



# Study Enrollment Package



[qlaboratories.com/legionella](https://qlaboratories.com/legionella)



1930 Radcliff Dr.  
Cincinnati, OH 45204



+(513) 471-1300



office@qlaboratories.com  
qlaboratories.com



Rapid Testing. Reliable Results.

Water Treatment Industry Professionals:

Thank you for your interest in participating in the Rapid *Legionella* Methods Evaluation Study being conducted by Q Labs LLC. Through Phase I of this study, Q Labs has been able to confirm the ability of several rapid, PCR based technologies, to accurately detect, quantify, and characterize live (not dead) *Legionella* in artificially contaminated waters prepared in our laboratory, and compare those results to parallel “Gold Standard” cultural method (ISO 11731/CDC *Legionella* method) results. We are now prepared to move to Phase II of this study which will involve further challenging the observations noted in Phase I with “real world” samples. This is where your help is needed.

We are recruiting Water Treatment Industry Professionals to provide these “real world” samples from their routine *Legionella* sampling locations. Specifically, we hope to collect a variety of samples including:

- Cooling Towers
- Boilers/Water Heaters
- Sinks/shower heads
- Ice Machines
- Decorative water features
- Other

By participating in this study, you will be providing support to generate data that will be critical in understanding the role rapid methods should play in monitoring premise water systems for *Legionella*. This foundational research is essential to establishing confidence in the purported high sensitivity of PCR-based technologies in routine premise water samples analysis, subsequent widespread adoption of these alternative technologies to facilitate rapid response to *Legionella* recoveries, and more agile interventions to maintain public health and safety.

All experimental supplies will be provided, and testing conducted, at Q Labs’ expense. In addition, for participating in the study, you will be provided with a summary of the study at its conclusion, and you will be acknowledged in published materials resulting from this study, (unless you notify Q Labs in writing that you wish to remain anonymous).

Thank you for your consideration, and please reach out to me directly with any questions you may have regarding potential participation in this study. If you would like to participate, please see our enrollment documentation.

Best regards,

**MICHAEL LOEWENSTEIN**  
VP, Scientific Consulting

📞 (513) 207-4943 | ☎️ (513) 471-1300

✉️ [MLoewenstein@qlaboratories.com](mailto:MLoewenstein@qlaboratories.com)

📍 1930 Radcliff Dr., Cincinnati, OH 45204



## Legionella Rapid Methods Evaluation Study: Enrollment Information



Rapid Testing. Reliable Results.

Thank you for your interest in participating in our **Legionella Rapid Methods Evaluation Study**. While execution of the study will be conducted by Q Labs, participation will require significant effort on the part of sample submission partners. Therefore, please make sure you read, and fully understand all the following information prior to final enrollment in the study. If you have any questions or concerns, please reach out to one of the contacts listed below.

Key Contacts	
<b>MICHAEL LOEWENSTEIN</b> VP, Scientific Consulting 📞 (513) 207-4943   📠 (513) 471-1300 ✉️ <a href="mailto:MLoewenstein@qlaboratories.com">MLoewenstein@qlaboratories.com</a> 🏠 1930 Radcliff Dr., Cincinnati, OH 45204	<b>JOE BENZINGER</b> Study Coordinator 📞 (513) 526-9321   📠 (513) 471-1300 ✉️ <a href="mailto:JBenzinger@qlaboratories.com">JBenzinger@qlaboratories.com</a> 🏠 1930 Radcliff Dr., Cincinnati, OH 45204

### Section 1: Information Required

To ensure the data can be appropriately interpreted, it will be imperative that certain information about each sample be obtained when being submitted. The submitter will be asked to complete a **Sample Submission Form** (copy attached; additional copies available by contacting Q Labs or downloading from [www.qlaboratories.com/legionella](http://www.qlaboratories.com/legionella)). Among the information requested to be recorded and submitted with each sample will be:

- Source (e.g., cooling tower, sink, etc.)
- Temperature
- Residual chlorine
- Time of collection
- Recent interventions (e.g., system treatment)
- Other relevant factors (e.g., pH)

### Section 2: Sampling Consistency

To minimize variability due to inconsistency between samplers/sampling techniques, all samplers will be asked to follow sampling instructions that will be provided to all study participants. The procedures will be industry standard, and Q Labs personnel can provide training if needed. We will also request that all study participants submit samples using the same sampling materials which will be provided by Q Labs.

### Section 3: Confidentiality

By signing below and enrolling in the study, you agree to maintain confidentiality regarding participation in, and any information you acquire during discussions with Q Labs about the study, unless written approval from Q Labs is granted. By signing below and enrolling in the study, you agree to maintain in strict confidence, and not to disclose to any other entity or person without Q Labs' prior written permission, the existence of the study, your participation in the study, or any other information, whether written, verbal or electronic, you may learn about the study generally or about any specific tests results.

### Section 4: Waiver of Data Reporting

This will be a blind study. As such, all samples will be immediately anonymized (blind coded) upon receipt at Q Labs. No Certificates of Analysis (CoA) will be generated for these samples, and no individual sample data

## Legionella Rapid Methods Evaluation Study: Enrollment Information



Rapid Testing. Reliable Results.

will be reported to any individual client. As this study will involve a direct comparison of PCR technologies to standard cultural methods, there is a significant possibility that the PCR technologies will report the positive detection of *Legionella* while the cultural methods will report “no recovery”, or vice versa. By signing below and enrolling in the study, you acknowledge your understanding of these terms, and forfeit the right to obtain the results of any individual samples you submit. You also acknowledge that Q Labs has no obligation to inform you or anyone else of, and has no liability to you or anyone else with respect to, any tests results, positive or negative, of any sample submitted by you or on your behalf.

### Section 5: Enrollment

The section below must be completed by an authorized representative of the company submitting samples for this study. If you represent a third-party vendor (e.g., water treatment company), signing below indicates that you are authorized by your client to enroll in this study, and submit samples, on their behalf.

By signing below, you agree to enroll in the **Legionella Rapid Methods Evaluation Study**. You further acknowledge your understanding and concurrence with all terms outlined in this document and its attachments. You acknowledge that failure to comply with terms of the study may result in your disqualification from the study, and that you may be otherwise disqualified from the study at the sole discretion of Q Labs at any time.

<b>Company Name:</b>		
<b>Primary Contact</b>	<b>Name:</b>	
	<b>E-mail:</b>	
	<b>Mailing Address:</b>	
	<b>Phone:</b>	

\_\_\_\_\_  
Signature of Authorized Company Representative

\_\_\_\_\_  
Date

#### This section is to be completed by Q Labs personnel.

Enrollment documentation complete?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	Date:
Non-Disclosure Agreement Signed?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	Date:
Participant approved for enrollment?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	Date:
Signature:			



## Legionella Rapid Methods Evaluation Study: Sampling Instructions



Rapid Testing. Reliable Results.

Thank you again for your participation in our **Legionella Rapid Methods Evaluation Study**. In order to properly interpret data, and analyze trends, it is important that as much variability as possible be eliminated from the sampling process. As such, we ask that all samplers follow the general guidelines listed below. If there are any questions or concerns regarding sampling, please do not hesitate to reach out to one of the “Key Contacts” listed below, or simply call Q Labs main office at 513-471-1300, and your question will be promptly directed and addressed.

### Key Contacts

**MICHAEL LOEWENSTEIN**

VP, Scientific Consulting

📞 (513) 207-4943 | ☎️ (513) 471-1300

✉️ [MLoewenstein@qlaboratories.com](mailto:MLoewenstein@qlaboratories.com)

🏠 1930 Radcliff Dr., Cincinnati, OH 45204

**JOE BENZINGER**

Study Coordinator

📞 (513) 526-9321 | ☎️ (513) 471-1300

✉️ [JBenzinger@qlaboratories.com](mailto:JBenzinger@qlaboratories.com)

🏠 1930 Radcliff Dr., Cincinnati, OH 45204

### Materials Needed:

#### Mandatory

- Sterile 250 mL bottles and shipment box (provided)<sup>1</sup>
- Sample Submission Form (provided)
- Submission Box (provided)
- Indelible writing instrument (pen/marker/etc.)

<sup>1</sup>The sterile 250 mL bottles provided contain sodium thiosulfate to neutralize residual chlorine. Do not rinse out the bottle before filling. Please contact Q Labs if additional sample vessels are needed.

#### Optional but Ideal<sup>2</sup>

- Thermometer
- pH test strips or pH meter<sup>2</sup>
- chlorine test strips/kit

<sup>2</sup>Recording of sample water temperature, pH, and residual chlorine is common practice but not required. If possible, please take and record these measurements. If this is not part of your normal practice, but you are willing to take these measurements, Q Labs can provide training/materials.

# ***Legionella* Rapid Methods Evaluation Study: Sampling Instructions**



Rapid Testing. Reliable Results.

## **Taking the Sample:**

Follow your existing sampling procedures so long as they are consistent with the [CDC Legionella Toolkit Sampling Procedures](#) or other industry recognized procedure. However, be sure to collect one full sample bottle (minimum of 250 mL) from each. The general procedure can be found below.

1. Open valve on sampling point and allow water to run for sample collection per existing procedure (see your existing procedure consistent with industry recognized standards, or reference [CDC Legionella Toolkit Sampling Procedures](#) for detailed sampling procedure recommendations by sample type). If sampling hot water, ensure water is warm but not hot (avoid heating the water to  $\geq 122^{\circ}\text{F}$ ) when sampling to avoid killing any vegetative cells that may be present.
2. Aseptically collect a minimum of **250 mL** of water from each sampling location.
3. Immediately label the sample with sample identifying information to include at minimum:
  - a. Sample location/description
  - b. Date of sampling
  - c. Time of sampling
4. Immediately complete the Sample Submission Form.
5. Take note of any unusual system circumstances. If unsure of whether to note it down, err on the side of taking more notes rather than less. Examples of things that should be noted:
  - a. Recent system disinfection/treatment
  - b. Other recent system maintenance/construction/intervention
  - c. Delays or other deviation from routine sampling procedures
  - d. Nearby maintenance/operations that makes normal aseptic sampling difficult.
6. Place the samples in the provided shipment box along with the completed Sample Submission Form, and mail to Q Labs using the provided, pre-paid shipment label. Shipments will ideally be posted the same day as sampling. If this is not possible, next day shipment is acceptable so long as samples are stored at room temperature (avoiding extreme temperatures and humidity). If shipment will be delayed further, please notate on the Sample Submission Form, and contact Q Labs.



Rapid Testing. Reliable Results.

# Legionella Rapid Methods Evaluation Study

## Sample Submission Form

1930 Radcliff Dr. Cincinnati, OH 45204  
Phone: (513) 471-1300 • Fax: (513) 471-5600  
• [www.QLABORATORIES.com](http://www.QLABORATORIES.com)  
• Email: [office@qlaboratories.com](mailto:office@qlaboratories.com)

Submitter Information						Sampling Date:					
Company:						Sampling Notes (please make note of any unusual sampling circumstances such as delays, nearby maintenance, etc.):					
Submitter Name:											
Phone #:											
ATTENTION: JOE BENZINGER											
Sample No.	Sample Description (e.g., location)	Temp		pH	Free Cl <sup>-</sup> (ppm)	Time Collected	Sample Type				
							Cooling Tower	Boiler	Sink/Faucet	Decorative Feature	Other (please describe in "Additional Notes")
1			°F / C			am/pm	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2			°F / C			am/pm	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3			°F / C			am/pm	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4			°F / C			am/pm	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5			°F / C			am/pm	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6			°F / C			am/pm	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7			°F / C			am/pm	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8			°F / C			am/pm	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Additional Notes:						Authorizing Signature					
Do you need additional supplies? <input type="checkbox"/> Yes <input type="checkbox"/> No Supplies Needed: _____ Qty: _____											