

Variant Reporting Guidance

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 can only report results to patients or providers when sequencing is performed in a CLIA certified laboratory and in CLIA-compliant manner. This means sequencing was performed in compliance with all applicable CLIA regulations, in addition to the laboratory obtaining a CLIA certificate. Not all laboratories perform SARS-CoV-2 genetic sequencing in a CLIA-compliant manner, as it is only necessary if results are intended to be used for the purposes of a person's diagnosis, prevention, treatment, or health assessment, and reported to the patient or provider. SARS-CoV-2 genetic sequencing results reported to public health do not have to be performed in a CLIA-compliant manner as reporting is for surveillance and public health purposes only.

Both scenarios require reporting to the Tennessee Department of Health (TDH) if the patient is a resident of Tennessee, regardless of where they were tested, or the specimen was obtained. Tennessee further requires the reporting of all results for specimens submitted by ordering providers in Tennessee regardless of the patient address.

How to Report SARS-CoV-2 Sequencing Results to the Tennessee Department of Health

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 TDH as well as guidance for those who are currently reporting results via our Emergency Use Template (EUT). If you are not currently reporting via either of these methods, please contact ceds.informatics@tn.gov to discuss set up. SARS-CoV-2 sequencing results should be reported as a follow-up to the original positive viral test result. 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. CDC requests that 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]) and the methods for linking that upload to your specific result reporting is included below.

Technical Guidance for ELR Reporting of Sequencing Results to the Tennessee Department of Health

The table below provides detailed guidance on reporting SARS-CoV-2 sequencing results to TDH 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 PHD	Ordering Provider / EHR				
Test result (performed)	Yes	Yes	Requested	Must use harmonized LOINC codes , when available	SARS-CoV-2 pango lineage identified through sequencing from the original specimen	Preferred: LOINC = 96895-8 SARS-CoV-2 (COVID-19) lineage [Identifier] in Specimen by Molecular genetics method Allowable: LOINC = 96741-4 SARS-CoV-2 (COVID-19) variant [Type] in Specimen by Sequencing OBX-2= Preferred CWE but can accept ST SNOMED-CT or PHL Values ¹ Please see the footnote below for current lists of codes.	OBX-3
Test result (values)							OBX-2
							OBX-5

¹ PLR and SNOMED values should be updated as new codes are defined and added to the Confluence site at <https://confluence.hl7.org/display/OO/Proposed+HHS+ELR+Submission+Guidance+using+HL7+v2+Messages?focusedCommentId=86968216>

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	Preferred: LOINC = 98062-3 Sequencing study identifier Allowable: 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		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**
- DI: Device Identifier**
- EHR: Electronic Health Record**
- 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**
- NCBI: National Center for Biotechnology Information**
- NPI: National Provider Identifier**
- OBR: Observation Request Segment**
- OBX: Observation/Result Segment**
- ORC: Common Order Segment**

PHD: Public Health Department **PID: Patient Identification Segment**
SNOMED-CT: Systematized Nomenclature of Medicine – Clinical Terms
SPM: Specimen Segment
ST: String data type
UDI: Universal Device Identification
UNK: Unknown

Example messages

1. Include prior PCR result that resulted in decision to do sequencing, if performed at the same lab (**Parent-child linking**, if possible)

MSH|...

SFT|...

PID|1|...

ORC|RE||425195^<FillerSystem>^<OID>^ISO|||||<NPI>^DoctorLastName^FirstName^^^^^NPI&2.16.840.1.113883.4.6&ISO^^^^NPI||20201103093552-0500||||HealthCare|301 Anystreet^^Daytona Beach^FL^32117|^PRN^PH^^^111^1234566|

OBR|1||425195^<FillerSystem>^<OID>^ISO |94500-6^SARS coronavirus 2 RNA [Presence] in Respiratory specimen by NAA with probe detection^LN^^^^2.69||20201102063552-0500|||||<NPI>^DoctorLastName^FirstName^^^^^NPI&2.16.840.1.113883.4.6&ISO^^^^NPI||||20201103093827-0500|||F

OBX|1|CWE|94500-6^SARS coronavirus 2 RNA [Presence] in Respiratory specimen by NAA with probe detection^LN^^^^2.69||260373001^Detected^SCT^^^^Vunknown||||F|||<CLIA>||Abbott RealTime SARS-CoV-2 assay_Abbott Molecular Inc._EUA^^99ELR^^^^Vunknown||20201103093827-0500|||Testinglab name^L^^^^CLIA&2.16.840.1.113883.4.7&ISO^XX^^^^<CLIA>|2110 Any Road^^Nashville^TN^37011

NTE|1|L|Abbott RealTime SARS-CoV-2 assay_Abbott Molecular Inc._EUA|RE^Remark^HL70364^^^^2.5.1

OBX|2|NM|30525-0^Age^LN^^^^2.68||40|a^year^UCUM^^^^Vunknown||||F|||<CLIA>|||20201103093827-0500|||Testinglab name^L^^^^CLIA&2.16.840.1.113883.4.7&ISO^XX^^^^<CLIA>|2110 Any Road^^Nashville^TN^37011||||QST

OBX|3|CWE|95419-8^Whether patient has symptoms related to condition of interest^LN^^^^2.69-pre||Y^Yes^HL70136^^^^2.5.1||||F|||<CLIA>|||20201103093827-0500|||Testinglab name^L^^^^CLIA&2.16.840.1.113883.4.7&ISO^XX^^^^<CLIA>|2110 Any Road^^Nashville^TN^37011||||QST

OBX|4|CWE|82810-3^Pregnancy status^LN^^^^2.68||60001007^Not Pregnant^SCT^^^^Vunknown||||F|||<CLIA>|||20201103093827-0500|||Testinglab name^L^^^^CLIA&2.16.840.1.113883.4.7&ISO^XX^^^^<CLIA>|2110 Any Road^^Nashville^TN^37011||||QST

SPM|1|^MOL20-003999&NEOLINK.STAG&2.16.840.1.113883.3.8589.4.2.29.2&ISO||258529004^Throat swab^SCT^^^^Vunknown|||||20201102063552-0500|20201103063552-0500

ORC|RE||425197^<FillerSystem>^<OID>^ISO|||||<NPI>^DoctorLastName^FirstName^^^^^NPI&2.16.840.1.113883.4.6&ISO^^^^NPI|||20201103093552-0500|||||HealthCare|301 Anystreet^^Daytona Beach^FL^32117|^PRN^PH^^^111^1234566|

OBR|2||425197^<FillerSystem>^<OID>^ISO | 96895-8^SARS-CoV-2 (COVID-19) lineage [Identifier] in Specimen by Molecular genetics method^LN^^^^2.70|||20201104093827-0500|||||<NPI>^DoctorLastName^FirstName^^^^^NPI&2.16.840.1.113883.4.6&ISO^^^^NPI|||||20201103093827-0500|||F|94500-6&SARS coronavirus 2 RNA [Presence] in Respiratory specimen by NAA with probe detection&LN^^Detected|||^425197&<FillerSystem>&<OID>&ISO

OBX|1|CWE|96895-8^SARS-CoV-2 (COVID-19) lineage [Identifier] in Specimen by Molecular genetics method^LN^^^^2.70||PLR4366^ SARS-CoV-2 variant B.1.1.7 (501Y.V1)^PLR^^^1.35|||||F||||<CLIA>||||20201104093827-0500||||Testinglab name^L^^^^CLIA&2.16.840.1.113883.4.7&ISO^XX^^<CLIA>|2110 Any Road^^Nashville^TN^37011

OBX|2|ST|98062-3^Sequencing study identifier^LN ||EPI ISL 250390
||||F||||<CLIA>||||20201104093827-0500||||Testinglab
name^L^^^^CLIA&2.16.840.1.113883.4.7&ISO^XX^^<CLIA>|2110 Any Road^^Nashville^TN^37011

SPM|1|^MOL20-003999&NEOLINK.STAG&2.16.840.1.113883.3.8589.4.2.29.2&ISO|258529004^Throat swab^SCT^^^^Vunknown|||||20201102063552-0500|20201103063552-0500

2. Include prior PCR result that resulted in decision to do sequencing, if performed at the same lab – no parent-child linkage

MSH|...

SFT|...

PID|1|...

ORC|RE||425195^<FillerSystem>^<OID>^ISO|||||<NPI>^DoctorLastName^FirstName^^^^^NPI&2.16.840.1.113883.4.6&ISO^^^^NPI|||20201103093552-0500|||||HealthCare|301 Anystreet^^Daytona Beach^FL^32117|^PRN^PH^^^111^1234566|

OBR|1||425195^<FillerSystem>^<OID>^ISO|94500-6^SARS coronavirus 2 RNA [Presence] in Respiratory specimen by NAA with probe detection^LN^^^^2.69|||20201102063552-0500|||||<NPI>^DoctorLastName^FirstName^^^^^NPI&2.16.840.1.113883.4.6&ISO^^^^NPI|||||20201103093827-0500|||F

OBX|1|CWE|94500-6^SARS coronavirus 2 RNA [Presence] in Respiratory specimen by NAA with probe detection^LN^^^^2.69||260373001^Detected^SCT^^^^Vunknown|||||F||||<CLIA>||Abbott RealTime SARS-CoV-2 assay_Abbott Molecular Inc._EUA^^99ELR^^^^Vunknown||20201103093827-0500||||Testinglab name^L^^^^CLIA&2.16.840.1.113883.4.7&ISO^XX^^<CLIA>|2110 Any Road^^Nashville^TN^37011

NTE|1|L|Abbott RealTime SARS-CoV-2 assay_Abbott Molecular Inc._EUA|RE^Remark^HL70364^^^^2.5.1

OBX|2|NM|30525-0^Age^LN^^^^2.68||40|a^year^UCUM^^^^Vunknown|||||F||||<CLIA>||||20201103093827-0500||||Testinglab name^L^^^^CLIA&2.16.840.1.113883.4.7&ISO^XX^^<CLIA>|2110 Any Road^^Nashville^TN^37011||||QST

OBX|3|CWE|95419-8^Whether patient has symptoms related to condition of interest^LN^^^^2.69-
 pre||Y^Yes^HL70136^^^^2.5.1||||F||||<CLIA>|||20201103093827-0500|||Testinglab
 name^L^^^^CLIA&2.16.840.1.113883.4.7&ISO^XX^^^<CLIA>|2110 Any Road^^Nashville^TN^37011||||QST

OBX|4|CWE|82810-3^Pregnancy status^LN^^^^2.68||60001007^Not Pregnant^SCT^^^^Vunknown||||F||||<CLIA>|||20201103093827-
 0500|||Testinglab name^L^^^^CLIA&2.16.840.1.113883.4.7&ISO^XX^^^<CLIA>|2110 Any Road^^Nashville^TN^37011||||QST

SPM|1|^MOL20-003999&NEOLINK.STAG&2.16.840.1.113883.3.8589.4.2.29.2&ISO||258529004^Throat
 swab^SCT^^^^Vunknown|||||||||20201102063552-0500|20201103063552-0500

ORC|RE||425197^<FillerSystem>^<OID>^ISO|||||||<NPI>^DoctorLastName^FirstName^^^^^NPI&2.16.840.1.113883.4.6&ISO^^^^NPI|||20201103 093552-
 0500|||||HealthCare|301 Anystreet^^Daytona Beach^FL^32117|^PRN^PH^^^111^1234566|

OBR|2||425197^<FillerSystem>^<OID>^ISO|96895-8^SARS-CoV-2 (COVID-19) lineage [Identifier] in Specimen by Molecular genetics method^LN
 ^^^2.70|||20201104093827- 0500|||||||<NPI>^DoctorLastName^FirstName^^^^^NPI&2.16.840.1.113883.4.6&ISO^^^^NPI|||||20201103093827-
 0500|||F|

OBX|1|CWE|96895-8^SARS-CoV-2 (COVID-19) lineage [Identifier] in Specimen by Molecular genetics method^LN ^^^2.70||PLR4366^ SARS-CoV-2
 variant B.1.1.7 (501Y.V1)^PLR^^^^1.35||||F||||<CLIA>|||20201104093827-0500|||Testinglab
 name^L^^^^CLIA&2.16.840.1.113883.4.7&ISO^XX^^^<CLIA>|2110 Any Road^^Nashville^TN^37011

OBX|2|ST|98062-3^Sequencing study identifier^LN||EPI ISL 250390 ||||F||||<CLIA>|||20201104093827-
 0500|||Testinglab
 name^L^^^^CLIA&2.16.840.1.113883.4.7&ISO^XX^^^<CLIA>|2110 Any Road^^Nashville^TN^37011

SPM|1|^MOL20-003999&NEOLINK.STAG&2.16.840.1.113883.3.8589.4.2.29.2&ISO||258529004^Throat
 swab^SCT^^^^Vunknown|||||||||20201102063552-0500|20201103063552-0500

Technical Guidance for Reporting Sequencing Results to the Tennessee Department of Health using Emergency Use Template

The table below provides detailed guidance on reporting SARS-CoV-2 sequencing results to TDH via the Emergency Use Template (EUT) and includes examples for 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 result still need to be included as well.

EUT Data Element	Reporting Requirement			Technical Specifications	Notes	Example
	Federal / CDC / HHS	State / Local PHD	Ordering Provider / EHR			

TestName	Yes	Yes	Requested	Must use harmonized LOINC codes , when available	Variant identified through sequencing isolate from the original specimen	LOINC = 96895-8 SARS-CoV-2 (COVID-19) lineage [Identifier] in Specimen by Molecular genetics method

² PLR and SNOMED values should be updated as new codes are defined and added to the Confluence site at <https://confluence.hl7.org/display/OO/Proposed+HHS+ELR+Submission+Guidance+using+HL7+v2+Messages?focusedCommentId=86968216>

Result	Yes	Yes	Requested	Send as string	Variant identified through sequencing isolate from the original specimen	The below are examples of current variant names. Please see the footnote below ² for where to get a list of variants. SARS-CoV-2 B.1.1.7 lineage SARS-CoV-2 B.1.351 lineage SARS-CoV-2 B.1.427 lineage SARS-CoV-2 B.1.429 lineage SARS-CoV-2 B.1.525 lineage SARS-CoV-2 B.1.526 lineage SARS-CoV-2 B.1.526.1 lineage SARS-CoV-2 P.1 lineage SARS-CoV-2 P.2 lineage SARS-CoV-2 lineage of unknown significance SARS-CoV-2 B.1.617 lineage SARS-CoV-2 B.1.617.1 lineage SARS-CoV-2 B.1.617.2 lineage SARS-CoV-2 B.1.617.3 lineage
Date Verified	Yes	Yes	Requested	mm/dd/yyyy or mm/dd/yyyy hh:mm:ss	Date of testing	Example: 05/10/2021 13:54
Sequence ID	Yes	Requested		Lab assigned Sequence ID	Please reach out to ceds.informat@tn.gov to discuss options for sending this field specific to your organization.	