Attachment B - Scope of Work
RFx #3000021605 (Revised 9/25/23)

The purpose of the contract is to provide COVID-19 testing services for Community-Based testing confinement facilities (correctional and psychiatric facilities), Congregate Setting (Nursing Homes, Long Term Care Facilities, State-Funded facilities and Homeless Shelters) in addition to K-12 (School-Based) testing statewide. Notwithstanding anything to the contrary contained in the contract or any ancillary documents thereto, Contractor acknowledges and agrees that in performing the underlying services, it shall at all times comply with any and all applicable State and Federal laws and regulations, governing the services to be provided herein, including but not limited to Attachment E - Coronavirus Aid Relief and Economic Security Act (CARES Act) as promulgated from time to time.

Testing Minimum Requirements

In order to provide testing services, including actual test sample collection and laboratory diagnostics, the Contractor must comply with minimum requirements as follows:

1. The Contractor must provide for the furnishing and distribution of COVID-19 testing collection kits and the appropriate laboratory staff, with appropriate Personal Protective Equipment (PPE), to conduct the diagnostic portion of testing, and any and all laboratory equipment needed to complete the tests, which includes but is not limited to:
    a. Wi-Fi and electricity
    b. Devices (Computers and iPads) needed for data entry
    c. Setup and breakdown of equipment
    d. Providing necessary services for collections. Services include but are not limited to, labeling patient information, performing a Nasopharyngeal or Nasal swab to collect specimens to test for Covid-19 via Polymerase Chain Reaction (PCR). It would also include maintaining infection control.
    e. Scheduling and management of the Strike Teams (rapid response mobile testing teams)
    f. Cleaning & sanitization
    g. Removal and disposal of all waste
    h. Strike Teams will communicate with the facilities and the Louisiana Department of Health (LDH) regarding PCR results so that the facility is able to activate COVID-19 outbreak plans such as masking, social distancing and isolating positive cases.
    i. Communication with the State's point of contact

2. The Contractor's lab shall remain fully accredited by an accrediting body that is approved under the Clinical Laboratory Improvement Act (CLIA) of 1988 standards for the full term of the contract. A copy of this accreditation should be provided with the bid response. The Contractor must submit documentation within five (5) business days after request if not submitted with their bid.

3. The Contractor must have a CLIA qualified and approved Lab Director. Contractor must provide proof of board certification before the contract can be effective. A copy of this certification should be provided with the bid response. The Contractor must submit documentation within five (5) business days after request if not submitted with the bid response. The Contractor shall notify LDH of any deviation from this requirement for this position within two (2) business days of such deviation.

4. The Contractor's COVID-19 laboratory must consist of both clinical and administrative staff necessary to ensure appropriate lab services, reporting of results, and data flow.

5. The Contractor shall provide an ordering provider for all tests collected.

6. The Contractor shall provide a collection of samples at sites as directed and approved by LDH - Office of Public Health (OPH).
    a. Biohazard waste collection and disposal shall be the responsibility of the Contractor.
    b. The Contractor shall ensure that field staff and courier teams are trained appropriately in the handling and transport of specimens and biohazard waste. The Contractor will provide Category B packaging (conceals infectious specimens) and shipping for samples. The Contractor will provide the best practices for COVID specimen collection, safety training, and competency documentation related to this activity, as requested by LDH.

7. Prior to commencing diagnostic testing in a lab, the Contractor must provide LDH with technical information detailing the testing platform and instrumentation equipment that will be utilized in performing extraction and Reverse Transcription Polymerase Chain Reaction (RT-PCR) analysis. The Contractor shall also provide the Emergency Use Agreement (EUA) approval, or other documented approval from the Food and Drug Administration (FDA), for the applicable testing systems. If another platform is to be substituted, the Contractor must provide LDH with a two (2) week prior written notice with the information above.

    The Contractor shall provide a web-based patient portal, which will allow for patients, collection staff, or facility staff to enter all required demographic information (eighteen (18) Data Elements required by the Center for Disease Control (CDC) as outlined in Attachment E - Cares Act) and obtain consent. This portal must also provide patients with notifications of the status of their test results and access to those results. The Contractor shall be responsible for providing computers, tablets and cellphones for data to be entered into the web-based portal and for the accuracy of all information entered into the web-based portal.

    a. When reporting results within confinement facilities, the Contractor shall be able to distinguish between specimens that belong to residents and staff within the facility.
    b. The Contractor will work with the individual facility to define a plan for batch entry of demographics and the reporting of results through an administrative portal. LDH wants to ensure that the Strike Teams have a streamlined process with collecting the specimens, transporting and resulting to ensure they are able to identify positive cases so the facilities can take necessary measures.

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

9. The test requisition process may be conducted electronically; however, the Contractor must include the option for a traditional paper requisition.

10. The Contractor shall indicate on each sample whether an individual is vaccinated or not, whenever possible.

11. The Contractor must provide its own courier system that must ensure that specimens

are properly labeled, packaged for infection control and are at the desired temperature for transport.

12. The Contractor shall make available eight (8) rapid response mobile testing teams (Strike Teams) at all times.
    Each team shall consist of at least three (3) members
    a. One (1) team lead
    b. One (1) individual for registering the resident(s)
    c. One (1) individual for collecting the specimen

13. The Contractor must be available to do testing seven (7) days a week.
    a. The Contractor must be available for testing any day of the week (Sunday – Saturday). These days will not necessarily be consecutive.
    b. The Contractor must be available to perform testing between the hours of 8:00am to 8:00pm CT.
    c. The State and the site's point of contact will coordinate the hours of operation with the Contractor.
    d. The Contractor must be available to do testing for a maximum of twelve (12) hours per day.

14. Upon the occurrence of an indeterminate, inconclusive, or apparent invalid testing result, the Contractor shall immediately review the analysis data and, if re-extraction is indicated, it shall require re-extraction of the original sample. The Contractor shall NOT repeat an analysis of the same extracted sample. If the sample specimen is indeterminate, inconclusive, or an apparent invalid testing result, the Contractor shall only invoice LDH half rate for the sample specimen.

15. If the sample specimen has been rejected and/or testing is otherwise impossible, the Contractor shall ensure that all appropriate steps when reasonably possible are completed to notify the individual 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.

16. Contractor shall comply with Attachment G - Healthcare Insurance Portability and Accountability Act (HIPAA) Business Associate Addendum.

17. Contractor shall comply with Attachment F – Office of Inspector General (OIG) Compliance Agreement.

DELIVERABLES:

1. Within twenty-four (24) hours of notification by LDH of a specific test collection site, the Contractor shall be available to the testing site to set up a rapid response mobile testing team(s). The Contractor is required to provide a continuous supply of any testing kits that may be necessary at the applicable testing site. The Contractor will work in coordination with state and local district contacts to setup:
    a. Testing location
    b. Testing time(s)
    c. Any other needs relevant to testing assigned area

2. The Contractor shall be available by phone or email to answer any questions from, or to provide guidance to, tested individuals.

3. The Contractor will provide the State with the qualifications/licensing stated below for the testing staff. This must be submitted to LDH within five (5) business days of written request.

    a. Medical Doctor (MD/DO), Physician Assistant (PA), Nurse Practitioner (NP), Certified Registered Nurse Anesthetist (CRNA).
    b. Pharmacist or Pharmacist Assistant.
    c. Registered Nurse (RN) and Licensed Practical Nurse (LPN) Louisiana Nursing License.
    d. Certified Nursing Assistant (CNA) and/or Clinical Medical Assistant (CMA), certification and/or certificate of completion from a training program from either a Community College and/or Vocational Institution.

4. The Contractor will provide the State with an explanation on how they will maintain temperature conditions and infection control of the testing materials and specimens during collection and transport to the laboratories for further analysis.

5. All laboratory testing shall be completed and reported to LDH within forty-eight (48) hours of collection, if possible. However, the Contractor agrees to complete all testing and reporting to LDH within seventy-two (72) hours of the specimen's collection time.
    a. In the event that a testing result is not obtained and reported to LDH within the seventy-two (72) hour timeline, the Contractor agrees to accept fifty percent (50%) of the contract amount.
    b. The laboratory shall have protocols and procedures in place to adequately document the specimen's time of collection and time of report to LDH.
    c. LDH will NOT be responsible for reimbursing for any test that is not completed and reported within one-hundred and twenty (120) hours of the specimen's time of collection.
    d. If the Contractor is unable, utilizing good faith efforts (testing at a facility beyond the set time period), to acquire test reagents, or other required testing material, they shall immediately notify LDH of the issue and the parties MAY agree to a temporary extension. This is at the discretion of LDH.

6. In order to execute on the Deliverables, LDH shall provide the Contractor with a two (2) week written notice, physical or electronic, to proceed with collection. This notice may only be given by the COVID-19 Congregate Testing Program Monitor or any designee as appointed by their Manager.

In addition, the Contractor shall provide the following deliverables:

- The Contractor must offer a process for test requisition of some elements which are included in the requirements of 42 CFR 493.1241. Specifically, LDH requires the following information to be provided by Contractor to State Epidemiologist with results:
    - The eighteen (18) Data Elements required with COVID-19 testing results for each collection made, which elements are listed in Attachment E - Cares Act, hereto and incorporated into this Agreement as Attachment E, including National Provider Identifier (NPI) of the authorized provider requesting the test.
    - The patient's name or unique identifier.
    - The test(s) to be performed.
    - The source of the specimen, when appropriate.
    - The date of specimen collection.
    - Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable.
- The Contractor shall report all results electronically to the State's epidemiology department through the state electronic laboratory reporting protocol. All lab results, including any

antigen testing that may be performed at no charge, are to be provided to the portal within twenty-four (24) hours of reporting.

- On a timeline communicated by LDH, the Contractor shall provide management a report with the following information:
    - The number of testing sites setup
    - The number of samples received for testing for each site
    - The number of samples rejected, with a rejection percentage
    - The number of samples tested
    - The average "turnaround" time for testing
    - The percent positivity of the samples collected
- Upon receipt of the results, the Contractor shall ensure the provider, if applicable, or the requesting individual, is notified of the result within twenty-four (24) hours of the report to LDH. Except for the reporting expressly mentioned herein, the Contractor shall NOT report any results, even de-identified, to any other party unless directed by LDH. Notwithstanding the foregoing, nothing contained herein shall preclude reporting results to the respective patient, and is only intended to preclude the sharing of data outside HIPAA approved purposes.
- The Contractor shall provide the State with a monthly invoice by the fifteenth (15^{th}) of every month with the following sample level data and any additional information deemed necessary by the Contract Monitor.
    - Sample unique identifier
    - Collection date & time and report data & time
    - Turnaround time calculation (in hours)
    - Facility / site location
    - Patient's vaccination status
    - If applicable, if the patient is a staff member or a resident

PERFORMANCE MEASURES:

The Contractor will achieve the goals and deliverables of the contract by submitting the following data to the Program Monitor for review on a weekly basis:

- Number of testing sites setup
- Number of test samples received
- Number of test samples reported
- Average turnaround time of the samples (expressed in hours) reported from the date & time of specimen collection to the date & time of the report to the provider/individual
- The percent positivity of the samples collected

MONITORING PLAN:

The Covid-19 Congregate Setting Testing Program Monitor, Erin Rogers or her designee or successor will:

- Review all documentation submitted to ensure accuracy and compliance with the terms of the contract resulting from this solicitation.
- Correspond with Contractor via email, telephone, and in-person and/or virtual meetings to ensure transparency at all levels
- Ensure Contractor is meeting deliverables on a bi-weekly basis as set forth above
- Communicate with the Contractor on the priorities of the Office of Public Health Laboratories.

State the name(s), telephone number(s) and email addresses of the contact people who will be responsible for administering the contract for your company.

Vendor Contact Information – please print

Name: _____

Phone #:_____

Cell Phone #: _____

Email Address: _____

Name: _____

Phone #:_____

Cell Phone #: _____

Email Address: _____