

SARS-CoV-2 Whole Genome Sequencing

The LA County Health Officer issued an Order on September 27, 2021 requiring 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 Los Angeles County Department of Public Health (LACDPH), report information about sequenced samples as directed, report findings of public health significance, and submit specimens upon request. This Frequently Asked Questions (FAQ) document provides additional guidance to entities performing SARS-CoV-2 sequencing on the implementation of the Order.

1. Why is LACDPH asking for this information?

- Knowing the prevalence of circulating variants of interest/concern/high consequence can help Public Health, healthcare providers, and the public better understand the local epidemiology of COVID-19.
- Linking sequence information with routinely collected surveillance data can help Public Health detect the next potential variant of interest/concern.
- Having more sequenced isolates from an outbreak can help Public Health better map the chain of transmission and identify potential exposures.
- Ultimately, having more granular information on COVID-19 cases and outbreaks can inform Public Health policies and programs to prevent additional cases.

2. Which laboratories are covered by this Order?

All laboratories conducting testing to identify COVID-19 variants are expected to comply with the Order. This includes 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 LACDPH jurisdiction.

3. How can laboratories conducting SARS-CoV-2 sequencing on LA County residents register with LACDPH?

- The registration form is available as a REDCap form via the following link:
<https://dphredcap.ph.lacounty.gov/surveys/?s=NAKKXYR977>
- After registering with LACDPH, a liaison will coordinate a process for each laboratory to submit required data to LACDPH.

4. If requested by LACDPH, how can laboratories submit sequencing data to LACDPH?

- Laboratories are required to submit the assembled genomic data as FASTA or sequence alignment data as BAM files within 7 days.
- DPH will coordinate directly with each lab to establish a mechanism for electronic secure file transfer protocol (SFTP).
- Alternatively, laboratories can meet this requirement to provide sequence data by uploading the sequence information into GISAID or NCBI and providing LACDPH with the accession number and corresponding patient information (please see below for additional information).

SARS-CoV-2 Whole Genome Sequencing

5. Are laboratories expected to retain specimens that test positive for SARS-CoV-2 in case LACDPH might request it?

No. LACDPH does not expect laboratories to systematically and routinely store specimens. It is anticipated that specimens will be requested in the following scenarios:

- I. LACDPH is aware of planned testing in an outbreak.
 - a. LACDPH will obtain a line list with the names of persons to be tested.
 - b. LACDPH will provide that line list to the laboratory of the persons who were tested.
 - c. LACDPH will provide additional instructions to the laboratory ahead of planned testing on which specimen to retain and for how long.
 - d. LACDPH will follow-up with the laboratory within a pre-determined time period to request specimen; specimen not requested within that time period can be discarded.
- II. Laboratory has specimen readily available.
 - a. In a scenario where LACDPH is able to contact a laboratory before the specimen has been discarded, the laboratory might be requested to retain that specimen for a pre-determined period of time or transfer it to LAC Public Health Laboratory.

6. What if our laboratory does not collect or have access to the patient metadata associated with the SARS-CoV-2 sequence data?

Laboratories are expected to develop procedures to link patient metadata with the sequence data. At a minimum, laboratories are expected to provide LACDPH with First Name, Last Name, Date of Birth, Address of Residence. If available, laboratories must also provide Medical Record Number, Email Address, and Phone Number.

7. Does reporting lineage information and sequence data to the California Department of Public Health meet the LA County Health Officer Order's reporting requirements?

- Title 17 section 2505 (p) now requires all laboratories to report lineage information via electronic laboratory reporting (ELR) as an HL7 ELR 2.5.1 message. In addition, laboratories can submit SARS-CoV-2 sequence data in one of two ways to CDPH, either through a) GISAID or NCBI or b) raw data files directly to CDPH.
- If LACDPH is able to verify receipt of sequence information submitted to CDPH, then reporting CDPH alone can fulfill the requirements of this Order.
- Upon registration, LACDPH will work directly with each lab to establish the procedures for submitting sequence information in a manner that fulfills the requirements of the Order.

8. Does reporting lineage information and sequence data to LACDPH meet the Title 17 section 2505 (p) reporting requirement?

No. SARS-CoV-2 sequence data must be reported to CDPH as specified by Title 17 section 2505 (p).

SARS-CoV-2 Whole Genome Sequencing

9. Our laboratory identifies variants of concern or interest using a method that other than whole genome sequencing (RT-PCR or other molecular assays). Does this Order apply to us?

Yes. All variants of concern or interest detected by molecular methods need to be reported to LACDPH.

10. What is considered a finding of urgent public health concern?

- At a minimum, this would include the first detection of a variant of concern or variant of high consequence by each laboratory and all suspected outbreaks (based on multiple positive SARS-CoV-2 PCR results linked to a single location or phylogenetic analysis that suggests a recent common source of transmission).
- LACDPH encourages laboratories to err on the side of caution and discuss all potentially concerning results with LACDPH. We defer to the laboratory director's judgment on what could be considered concerning.

11. How can laboratories provide GISAID or NCBI accession numbers and associated patient metadata to LACDPH?

- After registering with LACDPH, a liaison will coordinate a process for each laboratory to submit required data to LACDPH.
- If reporting to CDPH is verified to meet local reporting requirements, laboratories will no longer be expected to directly report to LACDPH.

12. What are examples of suspected outbreak of COVID-19 that a sequencing laboratory might be expected to report?

- I. Examples of scenarios that should be reported to LACDPH:
 - a. A laboratory conducting geospatial analysis identifies a greater than expected number cases of the same lineage occurring within a defined geographic area and time period.
 - b. A laboratory conducting phylogenetic analysis identifies a cluster of closely related specimens.
- II. LACDPH encourages laboratories to use their judgment on what qualifies as a suspected outbreak as defined in this Order, and to err on the side of caution and report potential clusters or outbreaks when in doubt.