

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 individual.

- 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, in partnership with the Chan-Zuckerburg Biohub (“Biohub”), 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, 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, including providing consultation services related to COVIDNet;
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. To maintain patient privacy, any Sample that the Participant sends to a Sequencing Lab must be de-identified and assigned a “Sample Code” or “Coded Identifier”; the Participant must maintain a list of the Samples sent to the Sequencing Lab that will contain the Sample Code and all

accompanying information for each Specimen and provide to CDPH upon request.

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 Specimen or Samples for genomic sequencing;
2. Participant believes it can supply approximately ____ COVID-19 Specimen or Samples per month 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 Specimen or Samples;
3. Participant is responsible for ensuring proper Sample, as defined herein (total nucleic acid or viral RNA), is extracted from COVID-19 Specimen before sending the Specimen to Sequencing Lab; and
 - a) If Participant is unable to properly extract RNA, Participant shall utilize a Processing Lab to properly extract total nucleic acid or viral RNA from COVID-19 Specimen. Participant shall work directly with Processing Lab to arrange transportation of COVID-19 Sample to its designated Sequencing Lab and to execute any legal agreements, when required.
4. Participant shall submit Samples to Sequencing Lab for genomic sequencing. Participant is solely responsible for cost of transportation of Samples to the Sequencing Lab's designated location. Participant shall ensure that the 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 create a Sample Code for each Specimen and maintain a secure list or database of Specimens Processed and sent out for sequencing that includes the personally identifiable information corresponding to each coded Sample;

- b) Participant shall follow industry standards in extracting total nucleic acid or viral RNA from the Specimen;
- c) Participant is solely responsible for all costs associated with processing COVID-19 Specimen; and
- d) Participant certifies that all Samples sent to Sequencing Lab are solely for purposes of SARS-CoV-2 sequencing.

2. Participant is available to assist other COVIDNet participants with total nucleic acid or viral RNA extraction. Participant agrees:

- a) Participant shall work directly with Sequencing Lab to arrange transportation of COVID-19 Specimens and any legal agreements, when required.

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 _____ 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 report on a monthly basis the below data element for each Sample sequenced in a given month to the CDPH Program Contact in Section VIII. This report shall be sent no later than the 5th day of the following month.
 - 1. Coded identifier;
 - 2. Either a) a consensus viral genome sequence, or b) variant calls relative to the Wuhan-1 reference genome, and minor variant calls (if any), sent to CDPH via secure FTP site, if data volume is too large for email;
 - 3. 3-digit zip code from the individual from whom it was collected; and

4. Date of collection, de-identified when applicable to the de-identification guidelines below.

- d) Participant certifies that Participant Data is de-identified, and CDPH may disclose or publish Participant Data and information derived from Participant Data; and
- e) 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 _____ 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; and
- c) Participant shall work directly with 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.
- d) Participant shall report on a monthly basis the below data element for each Sample sequenced in a given month to the CDPH Program Contact in Section VIII. This report shall be sent no later than the 5th day of the following month.
 - 1. Coded identifier;
 - 2. Either a) a consensus viral genome sequence, or b) variant calls relative to the Wuhan-1 reference genome, and minor variant calls (if any), sent to CDPH via secure FTP site, if data volume is too large for email;
 - 3. 3-digit zip code from the individual from whom it was collected; and

4. Date of collection, de-identified when applicable to the de-identification guidelines below.

E. Training: Participant, and its workforce members, agree to train and/or assist develop training for other participating COVIDNet laboratories to sequence the genome and/or analyze resultant data thereof. Participant agrees that all training and consultation for training are provided on a voluntary basis. Participant is solely responsible for all costs associated with training.

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, modeling, and COVIDNet.

VI. De-Identified Participant Data: Participant Data shall be de-identified (as defined in 45 C.F.R. § 164.514) in accordance with the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule prior to submitting Samples to a Sequencing Lab. Each Sample shall be assigned a Coded Identifier by Participant prior to Participant submitting the de-identified Samples. Each de-identified sample shall also include the Sample's collection date and first 3 digits of the zip code associated with the Sample. However, when there are less than five (5) Samples from the same 3-digit zip code with the same collection date, Participant shall choose a randomly selected date to be reflected for all samples in order to preserve an adequate level of de-identification. Participant will not subsequently provide any information that could be used to re-identify samples.

VII. 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.

VIII. 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

- IX.** Term of Agreement: Unless otherwise terminated earlier in accordance with the provisions set forth herein, this Agreement shall remain in effect for one (1) year after the latest signature date in the signature block below. After one (1) year, 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 VIII. Any amendment to this Agreement shall be in writing signed by all Parties.
- X.** 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.
- XI.** 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.
- XII.** 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.
- XIII.** 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.
- XIV.** 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.
- XV.** 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.

- XVI.** 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.
- XVII.** 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.

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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.

DocuSigned by:

C7A3DBA59CA8423

12/22/2020 | 1:50 PM PST

Elsa Jimenez, Director of Health (Print Name)

Date

Address:

1270 Natividad Road

Salinas, CA 93906

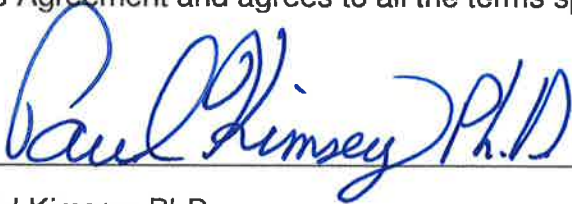
DocuSigned by:

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Marina Pantchenko

Deputy County Counsel

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.



January 27, 2021

Date

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

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