

ORDER OF THE HEALTH OFFICER FOR CONTROL OF COVID-19

SARS-CoV-2 Data Sharing and Reporting Order Issued: September 27, 2021

This Order is in effect until rescinded by the Health Officer.

Summary: California and local law empower the County of Los Angeles Health Officer (Health Officer) to take preventive measures necessary to protect the public from a public health hazard due to infectious disease including during a State of Emergency. The spread of COVID-19 poses a substantial danger to the health of the public of Los Angeles County. This Health Officer Order is issued with the intent of strengthening COVID-19 surveillance and reporting activities, which can help to slow the spread of this deadly disease.

COVID-19 is caused by a coronavirus known as SARS-CoV-2. Whole genome sequencing (WGS) (i.e., determining the virus' complete DNA sequence) and molecular testing of this virus provide high-resolution data that are instrumental to efforts to investigate viral pathogen genomes; understand outbreaks; monitor re-infection events; and identify mutations that may affect transmissibility, diagnosis, and medical countermeasures. Analysis of SARS-CoV-2 WGS data has led to important findings that have contributed to the development of diagnostic, treatment, control, and mitigation efforts. For example, WGS has been used to identify specific virus strains that are associated with outbreak clusters, develop molecular assays for COVID-19 testing, and guide the development of therapeutics and vaccines. Results of WGS and molecular testing can also impact public health decision making.

This Health Officer Order requires entities that are performing SARS-CoV-2 sequencing and molecular testing on specimens collected from residents of the Los Angeles County Public Health Jurisdiction to register with the Los Angeles County Department of Public Health (LAC DPH), report information about sequenced samples as directed, report findings of public health significance, and submit specimens upon request. It also encourages these entities to provide public access to WGS data. The World Health Organization (WHO) strongly supports making these data publicly available, to strengthen research efforts and inform public health decision-making during outbreaks.ⁱ

UNDER THE AUTHORITY OF CALIFORNIA HEALTH AND SAFETY CODE SECTIONS 101040, 101085, AND 120175, THE HEALTH OFFICER ORDERS THE FOLLOWING:

1) Registration with the Los Angeles County Department of Public Health

Any research or diagnostic laboratory, academic institution, or other entity ("Entity") that is performing whole genome sequencing for SARS-CoV-2 (COVID-19) and/or Polymerase Chain Reaction (PCR), molecular, or sequencing-based surveillance for variants of SARS-CoV-2 (COVID-19) on patient specimens collected from residents of the Los Angeles County Public Health Jurisdiction must register with LAC DPH within 14 days of the issuance of this Order and thereafter, annually submit updated registration information per instructions provided by LAC DPH.



2) SARS CoV-2 Sequences and Findings of Urgent Public Health Concern

Effective immediately, any research or diagnostic laboratory, academic institution, or other entity ("Entity") that is performing whole genome sequencing for SARS-CoV-2 (COVID-19) and/or PCR, molecular, or sequencing-based surveillance for variants of SARS-CoV-2 (COVID-19) on patient specimens collected from residents of the Los Angeles County Public Health Jurisdiction must, upon request, provide LAC DPH with information regarding sequenced samples, including associated patient information when available. Entity must provide any sequencing results that are requested, including results from specimens that were sequenced prior to issuance of this Health Officer Order. When requested, the Entity must report this information in an electronic format specified by LAC DPH, per the timeline specified by LAC DPH.

The Entity must report any suspected outbreak of COVID-19 that is identified based on coordinated specimen collection, detection of clusters of closely related specimens, or other analyses. The Entity must also report findings of urgent public health concern, including but not limited to, the Entity's first identification of a known <u>variant of concern, interest, and/or high consequence</u> in Los Angeles County. These findings must be reported within 1 working day to LAC DPH by phone (888-397-3993 or 213-240-7821) or electronically per instructions provided by LAC DPH.

3) Submission of SARS-CoV-2 Specimens

Effective immediately, if requested, any research or diagnostic laboratory, academic institution, or other entity ("Entity") that identifies SARS-CoV-2 (COVID-19) from patient specimens collected from residents of the Los Angeles County Public Health Jurisdiction is required to submit specimens to the LAC DPH Public Health Laboratories. Entity must include specimen CT or RLU value and identifiable patient information related to the specimen submission such as name, date of birth, date of collection, medical record number, address of residence, email address, and phone number when available.

4) Whole Genome Sequencing Data Repository

Any research or diagnostic laboratory, academic institution, or other entity ("Entity") that is performing whole genome sequencing for SARS-CoV-2 (COVID-19) on specimens collected from residents of the Los Angeles County Public Health Jurisdiction is strongly encouraged to make the WGS data publicly accessible. When sequence data meet acceptance standards for upload, the Entity should upload de-identified complete viral genomic sequence data within 7 days of the date that they become available into, at a minimum, the following publicly accessible repositories:

- Global Initiative on Sharing All Influenza Data (GISAID). When uploading sequences
 into GISAID, the metadata file should include "Location" column field information to
 the County level (i.e., North America / USA / California / Los Angeles County).
- National Center for Biotechnology Information (<u>NCBI</u>) GenBank. When uploading sequences into GenBank, the Entity should select SARS-CoV-2 submission and during the Source Modifier step, specify "USA: California, Los Angeles County" in the "Country" column.



For each sequence submitted, within 7 days of the date that results become available, Entity should submit the GISAID and GenBank accession number, along with specified corresponding patient identifiers when available, to LAC DPH electronically per instructions provided by LAC DPH.

These actions are required because they will enable the Los Angeles County Department of Public Health and other stakeholders to identify which SARS-CoV-2 virus strains are spreading locally, in the state, and in the nation, which will support the development of targeted strategies, diagnostics, and therapeutics.

5) Additional Terms

- a. If any subsection, sentence, clause, phrase, or word of this Order or any application of it to any person, structure, gathering, or circumstance is held to be invalid or unconstitutional by a decision of a court of competent jurisdiction, then such decision will not affect the validity of the remaining portions or applications of this Order.
- b. The violation of any provision of this Order constitutes an imminent threat and creates an immediate menace to public health, safety, and welfare. To protect the public's health, the County Health Officer may take additional action(s) for failure to comply with this Order.
- c. Violation of this Order is a misdemeanor punishable by imprisonment, fine or both under California Health and Section Code Section 120275 et seq and Los Angeles County Code Section 11.02.080.

This Order will remain in effect until rescinded, superseded, or amended in writing by the Health Officer.

If you have any questions about this Order, please call the LAC DPH Public Health Laboratories Director at (562) 658-1330.

For updated COVID-19 guidance and reference documents, please visit the LAC DPH website: http://ph.lacounty.gov/Coronavirus.

IT IS SO ORDERED:		
Yunga Ded Mo, all H	9/27/2021	
Muntu Ďavis, M.D., M.P.H.	Date	
Health Officer,		
County of Los Angeles		



RESOURCES

- Global Initiative on Sharing All Influenza Data (GISAID) https://www.gisaid.org
- National Center for Biotechnology Information (NCBI), National Library of Medicine https://www.ncbi.nlm.nih.gov/sars-cov-2
- Emerging SARS-CoV-2 Variants
 Centers for Disease Control and Prevention
 https://www.cdc.gov/coronavirus/2019-ncov/more/science-and-research/scientific-brief-emerging-variants.html
- SARS-CoV-2 Sequencing for Public Health Emergency Response, Epidemiology and Surveillance (SPHERES)
 Centers for Disease Control and Prevention https://www.cdc.gov/coronavirus/2019-ncov/covid-data/spheres.html
- Advanced Molecular Detection (AMD) Tools and Resources
 Centers for Disease Control and Prevention
 https://www.cdc.gov/amd/
- Genomic Epidemiology Data Infrastructure Needs for SARS-CoV-2:
 Modernizing Pandemic Response Strategies
 National Academies of Sciences, Engineering, and Medicine; Division on Earth and Life Studies; Board on Life Sciences; Health and Medicine Division; Board on Health Sciences Policy; Committee on Data Needs to Monitor Evolution of SARS-CoV-2 https://www.ncbi.nlm.nih.gov/books/NBK562778/
- SARS-CoV-2 Sequencing Data: The Devil Is in the Genomic Detail
 American Society for Microbiology
 https://asm.org/Articles/2020/October/SARS-CoV-2-Sequencing-Data-The-Devil-Is-in-the-Genome-page-4
- Sequencing of SARS-CoV-2
 European Centre for Disease Prevention and Control
 https://www.ecdc.europa.eu/sites/default/files/documents/sequencing-of-SARS-CoV-2.pdf
- COVID-19 Resources for the Public and Providers
 Los Angeles County Department of Public Health
 http://ph.lacounty.gov/Coronavirus

i R&D Blueprint: Public consultation - Pathogen genetic sequence data (GSD). WHO's draft code of conduct for open and timely sharing of pathogen genetic sequence data during outbreaks of infectious disease. Geneva, Switzerland: World Health Organization; 2019. Available at: https://www.who.int/blueprint/what/norms-standards/GSDDraftCodeConduct_forpublicconsultation-v1.pdf?ua=1