

EXHIBIT A

SCOPE OF SERVICES

The Contractor Agree to provide the following Services to the State:

I. SPECIMEN COLLECTION

- a. All specimens will be collected consistent with current and evolving Center for Disease Control (“CDC”) and U.S. Food & Drug Administration (“FDA”) guidance.
- b. Observed self-collected or clinician collected mid-turbinate, nasal or nasopharyngeal samples will be obtained. In the event that other modalities of collection are approved (including saliva) these may be used to collect molecular samples. Blood samples will be obtained via phlebotomy following standard precautions for antibody testing.
- c. Contractor will collect 100 samples per day as requested by the state beginning May 18, 2020 and will make a good faith effort to maximize sample collection capacity.
- d. Samples will be transported from the collection site to the Yale-New Haven Health System laboratory for analysis. All samples will be stored in appropriate conditions to maximize sample stability prior to analysis.

II. TESTING

- a. Contractor will perform molecular and/or antibody testing up to 200 tests per day for the State upon the execution of the contract.
- b. Contractor commits performing molecular and/or antibody testing up to 1,460 tests per day for the State by June 1, 2020
- c. Contractor commits performing molecular and/or antibody testing up to 3,860 tests per day for the State by July 1, 2020
- d. Contractor commits performing molecular and/or antibody testing up to 6,560 tests per day for the State by September 1, 2020
- e. Contractor shall use its best efforts to ensure that its turnaround time for processing test results shall not exceed twenty-four (24) hours from the time specimen to be tested is received by Contractor.
- f. The Parties understand and agree that market disruptions (e.g. supply chain) related to the pandemic may impact the ability of Contractor to provide the full testing commitments listed above. The Parties agree to maintain regular communication regarding the Services under this Agreement and any actual or anticipated impacts that are occurring or may occur. Should disruptions cause impacts to the commitments listed above, the Parties agree to work together to come to a mutual agreement on a solution. Comptroller agrees to assist Contractor in procuring testing supplies when possible.

III. REPORTING

- a. Contractor shall report, per manufacturer recommendations, positive, negative and inconclusive results to the ordering provider or client, as applicable.
- b. Contractor shall report results to DPH within 48 hours of identification in accordance with the State of Connecticut Public Health Code requirements described below:
 - i. STATE OF CONNECTICUT PUBLIC HEALTH CODE REQUIREMENTS:

1. 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#COVID19EUs>) 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-A3 Sec. 19a-36-A3. Persons required to report reportable diseases and laboratory findings).
- ii. Reporting Methodologies and Requirements:
 1. Contractor laboratories shall review reporting method(s) with DPH and obtain pre-approval before reporting is started. Pre-approval by DPH may include:
 2. Reporting method(s) must be secure (e.g., secure email, sFTP, or PHINMS).
 3. A review of a test file using the reporting method being reviewed by DPH. DPH will provide a review checklist with the laboratory.
 4. Contractor laboratories must 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.
 5. Contractor laboratories must report information to DPH including data elements and the data format and content as provided for in **Appendix 1** attached hereto.
- iii. Reporting Format
 1. To facilitate the reporting of SARS-CoV-2 testing, Contractor laboratories must be able to send reports in an electronic format, either HL7 or flat file, or other method(s) mutually agreed to by DPH.
 2. Contractor laboratories must 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).
 3. Contractor laboratories can submit results in a flat file format (e.g., Excel, csv).
 - a. If using a flat file, the data elements and content must meet the standards outlined in **Table 1 of Appendix I attached hereto**.

- b. Files must be formatted to include all of the data elements, even if they are not populated, and include headers.

APPENDIX I

REPORTING TO DPH

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#copyright19euas>) 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-A3 Sec. 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.

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 codedefined 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		

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.

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

Table 4 – Ethnicity definitions

Hispanic or Latino
Not Hispanic or not Latino
Unknown
Refused

Table 5- Result descriptions

SNOMED	Description
260373001	Detected
260415000	Not detected
10828004	Positive
260385009	Negative
419984006	Inconclusive
82334004	Indeterminate

EXHIBIT B

PRICING AND SCHEDULE OF PAYMENTS

I. Pricing

TEST TYPE	Price	HCPCS Codes as of 5/8/20
SARS CoV-2 (molecular)	65.00	U0003 (test)
SARS CoV-2 (serology)	33.00	36415 (collection), 86328 or 86769 (test)

- A. Pricing includes consumables and personnel and covers per test reimbursement for applicable populations batched and invoiced to the State. Populations include State of Connecticut employees, municipal employees and individuals that are uninsured. Individuals insured through Medicaid may also be included as/if determined by the State and communicate to Contractor in writing.

II. Payment

- A. The Contractor shall submit invoices in arrears, no less frequently than weekly. Invoices shall, at a minimum, include the Contractor name, the Contract Number, the Contractor’s Federal Employer Identification Number, the billing period, and an itemization of fees and authorized expenses.
- B. Each invoice must include a report with details necessary to identify patients, verify applicability and adjudicate payments. OSC and Contractor shall agree on the details for inclusion and format in advance of submission for the first billing period.
- C. The Contractor shall be compensated for its services based upon work performed, documented, and accepted by the Comptroller. Payment shall be made within two (2) Business Days after the State receives an invoice from Contractor. Except as set forth herein, the State shall have no right to offset disputed amounts or amounts due or allegedly due from Contractor from such payment. The State is exempt from any sales, use or other tax or assessment imposed under any applicable service, supply or product Invoice.
- D. Comptroller shall make all payments to the Contractor through electronic funds transfer via the Automated Clearing House (“ACH”). Contractor shall enroll in ACH through the Office of the State Comptroller prior to sending any invoice to the State. The Contractor may obtain detailed information regarding ACH at: <http://www.osc.ct.gov/vendor/directdeposit.html>.
- E. In the event the State is five (5) Business Days in arrears on its payment obligations under this Agreement, Contractor shall notify the State of non-payment. If the State fails to pay the invoiced amounts within 48 hours, Contractor may immediately, and without penalty or any liability suspend performance of Services hereunder until such time as the failure to pay ceases to exist. Suspension of performance by Contractor shall not constitute termination of this Agreement.

