NEW JERSEY DEPARTMENT OF HEALTH
Consumer, Environmental and Occupational Health Service
Environmental and Occupational Health Surveillance Program

**ANALYTICAL LABORATORY and SAMPLE COLLECTION SERVICES**

# Technical Specifications

## A. Laboratory

As the Program must follow Centers for Disease Control and Prevention recommendations and utilize current scientific methodologies to conduct analytical testing for *Legionella* in potable water, the qualified laboratory must meet all the criteria listed in Sections 1 – 8. The laboratory analytical services must be performed in accordance with the following criteria:

### 1. Laboratory Accreditation

The laboratory shall have satisfactorily completed the proficiency testing program 'Environmental *Legionella* Isolation Techniques Evaluation Program' (ELITE) offered by the Centers for Disease Control and Prevention (CDC). The ELITE Program issues documentation of proficiency to laboratories that have demonstrated the ability to isolate *Legionella* from simulated environmental samples by culture. The laboratory must be listed on the publicly available CDC ELITE Laboratory Member's List.

### 2. Analytical Methodologies

**Culture:**

Traditional culture methods remain the gold-standard for the identification and subsequent enumeration and serotyping of viable *Legionella* species. Therefore, the laboratory must provide identification and enumeration of:

- *L. pneumophila* serogroup 1,
- *L. pneumophila* serogroup 2-14,
- Plus other species including but not limited to: *L. anisa, L. bozemanii, L. dumoffi, L. longbeachae, L. micdadei.*

**Molecular:**

Quantitative polymerase chain reaction (qPCR) is a rapid molecular method that can be used to detect and quantitate *Legionella pneumophila* and *Legionella pneumophila* serogroup 1 in potable water samples. This is achieved by amplification of a target gene sequence that is unique to the genome DNA of *L. pneumophila* or *L. pneumophila* serogroup 1. The amplified sequence is detected using a fluorescent signal. Approximations of amount of target gene detected can be determined as low, moderate, or high by comparing the amount of fluorescence of the target gene to the amount of fluorescence of a known quantity of DNA (i.e. comparing to a standard curve). Testing can be performed in approximately 2 to 4 days as compared to 7 to 10 days for culture.

The laboratory must conduct qPCR analysis for at least *Legionella pneumophila*.

### 3. Quality Assurance /Quality Control Program

The qualified laboratory must have a written Quality Assurance / Quality Control (QA/QC) Program. A comprehensive program must assure the highest levels of reliability of test data which is in full compliance with all regulatory procedures. This includes Standard Operating Procedures (SOPs) for sample collection, handling, analysis, storage, disposal, documentation and reporting. Quality Control includes statistically based measurements for accuracy and precision of analytical data. This requires analysis and review of reference standards, blanks, matrix spikes, duplicate and replicate samples. The qualifications and training of all personnel involved in the analytical process and QA/QC Program must also be documented.

### 4. Sample Chain of Custody

The qualified laboratory must have a written program for Sample Chain of Custody. This includes specific tracking requirements for sample receipt or log-in, through the analytical process, and on to either sample storage or disposal and the final analysis report.

### 5. Timeline for Analytical Services

- The typical “turn around” time for the completion of *Legionella* culture is 7 to 14 days and 2 to 4 days for qPCR.

- Project aims to collect samples of 90 homes beginning August 1, 2020 through July 31, 2021. In total the project aims to sample 90 single-family homes with an estimated 5 outlets per home collected.

- The qualified laboratory will have to be available at least 5 days per week for sample drop-off or sample delivery.

**6. Sample Media, Equipment and Containers**

- Bulk water: The qualified laboratory will supply 1L bulk water collection bottles. Bottles should have 0.1N solution of sodium thiosulfate (Na2 S2 O3) (15.81 g/L in distilled water, filter sterilize, replace every 12 months) pre-added.
- Biofilm swabs: The qualified laboratory will provide disposable Dacron/polypropylene-tipped swabs with wooden or plastic stems. Do NOT use cotton-tipped swabs as they inhibit *Legionella* growth and sterile plastic 15 mL screw top tubes (with a tube rack) for biofilm swabs with a drop of 0.1N sodium thiosulfate solution to neutralize residual disinfectants pre-added.

**7. Transportation of Samples**

The qualified laboratory will provide free overnight shipping from FedEx and/or UPS or USPS New Jersey locations and provide all materials necessary for leak-free shipping.

**8. Environmental Sample Laboratory Analytical Report**

The qualified laboratory will provide for the completion of the environmental sample laboratory analytical report and chain of custody form at the conclusion of the analytical procedure. The laboratory analytical report must be sent to the Project Coordinator and Manager at the Consumer, Environmental and Occupational Health Service via E-mail on the day that it is completed. The qualified laboratory will provide online access to all sample reports, sample results, chain-of-custody forms and invoices.

**B. Sample Collection**

As the Program must follow Centers for Disease Control and Prevention recommendations and develop effective methods for the sample collection of single-family residences in New Jersey, the qualified sample collector must be able to meet all the criteria listed in Sections 1 – 6. The sample collection services must be performed in accordance with the following criteria:

**1. Certification**

Samples are to be collected by an employee or authorized representative of a laboratory certified for sampling. The use of authorized representatives by a certified laboratory for sample collection is permitted under N.J.A.C. 7:18, as long as the establishment collecting a sample is considered an authorized representative of the laboratory certified for sampling. Therefore, the establishment collecting the sample does not need to be contained on the list of laboratories certified for sampling.

**2. Project Time Frame**

Project aims to collect samples through 90 homes beginning August 1, 2020 through July 31, 2021. In total the project aims to sample 90 single-family homes with an estimated 5 outlets per home collected.

The number of locations will range from 7 to 20 sample locations per month. Ideally there will be flexibility as target numbers will likely taper more slowly at the start of the project and peak during summer months.

The sample collector must contact the program coordinator or manager via text message, email or phone call after the completion of the collection day and provide information on locations sampled and other necessary information as required.

**3. Sample locations**

A total of 90 sample collection sites will be collected and will be geographically representative across the state and will include collection in each of NJ's 21 counties. The samples will also be population-density representative meaning many samples will be collected in populated city centers including but not limited to Newark, Jersey City, and Paterson. Therefore, the qualified sample collector must be able to travel to all identified locations across the state.

At each home hot water bulk sample will be collected at the kitchen sink, and up to two (2) bathroom sinks and showers. Bathroom locations will be labeled as "Most Used" and "Most Distal" which shall be identified by the homeowner.

**4. Transportation**

The sample collector(s) must communicate with the program coordinator to determine sample locations on a daily and weekly basis. The qualified collector must use an insured vehicle to drive to locations identified and collect samples from single-family residential homes.

The sample collector shall then drop samples at the designated laboratory using a cooler and ice packs which shall be provided or package and ship overnight to the designated laboratory from a nearby FedEx, UPS or USPS location.

**5. Chain of Custody**

Sample collector must label each bulk water collection bottle and biofilm tube. They must complete all necessary information for the laboratory's chain of custody for each sample location.

**6. Sample Collection Methods**

The qualified sample collector must have experience collecting bulk water and biofilm samples from tap outlets and showers. Sample collection instructions will be provided to the sample collector in advance of any collection. No showerhead or aerator removal will be required.

The sample collector will also be requested to note the temperature of each bulk water sample immediately after collection and the thermometer will be provided.

**C. Evaluation**

Proposals will be evaluated based on the Vendors overall technical approach and plans to meet the requirements of this project Scope of Work. This narrative should convince the DOH that the Vendor understands the objectives that the Scope of Work is intended to meet, the nature of the required work and the level of effort necessary to successfully complete the project.

Additionally, proposals will be evaluated on price. Proposals will be evaluated and will recommend for award the responsible bidder whose bid proposal, conforming to this Scope of Work, is most advantageous to the State, price and other factors considered.