

Memorandum of Understanding
Of guidelines for local entities and community groups who would like to send collected
samples to the CDPH Valencia Branch State Public Health Laboratory for COVID-19 testing

Recitals

- A. WHEREAS, California is facing a pandemic arising from the spread of the novel coronavirus (COVID-19), including an anticipated surge in the number of people in California who are infected and have COVID-19 (the "Pandemic");
- B. WHEREAS, in response to the Pandemic, the Governor issued a Proclamation of State of Emergency dated March 4, 2020 and Executive Order (EO) N-25-20 dated March 12, 2020, and subsequent Executive Orders (collectively, and as may be further expanded from time to time, the "Emergency Declaration and Executive Order"), and the State Public Health Officer has issued State Public Health Officer Orders;
- C. WHEREAS, all agencies of the state government are required to perform any and all activities consistent with the direction of the State, pursuant to the Emergency Declaration and Executive Order;
- D. WHEREAS, the California Department of Public Health (CDPH) has determined that the capacity to test and the wait time for results has been significantly affected due to supply chain issues;
- E. WHEREAS, The CDPH Testing Taskforce has determined that increased testing and results response time is key to combating COVID;
- F. WHEREAS, the State of California, through CDPH Agreement 20-10586, has contracted with PerkinElmer in order to expand the State's capacity to respond to the Pandemic by providing laboratory equipment, software, and supplies necessary to increase capacity for laboratory testing of SARS-CoV-2, all equipment utilized for this agreement is proprietary;
- G. WHEREAS, PerkinElmer has received emergency use authorization by the federal Food and Drug Administration for its "PerkinElmer New Coronavirus Nucleic Acid Detection kit" which tests for SARS-CoV-2 in any individual, including individuals without symptoms or other reasons to suspect COVID-19 infection.
- H. WHEREAS, PerkinElmer, has contracted with Color to provide a software platform in order to help enable individuals to access SARS-CoV-2 testing and provide local entities and community groups and easy to use system for managing the data associated with sample collection, including registration, intake, and results reporting, and such software platform utilized for this agreement is proprietary;
- I. WHEREAS, CDPH's Valencia Branch State Public Health Laboratory, which is licensed as "CDPH Branch Laboratory" has been created to provide essential laboratory testing of specimens for SARS-CoV-2, and the State has contracted with PerkinElmer to run those tests at CDPH's Valencia Branch State Public Health Laboratory;

- J. WHEREAS, the State of California through CDPH Agreement 20-10727 has contracted with Color in order to expand the State’s capacity to respond to the Pandemic by providing sample collection kits and shipping materials to help increase capacity for sample collection for SARS-CoV-2 in sites throughout the State;
- K. WHEREAS, local entities and community groups who would like to send collected samples to the CDPH’s Valencia Branch State Public Health Laboratory for SARS-CoV-2 testing may do so upon agreeing to comply with the terms, conditions and requirements set forth in this Memorandum of Understanding.
- L. WHEREAS, the local entity or community group signing below as Provider (Provider) desires to send collected samples to the CDPH’s Valencia Branch State Public Health Laboratory for SARS-CoV-2 testing and hereby enters into this Memorandum of Understanding to agree to comply with the terms, conditions and requirements set forth herein.

1. Term

A. The term of the Agreement 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 provisions of this Agreement, either party may terminate this agreement or cancel a portion of the service for any reason with thirty (30) days written notice.

2. Service Overview

The Provider shall comply with the scope, the terms, conditions and requirements set forth herein for the laboratory testing of samples by the CDPH’s Valencia Branch State Public Health Laboratory for SARS-CoV-2, and with the requirements and system developed by PerkinElmer, either itself or through its subcontractors, for participant registration, specimen labelling, packaging, handling and transportation, and results return, incorporated herein.

3. Service Location

The services shall be performed at CDPH’s Valencia Branch State Public Health Laboratory located at 28454 Livingston Avenue, Valencia, CA 91355.

4. Project Representatives

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

<p>California Department of Public Health Sabel Davis Telephone: 916-865-8717 E-mail: sabel.davis@cdph.ca.gov</p>	<p>Provider: <input type="text" value="County of Santa Barbara"/> Contact manager: <input type="text" value="Maria Elena De Guevara"/> Telephone: <input type="text" value="805-568-2817"/> Fax: <input type="text" value="805-568-2833"/> E-mail: <input type="text" value="ytorres@sbcountyhr.org"/></p>
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B. Direct all inquiries to:

California Department of Public Health Testing Task Force Attention: Sabel Davis Telephone: 916-865-8717 E-mail: testing.taskforce@state.ca.gov	Provider name: County of Santa Barbara Section or Unit: County Human Resources Attention: Yvonne Torres Street address 1226 Anacapa Street Santa Barba, CA 931101 Telephone: 8054502285 Fax: 805-568-2833 E-mail: ytorres@sbcountyhr.org
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5. Services to be Performed by CDPH’s Valencia Branch State Public Health Laboratory

A. Laboratory testing of samples for SARS-CoV-2.

CDPH’s Valencia Branch State Public Health laboratory shall perform laboratory testing of collected samples for SARS-CoV-2 using equipment and supplies provided by PerkinElmer on behalf of CDPH. PerkinElmer will operate the laboratory equipment to perform the testing for SARS-CoV-2 including, but not limited to, extraction of nucleic acids from samples, preparation of samples for reverse transcriptase polymerase chain reaction (RT-PCR), and running samples on a PCR machine to detect the presence of SARS-CoV-2.

Samples will be tested only for SARS-CoV-2, unless an Emergency Use Authorization is granted for a Flu pack including SARS-CoV-2, Influenza A, Influenza B, and RSV.

B. Management of participant registration data and delivery of test results

CDPH, via Color as its contractor under CDPH Contract 20-10727, will provide sample collection kits and shipping materials necessary for collecting samples at each testing site and shipping them to the laboratory based on requests made by the Provider and approved by CDPH.

PerkinElmer, via Color as its contractor, shall provide software to each Provider for participant registration, intake, and association of the participant file with the specimen on behalf of PerkinElmer and CDPH. PerkinElmer, via Color as its contractor, will provide each Provider user of the software with training materials and access to support for troubleshooting.

PerkinElmer, via Color as its contractor, agrees to notify patients that test results are available through SMS and/or email message, within 48 hours after the specimen to be tested is received at CDPH’s Valencia Branch State Public Health Laboratory.

PerkinElmer, via Color as its contractor, agrees to report test results to CDPH pursuant to 17 CCR 2505 within 48 hours after the specimen to be tested is received at CDPH's Valencia Branch State Public Health Laboratory.

C. Records

1. Provider must provide PE and CDPH with the relevant medical records and laboratory records of any and all samples sent to CDPH's Valencia laboratory for testing, and PE must maintain the records in accordance with CLIA and state lab laws.

6. Payment and Billing

Unless otherwise agreed to in writing, CDPH will be responsible for the costs for laboratory testing of collected samples at the Valencia Branch State Public Health Lab, and 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 Providers will not balance bill patients for amounts billed to but not paid by Third Party Payers.

The State intends to cover the costs of, and seek reimbursement for, all costs of lab processing at the Valencia Branch State Public Health Lab. The parties will bear their own costs in providing services under this MOU, unless otherwise agreed to in writing. 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 Providers will not balance bill patients for amounts billed to but not paid by Third Party Payers.

7. Provider's agreement and obligations to label, handle, package and provide transportation of the samples in compliance with PerkinElmer specifications

Providers agree to follow all requirements and instructions for collection, labelling, handling, packaging and transportation of the specimens (i.e., type of swabs, tubes, etc.) by Provider to CDPH's Valencia Branch State Public Health Laboratory as provided by PerkinElmer, CDPH or Color.

8. Indemnification

Provider agrees to indemnify, defend, and save harmless the State, PerkinElmer, Color, and their respective officers, agents and employees from any and all claims and losses accruing or resulting from Provider's breach of this Agreement, negligence, or willful misconduct

9. Confidentiality of Information:

- A. The Provider and its employees, agents, or subcontractors shall protect from unauthorized access, use, or disclosure names and other personally identifying information and/or protected health information concerning persons either receiving services pursuant to this Agreement or persons whose names or identifying information become available or are disclosed to the Provider, its employees, agents, or subcontractors as a result of services performed under this Agreement, except as required or permitted by state or federal law.
- B. For purposes of this provision, identity shall include, but not be limited to name, identifying number, symbol, or other identifying particular assigned to the individual, such as finger or voice print or a photograph.
- C. As deemed applicable by CDPH, this provision may be supplemented by additional terms and conditions covering protected health information (PHI) or personal, sensitive, and/or confidential information (PSCI). Said terms and conditions will be outlined in one or more exhibits that will either be attached to this Agreement or incorporated into this Agreement by reference.

10. Avoidance of Conflict of Interest by Provider:

- A. CDPH intends to avoid any real or apparent conflict of interest on the part of the Provider, subcontracts, or employees, officers and directors of the Provider 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 Provider 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 Provider or any of its subcontractors, or any employee, officer, or director of the Provider or subcontractor has an interest, financial or otherwise, whereby the use or disclosure of information obtained while performing services under this Agreement would allow for private or personal benefit or for any purpose that is contrary to the goals and objectives of this Agreement.
 - 2. An instance where the Provider'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 Provider will be given an opportunity to submit additional information or to resolve the conflict. A Provider 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 Agreement. CDPH may, at its discretion upon receipt of a written request from the Provider, authorize an extension of the timeline indicated herein.

11. Intellectual Property

CDPH, PerkinElmer, and Color retain all right, title and interest in and to their respective proprietary technology, processes, procedures and tools used to perform the services under this Agreement, and all intellectual property rights therein, including but not limited to all modifications, enhancements, improvements and derivative works thereto (collectively, the "IP"). No title to or ownership of the IP are transferred to the Provider in connection with this Agreement.

12. Dispute Resolution


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

13. Execution


This Memorandum of Understanding 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 9/20/2021

Provider

Print Provider's full legal name
County of Santa Barbara
By 
Title Director of Human Resources
Date 9/20/2021