State of Illinois
At-Home Saliva COVID-19 Testing Program
Request for Proposal
Due 3/18/2021, 5:00 p.m., CST

Background

The State of Illinois seeks proposals from private sector vendors with current Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration (FDA) to implement an at-home saliva based COVID-19 Polymerase Chain Reaction (PCR) test program. All services and provisions delineated must adhere to guidelines set forth in the EUA. At the direction of the State, the selected vendor will need to establish and operate a COVID-19 diagnostic and screening program available to State of Illinois residents that uses an at-home saliva-based PCR test kit. The Testing Program will be made available to residents four years of age and older, a population estimated to include approximately 12,000,000 individuals. The initiation and operation of the program, including the prioritization of selected populations, will be at the State's direction and will vary based on determined need.

The vendor will be expected to have a supervising and oversight physician, in good standing with the Illinois Department of Professional Regulation or any other state licensure body within the United States, to place and receive requests from residents. The supervising and oversight physician must be able to prescribe and issue an order for the at-home saliva test. The vendor will need to secure and ship the test kits to the residents' homes and arrange for the specimens to be returned so they can be processed by the vendor. Results must be reported to the resident as well as to the Illinois Department of Public Health (IDPH) via the Illinois National Electronic Disease Surveillance System (I-NEDSS). Relevant data, including testing data and patient information, must also be provided to IDPH. The vendor must use a reliable transport service to pick up and drop off specimen that handles all cargo at the appropriate temperature, safety, and security.

Any equipment, supplies, staffing, technology systems or other resources used or acquired by the vendor in the performance of this initiative during the term of the contract will be at the vendor's expense and shall remain the property of the vendor.

The proposal must include the vendor's current insurance coverage plan applicable to the proposed operations and continuing operational management of all proposed deliverables during the contract term. Such insurance coverage must meet the State's standard contract terms.

The proposal must provide for the employment of, or contract with, a supervising and oversight physician and other appropriate licensed professionals to cover the clinical operations of the vendor. Personnel engaged in the performance of the contract, including the ordering physician and those monitoring specimen collection, will be supervised by the vendor, not the State. The State will not issue any standing orders or prescriptions for tests.

The initial term of the contract will be 12 months from the date of contract execution. The term may be extended at the State's discretion.

The State will evaluate the proposals and make one award that makes test kits accessible to residents throughout the State of Illinois. An award will be made to a vendor that can fulfill all the services requested. Partial awards will not be considered. However, the vendor may engage subcontractors to perform part or all of the services. If subcontractors will be engaged, the vendor must include a complete list of all subcontractors intended to be used, their addresses, and a description of the work each subcontractor will be performing in the proposal.

Any vendor requiring clarification of any section of this RFP or wishing to comment on any requirement of the RFP must submit specific questions in writing no later than the deadline for questions indicated in the "Key Dates" section of this RFP. Questions may be emailed to the point of contact for this RFP and listed below. Questions or comments not raised in writing on or before the deadline to submit questions are thereafter waived. At the close of the question period a copy of all questions or comments and the State's responses will be posted on the State's web site shown below. Every effort will be made to post this information as soon as possible after the question period ends, contingent on the number and complexity of the questions.

Key Dates

3/10/2021	RFP Released
3/12/2021	All questions from prospective vendors due via email to Dawn.Crowhurst@illinois.gov
3/16/2021	Answers to questions from prospective vendors released via IDPH COVID-19 website link below: http://www.dph.illinois.gov/rfp/covid19-home-tests.
3/18/2021	Submissions due via email to Dawn.Crowhurst@illinois.gov not later than 5:00 p.m. CST
3/22/2021 (estimated)	Contract award
3/31/2021 (estimated)	Start date

Directions

The State is seeking proposals from interested vendors, with Emergency Use Authorization from the U.S. Food and Drug Administration, and the ability to provide an at-home saliva-based COVID-19 PCR testing program.

The proposal must be submitted as two separate documents. The first document will include the vendor's response as to how it will deliver the services required and cannot include any pricing information. The pricing information must be presented on the attached budget template (see Attachment A). Each document will be evaluated separately. Proposals should include:

- Name of vendor, vendor's address, and contact person, including work phone, cell phone, and email address.
- Operational Plan (not to exceed ten pages total) that describes the vendor's proposal as described in the Scope of Work.

- Timeline that includes dates allowing for initial offering of at-home testing by March 31, 2021.
- Plan for data collection, tracking, and submission of necessary data to the State. All data must be exportable to Excel or otherwise transferrable to the State in an agreed upon format upon contract termination.
- Plan for obtaining and maintaining access to adequate supply of all necessary testing materials.
- Plan for provision of language access services and services for individuals who are non-native English speaking or are deaf or hard of hearing.
- References, which shall include the names and contact information for three entities for whom the vendor has provided similar services described in the proposal.
- Proposed pricing (submitted as a separate, clearly labeled attachment from the rest of the proposal).

Proposals must be submitted via email not later than 5:00 p.m., Central Standard Time on 3/18/2021 to:

Dawn Crowhurst
Illinois Department of Public Health
Office of Health Protection
Dawn.Crowhurst@illinois.gov

The State reserves the right to award the vendor(s) that has the best overall proposal within the State's timelines and to issue supplemental solicitations as warranted.

Scope of Work

A) **Overview.** In order to ensure the operation of a fully functioning statewide, at-home, monitored, physician ordered, COVID-19 saliva testing program, the State seeks proposals that include vendor provisions of the following:
   a. Test kits
   b. Shipping of test kits to resident's home or other designated location and return shipping to vendor's laboratory
   c. Verification of resident's identity. Vendor will verify resident's identity consistent with health care best practices to ensure resident is the designated and identified consumer/patient
   d. Screening of resident's medical need, including symptoms, exposure and other relevant information for the test
   e. Monitoring of specimen collection by direct observation of the patient as they collect the specimen. This may be provided either in-person or virtually.
   f. Services of supervising and ordering physician
   g. Portal or other electronic means by which residents may request testing and receive results
   h. Customer support for residents
   i. Laboratory processing in a CLIA certified laboratory, including all necessary equipment, supplies and personnel
   j. Communication of results to resident that appropriately protects the individual's health information and encourages adherence to local standards of isolation and quarantine.
   k. Billing to commercial insurance, Medicaid, Medicare, and HRSA

l. Weekly reporting of program data to the State in addition to adherence to mandatory disease reporting via the Illinois National Electronic Disease Surveillance System (I-NEDDS) (see Appendix A for details)
m. Provision of access to services for non-native speakers of English or hard of hearing individuals as needed. Vendors must include their plan for language access services in their proposal.
n. Contribute to targeted marketing and/or engagement efforts to drive utilization among key subpopulations of residents

B) **Operations and Management.** The vendor must provide:
a. Physician ordered, at-home, saliva-based PCR COVID-19 testing services available statewide to all residents four years of age and older meeting relevant clinical guidelines of both the State and Federal government
b. An electronic system by which resident may request testing and receive results
c. Monitored collection of samples available from 8:00 am to 7:00 pm (CST) 7 days a week, with the exception of State holidays
d. Tests shipped to residents in such a manner that the resident receives a test kit within 24 hours of their request, regardless of the day of the week the test kit was requested
e. Return packaging and shipping label such that the test kit is received by the vendor laboratory within 24 hours of the kit being shipped by the resident, regardless of the day of the week the resident ships the test kit
f. A reminder system to residents who have not returned their specimens via return packaging and a shipping label provided by vendor to ensure that all specimens collected are being returned for processing
g. Customer support for residents on weekdays from 8:00am-7:00pm (CST).
h. The ability to initiate services by March 31, 2021. The proposal must provide information on readiness to begin testing by that date, including details such as supply availability, trained staff, supervising and ordering physician, and testing capacity.
i. Up to 2,000 test kits per day for distribution and analysis at launch through the first month and a capacity for 5,000 test kits per day for distribution and analysis by the second month through the duration of the contract.

C) **Physician Ordering and Specimen Collection:** The vendor must provide:
a. The services of an ordering physician to provide orders and oversee the testing program, and eligibility screening by which the resident's medical need for a test can be determined
b. Verification of resident's identity. Vendor will verify resident's identity consistent with health care best practices to ensure resident is the designated and identified consumer/ patient prior to administering the test.
c. Monitoring (in person or virtually) of the collection of the saliva sample

D) **Laboratory Services:** The vendor must provide the following services:
a. Polymerase Chain Reaction (PCR) testing for COVID-19 clinical samples
    i. All tests must be performed in accordance with Clinical Laboratory Improvement Amendments (CLIA) and the relevant Emergency Use Authorization
    ii. Vendor must be able to receive and process specimens seven days per week
b. Vendor must notify the State and its designee of each test result performed on behalf of the State via the Electronic Lab Reporting system (ELR) in HL7 2.3.1 format or 2.5.1 with Logical

Observation Identifiers Names and Codes (LOINC) and Systematized Nomenclature of Medicine (SNOMED) codes to specify testing information and results.

i. Information to be reported is detailed in Appendix A
ii. Vendor should indicate whether vendor is able to provide batched reporting if requested

c. Vendor must report the number of specimens per week for which a gene target failure (e.g., s-gene target failure) associated with certain variants of interest occurs
d. Vendor must submit up to 100 specimens/week, based on criteria established by the State, to the State for sequencing and variant surveillance.
e. Turnaround time within 24-48 hours from receipt to resulting of specimens required
    i. Vendor must provide a daily report to the State on the average turnaround time of samples processed the previous day, the number of samples that exceeded 48 hours turnaround time, and the number of samples received that the vendor has yet to process.
    ii. If the vendor delivers an average turnaround time of less than 24 hours over a week (Monday-Sunday), the State will pay a bonus of 10% over the per test quote submitted. The average turnaround time must be verified by the State prior to the payment of any such bonus.
    iii. If the vendor delivers an average turnaround time of more than 48 hours a week or exceeds 48 hours turnaround time for more than 5% or more samples over a week (Monday-Sunday), the State will assess a penalty and deduct 10% from the per test quote submitted.

E) **Billing:** Vendor must be able to provide the following:
a. The vendor must accept electronic test requisition forms, including accepting electronic test requisition forms obtained from the State's online portal for COVID-19 testing or other similar method adopted by the State or a partner of the State.
b. Vendor must be able to bill resident's insurance on behalf of the State, or seek reimbursement for uninsured residents from the U.S. Department of Health and Human Services (HHS), which provides claims reimbursement to health care providers, generally at Medicare rates, for testing uninsured individuals for COVID-19, before seeking payment from the State. The vendor must be able to bill the State for the total cost of tests it performs less any amount received through insurance reimbursement. The vendor must be able to detail all insurance reimbursements and agree to work closely, and in good faith with the State to maximize insurance reimbursements in accordance with applicable State law. The vendor must be able to notify the State within one business day of being notified that any insurance refuses to reimburse for a test or reimburses less than the specified rate for a test.
c. Vendor must achieve an 85% reimbursement rate for orders with necessary insurance information

F) **Data Collection and Reporting.** Proposals must address the methodology to ensure the following data collection and reporting:
a. Collection of all data consistent with the State's provided test requisition form (See Appendix B)
    i. The data must be provided to the State on an agreed upon method.
    ii. The State reserves the right to amend the test requisition form in the future, including adding screening questions regarding epidemic spread and will work through any resulting reduction in throughput maximum numbers in good faith with the vendor.
b. Electronic collection of insurance information as follows:

i. Full insurance information required for test reimbursement from private insurance, Medicare, Medicaid, or any other applicable medical insurance, or
ii. A fully completed "uninsured resident questionnaire" to be supplied by the State that will include specific questions useful for diagnosing epidemic spread and an attestation by the applicant that they lack insurance and consent to a Medicaid application being submitted on their behalf for the limited purpose of COVID-19 testing.
iii. Failure to collect either full insurance information required for processing insurance reimbursement or a fully completed uninsured resident questionnaire for more than 5% of specimens collected in a given day will result in a proportional 5% reduction in payment per missing form.
iv. When requested, the vendor shall supply the required insurance information to the State

c. Reporting of operational data on a weekly (or as requested) basis to include: number of requests for tests, number of collection kits shipped, number of collection kits returned, number of specimens resulted.
d. Reporting of test results, by specimen on a weekly (or as requested) basis.
e. Reporting of date and time received and date and time resulted, by specimen, as requested.
f. Reporting of resident-level data on a weekly (or as requested basis) must include: date of birth, gender, zip code, race and ethnicity (using State specified categories), status as symptomatic or asymptomatic according to CDC guidelines, status as having exposure via a close contact,. Patient-level data should be recorded and reported in a manner that allows for tying to data on test processing and results.
g. Vendor must have the ability to reconcile orders created and results not delivered within 48hours in order to provide IDPH with quality assurance of services. Reconciliation reports should be delivered to IDPH every weekday, outlining reason for delay and measures to correct problems and update patients.
h. Compliance with the Health Insurance Portability and Accountability Act of 1996 and all applicable laws and regulations.

Additional Requirements

A) Any clinical personnel supplied by the vendor will be required to demonstrate the necessary qualification to perform any medical services required under the contract. Vendor must supply the required attestations from the supervising medical doctor required for all activities.
   - Specific medical licensure requirements, regulatory statute, and administrative rules for various professions can be downloaded from https://www.idfpr.com

B) There is a Business Enterprise Program (BEP) target of 4% for this solicitation. Vendor submissions should include all BEP target information through a Utilization Plan (see Attachment B). Failure to submit a Utilization Plan may render the offer non-responsive. Businesses included in Utilization Plans as meeting BEP requirements as prime vendors or subcontractors must be certified by the Department of Central Management Services as BEP vendors. Vendors may visit https://cms.deiversitycompliance.com to search for certified BEP vendors. The NIGP codes used to calculate the Business Enterprise Goal, and a list of vendors associated with those codes, are attached to this solicitation as Attachment C. This is not an all-encompassing list of vendors that may be used as subcontractors to fulfill this goal. If the vendor has a potential subcontracting

opportunity for goods or services that would be considered applicable to this contract, the vendor may use that subcontractor to fulfill the BEP goal, assuming that subcontractor is BEP certified with the State of Illinois.

C) Prevailing Wage Rates shall apply, if applicable.
D) Vendor's proposed pricing shall be inclusive of all costs.

The chart below describes the elements of responsiveness that IDPH will evaluate in the vendors' proposals.

Proposal Specification Checklist Table:

Please indicate, utilizing the table below, the section and page number where the requested information is in your proposal. Respondent must complete this Proposal Specification Checklist Table provided as Attachment D to identify how their proposal meets the requirements of the solicitation.

Mandatory Criteria	**Vendor's Proposal Page Reference**
Emergency Use Authorization from the U.S. Food and Drug Administration for a saliva-based, PCR test for SARS-CoV-2 for at-home specimen collection for individuals four years of age and older.	Section Page(s)
Established process and platform to screen patients, accept requests for tests, and to provide test results to patients.	Section Page(s)
Established lab capacity (either internal or via a partnership) to process up to 5,000 saliva specimens per day	Section Page(s)
Ability to report test results to the State via the Illinois National Electronic Disease Surveillance System (I-NEDSS).	Section Page(s)
Demonstrated success in receiving reimbursement from commercial insurers, Medicaid, Medicare, and HRSA for completion of at-home, saliva-based SARS-CoV-2 tests.	Section Page(s)
Describe capacity for providing language translation services and services for individuals who are deaf and hard of hearing. Please list vendors who will perform these services.	Section Page(s)
Ability to meet Business Enterprise Program target.	Section Page(s)
	Vendor's Proposal Page

Evaluation Criteria	**Reference**
Plan to launch testing program by March 31, 2021	Section Page(s)
Ability to provide the services of a licensed physician to order tests and to provide medical supervision of the testing program.	Section Page(s)
Established process and platform for live verification of patient identity and monitoring of saliva collection, for up to 5,000 patients per day.	Section Page(s)
Established process and capacity to ship up to 5,000 test collection kits daily to residents' homes within 24 hours of request and to provide for 24-hour return shipping to the laboratory.	Section Page(s)
Average turnaround time, based on past performance, and defined as the time between receipt of specimen and result made available to the patient.	Section Page(s)
Ability to submit to the State up to 100 specimens per week for sequencing and variant surveillance.	Section Page(s)
Plan to provide convenient hours of operation for customer support.	Section Page(s)
Average time, based on past performance, between resident request for testing and shipping of test kit.	Section Page(s)
Percent of tests resulted, of which insurance information is available, for which reimbursement from insurers or HRSA is received.	Section Page(s)
Plan to collect and report patient, test, and performance data to the State on a weekly basis.	Section Page(s)
Rate of successful reimbursement for resulted tests for which insurance information is available.	Section Page(s)
Plan to provide support for marketing and outreach to targeted populations.	Section Page(s)
Quality control plan to ensure that all patients receive results in a timely manner.	Section Page(s)