

## CDPH ANTIGEN TESTING LABORATORIES MEMORANDUM OF UNDERSTANDING

### 1. Term

- A. The term of the Memorandum of Understanding (“MOU”) shall be from the date of execution (the “Effective Date”) until thirty (30) days after the lifting of the declaration of the COVID-19 state of emergency.
- B. In addition to any other provision of this MOU, the California Department of Public Health (“CDPH”) or the organization wishing to provide Abbott BinaxNOW antigen testing at their site (“Participant”) may terminate this MOU or cancel a portion of the service for any reason with fourteen (14) days written notice.

### 2. Service Overview

The Participant shall comply with the scope, the terms, conditions, and requirements set forth herein for the laboratory testing of samples for SARS-CoV-2 using the Abbott BinaxNOW antigen test.

### 3. Service Location

The services shall be performed at a temporary testing site identified by Participant that has been approved by the Laboratory Director of CDPH Antigen Testing Laboratories.

### 4. Project Representatives

- A. The project representatives during the term of this MOU will be:

<b>California Department of Public Health</b> Sabel Davis Telephone: 916-865-8717 E-mail: <a href="mailto:testing.taskforce@cdph.ca.gov">testing.taskforce@cdph.ca.gov</a>	<b>Enter Participant</b> Contract Manager Telephone: E-mail:
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- B. Direct all general inquiries to:

<p><b>California Department of Public Health</b>  Testing Task Force  Attention: CDPH Antigen Testing Laboratories  850 Marina Bay Parkway  Building P  Richmond, CA, 94804</p> <p>E-mail: <a href="mailto:testing.taskforce@state.ca.gov">testing.taskforce@state.ca.gov</a></p>	<p><b>Participant Name:</b></p> <p>Attention:  Address:  City:  State:  Zip Code:</p> <p>Telephone:  Fax:  E-mail:</p>
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## 5. Services to be Performed by CDPH's Antigen Testing Laboratories

CDPH Antigen Testing Laboratories shall supervise and oversee, under its state clinical laboratory registration and federal CLIA certificate of waiver, laboratory testing of collected samples for SARS-CoV-2 using equipment and supplies provided by CDPH. Samples will be tested only for SARS-CoV-2 using the Abbott BinaxNOW antigen test. The CDPH Valencia Branch State Public Health Laboratory shall be the preferred laboratory for performing molecular testing for SARS-CoV-2 once that laboratory is integrated with Primary Diagnostics, Inc. in accordance with the CDPH Agreement referenced below. This testing may also be arranged or provided for at the discretion of the Laboratory Director. CDPH Antigen Testing Laboratories shall also make available the services of an authorized health care provider ("Ordering Physician") to make assignments for test reports for the performance of tests described in this MOU. CDPH, through CDPH Agreement 20-10982, has contracted with Primary Diagnostics, Inc. and via Primary Diagnostics, Inc. will provide patient registration services and laboratory and medical records data collection, management, storage, and reporting services.

## 6. Services to be Performed by Participant

Participant shall be responsible for the direct oversight of testing personnel at the designated temporary testing site and shall ensure that personnel meet the training and competency criteria established by the Laboratory Director of CDPH Antigen Testing Laboratories. Participant shall comply with all operational guidelines established by the Laboratory Director.

Participant shall be responsible for all of the following:

1) Comply with all requirements and specifications of the Laboratory Director, and its contractor, Primary Diagnostics, Inc., to ensure that all test results and data reporting, storage, and management requirements applicable under state and federal law are satisfied;

2) Maintain adequate site inventory control of tests;

3) Securely transmit copies of patient results and Participant site records, including, but not limited to quality control logs, testing personnel training records, and test inventory records, to CDPH in accordance with the operational guidelines established by the Laboratory Director, at the frequency determined by the Laboratory Director to ensure regulatory compliance, and upon the termination of the testing program, as described in Paragraph 8.H.;

4) Securely report and transmit, in accordance with the Laboratory Director's operational guidelines, patient adverse event information and suspected false negatives, suspected false positives, and any significant test performance deviations to the CDPH Ordering Physician and CDPH Laboratory Director via a secure CDPH electronic mail address to be identified by the CDPH Laboratory Director.

5) Coordinate with CDPH in arranging for any confirmatory molecular testing for individuals who have a positive antigen test result and also for individuals who are symptomatic and have a negative antigen test result. The follow-up molecular testing shall only be performed at a laboratory approved by the Laboratory Director of CDPH Antigen Testing Laboratories.

## **7. Payment and Billing**

Unless otherwise agreed to in writing, CDPH will be responsible for the cost of the Abbott BinaxNOW tests used to perform testing on samples at the temporary testing site identified by the Participant. The Participant may not charge for the cost of the Abbott BinaxNOW tests provided by CDPH. The parties will otherwise bear their own costs in providing services under this MOU. Nothing under this MOU precludes either party from seeking payment from health plans, insurers, or other third-party payers ("Third Party Payers") for services rendered. It is the expectation of CDPH that Participants will not balance bill patients for amounts billed to but not paid by Third Party Payers.

## **8. Confidentiality of Information/Data and Privacy Use**

- A. **Use and Disclosure of Data Set:** For purposes of this MOU, "Protected Data" means any data obtained and stored by the Participant while undergoing any of the activities described in this MOU. Participant agrees to maintain the confidentiality of the Protected

Data. Participant agrees not to use or disclose any Protected Data in any manner not permitted by applicable state or federal health information privacy laws and shall require that its directors, officers, employees, contractors, subcontractors and agents do not use or disclose the Protected Data in any manner that would constitute a violation of this MOU.

- B. **Legal Authority:** Participant and CDPH have the legal authority to exchange the Protected Data pursuant to California Health and Safety Code sections 131050 and 120175.
- C. **Minimum Necessary Information:** Participant agrees, to the extent Protected Data is shared, only the minimum necessary Protected Data for the accomplishment of CDPH and Participant's goals will be shared.
- D. **California Civil Code section 1798.29:** CDPH and Participant agree to comply with applicable privacy breach notification laws, including California Civil Code section 1798.29, with regard to the Protected Data. Participant agrees to notify CDPH as soon as practicable, without unreasonable delay, of any breach that triggers a response under this section.
- E. **Safeguards Against Misuse of Information:** CDPH and Participant shall use appropriate administrative, technical, and physical safeguards to prevent use (sharing, employment, application, utilization, examination, or analysis of information) or disclosure of the Protected Data that is prohibited under applicable state and federal health information privacy laws:
- CDPH and Participant shall comply with the information security standards, which standards shall be at least as stringent as those set forth in NIST 800-53. These standards shall also include encryption of the Protected Data using a FIPS 140-2 certified algorithm, such as AES, with a 128bit key or higher when Protected Data is being sent outside Participant's network boundary.
  - Each party is individually responsible for abiding by the applicable laws and regulations pertaining to the Protected Data in its possession.
  - Nothing in this MOU shall relieve either party from abiding by relevant laws or regulations.
- F. **Agreements by Third Parties:** Participant shall require each subcontractor or agent it intends to grant access to the Protected Data to agree to materially the same terms of this MOU in writing.

- G. **No Third-Party Beneficiaries:** Nothing express or implied in the terms and conditions of this MOU is intended to confer, nor shall anything herein confer, upon any person other than CDPH or Participant and their respective successors or assignees, any rights, remedies, obligations or liabilities whatsoever.
- H. **Return or Destruction of Protected Data on Expiration or Termination:** Upon expiration or termination of the MOU between Participant and CDPH for any reason, Participant shall securely return or destroy the Protected Data. If return or destruction is not feasible, Participant shall provide a written explanation to CDPH using the contact information listed in Paragraph 4. When the Protected Data is no longer needed, the MOU has terminated, or any retention period has expired, it must be sanitized. All electronic or physical forms of Protected Data must be sanitized using NIST Special Publication 800-88 standard methods for data sanitization.
- I. **Survival:** If Participant does not return or destroy the Protected Data upon the completion or termination of the MOU, the respective rights and obligations of Participant under clauses D, E, and H of this Paragraph shall survive the completion or termination of the MOU between Participant and CDPH.
- J. **No HIPAA Business Associate Agreement or Relationship Between CDPH and Participant:** This MOU and the relationship it memorializes between CDPH and Participant do not constitute a business associate agreement or business associate relationship pursuant to Title 45 of the Code of Federal Regulations, Part 160.103 (definition of "business associate"). Accordingly, this MOU is neither intended to, nor at any time shall result in, nor shall be interpreted or construed by the parties as to create a business associate relationship between CDPH and Participant. By signing this MOU, CDPH and Participant expressly disclaim the existence of any business associate relationship.

## 9. Indemnification

Participant agrees to indemnify, defend, and save harmless the State of California, CDPH, and CDPH Antigen Testing Laboratories and their respective officers, agents and employees from any and all claims and losses accruing or resulting from Participant's breach of this MOU, or Participant's negligence or willful misconduct related to the performance of this MOU.

## 10. Avoidance of Conflict of Interest by Participant:

- A. CDPH intends to avoid any real or apparent conflict of interest on the part of the Participant, subcontractors, or employees, officers and directors of the Participant or subcontractors. Thus, CDPH reserves the right to determine, at its sole discretion, whether any information, assertion or claim received from any source indicates the existence of a real or apparent conflict of interest; and, if a conflict is found to exist, to require the Participant to submit additional information or a plan for resolving the conflict, subject to CDPH review and prior approval.
- B. Conflicts of interest include, but are not limited to:
1. An instance where the Participant or any of its subcontractors, or any employee, officer, or director of the Participant or subcontractor has an interest, financial or otherwise, whereby the use or disclosure of information obtained while performing services under this MOU would allow for private or personal benefit or for any purpose that is contrary to the goals and objectives of this MOU.
  2. An instance where the Participant's or any subcontractor's employees, officers, or directors use their positions for purposes that are, or give the appearance of being, motivated by a desire for private gain for themselves or others, such as those with whom they have family, business or other ties.
- C. If CDPH is or becomes aware of a known or suspected conflict of interest, the Participant will be given an opportunity to submit additional information or to resolve the conflict. A Participant with a suspected conflict of interest will have five (5) working days from the date of notification of the conflict by CDPH to provide complete information regarding the suspected conflict. If a conflict of interest is determined to exist by CDPH and cannot be resolved to the satisfaction of CDPH, the conflict will be grounds for terminating this MOU. CDPH may, at its discretion upon receipt of a written request from the Participant, authorize an extension of the timeline indicated herein.

## **11. Dispute Resolution**

Any dispute concerning a question of fact arising under the terms of this MOU that is not disposed of within fifteen (15) calendar days by the Participant and State employees normally responsible for the administration of this MOU shall be brought to the attention of the designated representative for the Participant and the Deputy Director CDPH (or designated representative) for joint resolution.

## **12. Execution**

This MOU may be executed in counterparts with the same force and effectiveness as though executed in a single document. The parties agree that an electronic copy of a signed agreement, or an electronically signed agreement, has the same force and legal effect as an agreement executed with an original ink signature. The term “electronic copy of a signed agreement” refers to a transmission by facsimile, electronic mail, or other electronic means of a copy of an original signed agreement in a portable document format. The term “electronically signed agreement” means an agreement that is executed by applying an electronic signature using technology approved by the State.

*In witness whereof, this Memorandum of Understanding has been executed by the parties hereto:*

**California Department of Public Health**

By \_\_\_\_\_

Print name: Sabel Davis

Title: Testing Task Force Lead Contract Analyst

Date \_\_\_\_\_

In Process

**Participant**

Print Participant's full legal name \_\_\_\_\_

By \_\_\_\_\_

Print name \_\_\_\_\_

Title \_\_\_\_\_

Date \_\_\_\_\_