State of Connecticut

Request for Proposal #20PSX0057

TESTING SERVICES - NOVEL CORONAVIRUS DISEASE 2019

Date Issued: May 8, 2020

Due Date: **May 15, 2020 at 2:00 pm Eastern Time**

Department of Administrative Services
Procurement Division

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Request for Proposal (RFP)

TESTING SERVICES – NOVEL CORONAVIRUS DISEASE 2019

The State of Connecticut Department of Administrative Services ("DAS") is issuing this Solicitation as a Request for Proposal ("RFP") pursuant to Governor Lamont's Executive Order No. 7Z to solicit responses for testing services for the Novel Coronavirus Disease 2019 **("**COVID-19") for all geographic locations throughout the State of Connecticut. The State will issue multiple Supplemental Solicitations in order to provide continuous recruitment of adequate resources to accommodate testing service needs throughout the duration of the COVID-19 pandemic. Proposers need only to respond once for consideration. Results of any Supplemental Solicitation(s) will be incorporated into the resultant Contract #20PSX0054. It is the intention of the State to make partial contract awards as successful contract negotiations are completed.

Overview

On March 10, 2020, Governor Lamont declared a public health emergency to bolster Connecticut's efforts to contain Novel Coronavirus Disease 2019 (COVID-19) and has taken several emergency actions in response to the COVID-19 outbreak. These emergency actions include the formation of a panel of experts from within the state's medical and business community, including the Department of Public Health (DPH), to consult with, and advise, his administration regarding the re-opening of Connecticut's economy.

To that end**,** the State of Connecticut (State), Department of Administrative Services, on behalf of the Department of Public Health is seeking solutions for the implementation of a comprehensive approach to widespread, high volume testing in Connecticut for the presence of COVID-19 infection by testing for SARS-CoV-2 virus and/or antibodies using protocols as defined by the Food and Drug Administration (FDA) (https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-diagnostic-testing-sars-cov-2#general).

Qualified proposer's will have the opportunity to offer solutions that support a demand for high volume, high throughput testing of symptomatic and asymptomatic Connecticut residents. The State will partner with a set of successful proposers in a statewide contract for these testing services and intends to have the resulting contract with an initial term of one (1) year with the option to renew.

SERVICE OBJECTIVES

I. Testing Services

Testing service solutions for SARS CoV-2 virus and/or antibody testing that provide collection, including solutions for collection of testing (collection kits, transport), and/or testing services, including testing kits. Responses may reflect the ability to provide all or individual components of these testing services.

A. Describe how your service(s) complies with Federal and State of Connecticut licensing requirements, including but not limited to Food and Drug Administration (FDA) and State of Connecticut Public Health Code.

B. Describe how your service(s) offers options to perform molecular and/or antibody based testing, including:

1. the ability to implement laboratory tests using molecular technologies;

2. the capacity to provide serological testing for SARS-CoV-2 antibodies; and

3. the name of test kit and manufacturer.

C. Describe your ability to receive, process and test specimens based on the FDA approved manufacturer criteria, per testing methodology guidelines. Include turnaround time from specimen collection through final patient test report to provider or patient, as applicable. The state is looking for the fastest turn around time of results for real-time contact tracing capabilities and therefore a turn around time of 24 hours is desirable.

D. Describe the capacity of your service(s) offered and how your service(s) will include or ramp up to the highest throughput for the anticipated high volume testing.

E. Provide a specimen collection plan compliant with current and evolving Center for Disease Control and Prevention (CDC) and FDA guidance. Proposals must include on-site collection options as well as remote collection, including but not limited to collection and testing in underserved areas or to non-mobile populations.

II. Qualifications

A. Licensing requirements:

1. Moderate and high complexity laboratories must have a current, valid Connecticut Clinical Laboratory license and submit a laboratory director's credentials.

2. Waived complexity laboratories: A Connecticut Clinical Laboratory license is not required.

B. Certification requirements:

1. Clinical Laboratory Improvement Amendments (CLIA) certificate must be included for all moderate, high and waived complexity laboratories.

III. Reporting

A. Describe how you will report, per manufacturer recommendations, positive, negative and inconclusive results to ordering provider or client, as applicable.

B Describe how your service(s) will report results to DPH within 48 hours of identification in accordance with the State of Connecticut Public Health code requirements described below:

STATE OF CONNECTICUT PUBLIC HEALTH CODE REQUIREMENTS:

Effective February 5, 2020, the Commissioner of the Connecticut Department of Public Health (DPH), amended the List of Reportable Diseases, Emergency Illnesses and Health Conditions and the List of Reportable Laboratory Findings by adding "COVID-19" and "SARS-CoV-2" to such lists (https://portal.ct.gov/-/media/DPH/EEIP/CTEPI/Vol40_No2.pdf?la=en). This action was taken pursuant to Connecticut General Statutes Section 19a- 2a and Section 19a-36-A7 of the Public Health Code. Laboratories performing tests to identify infections caused by SARS-CoV-2 based on FDA guidelines (https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#covid19euas) are required to report results to the Connecticut Department of Public Health within 48 hours of identification of results (Sec. 19a-36 page 6 (12-08) Department of Public Health§ 19a-36-A3Sec. 19a-36-A3. Persons required to report reportable diseases and laboratory findings).

1. Laboratories are required to report positive, negative, and inconclusive results as defined by the test(s) being used. Only results of tests performed on Connecticut residents need to be reported.

2. Information to be reported is in Section E, Table 1 of this RFP Document, including data elements and the data format and content. Requirements for including the data elements are listed in Table 2, Usage Definition. The order of the data elements should match the order in Table 1. Laboratories must make every effort to request on test requisitions the information required.

3. To facilitate the reporting of SARS-CoV-2 testing, laboratories must be able to send reports in an electronic format, either HL7 or flat file. Adherence to these standards will allow DPH to process results in an automated fashion to be able to more quickly disseminate results for public health use.

    a. Laboratories can use either HL7 v2.5.1 (preferred) or HL7 v2.3.1 message formats based on national electronic laboratory reporting (ELR) standards, and as defined in the DPH ELR HL7 2.5.1 Local Implementation Guide (https://portal.ct.gov/-/media/DPH/EEIP/CT_ELR_Local_Guide.pdf?la=en).

    b. Laboratories can submit results in a flat file format (e.g., Excel, csv). If using a flat file, the data elements and content must meet the standards outlined in Table 1. Files must be formatted to include all of the data elements, even if they are not populated, and include headers.

4. Method of reporting will be determined in discussion with each laboratory. Reporting methods need to be secure, for example, secure email, sFTP, or PHINMS.

5. Regardless of reporting file format or method, laboratories will need to review these reporting requirements with DPH and obtain preapproval before reporting is started. This

review will include a review of a test file using the reporting method proposed. A review checklist will be shared with the laboratory.

6. Table - 1 Laboratory Result Information to be Reported to DPH

Data element name/header	**Usage (Table 2)**	**Content requirements**	**Notes/comments**
Laboratory Identified	Required	CLIA number	CLIA number of the testing laboratory
Patient Last Name	Required	Character	
Patient First Name	Required	Character	
Patient Middle Initial	Required	Character	
Patient Address	Required	Residential address of the person being tested	This is the residence at the time of testing
Address 2	Required	Secondary address, e.g., Apt, Bldg, Floor, etc. using standard abbreviations	Put in a separate field than residential address https://pe.usps.com/text/pub28/28apc_003.htm
Patient City	Required	Character	
Patient State	Required	two letter abbreviation	
Patient Zip Code	Required	five or nine digit format allowed	
Patient Phone	Required	10 digit format	
Date of Birth	Required	mm/dd/yyyy	
Patient Gender	Required	Male, Female, Other, Unknown	
Patient Race	Required	See Table 2	multiple race selections allowed
Patient Ethnicity	Required	See Table 3	should be asked/reported separately from race
Patient Occupation	Required but can be empty	Character	If available
Patient Medical Record Number (MRN)	Required but can be empty	Character	ID that identifies the person at the provider or in the laboratory system. NOTE: Cannot be a person's social security number.
Accession Number/Lab ID	Required	Character	this is the ID that is assigned to the specimen in the laboratory system
Specimen Source	Required	SNOMED code or PHIN VADS standard abbreviation	https://phinvads.cdc.gov/vads/ViewValueSet.action?id=E1399690-F6D4-E111-AC0B-0050568D00F8

Data element name/header	Usage (Table 2)	Content requirements	Notes/comments
Test Method	Required	LOINC code defined for the SARS-CoV-2 test	DPH can assist with finding the proper LOINC https://loinc.org/prerelease/ for SARS-CoV-2 LOINCS
Result description	Required	Standard description or SNOMED code (Table 4)	Results as described by the manufacturer of the test
Specimen Collection Date	Required	mm/dd/yyyy	
Specimen Received Date	Required but can be empty	mm/dd/yyyy	
Tested Date	Required but can be empty	mm/dd/yyyy	
Ordering Facility	Required but can be empty	Character	The facility that submitted the specimen, if applicable
Ordering Provider Last Name	Required	Character	
Ordering Provider First Name	Required	Character	
Ordering Provider Phone	Required	10 digit format	
Ordering Provider Address	Required but can be empty		
Ordering Provider City	Required but can be empty		
Ordering Provider State	Required but can be empty		
Ordering Provider Zip	Required but can be empty		

7. Table 2 – Usage Definitions

Usage definitions are based on HL7 requirements but apply to laboratories who will be submitting flat files.

Usage	Comment for Submitting Laboratory	DPH Comment
Required	The Submitting Laboratory **SHALL** populate all Required elements with a non-empty value.	DPH **SHALL** process or ignore the information conveyed by required elements. DPH **must NOT** raise an error due to the presence of a

Usage	Comment for Submitting Laboratory	DPH Comment
	DPH expects these to be populated.	required element, but **MAY** raise an error due to the absence of a required element. **DPH will contact submitting laboratories by email or other methods to let them know if required elements are missing.**
Required but may be empty	The element may be missing from the message, but it **MUST** be sent by the Submitting Laboratory **IF** there is relevant data. A Submitting Laboratory should be capable of providing all "RE" elements. If the Submitting Laboratory knows the required values for the element, then it **MUST** send that element. If the Submitting Laboratory does not know the required values, then that element can be omitted if using an HL7 message.	For HL7 messages: DPH will be expected to process data contained in the element, but **MUST** be able to successfully process the message if the element is omitted (no error message should be generated because the element is missing). Laboratories submitting flat files should include the data element header in the message, even if content is not available to be included.

8. Table 3 – Race categories

American Indian or Alaska Native
Asian
Black or African American
Native Hawaiian or Other Pacific Islander
White
Other Race
Unknown
Refused

9. Table 4 – Ethnicity definitions

Hispanic or Latino
Not Hispanic or not Latino
Unknown
Refused

10. Table 5- Result descriptions

SNOMED	Description
260373001	Detected
260415000	Not detected

10828004	Positive
260385009	Negative
419984006	Inconclusive
82334004	Indeterminate

Pricing

Provide a pricing proposal that takes into consideration the public service associated with the testing services solicited in this RFP. The State is asking all proposers to respond with their best, most competitive pricing given the immediate need to provide testing services to Connecticut residents in a safe, comprehensive and efficient manner during these unprecedented times.

All price offerings must reflect net pricing, inclusive of any time or materials required to perform the services proposed.

Selection Criteria

DAS may award by individual item, group of items, or the entirety of all items. DAS may also reject any and all responses in whole or in part, and waive minor irregularities and omissions if, in the judgment of DAS, the best interest of the State will be served.

It is the intention of the State to partner with multiple qualified, responsible proposers that meet the specifications and requirements in order to best meet the testing demands of the COVID-19 pandemic and accommodate, in whole or in part, testing of residents within various geographic locations throughout the State.

Instructions to Proposers

1. Proposal Schedule

RELEASE OF RFP:	Date:	5/8/2020

RFP DUE DATE:	Date:	5/15/2020 at 2:00 pm Eastern Time

2. Questions

Questions for the purpose of clarifying this RFP must be directed to Tina Costanzo, via email: tina.costanzo@ct.gov

3. Solicitation Submission

Solicitations shall be submitted online by the RFP due date and time only. Proposers shall upload their solicitation submission to their BizNet Account. For guidelines on uploading documents, please refer to Attachment A, Guide to Electronic Proposal Submittals.