are willing to share it, we will use your method to develop the test.
    Answer: Refer to guidelines issued by NYS regarding ELAP Legionella certification (http://www.wadsworth.org/regulatory/elap/legionella)

14. **Question**: It isn't clear whether a simple statement of Expression of Interest is due on the Due Date or whether your definition of an expression of interest includes application items listed on page 14 of the solicitation and that is due on the Due Date. Please advise.
    Answer: Expressions of Interest should include a complete application, as outlined in Section III of the solicitation (see pages 14 – 16). Applicant must submit their completed Expressions of Interest on or before the Due Date.

15. **Question**: I understand this Bid has provisions on Subcontracting however, what if company has 2 separate divisions under different names would 2 separate responses would need to be submitted or can they be combined together?
    Answer: If the entities have both different names and different tax identification numbers, they would need to submit separate responses.

16. **Question**: Will the agency allow for subcontracting of some of the chemical testing parameters that we are currently not certified for?
    Answer: As indicated under Section I.1 on page 3, the Agency anticipates that there will be no subcontracting under the contracts that result from this solicitation.

17. **Question**: Will DOHMH pre-review applicant's minimum qualification documents prior to the application deadline?
    Answer: No. Applicants are directed to submit all documents, including proof of satisfaction of the minimum qualification requirements on pages 4 and 5 of the solicitation document.

18. **Question**: Can a laboratory use AIHA Environmental Microbiology (EMLAP) Accreditation in lieu of NELAP or State Accreditation? AIHA EMLAP is ISO 17025 compliant and is recognized both Nationally and Internationally (ILAC).
    Answer: No. As stated in Section I(6)– Minimum Qualification Requirements/Minimum Submission Requirements (page 4 of the solicitation document), the minimum submission requirements are CDC ELITE certification and at least one of the following: NELAP, New York State ELAP, or equivalent program overseen by another state. In addition, the lab must also submit proof that they have obtained interim status for ELAP Certification for Legionella from NYS Department of Health.

19. **Question**: The Scope of Work description for Real Time PCR says "quantitative and serotyping." We are unaware of a way to equate a real time PCR result to CFU/mL. Molecular marker negative screening has a result of "Detected" or "Not Detected." Also, PCR is generally not used for serotyping. Serotyping is performed using a technique called DFA and is typically done in conjunction with culture tests for *Legionella*. Could PCR test results be in terms of detection rather then CFU/mL and not include serotyping? Please advise.
    Answer: DOHMH expects the selected vendor(s) to provide semi-quantitative rtPCR results (e.g., 'high' and 'low' positives along with the basis for such determinations). When PCR tests are requested by the Department (during certain conditions), the ability to identify species (e.g. *pneumophila) and* a PCR-based serotyping of at least serogroup 1 is required.

20. **Question**: For required testing: "Culture tests for Legionella (including quantitative and serotyping)," it is standard practice for labs to conduct ISO 11731 Standard testing and include designating positive results into the following:

    - *Legionella pneumophila* serogroup 1
    - *Legionella pneumophila* serogroups 2-14
    - *Non-pneumophila Legionella* species

Serogroup identification beyond this is typically unnecessary because the response is typically the same regardless of serogroup. Serogroup identification beyond this will increase the cost of this testing. Please clarify what is required for serotyping. If serogroup identification is required beyond what is listed above, could a separate line item for identifying serogroups 2-14 be a separate line item? That will ensure NYC Health is not paying for this type of testing on all samples, as it will only be necessary on positive *Legionella pneumophila* samples.

Answer: Serogroup identification to the specificity listed above, in accordance with ISO 11731 and ELAP certification is acceptable in most conditions. However, the lab must have the ability to identify all serogroup if specifically requested by DOHMH.

21. **Question**: Periphyton and algae biomass is used for testing microorganisms growing on stones, sticks, etc. in lakes and streams. This type of testing is not typically done on cooling tower water. Could this testing is removed from the Scope of Work or more detailed instructions for this testing be provided? If the requirement will remain, we need to know the following:

    - By "Biomass" do you mean dry weight (DW) and Ash Free Dry Weight (AFDW) of the periphyton and algae?
    - Do we need to scrape the periphyton samples or will we be receiving the biological samples from which the periphyton must be removed?
    - If the latter, from what substrates will we be removing the periphyton?
    - Do you need a weight or measurement of the substrate to get a density measure of grams periphyton per gram or grams per substrate area (cm2)?
    - Do you want macroinvertebrates and other debris removed from the algae biomass before obtaining biomass?

    Answer: Some cooling towers have shown elevated and visible amount of algae. As a surrogate, chlorophyll concentration can be used for algae biomass. Periphyton is not likely to be requested. If needed, the lab will be provided with a biological sample (likely a piece of metal), to be measured in grams per substrate area. Macroinvertebrates should be removed.

22. **Question**: Heterotrophic Plate Count tests take 7 days to receive results. Could results be due in that time frame rather than the 48 hours listed in the Scope of Work?
    Answer: Incubation at 35 C for 48 hours is required. Refer to The Standard Methods of Examination for Water and Wastewater, Section 9215A (2012 edition, ISBN 978-087553-013-0).

23. **Question**: Can we use sister laboratories for analyses?
    Answer: If "sister laboratories" refers to engaging subcontractors to perform a portion of the work, as indicated under Section I.1 on page 3, the Agency anticipates that there will be no subcontracting under the contracts that result from this solicitation. If, however, "sister laboratories" refers to legally related entities, please see Question #15 and DOHMH answer.

24. **Question**: P89 Affirmation – is a corporate seal required?
    Answer: No. A corporate seal is not required.

25. **Question**: Will analyses need to comply with potable water testing protocols and certification?
    Answer: The lab needs to be CDC ELITE certified and ELAP/NELAP/equivalent from another state certified.

26. **Question: PCR Legionella pneumophila:** Is a general quantitative PCR test including L. pneumophila and other species acceptable? Also, in an outbreak situation would cultures need to be run alongside to confirm positive growth?
    Answer: We require a qPCR test for Legionella species. Cultures would be run alongside during an outbreak to confirm viability.

27. **Question: Preparation of culture isolate:** How long after the results are reported/reviewed will the lab be notified that a isolate(s) culture(s) are needed for delivery?
    Answer: The protocol for delivery decisions is currently being developed and will be distributed to the selected vendor(s).

28. **Question**: How quickly will the lab be notified of an outbreak to ensure laboratory supplies that can be high demand/shortage during an outbreak situation?
    Answer: DOHMH will notify the laboratory as soon as the decision is made to collect samples. Samples will then be delivered to the lab the following day.

29. **Question**: What field tests are completed on the scene by the sampler performing legionella sampling since pH, temperature, chlorate and bromate are normally done in the field by the sampler?
    Answer: The selected vendor(s) will not conduct field testing; any field testing will be handled by DOHMH personnel. However, DOHMH may request that chemical tests be taken by the successful vendor(s) upon receipt of the samples for QA/QC purposes.

30. **Question**: ORP and Conductivity are typically field tests. Will the sampler be performing these in the field?
    Answer: The selected vendor(s) will not conduct field testing; any field testing will be handled by DOHMH personnel. However, DOHMH may request that chemical tests be taken by the successful vendor(s) upon receipt of the samples for QA/QC purposes.

31. **Question: Heterotrophic Plate Count (HPC):** Water type (Potable or Non-Potable) and are any specific state accreditations for drinking water or wastewater testing required? Also, would these samples be taken from the cooling towers and tested alongside the Legionella samples?
    Answer: Water type is non-potable. The lab needs to be Elite, ELAP/NELAP certified. Yes, the samples will be taken from cooling towers.

32. **Question: Periphyton and algae biomass:** Would a count of algae per mL with crude classification (e.g. green algae, diatoms) be acceptable for this request.
    Answer: Yes, or chlorophyll in lieu of biomass.

33. **Question:** Will the Agency ship samples to more than one location? The laboratory would provide the Agency with a flow chart detailing instructions for sample submission to specialized laboratories based on required services.
    Answer: The Department may ship samples to more than one location. However, as indicated under Section I.1 on page 3, the Agency anticipates that there will be no subcontracting under the contracts that result from this solicitation.

34. **Question:** If a lab is CDC ELITE approved using only the culture method, will it be eligible for this contract if it does not offer the quick PCR methods?
    Answer: As indicated in Section I.7 on page 4, applicants should have at least 3 years of experience in the operation of a microbiological laboratory, **including the detection and enumeration of Legionella by culture and qPCR testing.** In addition, as described in Section II(A)(1) on pages 8 and 9, the selected vendor would be able to perform qPCR testing, when requested by DOHMH. Applicants that do not meet these standards will be evaluated accordingly.

35. **Question:** The ELAP certification for *Legionella* culture is in the process of being developed. It is not yet in place. Please advise.
    Answer: Applicants are required to meet the certification requirements at the time of application, including interim ELAP status for Legionella. The selected vendor(s) will be required to maintain all certifications for the duration of any contract. Once NYSDOH establishes an ELAP certification for Legionella, contractor(s) will be required to meet that standard in order to continue to meet the terms of the contract.

36. **Question:** Culture isolates prepared for shipment: is this a requirement for all positive samples both routine and outbreak?
    Answer: No. DOHMH will specifically request culture isolates for shipment, when needed, and will try to identify these in advance.

37. **Question**: Can you describe further what is meant by "HTTP Post with a structured XML message"?
    Answer: With respect to the Organizational Capability Requirement in Section 1(8)(d), "HTTP Post with a structured XML message" means electronic posting using a dedicated web service based in XML language, currently being developed at DOHMH.

38. **Question**: What method do you want us to use confirm receipt of sample shipment? Can we confirm receipt by sending a pending prelim report with CoC attached?
    Answer: Acceptable methods will be determined between the selected contractor(s) and DOHMH. The above-referenced method would be acceptable.

39. **Question**: What is your preferred method for periphyton and algae biomass testing?
    Answer: Chlorophyll or microscope counts are acceptable.

40. **Question**: How will notice be received for the need Sunday and Holiday coverage in the lab?
    Answer: DOHMH will contact the lab by telephone with outbreak notification. Contractors will be required to provide DOHMH with after-hours contact information.

41. **Question**: (5 a.) What kind of interpretation of results are required with reports?
    Answer: List of results, method used, presence/absence of species and QA/QC tags.

42. **Question**: Section II(A)(5)(e) Reporting on Specimen Results on page 12: in regards to 48 hr TAT for HPC- If samples received on Friday, reporting on Monday OK?
    Answer: Yes, if the 48 hour TAT would mean reporting on a Saturday or Sunday, reporting on Monday is acceptable, unless it is an outbreak situation in which case the PCR reporting is required within 24 hours.

43. **Question**: Section 2(A)(6)(a) – Quality Assurance and Control (Page 12). We do not routinely do duplicate tests on our QC samples, is this OK?
    Answer: The contractor must follow the proper QA/QC regulations based on ELITE and NELAP/ELAP certifications.

44. **Question**: Section II(A)(1)(a) (Page 8):
    -"report back to DOHMH within one week of result being reported"- Define "report back to" if they mean something other than the primary report.
    -Are the samples you are sending for serotyping isolates?
    -Do you want a report or a list of isolate shipped?

    Answer: The primary report is what is required in regards to "report back to DOHMH". Samples being sent for stereotyping are not isolates. DOHMH will inform selected vendor(s) of the need to collect isolate from specific culture positive samples for shipment. We require confirmation of shipment.

45. **Question**: Section II(A)(5)(a) Reporting of Specimen Results on Page 11:
    -Define scales.

    -Is it the criteria used to give interpretation?

    -Is report of interpretations and criteria a one-time only report?

    Answer: Scales means the units of the results. Interpretation means the amounts, an answer as to whether the species were detected, and any QA/QC tags. Methods can be reported one time, provided the methods remain constant.

46. **Question**: Section II(A)(6) Quality Assurance and Control on page 12:
    -Is monthly QA report submitted if there are none of the listed problems?

    -Does plan equal corrective action report?

    Answer: A monthly report of the QA activities is required regardless of whether there are problems to list. In this context of this section, plan means corrective action report.

47. **Question**: Section II(A)(6) Quality Assurance and Control on page 12 in regard to Duplicate tests:
    -We do not routinely do duplicate tests on our QC samples, is this OK?

    -What if some testing, e.g., chemistries, is sub-contracted and we don't have access to the information?

    Answer: The contractor must ensure proper QA/QC based on ELITE and NELAP/ELAP certifications for all work performed under the contracts that result from this solicitation.

48. **Question**: Our laboratory has well over 3 years experience with Microbiology and Legionella, but are in the process of setting up qPCR. Does the lab needs to specifically have 3 years of experience in qPCR in order to qualify?
    Answer: As indicated in Section I.7 on page 4, applicants should have at least 3 years of experience in the operation of a microbiological laboratory, **including the detection and enumeration of Legionella by culture and qPCR testing.** Applicants that do not meet this standard will be evaluated accordingly.

49. **Question**: Must the lab bid on all line items, or can we no-bid particular tests?
    Answer: As indicated in Attachment B – Price Proposal Sheet (page 21) – Note 3: "Applicants must propose pricing for all items. Applicants that do not provide pricing for all items may be found non-responsive."

50. **Question**: Since qPCR is not the preferred method by CDC, would it be safe to assume that follow up culture tests will be required for any positive results completed by qPCR?
    Answer: Yes.

51. **Question**: Can it be assumed that the TAT starts once the samples are received at the laboratory?
    Answer: Yes.

52. **Question**: Heterotrophic Plate Count (HPC) has a holding time of 8 hours. With shipping samples to the laboratory is it assumed data for HPC run out of hold is acceptable?
    Answer: Samples will be kept cold (below 8 degrees C) prior to shipping. The Standard Methods of Examination for Water and Wastewater (2012 edition, ISBN 978-087553-013-0) accepts keeping samples to up to 24 hours for non-regulatory microbiological analyses.

53. **Question**: pH is classified as an "immediate" holding time (15 minutes). With shipping samples to the laboratory is it assumed data for pH run out of hold is acceptable?
    Answer: Yes. DOHMH personnel will also measure pH in the field by.

54. **Question**: Temperature will be augmented by the ice preservative the samples will be shipped on. Should our bid contain a cost for temperature or will this be done at the time of collection by the sampler?
    Answer: The cost per test is to be "fully loaded" as indicated on page 21, Note number 5. Although the contractor will not conduct field testing, DOHMH may request that temperature be taken by the Contractors upon receipt of the sample for QA/QC purposes. The cost of this is to be included in the cost for each requested test.

55. **Question**: Can the Incumbent and current pricing structure be made public?
    Answer: The Department does not currently contract for the full spectrum of services indicated in this solicitation.

56. **Question**: Can the price sheet be issued in a[n] editable format such as Word or Excel?
    Answer: Applicants should hand-write or type pricing into the price sheet.

57. **Question**: Typically shipments cannot be delivered on Sundays or Holidays by most carriers. What carriers will the City be using to have samples delivered on Sunday's/Holidays?
    Answer: To be determined depending on destination and circumstances.

58. **Question**: As this bid is not indicated as sole-source will the fact that we currently don't have qPCR capabilities in house prevent us from winning all or part this bid?
    Answer: As indicated in Section I.7 on page 4, applicants should have at least 3 years of experience in the operation of a microbiological laboratory, **including the detection and enumeration of Legionella by culture and qPCR testing.** Applicants that do not meet this standard will be evaluated accordingly.