

COVIDNet Participation Agreement

This COVID Network of California Laboratories for SARS-CoV-2 Whole Genome Sequencing (“COVIDNet”) Participation Agreement (“Agreement”) sets forth the understandings and obligations of the **County of Monterey Public Health [Laboratory]** (“Participant”), and the California Department of Public Health (“CDPH”) (collectively, “Parties”) with respect to their participation in COVIDNet. Participant shall check all applicable boxes in Section IV of this Agreement to indicate their involvement in COVIDNet.

- I. **Supersession:** This Agreement supersedes any prior COVIDNet Agreement between CDPH and Participant.
- II. **Definitions:** For purposes of this Agreement, the following definitions shall apply:
 - a. **COVID-19 Specimen:** “COVID-19 Specimen” means a respiratory or other medical specimen that was tested by industry standard practices for SARS-CoV-2 virus where this virus was detected (i.e., a SARS-CoV-2 positive specimen).
 - b. **Diagnostic Testing Lab:** “Diagnostic Testing Lab” means a CLIA-certified laboratory within California which is authorized to test specimens originating from California that can provide COVID-19 Specimens and/or Samples to a Sequencing Lab, as defined herein, either directly or indirectly through a Processing Lab, as defined herein.
 - c. **Disclosure:** “Disclosure” means the release, transfer, provision of, access to, or divulging in any other manner of information.
 - d. **COVIDNet Partner Data:** “COVIDNet Partner Data” means any COVID-19 Specimen and/or Sample, as defined herein, received by Participant either from or belonging to another COVIDNet participant, as well as any information or data associated with the COVID-19 Specimen and/or Sample, including the date of collection and 3-digit zip code.
 - e. **Participant Data:** “Participant Data” means any COVID-19 Specimen and/or Sample, as defined herein, received from Participant and any information or data associated with the Sample, including the date of collection and 3-digit zip code.
 - f. **Processing Lab:** “Processing Lab” means a California laboratory which can provide the viral RNA extract or Sample, as defined herein, from a COVID-19 Specimen.
 - g. **Sample:** “Sample” means the extracted total nucleic acid or viral RNA from a SARS-CoV-2 specimen.
 - h. **Sample Code or Coded Identifier:** “Sample Code” or “Coded Identifier” means a de-identified unique identifier which corresponds to a specific COVID-19 Specimen.

- i. Sequencing: “Sequencing” as used herein denotes the process performed by a Sequencing Lab, as defined herein, to determine the order of nucleotides from a Sample, as defined herein.
- j. Sequencing Lab: “Sequencing Lab” means CDPH, Biohub, or another California laboratory member of COVIDNet which will provide genomic sequencing of COVID-19 Samples.
- k. Use: “Use” means the sharing, employment, application, utilization, examination, or analysis of information.
- l. Workforce Member: “Workforce Member” means an employee, agent, volunteer, trainee, or other person whose conduct, in the performance of work for Participant, is under the direct control of Participant, whether or not they are paid by Participant.

III. Background and Purpose:

CDPH seeks to conduct and/or facilitate whole genome sequencing (“WGS”) of COVID-19 Specimens in order to better inform outbreak investigations and public health surveillance. COVIDNet strives to transform how laboratory scientists and epidemiologists approach the detection, characterization, and investigation of SARS-CoV-2 virus transmission and containment, allowing California health jurisdictions to better trace and track outbreaks, including those that would have previously gone undetected, in order to inform public health action pursuant to Health and Safety Code section 100325. COVIDNet will use WGS data to generate and maintain a timely and sufficiently comprehensive phylogenetic tree of California SARS-CoV-2 viruses through the COVIDNet partnerships and apply such data for use as warranted for local outbreaks and contact tracing investigations.

IV. Participant Responsibilities:

A. General Requirements: Participant agrees to:

1. Work cooperatively with CDPH and all COVIDNet Participants;
2. Communicate with CDPH and COVIDNet Participants, as needed, any obstacles, barriers, or hindrances that will or may impede fulfilling COVID-19 Specimen Processing or Sequencing in the agreed upon timeframe; and
3. Comply with CDPH instructions for transporting specimens to CDPH for sequencing, and to provide requested metadata to CDPH regarding specimens submitted for sequencing.

B. Diagnostic Testing Lab: Participant shall serve as a Diagnostic Testing Lab, as defined above, for COVIDNet. Participant agrees:

1. Participant is a Diagnostic Testing Lab that is CLIA-certified and registered with the CDPH Laboratory Field Services as authorized to test specimens originating from California that has the ability to provide COVID-19 Specimens or Samples to CDPH for genomic sequencing;
2. Participant believes it can supply approximately 30 COVID-19 Specimen or Samples per month to CDPH to be sequenced. Participant and CDPH acknowledge this amount is an estimate and may be subject to change based on availability and condition of COVID-19 Specimens or Samples; and
3. Participant shall submit COVID-19 Specimens or Samples to CDPH for genomic sequencing. Participant is solely responsible for cost of transportation of Samples to CDPH. Participant shall ensure that the COVID-19 Specimens and/or Samples are properly handled and transported in accordance with industry standard practices for such Samples.

C. Processing Lab: Participant shall serve as a Processing Lab, as defined above, for COVIDNet.

1. Participant shall serve as its own Processing Lab. Participant agrees:
 - a) Participant shall follow industry standards in extracting total nucleic acid or viral RNA from the Specimen;
 - b) Participant is solely responsible for all costs associated with processing COVID-19 Specimen; and
 - c) Participant will either sequence resulting Samples (extracted total nucleic acid or viral RNA) or will ship Samples to CDPH for sequencing.
2. Participant is available to assist CDPH with total nucleic acid or viral RNA extraction. Participant agrees:
 - a) Participant shall work directly with CDPH to arrange transportation of COVID-19 Specimens to Participant's site for extraction of total nucleic acid or viral RNA from COVID-19 Specimens.

D. Sequencing Lab: Participant shall serve as a Sequencing Lab, as defined above, for COVIDNet.

1. Participant shall serve as its own Sequencing Lab. Participant agrees:

- a) Participant anticipates an ability to sequence approximately 30 Samples per month. Participant and CDPH acknowledge this amount is an estimate and may be subject to change based on availability and condition of Samples;
- b) Participant shall follow industry standards in sequencing Samples;
- c) Participant shall upload resulting raw sequence data files (either FASTQ or BAM files) to Terra cloud environment set up by CDPH or other mutually agreed upon sequence repository; and
- d) Participant is solely responsible for all costs associated with sequencing Specimen.

2. Participant is available to assist other COVIDNet participants with genomic sequencing. Participant agrees:

- a) Participant anticipates an ability to sequence approximately 30 Samples per month for other COVIDNet participants. Participant and CDPH acknowledge this amount is an estimate and may be subject to change based on availability and condition of Samples;
- b) Participant, and its workforce members and agents, shall not attempt re-identification of COVIDNet Partner Data, including utilization of any publicly available or non-publicly available sources;
- c) Participant shall work directly with CDPH and/or COVIDNet Diagnostic Testing Lab or Processing Lab that sends the Samples to be sequenced, including to arrange payment, transportation, and any legal agreements, when required; and
- d) Participant shall upload resulting raw sequence data files (either FASTQ or BAM files) to Terra cloud environment set up by CDPH or other mutually agreed upon sequence repository.

V. CDPH Responsibilities: To the extent practicable, CDPH shall be available for consultation with Participant regarding obligations under this Agreement, including sequencing, bioinformatics, and data analysis.

VI. COVIDNet Partner Data: If Participant receives COVIDNet Partner Data from participating COVIDNet labs, Participant, and their workforce members and agents, shall not attempt re-identification of COVIDNet Partner Data, including by using any publicly available or non-publicly available sources. Participant, and its workforce members and agents, shall safeguard the COVIDNet Partner Data to which they have access from unauthorized use. Participant, and its workforce members and agents, shall not use any COVIDNet Partner Data for any purpose other than carrying out the Participant's obligations under this Agreement, under a direct agreement with another COVIDNet participant, or as otherwise required by law. Participant shall implement administrative, physical, and technical safeguards that reasonably and appropriately protect the privacy, security, integrity, and availability of COVIDNet Partner Data.

VII. Key Contacts: The following individuals shall be responsible for overseeing their respective Party's performance under this Agreement:

A. For CDPH:

Debra A. Wadford, PhD
Chief, Viral and Rickettsial Disease Laboratory
Infectious Diseases Laboratory Branch
California Department of Public Health
Debra.Wadford@cdph.ca.gov
VRDL.Mail@cdph.ca.gov

B. For Participant:

Name: Donna Ferguson
Title: Laboratory Director
Organization: Monterey County Public Health Laboratory
Email Address: FergusonD@co.monterey.ca.us

VIII. Term of Agreement: Unless otherwise terminated earlier in accordance with the provisions set forth herein, this Agreement shall remain in effect for three (3) years after the latest signature date in the signature block below. After three (3) years, this Agreement will expire without further action. If the Parties wish to extend this Agreement, they may do so by reviewing, updating, and reauthorizing this Agreement. If one or both of the Parties wish to terminate this Agreement prematurely, they may do so upon 30 days advanced written notice to the Program Contact of the respective Party in Section VII. Any amendment to this Agreement shall be in writing signed by all Parties. Participant shall securely return, or upon CDPH approval, destroy any specimens/samples that they have received from other participants prior to termination of this agreement and certify in writing specimens have been securely returned or destroyed, including the date and method used. If return or destruction is not feasible, Participant shall provide a written explanation to CDPH.

- IX.** Indemnification: Participant hereby agrees to indemnify, hold harmless, and defend the CDPH from and against any and all claims, losses, liabilities, damages, costs and other expenses (including attorneys' fees) that result from or arise directly or indirectly out of or in connection with any negligent act or omission or willful misconduct of Participant, its officers, workforce members or agents relative to this Agreement.
- X.** Transfer of Rights: Participant has no right and shall not delegate, assign, or otherwise transfer or delegate any of its rights or obligations under this Agreement to any other person or entity. Any such transfer of rights shall be null and void.
- XI.** No Third-Party Beneficiaries: Nothing express or implied in the terms and conditions of this Agreement is intended to confer, nor shall anything herein confer, upon any person other than CDPH or Participant, any rights, remedies, obligations or liabilities whatsoever.
- XII.** Interpretation: The terms and conditions in this Agreement shall be interpreted as broadly as necessary to implement and comply with regulations and applicable State and Federal laws. The Parties agree that any ambiguity in the terms and conditions of this Agreement shall be resolved in favor of a meaning that complies and is consistent with Federal and State laws.
- XIII.** Survival: The respective rights and obligations of Participant under Sections VII and X of this Agreement shall survive the termination or expiration of this Agreement.
- XIV.** Entire Agreement: This Agreement, including all attachments, constitutes the entire agreement between CDPH and Participant. Any and all modifications of this Agreement must be in writing and signed by all Parties. Any oral representations or agreements between the Parties shall be of no force or effect.
- XV.** Severability: The invalidity in whole or in part of any provisions of this Agreement shall not void or affect the validity of any other provisions of this Agreement.
- XVI.** Choice of Law and Venue: The laws of the state of California will govern any dispute from or relating to this Agreement. The Parties submit to the exclusive jurisdiction of the state of California and federal courts for or in Sacramento and agree that any legal action or proceeding relating to the Agreement may only be brought in those courts.
- XVII.** Insurance Requirements: Without limiting the indemnification obligation of Participant as stated herein, it is understood and agreed that the Parties shall each maintain, at their sole expense, insurance policies or self-insurance programs including, but not limited to, an insurance pooling arrangement and/or Joint Powers Agreement including general liability, automotive liability, and professional, cyber, and workers' compensation. Evidence of insurance, e.g., Certificates of Insurance, public-liability letters, or other similar documentation, shall be provided at the request of either party under this Agreement. Each party shall provide a Waiver of Subrogation under the Worker's Compensation policy in favor of the other party as applicable to and available under that party's insurance program.

Parties understand and accept the following:

- A.** In accordance with Government Code section 11007.4, the State of California has elected to be self-insured for liability exposures. Under this form of insurance, the State and its employees acting in the course and scope of their employment are insured for tort liability arising out of official State business. All claims against the State of California based on tort liability should be presented as a government claim to the Government Claims Program, P.O. Box 989052 MS 414, West Sacramento, CA 95798-9052. (Gov. Code section 900, et. seq.) Internet link: <https://www.dgs.ca.gov/ORIM/Services/Page-Content/Office-of-Risk-and-Insurance-Management-Services-List-Folder/File-a-Government-Claim>.

- B.** The State of California has also elected to be insured for its motor vehicle liability exposures through the State Motor Vehicle Liability Self-Insurance Program (VELSIP). This program provides liability coverage arising out of the operations of motor vehicles used by state employees for official state business (California Vehicle Code Sections 17000 and 17001). Motor vehicle liability claims against the State of California should be presented to the Office of Risk and Insurance Management, P.O. Box 989052 MS-403, West Sacramento, CA 95798-9052, (800) 900-3634, claims@dgs.ca.gov. If your motor vehicle liability claim is not resolved within six months from the date of loss, California law requires you to file a formal claim with the Government Claims Program, P.O. Box 989052 MS 414, West Sacramento, CA 95798-9052. (Gov. Code section 900, et. seq.) Internet link: <https://www.dgs.ca.gov/ORIM/Services/Page-Content/Office-of-Risk-and-Insurance-Management-Services-List-Folder/File-a-Government-Claim>.

The State of California has a Master Agreement with the State Compensation Insurance Fund regarding workers' compensation benefits for all state employees, as required by the Labor Code.

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XVIII. Signatures:

IN WITNESS, WHEREOF, the Parties have executed this Agreement as follows:

On behalf of Monterey County [Participant], the undersigned individual hereby attests that he or she is authorized to enter into this Agreement and agrees to abide by and enforce all the terms specified herein.

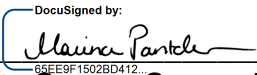
Elsa Jimenez, Director of Health (Print Name)

Date

Address:

Approved as to Form:

1270 Natividad Road

By:  Date: 6/23/2022 | 9:08 AM
Deputy County Counsel

Salinas, CA 93906

On behalf of CDPH, the undersigned individual hereby attests that he or she is authorized to enter into this Agreement and agrees to all the terms specified herein.

Paul Kimsey, PhD
Deputy Director, State Public Laboratory Director
Office of the State Public Health Laboratory Director
California Department of Public Health
850 Marina Bay Parkway
Richmond, CA 94804

Date

Return Executed Agreement to:

Debra A. Wadford, PhD
Chief, Viral and Rickettsial Disease Laboratory
Infectious Diseases Laboratory Branch
California Department of Public Health
850 Marina Bay Parkway
Richmond, CA 94804
Debra.Wadford@cdph.ca.gov