State of California—Health and Human Services Agency
California Department of Public Health

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Director and State Public Health Officer

GAVIN NEWSOM
Governor

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Dear Laboratory Colleagues,

The data provided by laboratories continue to be a critical component of California's COVID-19 pandemic response. The California Department of Public Health (CDPH), in consultation with the California Conference of Local Health Officers, has updated Title 17 of the California Code of Regulations (17 CCR), section 2505 with subsection (q) to require the 1) reporting of variants of public health importance and 2) submission of SARS-CoV-2 sequence data. This information allows public health professionals to better understand the genetic diversity, spread, and evolution of SARS-CoV-2, including variant lineages.These new requirements apply to both Clinical Laboratory Improvement Amendments (CLIA) and non-CLIA certified laboratories and **go into effect immediately**. Data must be submitted for all SARS-CoV-2 genomic sequencing done beginning (July 7, 2021). Instructions for meeting each requirement can be found below.

In addition, 17 CCR section 2505 (p), effective April 9, 2021, specifies that upon request by the state or local health department, laboratories are required to submit SARS-CoV-2 specimens and/or nucleic acid extracts to the state or local public health laboratory.

1) Requirement to Report SARS-CoV-2 Variants of Public Health Importance to CalREDIE

- Information about all strains (lineages) of SARS-CoV-2 is needed to monitor the virus in California. Therefore, ALL strains (lineages) of SARS-CoV-2 are of public health importance and reportable. This allows public health officials to monitor and understand the genetic diversity and evolution of SARS-CoV-2.
- Results for all specimens sequenced by the laboratory must be sent via electronic laboratory reporting (ELR) via HL7 ELR 2.5.1 message
    - These results should be reported as a follow-up to the original positive viral test, if information regarding the original test result is available.
    - Reports should include all of the original patient demographic data (including but not limited to **First Name, Last Name, Middle Initial, Date of Birth, Gender, and Full Address** as specified in 17 CCR section 2505 (c)) along with both the original viral diagnostic test report content

(including but not limited to **CLIA number of original testing lab and Accession number of original specimen).**
    - The **sequencing test report should provide the SARS-CoV-2 variant lineage identified**.
    - Results must be **reported within seven (7) working days of sequence analysis completion.**
    - If the sequence data has already been submitted to GISAID or NCBI, please include the associated GISAID/NCBI numbers.
- Technical guidance for reporting variant results via ELR can be found here: https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/reporting-sequencing-guidance.html.
- Questions about reporting variant results can be sent to calredieelr@cdph.ca.gov.

2) Requirement to Submit SARS-CoV-2 Sequence Data

- For laboratories that do not provide GISAID or NCBI reference numbers by ELR, as instructed above, or laboratories that have not submitted data to GISAID or NCBI, the raw sequence data files in the form of BAM or FASTQ files must be transmitted to CDPH, with attendant metadata, in a secured/encrypted manner via SFTP as outlined below.

- Additionally, for sequence data submissions rejected by GISAID or NCBI, the raw sequence data files, in the form of BAM or FASTQ files, must be transmitted to CDPH, with attendant metadata in a secured/encrypted manner via SFTP as outlined below. CDPH will address causes of data rejection and re-submit sequences to GISAID and/or NCBI in compliance with de-identification guidelines. If needed, further bio-informatic analysis will be performed using provided raw sequence data files.

- Via SFTP, sequence data should include or be accompanied by the following information (metadata):
    1. Name of whole genome sequencing (WGS) laboratory
    2. Name of original diagnostic testing laboratory
    3. Date diagnostic test results were reported
    4. Date specimen received by original diagnostic laboratory
    5. Unique accession number associated with original diagnostic testing laboratory
    6. Specimen collection date
    7. County of original submitter
    8. County of residence of the patient from whom the specimen was obtained
    9. Analytical parameters (library prep method, sequencing prep method)

10. Sequences rejected by GISAID/NCBI – indicate YES or NO

Laboratories must submit BAM or FASTQ files to CDPH within one (1) week **of sequencing completion** via SFTP.

- To obtain an SFTP account, laboratories must register with CDPH COVIDNet at COVIDNet.Registration@cdph.ca.gov.
- Questions about submitting SARS-CoV-2 sequence data can be sent to COVIDNet.TechSupport@cdph.ca.gov.

We sincerely appreciate the extraordinary work our laboratory partners have undertaken over the last year.

Sincerely,

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