The Water Research Foundation
Request for Qualifications (RFQ)

Interlaboratory and Methods Assessment of the SARS-CoV-2 Genetic Signal in Wastewater (WRF 5089)

RFQ Due Date: 06/19/2020, 2:00pm MDT
Maximum Funding: $200,000

PURPOSE

The purpose of this RFQ is to identify a research team to assist The Water Research Foundation (WRF) in evaluating existing methods and testing reliability for the genetic signal for SARS-CoV-2 in untreated wastewater. The selected research team will assess the existing methods used by laboratories (see Attachment A for potential US-based laboratories) and perform statistical analyses and comparison of the test results. This project will not involve the development of a new standard method, nor will it focus on the design of a sampling regime for wastewater surveillance of SARS-CoV-2.

The primary goal of this project is to provide an assessment of the methods currently used at a number of laboratories and facilities to determine which method(s) provides a reliable and repeatable measurement of the SAR-CoV-2 genetic signal (copies of RNA) in untreated wastewater. The results of this project will provide much-needed information on preferred methods to be used for performing analyses for wastewater surveillance studies and understanding the limits of detection of existing methods. The proposed research should be completed in time to inform wastewater surveillance in the early fall of 2020.

BACKGROUND

This project was identified as a high priority research opportunity during WRF's International Water Research Summit on Environmental Surveillance of COVID-19 held on April 27 - April 30, 2020. Currently, no standard methods have been established for the detection of the genetic signal for SARS-CoV-2 in wastewater. While wastewater surveillance of wastewater has the potential to serve as a useful gauge of community-level trends in SARS-CoV-2, these data will be most useful for public health decision-makers if they can be demonstrated to be repeatable and comparable across laboratories and facilities that are analyzing samples.

SUMMARY OF PROJECT

The research team will be tasked with identifying and collecting several composite, untreated wastewater samples that will be homogenized, tested, and measured by the research team's laboratory, and submitted to the participating laboratories for testing. The sample should be collected from an existing wastewater system from a region experiencing a known high level of COVID-19 cases. The research team shall be responsible for providing inactivated samples to the participating laboratories, and must include this effort in their budget. The research team must verify that there is no presence of live microorganisms after inactivation, and ensure that the inactivated sample has a detectable genetic signal for testing (include documentation of signal before and after inactivation). Following selection, WRF and its Project Advisory Committee (PAC) will discuss and refine this approach with the research team. Documentation of the participating laboratories' specific concentration, extraction, and assay methods will be required and held confidential by the research team.

The key questions to be answered by this project are:

1. Which laboratory methods are best-suited for producing reliable quantitative genetic signals for SARS-CoV-2?
2. To what extent are laboratories able to reproduce sample results by following documented QA/QC procedures?
3. Which steps within a given method are most critical to ensure accuracy and precision?
4. What is the limit of detection for the recovery of a genetic signal for SARS-CoV-2 in wastewater and how does it vary across the available methods?

The research team will be responsible for designing and implementing the trial to test standardized wastewater samples at multiple laboratories and outlining an approach for assessing methods, including:

- Identifying criteria for the selection of laboratories to participate in the study
- Developing controls for use in the study
- Estimating the limit of detection of the genetic signal
- Outlining the logistics for collection, preparation, sub-sampling, pre-treatment and distribution of homogenous wastewater samples with a range of signal strengths
- Management of metadata associated with sample collection at the selected water resource recovery facilities
- Collation of method documentation and assessment of the participating laboratory methods
    - Methods used (concentration, extraction, and detection)
    - QA/QC procedures

- Statistical analysis and reporting of results

WRF has invited laboratories to participate in the study by analyzing a suite of standard samples using their own methods and reporting results. The list of volunteer laboratories and contact information are provided in Attachment A. These laboratories have committed to participate in the project and test a minimum of 10 samples at their own expense. For budgeting purposes, the research team should assume a maximum of 30 participating laboratories and a maximum of 600 samples (e.g., 10 samples per laboratory, samples for homogeneity testing, and retained samples to replace lost samples or for additional laboratory participants, etc.). Each laboratory will use its own method to test the provided samples and will be required to report:

- Standard operating procedure for concentration, extraction, and genetic assay
- QA/QA controls including recovery efficiency and limit of detection. A list of QA/QC requirements for the lab is included as Attachment B.

1. QA/QC Requirements

The research team will be responsible for developing, distributing, and maintaining a quality assurance project plan (QAPP). The labs are expected to follow the QAPP requirements in addition to their specific lab QA plans. Each research team submitting a proposal is required to have a QAPP that meets the minimum requirements identified in Attachment B, and copies of the QAPPs are required to be provided with the Statement of Qualifications.

The research team's QA/QC officer will be responsible for the following tasks and will be required to adhere to the QAPP requirements:

- Wastewater sample collection, pre-treatment, sub-sampling, preservation, and analysis for homogeneity and signal strength
- Distribution of blind-coded samples to participating labs
- Data collection and analysis

The research team's QA/QC officer will check that results meet the specified QA/QC acceptance criteria. If the results do not meet the specified QA/QC acceptance criteria, the QA/QC officer will notify the lab. The research team will be responsible for corresponding with the appropriate laboratory to repeat the analysis on a new sample.

If the results do not meet the specified QA/QC acceptance criteria, the lab will be expected to repeat the analysis with a new sample at no cost. This repeat sample will be in addition to the samples already scheduled for analysis (i.e., the repeat sample should not delay the schedule). Because some repeat samples are anticipated, the laboratory must have the capability of analyzing up to 10 samples over the study period and the ability to analyze multiple samples at a time.

2. Reporting Results

The laboratories will report the results from each of the analyses (including the QA/QC

results) using a reporting template provided by the research team, within seven days of receiving the sample. The participating labs will report the results to the research team, and the research team will report all results to the QA/QC officer after reviewing the results received from the participating labs for completeness.

3. Deliverables

The research team is expected to provide the following deliverables, at a minimum, for this project:

- A report (draft and final) that outlines the standard deviations between laboratories. If there are sufficient results for comparative analysis, the report will also summarize results for specific types of methods or method steps. In addition, the report should also answer the four key questions identified above.
- A virtual workshop with the project participants to discuss the method results, before the final report submission.
- A WRF-sponsored webcast following final report submission.
- A peer-reviewed publication following final report submission.

RESEARCH TEAM QUALIFICATION REQUIREMENTS

The following is a list of the minimum requirements that the research team must demonstrate in order to be considered for selection. If one of these items is missing from the submittal, the submittal will be rejected:

- Program manager with successful and timely completion of similar interlaboratory testing projects within the past 5 years, including the following details:
    - Project scope
    - Budget
    - Duration (planned and actual)
    - Client reference and contact information (note that WRF staff may interview references)
- Team members with experience in the wastewater sector and microbial laboratory methods.

PROJECT SCHEDULE

Project duration is anticipated to be 4 to 6 weeks.

SUBMITTAL AND AWARD STEPS

1. **RFQ Submittal:** Statements of Qualifications must be received via email by 2:00 PM MDT on June 19, 2020. **Please send RFQ submittals to Stephanie Fevig, at** RFQ5089@waterrf.org; Phone: (303) 347-6103.

A Statement of Qualifications must be submitted as **a single (one) PDF file,** include the following items, and detail how the respondent(s) meets the evaluation criteria:

1.1. Research team qualifications as outlined above (maximum 5 pages).
1.2. Resumes or CVs outlining the research team's experience and experience of key team members. (2 pages each per resume/CV)
1.3. Scope of Work (SOW) including research approach, budget narrative, and schedule (maximum 6 pages). The SOW must include:
- Research approach, including the proposed selection process for identifying partnering laboratories, proposed sample collection and distribution plan, data collection and management plan, statistical design approach (summarizing of the statistical results), and presentation of the data.
- Estimate of budget (line items for labor, transport and shipping, indirect costs)
- Estimate of schedule of deliverables

1.4. Example project QAPP and copies of the participating labs' QA plans.
1.5. Part of a successful response to this RFQ will be the ability of the research team to contract quickly with WRF. In your response to this RFQ, please indicate that you are able to accept the following terms:
- This project will be contract for hire.
- Contracting must be completed and executed by July 10, 2020, or two weeks after selection/award. This is non-negotiable – please confirm your acceptance and confirmation of this deadline.
- WRF will own the intellectual property of the final results.
- Liability insurance of $1 million US dollars.
- Applicable law and venue is Colorado.
- Please become familiar with the WRF budget form (see Research Priority Program, Forms).
- Must comply with all US laws and regulations, including 2 CFR 200, GAAP, and guidelines found in WRF proposal guidelines.

2. Evaluation Criteria:

2.1. SOW: Research approach, budget narrative, schedule, deliverables, and applicability (20%)
2.2. Qualifications, capabilities, and management (80%). Competitive candidates will demonstrate strong experience and qualifications in the following areas:
2.2.1. Relevant project experience (30%)
2.2.2. Research team and participating lab qualifications (20%)
2.2.3. Qualifications of personnel (20%)
2.2.4. QA/QC documentation (10%)

3. **RFQ Evaluation and Award:** WRF will evaluate RFQs and may elect to interview a short-list of candidates. Award notification is anticipated the week of June 22nd. The selected research team should be available to begin work immediately upon contract award.

4. **Submittal and Acceptance of Required Contract Elements:** The maximum funding for this project is $200,000. This project is funded by WRF and will be administered by WRF. After selection and award, the research team will develop, at their own expense, a refined and final SOW, budget narrative, and budget form addressing comments from WRF's PAC, and present it to WRF and the PAC for discussion and approval. Please visit the WRF website for instructions for budget preparation (including the budget narrative) and the budget form. The refined SOW will be due within one week of award.

5. **Execution of Contract/Agreement:** If the contract/agreement cannot be executed within two weeks following selection, WRF will consider awarding the project to the next highest ranked research team.

6. **Timeframe:**

   RFQ Release: June 5, 2020
   RFQ Submissions Due: June 19, 2020
   Research Team Selection: Week of June 22nd
   Final SOW Due: Week of June 29th
   Contracting Completed: Week of July 6th
   Project Start Date: Week of July 13th
   First Distribution of Samples for Analysis: Week of July 20th
   Draft Deliverable Due: Week of August 17th
   Final Deliverable Due: Week of August 31st

Attachment A: List of Participating Laboratories and Contact Information
Updated 6/18/2020

As additional laboratories express interest, their information will be added below within 24 business hours of receipt of a participation form, and this RFQ will be re-posted with the new information. The list provided below only includes US-based laboratories. This project may be expanded to the international laboratory participants pending additional funding opportunities. (Depending upon your settings, you may need to click refresh on your browser to load the latest file.)

Lab/Organization Name	Contact Name	Contact Email
American Water Research & Development	Zia Bukhari	Zia.bukhari@amwater.com
BCS Laboratories, Inc.	Bonnie Mull	info@microbioservices.com
Cel Analytical, Inc.	Yeggie Dearborn	yeggie@celanalytical.com
University of Colorado - Boulder, Environmental Engineering Laboratory	Cresten Mansfeldt	cresten.mansfeldt@colorado.edu
Columbia University	Kartik Chandran	kc2288@columbia.edu
CosmosID	Manoj Dadlani	manoj@cosmosid.com
CUNY Team (John Dennehy-Queens College, Monica Trujillo-Queensborough Community College and Davida Smyth-The New School)	Monica Trujillo	mtrujillo@qcc.cuny.edu
East Bay Municipal Utility District	Donald Gray	donald.gray@ebmud.com
Eurofins QC, LLC	Brandon Spradlin	brandonspradlin@eurofinsus.com
Hampton Roads Sanitation District, Molecular Pathogen Program	Raul Gonzalez	rgonzalez@hrsd.com
Howard University	Jeseth Delgado Vela	jeseth.delgadovela@howard.edu
IDEXX	Dave Townsend	dave-townsend@idexx.com
Los Angeles County Sanitation Districts, San Jose Creek Water Quality Laboratory	Shawn Thompson	sthompson@lacsd.org
Medical Diagnostics Laboratory, LLC	Martin	madelson@mdlab.com
Michigan State University	Joan Rose, Nishita D'Souza	rosejo@msu.edu;dsouzan1@msu.edu
MYCOMETRICS, LLC	Rose Lee	huiling@mycometrics.com

Lab/Organization Name	Contact Name	Contact Email
Newtown Creek Microbiology Laboratory - NYCDEP, Bureau of Wastewater Treatment	Dimitri Katehis	dkatehis@dep.nyc.gov
National Center for Toxicological Research/U.S. FDA	Camila Silva	Camila.Silva@fda.hhs.gov
Civil, Construction and Environmental Engineering Department at North Carolina State University	Francis de los Reyes	fldelosr@ncsu.edu
Ohio State University	Jiyoung Lee	llee.3598@osu.edu
Orange County Public Health Water Quality Laboratory / Orange County Health Care Agency	Joseph Guzman	JGuzman@ochca.com
Oregon State University (in collaboration with Clean Water Services)	Tyler Radniecki	tyler.radniecki@oregonstate.edu
Promega Corporation	Subhanjan Mondal	subhanjan.mondal@promega.com
RAIN Incubator	Stanley Langevin	slangevin@rainincubator.org
Stadler Lab, Department of Civil & Environmental Engineering, Rice University	Lauren Stadler	lauren.stadler@rice.edu
Environmental Engineering Lab, Rutgers, The State University of New Jersey	Nicole Fahrenfeld	nfahrenf@rutgers.edu
Saginaw Valley State University	Tami Sivyi	tsivy@svsu.edu
Southern Nevada Water Authority, Water Quality R&D	Daniel Gerrity	daniel.gerrity@snwa.com
SUNY-ESF	Hyatt Green	hgreen@esf.edu
Scottsdale Water	Joe Hernandez	JoeHernandez@ScottsdaleAZ.gov
SiREM Laboratory	Duane Graves	dgraves@siremlab.com
Source Molecular	Yiping Cao	ycao@sourcemolecular.com
Stanford University	Alexandria Boehm & Krista Wigginton	aboehm@stanford.edu;kwigg@umich.edu
School of Public Health and Tropical Medicine, Tulane University	Tiong Gim Aw	taw@tulane.edu
Tulane University	Samendra Sherchan	sshercha@tulane.edu
Twist Bioscience	Kristin Butcher	kbutcher@twistbioscience.com
University of California, Berkeley	Kara Nelson	karanelson@berkeley.edu
Civil and Environmental Engineering, UC Irvine	Sunny Jiang	sjiang@uci.edu

Lab/Organization Name	Contact Name	Contact Email
Butler Lab, Civil and Environmental Engineering, University of Massachusetts, Amherst	Caitlyn Butler	csbutler@umass.edu
USGS-Leetown Science Center	William Schill	wschill@usgs.gov
University of Arizona WEST Center	Ian Pepper	ipepper@ag.arizona.edu
University of Connecticut COR2E MARS	Kendra Maas	kendra.maas@uconn.edu
University of Florida, Department of Environmental and Global Health, Emerging Pathogens Institute	Joseph Bisesi	jbisesi@phhp.ufl.edu
University of Hawaii at Manoa	Tao Yan	taoyan@hawaii.edu
University of Illinois at Chicago	Rachel Poretsky	microbe@uic.edu
University of Kansas	Belinda Sturm	bmcswain@ku.edu
Department of Civil and Environmental Engineering, University of Maryland	Birthe Kjellerup	bvk@umd.edu
University of Missouri-School of Medicine	Marc Johnson	marcjohnson@missouri.edu
University of Nebraska Medical Center, Severe & Emerging Infections Reference Laboratory	Mara Jana Broadhurst	jana.broadhurst@unmc.edu
Univ. of Nebraska-Lincoln	Xu Li	xuli@unl.edu
University of Notre Dame	Kyle Bibby	kbibby@nd.edu
University of Southern California	Adam Smith	smithada@usc.edu
University of Texas at San Antonio	Vikram Kapoor	vikram.kapoor@utsa.edu
University of Utah	Jennifer Weidhaas	jennifer.weidhaas@utah.edu
University of Wisconsin-Milwaukee, School of Freshwater Sciences	Sandra McLellan	mclellan@uwm.edu
Utah State University NanoBioPhotonics Laboratory, Department of Biological Engineering	Donald Roper	keith.roper@usu.edu
Vitalant Research Institute	Eric Delwart	edelwart@vitalant.org
WA State Public Health Laboratories	Ailyn Perez-Osorio	ailyn.perez-osorio@doh.wa.gov
Water ARC / Carollo Engineers, Inc.	Justin Sutherland	jsutherland@carollo.com
Weck Laboratories	Agustin Pierri	agustin.pierri@wecklabs.com
Wisconsin State Laboratory of Hygiene	Jocelyn Hemming	jocelyn.hemming@slh.wisc.edu

Attachment B: **Participating Lab Qualifications and Quality Assurance Requirements**

Participating laboratories must meet the following minimum qualifications to be considered for this study:

- Ability to test 10 samples at their own expense
- Has a developed method for the detection of the genetic signal of SARS-CoV-2 (written protocol to be provided, with controls described)
- Is routinely analyzing, or planning to routinely analyze, wastewater samples for the genetic signal of SARS-CoV-2 for wastewater surveillance
- Ability to handle untreated wastewater samples that have been pre-treated to inactivate live microorganisms (samples that have undergone pre-treatment [i.e., pasteurization])
- Has the reagents and equipment to quickly process samples supplied by the selected research team.
- Is established as an environmental microbiology or research laboratory (provide any accreditation if available)
- Has a Quality Assurance Plan for the overall operation of the lab that can be submitted to requesting RFQ respondents
- Has the ability to share data with the selected research team

Each laboratory must have a written Quality Assurance Plan that addresses the following:

Laboratory organization and responsibility: This section must (1) include a list that identifies the laboratory QA manager(s) and key individuals who are responsible for ensuring the production of valid measurements and the routine assessment of QC data, (2) specify who is responsible for internal audits and reviews of the implementation of the QA plan and its requirements, and (3) include a chart showing the laboratory organization and line authority.

Personnel: This section must list each analyst's academic background and experience, describe how each analyst is trained to perform the method, and describe how training is documented.

Facilities: This section must describe the arrangement and size of laboratories, workflow patterns to minimize cross contamination, air system(s), the laboratory reagent water system, and the waste disposal system.

Field sampling procedures: This section must describe the laboratory chain-of-custody procedures, including the sample identification and information recording system, and describe how field samples are collected and transported, including transportation time and temperature.

Laboratory test sample handling procedures: This section must describe test sample-holding times and temperature during analyses, and the procedures for maintaining the integrity of the test samples (i.e., logging and tracking of samples from receipt through analyses and disposal).

Equipment: This section must describe the specifications, calibration procedures, preventive maintenance, and maintenance of quality control records for each item used during the performance of the method. All calibrations must be traceable to national standards, when they are available.

Supplies: This section must describe the specifications, storage conditions, and documentation of catalog and lot numbers for chemicals, reagents, and media.

Laboratory practices: This section must describe the preparation of reagent-grade water, glassware washing and preparation procedures, and sterilization procedures. It should also describe the workflow requirements among laboratories to prevent cross contamination, especially for molecular procedures.

Analytical procedures: This section must reference the laboratory SOPs.

Quality control checks: This section must describe all laboratory procedures that are implemented to ensure the quality of each analyst's data.

Data reduction, verification, and reporting: This section must describe any procedures for converting raw data to final data, identify procedures for ensuring the accuracy of data transcription and calculations, and describe the laboratory's procedures.

Corrective actions: This section must describe how the laboratory will respond to performance evaluation (PE) and QC failures and failures of its own internal QC procedures, identify the person(s) responsible for taking corrective action, and describe how the effectiveness of the actions will be documented.

Recordkeeping: This section must describe how records are maintained (e.g., hard copy, electronic, or laboratory information management system [LIMS], etc.), how long records are kept, and where records are stored.