Coronavirus Disease 2019 (COVID–19)

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How to Report COVID-19 Laboratory Data

Updated July 29, 2020   Print

Summary:

Laboratories are required to report to state and local public health authorities in accordance with applicable state or local law. Additionally, the Coronavirus Aid, Relief, and Economic Security (CARES) Act (CARES Act Section 18115 📄 🔗) and its implementation guidance require every laboratory to report every test it performs to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (e.g., viral, serology). Tests must be reported to the appropriate state or local public health department, based on the individual's residence. Laboratories that currently report directly to CDC should continue sending these data to CDC. Email questions to DLSinquiries@cdc.gov.

Who must report

All laboratories with a Clinical Laboratory Improvement Amendments (CLIA) 🔗 certificate must report the results of the COVID-19 tests that they conduct to the appropriate state or local public health department. Laboratories are defined as

- Laboratories that perform clinical diagnostic testing under CLIA,
- non-laboratory COVID-19 testing locations, and
- other facilities or locations offering point-of-care testing or in-home testing related to COVID-19.

Laboratories must report data for all testing completed, which includes viral and antibody testing, for each individual tested. This data must be reported within 24 hours of test completion, on a daily basis, to the appropriate state or local public health department, based on the individual's residence.

How to report

Laboratory data elements may be reported in the following ways:

- Submit laboratory testing data directly to state or local public health departments according to state/or local law or policy. Data must be sent using existing reporting channels to ensure rapid initiation of case investigations, and concurrent reporting of results must be shared with ordering provider or patient, as applicable.
- Submit laboratory testing data to state and local public health departments through a centralized platform (such as the Association of Public Health Laboratories' AIMS platform 🔗), where the data will then be routed to the appropriate state and local authorities and routed to CDC after removal of personally identifiable information according to applicable rules and regulations.

- Submit laboratory testing data through a state or regional Health Information Exchange (HIE) to the appropriate state or local public health department and then to CDC as directed by the state.

Public health departments will submit de-identified data to CDC on a daily basis, using either Health Level 7 (HL7) messaging or the CDC-provided CSV format.

What to report

Complete laboratory data must include the following data elements for state and jurisdictional health departments.

1. Test ordered – use harmonized LOINC codes provided by CDC
2. Device Identifier
3. Test result–use appropriate LOINC and SNOMED codes, as defined by the Laboratory In Vitro Diagnostics (LIVD) Test Code Mapping for SARS-CoV-2 Tests provided by CDC
4. Test Result date (date format)
5. Accession # / Specimen ID
6. Patient age
7. Patient race
8. Patient ethnicity
9. Patient sex
10. Patient residence zip code
11. Patient residence county
12. Ordering provider name and NPI (as applicable)
13. Ordering provider zip
14. Performing facility name and CLIA number
15. Performing facility zip code
16. Specimen Source – use appropriate LOINC, SNOMED-CT, or SPM4 codes, or equivalently detailed alternative codes
17. Date test ordered (date format)
18. Date specimen collected (date format)

The following additional demographic data elements should also be collected and reported to state or local public health departments.

1. Patient name (Last name, First name, Middle Initial)
2. Patient street address
3. Patient phone number with area code
4. Patient date of birth
5. Ordering provider address
6. Ordering provider phone number

To protect patient privacy, any data that state and jurisdictional health departments send to CDC will be deidentified and will not include some patient-level information. The deidentified data shared with CDC will contribute to understanding COVID-19's impact, positivity trends, testing coverage, and will help identify supply chain issues for reagents and other

materials.

What to include in laboratory test orders

Anyone who orders a COVID-19 test, collects a specimen, or performs a laboratory test must make every reasonable effort to collect complete demographic information as well as responses to the following "ask on order entry" (AOE) questions. These data elements are critical for the COVID-19 public health response, and including them with test orders enable the laboratories that perform the test to report the information to state and jurisdictional health departments, as required. These elements should be collected in accordance with the HL7 Version 2.5.1 Lab Order Interface Implementation Guide ⬈ and associated standards.

When information is not available, the healthcare providers (or their designees) who ordered the COVID-19 test and laboratories performing those tests should consider leveraging other information sources to obtain these data (e.g., health information exchanges, employee records, school records).

Healthcare providers could answer the following questions on behalf of the individual being tested for COVID–19:

Questions	Why is the question needed?	Data Input
1. Do you currently work in a healthcare setting with direct patient contact?	To determine if the individual, at the time of this COVID-19 test order, works with patients in a high-risk role, such as, but not limited to • first responders, • front-line clinicians, • nursing home staff, • environmental staff, or • therapists in direct contact with patients.	LOINC: 95418-0 ⬈ HL7: OBX-5 ⬈ Value Set (HL7 0136 ⬈): • Yes (Y^Yes^HL70136) • No (N^No^HL0136) • Unknown (UNK^Unknown^NULLFL) [Optional] If yes: SNOMED-CT Values: • 223366009 ⬈ Healthcare Professional • More Detailed Healthcare Professional List ⬈ ⬈

2. Do you currently have one or more of the following symptoms?

- Fever or chills
- Cough
- Shortness of breath or difficulty breathing
- Fatigue
- Muscle or body aches
- Headache
- New loss of taste or smell
- Sore throat
- Congestion or runny nose
- Nausea or vomiting
- Diarrhea

To determine if the individual is symptomatic based on CDC guidance at the time of this COVID-19 test order.

LOINC: 95419-8 ⬈

HL7: OBX-5 ⬈

Value Set (HL7 0136 ⬈):

- Yes
- No
- Unknown

[Optional] If yes: SNOMED-CT Values:

- 426000000 ⬈ Fever over 104F
- 103001002 ⬈ Feeling feverish
- 43724002 ⬈ Chills
- 49727002 ⬈ Cough
- 267036007 ⬈ Shortness of breath
- 230145002 ⬈ Difficulty breathing
- 84229001 ⬈ Fatigue
- 68962001 ⬈ Muscle or body aches
- 25064002 ⬈ Headache
- 36955009 ⬈ New loss of taste
- 44169009 ⬈ New loss of smell
- 162397003 ⬈ Sore throat
- 68235000 ⬈ Nasal congestion
- 64531003 ⬈ Runny nose
- 422587007 ⬈ Nausea
- 422400008 ⬈ Vomiting
- 62315008 ⬈ Diarrhea

3. (Optional) [If yes to question #2] When did your symptoms start?	To determine the onset of any COVID-19 symptoms the individual is experiencing.	LOINC: 65222-2 [↗] HL7: OBX-19.1 [↗] Value: YYYY[MM[DD]]
4. [If the individual is female] Are you currently pregnant?	To determine the current pregnancy status of the individual.	LOINC: 82810-3 [↗] HL7: OBX-5 [↗] SNOMED-CT Pregnancy Status: • 77386006 [↗] Pregnant • 60001007 [↗] Not Pregnant • UNK^Unknown^NULLFL

5. Do you currently reside in a congregate (group) care setting, such as, but not limited to

- a nursing home,
- a residential care location for people with intellectual and developmental disabilities,
- a psychiatric treatment facility,
- a group home,
- a dormitory,
- a board and care home,
- a homeless shelter, or
- foster care setting.

To determine if the individual lives in a congregate (group) care facility at the time of this COVID-19 test order.

LOINC: 95421-4 ☑

HL7: OBX-5 ☑

Value Set (HL7 0136 ☑):

- Yes
- No
- Unknown

[Optional]
75617-1^Residence type^LN

If yes: SNOMED-CT Values:

- 22232009 ☑ Hospital
- 2081004 ☑ Hospital ship
- 32074000 ☑ Long term care hospital
- 224929004 ☑ Secure hospital
- 42665001 ☑ Nursing home
- 30629002 ☑ Retirement home
- 74056004 ☑ Orphanage
- 722173008 ☑ Prison-based care site
- 20078004 ☑ Substance abuse treatment center
- 257573002 ☑ Boarding house
- 224683003 ☑ Military accommodation
- 284546000 ☑ Hospice
- 257628001 ☑ Hostel
- 310207003 ☑ Sheltered housing
- 257656006 ☑ Penal institution
- 285113009 ☑ Religious institutional residence
- UNK^Unknown^NULLFL

Question	Why is the question needed?	Possible Answers
6. [Optional] Is this the first test you have had for COVID-19?	To determine if this is the individual's first COVID-19 test (e.g., molecular, antigen, antibody), or if they are being retested.	LOINC: 95417-2 ⧉ HL7: OBX-5 ⧉ Value Set (HL7 0136 ⧉): • Yes • No (move to question #7) • Unknown
7. [Optional] [If No for question #6] What type of test was the most recent prior test, what was the result, and what date was the test performed?		Type of Test, Value Set: • Molecular • Antigen • Antibody • Unknown Result, Value Set: • Detected • Not Detected • Unknown Test Performed Date, Value: YYYY[MM[DD]]

Healthcare providers could answer the following questions on behalf of the individual being tested for COVID–19:

Question	Why is the question needed?	Possible Answers

8. Is the individual hospitalized with confirmed or suspected COVID-19?	To determine if the individual is currently hospitalized for confirmed or suspected COVID-19 at the time of this COVID-19 test order.	LOINC: 77974-4 ↗ HL7: OBX-5 ↗ Value Set (HL7 0136 ↗): • Yes • No • Unknown [Optional] If Yes, SNOMED-CT Values: • 840544004 ↗ Suspected disease caused by 2019 novel coronavirus (situation) • 840539006 ↗ Disease caused by 2019 novel coronavirus (disorder)
9. [If yes to question #8] Is the individual in an intensive care unit?	To determine if the individual is currently in the ICU for confirmed or suspected COVID-19 at the time of this COVID-19 test order.	LOINC: 95420-6 ↗ HL7: OBX-5 ↗ Value Set (HL7 0136 ↗): • Yes • No • Unknown [Optional] If Yes, SNOMED-CT Value: • 309904001 ↗ Intensive care unit (environment)

How to report using standard terminology

The public health response to COVID-19 depends on comprehensive laboratory testing data. These data will contribute to understanding COVID-19's impact and testing coverage and can contribute to the identification of supply chain issues for reagents and other materials. The information below outlines reporting requirements for laboratories. Additional technical guidance on implementing the COVID-19 laboratory reporting requirement to comply with the CARES Act Section 18115 🔗 🗗 is forthcoming.

CDC has posted a LOINC In-Vitro Diagnostic (LIVD) Test Code Mapping Guide for COVID-19 test results for tests with emergency use authorization from the U.S. Food and Drug Administration (FDA) that can be used by clinical laboratories and instrument manufacturers. This specification supports the use of standardized LOINC and SNOMED Clinical Terms (CT) codes to improve the accuracy of reporting tests for the SARS-CoV-2 virus. Using these harmonized LOINC and SNOMED-CT codes helps ensure that the same type of test is represented uniformly across the United States.

For those COVID-19 tests that have not yet received FDA emergency use authorization, CDC encourages test developers and laboratories that use COVID-19 tests to work together to obtain appropriate and interoperable LOINC and SNOMED-CT codes for reporting purposes.
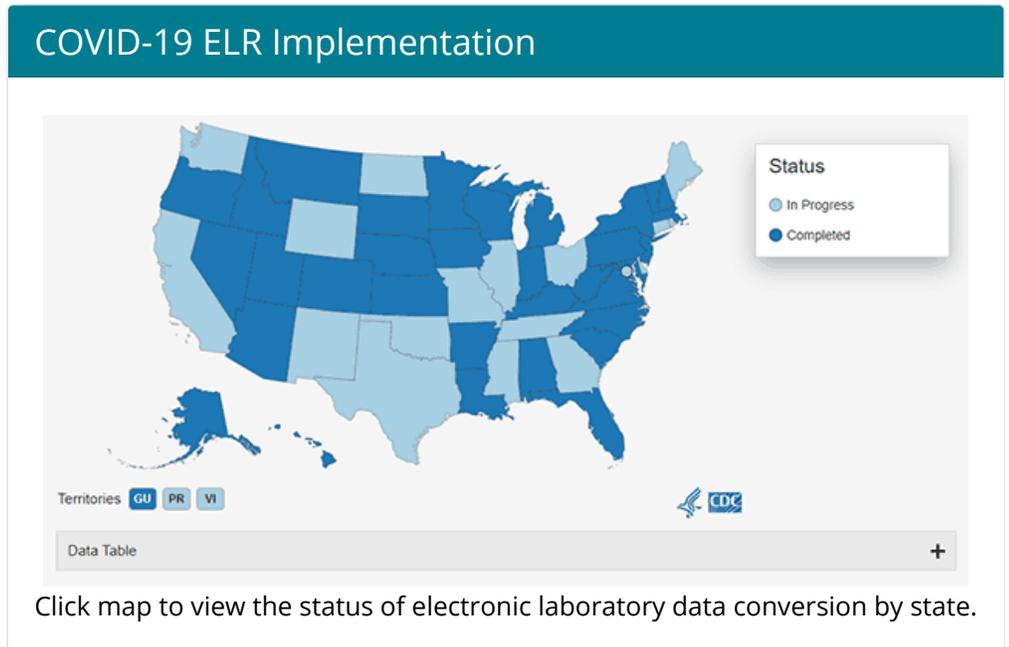
LOINC codes must be used to represent the "question" a viral test asks of a specimen (e.g., does this specimen have SARS-CoV-2 RNA?), and SNOMED-CT codes must be used to represent the diagnostic "answer" (e.g., what was detected?). More background on these terminology standards can be found here:

- LOINC Term 🗗
- SNOMED CT 🗗

Whenever possible, laboratories must use standard codes that already exist. Before requesting a new code, search the list of currently available LOINC 🗗 for SARS-CoV-2 tests. If a LOINC test code cannot be identified whose attributes appropriately match the test for which coding is needed, new terms can be submitted, and a new code requested through the LOINC 🗗 .

Technical assistance for electronic reporting

Electronic reporting options are available to reduce the burden on providers reporting test results. Laboratories that are not currently reporting electronically to their state or local health department and want assistance in establishing electronic reporting can contact CDC's Emergency Operations Center, Laboratory Reporting Working Group at eocevent405@cdc.gov.

COVID-19 ELR Implementation

Click map to view the status of electronic laboratory data conversion by state.

Frequently Asked Questions on Laboratory Data Reporting Guidance for COVID-19 Testing

New guidance from HHS 📕 ⬈ specifies what data must be reported to comply with the COVID-19 laboratory reporting requirement in CARES Act Section 18115. The new guidance requires facilities and ordering providers to gather more complete patient demographic information to send to state and local public health departments. State and local health departments will then forward the deidentified data to CDC.

1. Does this guidance require the reporting of all laboratory tests, including antibody tests and negative test results, at the case level? _

Yes, the CARES Act and the implementing guidance require all clinical laboratories and testing providers that perform diagnostic testing under a Clinical Laboratory Improvement Amendments (CLIA) certificate to **report the results of any test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19** (e.g., viral, antibody**),** not just positive tests, to state or local public health departments. Laboratories that conduct surveillance testing for SARS-CoV-2 must not report their results as diagnostic results to state or local public health departments.

2. Will facilities or healthcare providers that order COVID-19 tests be required to collect the "ask on order entry" (AOE) questions? _

Yes, this information is critical for state and local public health departments to plan and execute COVID-19 control and mitigation efforts. These elements must be collected and be conformant with the HL7 Version 2.5.1 Lab Order Interface Implementation Guide ⬈ and associated standards.

3. Should AOE questions be sent to the health department in the electronic laboratory report messages?

Yes, all data fields are expected to be collected and reported to state and local public health departments in the electronic laboratory report messages.

4. Will CDC accept COVID-19 electronic laboratory reporting (CELR) extracts if they do not include all required data elements?

Yes, CDC will still accept the data. CDC recognizes that in many cases, this information is not provided in testing orders.

The new HHS guidance aims to increase the reporting of important data elements, such as race and ethnicity. The guidance states that "any person or entity ordering a diagnostic or serologic test, collecting a specimen, or performing a test should *make every reasonable effort to collect complete demographic information* and should include such data when ordering a laboratory test to enable the entities performing the test to report these data to state and local public health departments."

5. Have LOINC codes been assigned to these tests?

Yes, harmonized LOINC codes can be found on CDC's website.

6. How will the laboratory data reported to state and jurisdictional health departments be used?

Laboratory data reported to state and jurisdictional health departments will be used to help track the spread of COVID-19 and identify areas that are highly impacted by the infection. The data will also be used to track when the spread of infection appears to be slowing down by location. On a national level, the deidentified data shared with CDC will contribute to understanding national disease incidence and prevalence, positivity trends, and testing coverage, and will help identify supply chain issues for reagents and other materials.

7. For a clinical research trial approved by the Institutional Review Board (IRB), are laboratories required to report laboratory testing data from CLIA-certified COVID-19 testing (nucleic acid, antigen, or antibody) if the specimens are de-identified and results are not returned to the ordering clinician?

In general, no. Laboratories are not responsible for reporting these data. However, state health department rules and regulations apply and may differ from this general guidance.

8. For an IRB-approved clinical research trial, what are the requirements for reporting laboratory testing data from CLIA-certified COVID-19 testing (nucleic acid, antigen, or antibody) if the specimens are de-identified and results are being returned to the ordering clinician for patient care?

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The reporting requirements differ for laboratories and research clinicians:

Laboratories

Laboratories are not responsible for reporting these data since laboratories do not have the patient-identifying information required for compliance with reporting requirements. However, state health department rules and regulations apply and may differ from this general guidance.

Research Clinicians

In clinical trials, research clinicians who are responsible for clinical care of trial participants are responsible for linking de-identified specimen test results to participant demographic information and are required to report the positive results daily to the appropriate state or local public health department based on the patient's residence. Demographic information required for reporting is detailed in HHS's June 4, 2020 guidance ⧉ .

Research clinicians are not required to report negative test results. However, state health department rules and regulations apply and may differ from this general guidance.

If a clinician receives COVID-19 test results from duplicate specimens that were collected in the same manner and tested with different test methods (e.g., different platforms) or in different CLIA laboratories, the clinician should not report both results. In the case of two positive test results, the clinician should report the result that is provided first. In the case of discrepant test results, the clinician should report the positive result. However, state health department rules and regulations apply and may differ from this general guidance.

If the clinician requests COVID-19 testing for study participants independent of research activities or for clinical management, results should be reported to the appropriate state or local public health department.