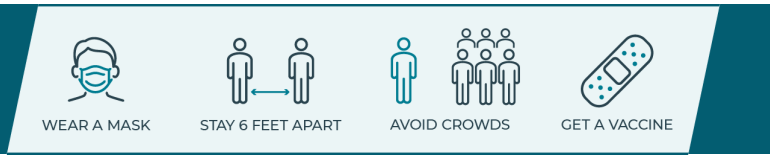
Centers for Disease Control and Prevention
CDC 24/7: Saving Lives, Protecting People™

COVID-19



Guidance for Reporting SARS-CoV-2 Sequencing Results

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Key Points

- CDC requests laboratories that are sequencing SARS-CoV-2 positive specimens to report those data to state, local, tribal, or territorial public health departments.
- The technical guidance provides detailed instructions and examples for how to report SARS-CoV-2 sequencing results to state, local, tribal, or territorial public health departments.

It is critically important for the nation's COVID-19 pandemic response to understand the genetic diversity, spread, and evolution of SARS-CoV-2, including variant viruses.

Regulatory Position on Reporting Sequencing Results to Public Health Departments

The Centers for Medicare and Medicaid Services (CMS) published information that allows both non-CLIA Clinical Laboratory Improvement Amendments (CLIA) and CLIA-certified facilities that perform SARS-CoV-2 genetic sequencing on identified specimens to report patient-specific results to state, local, tribal, or territorial public health departments. Any sequencing data can be reported to public health.

Laboratories should only report results to patients or providers when sequencing is done under a CLIA certification. If the SARS-CoV-2 genetic sequencing result is reported to the ordering provider or patient and is intended to be used for the purposes of a person's diagnosis, prevention, treatment, or health assessment, then the test must be performed in a CLIA-certified laboratory or facility and must comply with all applicable CLIA regulations.

In both scenarios, CDC strongly recommends and requests that labs send sequencing results to state, local, tribal, or territorial public health departments.

How to Report SARS-CoV-2 Sequencing Results to Public Health Departments

This guidance outlines the process for adding a SARS-CoV-2 genetic sequencing result to an existing electronic laboratory report to provide that information to the state, local, tribal, or territorial health departments. SARS-CoV-2 sequencing results should be reported as a follow-up to the original positive viral test result and reported to the same public health department. The electronic reporting of the sequencing data should include all the original patient demographic data, along with both the viral test report content and the second ordered test with viral genetic lineage identified. Laboratories and facilities that have SARS-CoV-2 positive specimens and intend to report -CoV-2 lineages, including variants, should upload sequence data to a public database (National Center for Biotechnology Information [NCBI] , Global Initiative on Sharing Avian Influenza Data [GISAID]).

Technical Guidance for Reporting Sequencing Results to Public Health Departments

The table below provides detailed guidance on reporting SARS-CoV-2 sequencing results to state, local, tribal, or territorial public health departments and includes examples for packaging data elements. This technical guidance is **subject to change as new information becomes available about the impact of SARS-CoV-2 evolution on public health**. For simplicity, only the fields needing more guidance in the additional observations for the variant lineage and the ID for the sequence sample are highlighted here. Other data elements normally part of each Observation/Result Segment (OBX), such as the result date, still need to be packaged as well.

Data Element	Reporting Requirement			Technical Specifications	Notes	Example	HL7 Field
	Federal / CDC / HHS	State / Local / Tribal / Territorial PHD	Ordering Provider / EHR*				
Test result (performed and values)	Yes	Yes	Requested	Must use harmonized LOINC codes, when available - - - -	SARS-CoV-2 pango lineage identified through sequencing from the original specimen	LOINC: 96741-4 : SARS-CoV-2 (COVID-19) variant [Type] in Specimen by Sequencing OBX-2 = ST Example answers so far: SARS-CoV-2 – B.1.1.7 lineage SARS-CoV-2 – B.1.351 lineage SARS-CoV-2 – P.1 lineage SARS-CoV-2 variant CA-B.1.429 lineage	OBX-3 OBX-2 OBX-5

						SARS-CoV-2 variant NCY B.1.526 lineage SARS-CoV-2 variant CA-B.1.427 lineage SARS-CoV-2 variant P.2 lineage	
Test result date	Yes	Yes	Requested	YYYY[MM[DD]]	Date the test result was obtained	Example: 20200716	OBX-19.1
Device Identifier	Yes	Yes	Requested	Must use harmonized Device Identifiers, when available. The DI is contained within the UDI, created by manufacturer	Manufacturer requests UDI issuance, then provides DI, or pull from GUDID database If DIs unavailable: Use the Unique Trade Name (controlled under 21 CFR 209.10(b)(1))	Example DI: 01234567891011 Example Trade Name: SARS-CoV-2 Test_Company_MNT^^99ELR	OBX-17 OBX-18
Sequence ID	Yes	Yes	N/A	Lab assigned Sequence ID	Add as an additional observation to the original report	PLT2397^Filler Lab Assigned Genetic Sequence Identifier^PLT OBX-2 = ST <WHATEVER FORMAT THE LAB USES>	OBX-3 OBX-2

							OBX-5
Performing facility name; CLIA #	Yes; if known	Yes; if known	N/A	Alpha; ##D#######	CLIA Laboratory Search	Example: 21D1234567	OBX-23.10

Acronyms:
CDC: Centers for Disease Control and Prevention

CFR: Code of Federal Regulations

CLIA: Clinical Laboratory Improvement Amendments

CX: Extended Composite ID

DI: Device Identifier

EHR: Electronic Health Record

GISAID: Global Influenza Surveillance AID

GUDID: Global Unique Device Identification Database

HHS: Department of Health and Human Services

HL7: Health-Level Seven

ID: Identifier

LOINC: Logical Observations Identifiers Names and Codes

NAAT: Nucleic Acid Amplification Test

NCBI: National Center for Biotechnology Information

OBX: Observation/Result Segment

PHD: Public Health Department

RT-PCR: Reverse Transcription Polymerase Chain Reaction

ST: Structured Text

UDI: Universal Device Identification

*Note: Follow CLIA regulations when reporting sequencing results to an ordering provider.

Reporting Scenarios

Below are scenarios that provide examples of how to report SARS-CoV-2 sequencing results to public health departments. The first two examples are the preferred methods, and the third is an alternative method. Specific details for each example can be found on Confluence.

Preferred scenario (1): Send the sequencing results/SARS-CoV-2 lineage with the original (RT-PCR) or NAAT result that led to the decision to perform sequencing, if performed at the same laboratory or facility (parent-child test result linkage, if possible)

Preferred scenario (2): Send the sequencing results/SARS-CoV-2 lineage with the original RT-PCR or NAAT result that resulted in the decision to perform sequencing, if performed at the same laboratory or facility (no parent-child test result linkage)

Alternative scenario: Send only the sequencing results/SARS-CoV-2 Lineage as a new report with reference to the laboratory generated sequence ID (sent as a ST datatype, if CX (HL-7 datatype) is not possible)

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