LOUISIANA DEPARTMENT OF HEALTH

Louisiana Office of Public Health Lab

EMERGENCY
Request for Information (RFI)

For

Whole Genome Sequencing of SARS-CoV2 Positive Samples

RFI due date/time: Wednesday, 3/10/2021 at 11:59PM_(CST/CDT)

NOTE: This Request For Information ("RFI") is issued under authority of Governor John Bel Edwards Proclamation of Emergency, 7 JBE-2021, - Renewal of State of Emergency for COVID-19. Time is of the essence in identifying and contracting with qualified laboratories to perform whole genome sequencing of SARS-COV2 positive samples obtained from other testing site locations. This endeavor is necessary to respond to the public health emergency created by COVID-19. Due to the public health emergency, this RFI is being issued as an emergency solicitation under authority of La. R.S. 39:1598 and ordinary procurement laws are suspended.

This Request for Information (RFI) is to obtain information and costs for planning purposes and while for the purposes of granting an award, it does not guarantee an award. This information will be reviewed and discussed by the state agency and may result in the advertisement of a formal and competitive Request for Proposal for any or all of the services included in the RFI.

Only information which is in the nature of legitimate trade secrets or non-published financial data may be deemed proprietary or confidential. Any material within a response to this RFI identified as such must be clearly marked and will be handled in accordance with the Louisiana Public Records Act. R.S. 44:1-44 and applicable rules and regulations.

Any response marked as confidential or proprietary in its entirety may be rejected without further consideration or recourse.

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1 GENERAL INFORMATION

1.1 Background

Laboratories in the United States (US) and across the world have generated hundreds of thousands of SARS-CoV-2 genetic sequences by testing strains of the virus from patient specimens. Even so, considerable gaps exist in the representativeness of US sequencing surveillance data for SARS-CoV-2. CDC is currently boosting these efforts by collaborating with state public health laboratories and partners such as the Association of Public Health Laboratories to increase the number of specimens that are sequenced as part of the National SARS-CoV-2 Strain Surveillance (NS3) program.
https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/variant-surveillance/genomic-surveillance-dashboard.html

Currently, participation in NS3 consists of the submission of de-identified samples with metadata for CDC to sequence and further characterize. To go a step further, the Louisiana Department of Health (LDH) Office of Public Health Laboratory (OPH Lab) will also be implementing on-site SARS-CoV-2 sequencing and contracting additional sequencing to external laboratories.

1.2 Purpose of RFI

This RFI is issued for the purpose of gathering information and cost information from qualified companies, individuals, etc. who demonstrate the capacity to provide sequencing services to the State of Louisiana.

1.3 Project Overview

LDH views these contracts as a partnership in providing a more robust surveillance system for SARS CoV-2 monitoring. To that end, the quality of analysis, the evaluation of data, and the sharing of information in a manner that protects privacy, secures the data and provides actionable information for public health mitigation and response are paramount to this initiative.

In order to ensure desired processes and quality of services, the State prefers to contract with entities who can demonstrate the following in their responses.

1. Contractor practices Good Laboratory Practices and employs a system for quality assurance.
   Recommended response: Provide laboratory leadership qualifications, organizational chart for positions which ensure technical accuracy, operational efficiency and management.

2. Contractor currently accepts samples for SARS CoV-2 sequencing for Louisiana based entities.
   Recommended response: List any entities currently being serviced.

3. Contractor uses modern technology and can manage a robust workload.
   Recommended response:
   a) List the next generation sequencers currently used.
   b) Provide the volume of samples that can be processed per run on each sequencer.

4. Contractor will implement a standardized labeling format for sample sequences.

Recommended response: Contractor will commit to implementation of the sample formatting required.

5. Contractor will provide data files as required by LDH.

Recommended response: Describe Contractor resources and expertise relative to ability to manage data as required.

6. Contractor will review analyzed data and advise LDH of data of interest.

Recommended response:

a) Describe the expertise that the entity has in evaluating data, as well as the process proposed to analyze the data.

b) Describe experience or expertise specifically with identifying variants of interest.

c) Further explain how information of interest to LDH will be communicated and shared to both the OPH Lab and the OPH Bureau of Epidemiology.

7. Contractor will provide routine workload reports as requested by LDH, as well as a monthly billing statement, following LDH's reporting template. Supporting data will be provided as required.

Recommended response: Confirm the ability to provide reporting per minimum requirements and deliverables.

It is understood that sequencing testing does not require compliance with the Clinical Laboratory Improvement Act of 1988 (CLIA). Therefore, results generated cannot be used for diagnostic purposes. However, OPH Infectious Disease Epidemiology will, as part of contact tracing associated with public health response, require patient identifying information.

1.4 Minimum Requirements:

In order to provide testing services, including actual sequence testing, data evaluation, upload and results notification, the contractor must comply with these requirements:

1. Contractor will implement a standardized labeling format for sample sequences. State prefers 4 letter code to designate testing laboratory and 6 digit sequential # for samples.

2. Contractor will provide Whole Genome Sequencing (WGS) on SARS-CoV-2 positive samples with a minimum of 90% genome coverage and a minimum 20x coverage depth.

3. Contractor will upload sequence files to GISAID within 14 days. This turn-around-time (TAT) is defined as

- from "sample receipt to upload" –for samples provided by the OPH Lab and
- from "PCR result reporting to upload" for locations sequencing samples already on hand from diagnostic PCR testing

The Contractor shall have protocols and procedures in place to adequately document each specimen's time of arrival and time of upload. If the Contractor is unable, utilizing good faith

efforts, to acquire test reagents, or other required testing material, it shall immediately notify LDH of the issue and the parties MAY agree to a temporary extension at the sole discretion of LDH. Failure to comply with the foregoing provisions regarding timelines may result in non-payment for those tests

4. Contractor will provide raw data files (*examples: fastQ and fast5 from nanopore, fastQ from illumina*) deposited into a Google cloud storage location designated by the OPH Lab.

a) This is required for every sequence regardless of whether the sample meets the quality parameters.
b) Raw data is required for sequences uploaded into GISAID.

5. For Contractors that are sequencing samples already in the laboratory from the diagnostic PCR testing, .csv files will be sent securely to the OPH Lab. Data is to include Patient Name, Patient DOB, Specimen ID, Test Method, Ct or RLU values, Gender, Age, Case City, Case Postal Code, and GISAID Accession. Additional desirable data that should be included (if provided) are whether the sample is from a Symptomatic vs Asymptomatic individual; whether the individual is a staff member or resident of a congregate setting and the sample Source and Media used in collection.

6. Contractors will review analyzed data and flag variants or clusters of interest. At a minimum, CDC designated variants of interest are to be flagged and notification performed via email to a designated contact or contact(s) in OPH Bureau of Infectious Disease Epidemiology.

7. Contractor will provide Category B Packaging and Shipping for samples that require transport. Contractor will provide appropriate procedures, safety training, and competency documentation related to this activity as requested. Contractor's performing initial PCR will ship, on dry ice to the OPH Lab, 500µL aliquots of original sample in Viral Transport Media, in 1.5-2.0mL screw cap tubes. This applies only to samples originally received in Viral Transport Media. Shipping to be at contractor's cost every two weeks.

8. Contractor will provide routine management reports as requested by LDH to monitor volume of testing and TATs.

9. Contractor will produce monthly billing statements along with accompanying supporting documentation as an excel or .csv file to include sample level data: specimen ID, PCR report date (if applicable), GISAID#, % genome coverage, coverage depth, GISAID upload date, Cloud upload date.

10. The Contractor shall notify LDH of any deviation from this requirement for this position within two business days of such deviation.

11. If the laboratory transcribes or enters test requisition or authorization information into a record system or a laboratory information system, the laboratory must ensure the information is transcribed accurately.

12. If a sample specimen has been rejected and/or testing is otherwise impossible, the Contractor shall ensure that all appropriate steps are completed to obtain a new sample and a timely test is

completed. The Contractor shall NOT invoice LDH for any test that results in a rejected sample.

1.5 Deliverables:

The Contractor will provide the professional services listed above as detailed under the heading "Minimum Requirements" above. In summary, the Contractor will provide the following deliverables:

1. Sequencing testing shall be completed and uploaded to GISAID within 14 days.
2. Contractor will provide raw data files and/or sample demographic data as required in "Minimum Requirements" above based on a reporting routine determined by LDH.
3. Contractor will provide shipping as required in "Minimum Requirements" at Contractor's cost.
4. The Contractor shall provide LDH, on a timeline communicated by LDH, with operational management information as follows:
   - The number of samples received for sequencing;
   - The number of samples rejected, with a rejection %;
   - The number of samples tested and uploaded to GISAID (and to LDH);
   - If variants were detected, the number and type of variant samples identified;
   - The number samples that failed to meet sequencing parameters; and
   - The average "turn around" time for samples uploaded.
5. Contractor will provide LDH invoice billing on a monthly basis with supporting documentation as detailed above in "Minimum Requirements."
6. Contractor will be required to ensure compliance with Office of Inspector General (OIG) training as required for participation in federal funding. In addition, Contractor will submit to Louisiana Department of Health, Office of Public Health all required reports / supporting documents to meet federal reimbursement guidelines.

2 REQUEST RESPONSE

2.1 RFI Coordinator

The RFI coordinator is listed below:

Name: Danielle Haydel
Title: Molecular Biology and Virology Manager
Department/Office: Louisiana Office of Public Health Lab
Physical and Mailing address: 1209 Leesville Avenue, Baton Rouge, LA 70802
Email Address: Danielle.haydel@la.gov

2.2 Schedule of Events

Activity/Event	**Date**
Public notice of RFI	03/01/2021
Deadline for receipt of written inquiries	03/04/2021
Response to written inquiries	03/07/2021

Deadline for receipt of RFI 03/10/2021

Louisiana Office of Public Health Lab reserves the right to deviate from this Schedule of Events.

2.3 Response Content

LDH understands the most cost effective sequencing occurs when WGS cartridges are run at full capacity. This differs with the sequencer being used, size of the cartridge, pooling etc. However, when tracking clusters and variants, speed is essential for response efforts and waiting for full cartridge capacity may not always be possible. In addition, required number of samples for sequencing may fluctuate over time. For example, when positivity rates are high, more sequencing may be required than when positivity rates are low. It is for these reasons that contracts may be, in part, tailored to the capacity and workflow of the responder's organization. It is the responder's responsibility to provide workflow and capacity details when providing information requested.

To facilitate LDH needs, contracts may be awarded to more than one responder

Respond concisely and in plain language. You may use any structure or layout that presents your information well. You must respond to all response sections below, but you can include other relevant information. You may also include links to online material or interactive presentations. Clearly mark any proprietary information, and place it in its own section or file.

2.3.1 Executive Summary

This section should serve to introduce the scope of the response and allow the Contractor to describe their approach and propose pricing for their services based on the approach provided. It should include administrative information including, at a minimum, responder's contact name and phone number, email address and any other pertinent contact information. This section should also include a summary of the responder's qualifications and ability and willingness to comply with LDH's requirements.

2.3.2 Corporate Background and Experience

The Contractor should give a brief description of the company including a brief history, corporate structure and organization and number of years in business. Responders should also describe their experience with projects of this type with other states or corporate/governmental entities of comparable size and diversity.

2.3.3 Approach and Methodology

The responder should provide approach and methodology recommended to accomplish the scope of services described. Best practices garnered from previous experience with this scope of services should be described. Identify any information that you think is important for the agency

to consider. Provide alternative solutions for accomplishing the project objectives, if applicable, and any other additional pertinent information.

2.3.4 Cost Estimate

Information below should be based on a $1,500,000 budget to be expended from contract commencement through June 2023, as this is the end of the grant funding this initiative. Pricing unit will be per sequenced and uploaded sample. Proposed testing volumes per week will be dependent on the workflow and instrumentation of the Contractor.

Choose the appropriate category for your facility below and fill in the table.

Category 1: For Contractors where samples are provided by OPH Lab, samples will be provided pre-screened for SARS-CoV-2 and come with associated Ct values. Extracted product will not be provided. Fill in the table below

Awarded Amount	Total Number of Sequences Performed for Awarded Amount	Price per Sequence ($)
$1,500,000	½ to full run volume	
	Less than full run volume	

Category 2: For Contractors where samples will be chosen from PCR positive SARS-CoV-2 samples tested at the responder's CLIA licensed facility, LDH Infectious Disease Epidemiology will determine which samples to sequence. This may be done with broad guidance or by specifying samples from those reported as being tested at the responder's facility.

Awarded Amount	Total Number of Sequences Performed for Awarded Amount	Price per Sequence ($)
$1,500,000	½ to full run volume	
	Less than full run volume	

2.4 Response Instructions

RFI responses are to be submitted electronically to LDH by emailing the responsive document to danielle.haydel@la.gov no later than the deadline for response to RFI as stated in the Schedule of Events. Please indicate "RFI Response" in the subject line of the email. Submissions received after the deadline will not be reviewed. It is recommended that a delivery receipt be requested.