How to Report COVID-19 Laboratory Data

Updated Aug. 17, 2020 Print

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Summary:

The Coronavirus Aid, Relief, and Economic Security (CARES) Act (CARES Act Section 18115) and its implementation guidance require every COVID-19 testing site to report every diagnostic and screening test performed to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (e.g., molecular, antigen, antibody) 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.

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.

Who must report

All COVID-19 diagnostic and screening testing sites must

- have a Clinical Laboratory Improvement Amendments (CLIA) certificate – compliance, accreditation, waiver, or provider performed microscopy
- meet all requirements to perform testing, including only using FDA-authorized test systems according to their instructions for use, and
- report the results of the COVID-19 diagnostic and screening tests that they perform to the appropriate state or local public health department.

COVID-19 testing sites are defined as

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

Testing sites must report data for all diagnostic and screening testing completed, which includes molecular, antigen, and antibody testing, for each individual tested. These data must be reported daily, within 24 hours of test completion, to the appropriate local, state , territorial or tribal health department, based on the individual's residence.

Testing sites that perform COVID-19 surveillance testing on de-identified samples, regardless of their CLIA status, should not report the results of their surveillance testing to local, state, territorial, or tribal health departments. If at any time a facility intends to report a patient-specific test result, it must first obtain a CLIA certificate and meet all requirements to perform testing. For more information, see the Center for Medicare and Medicaid Services' (CMS) Research Testing and Clinical Laboratory Improvement Amendments of 1988 (CLIA) Regulations and the CDC Division of Laboratory Systems' CLIA webpage.

For information about the CLIA Certificate application process, see CMS' How to Apply for a CLIA Certificate, Including International Laboratories webpage.

For definitions of COVID-19 diagnostic, screening, and surveillance testing, see CDC's Interim Guidance for Use of Pooling Procedures in SARS-CoV-2 Diagnostic, Screening, and Surveillance Testing.

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.

How to report using standard terminology

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:

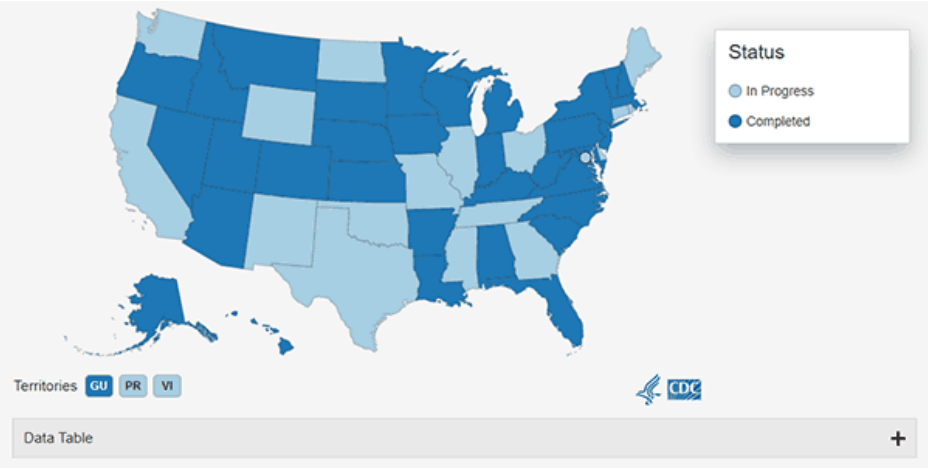
- LOINC Term
- SNOMED CT

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 the Department of Health and Human Services (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 de-identified data to CDC.

Data reporting requirements

1. Why are laboratories being required to collect patient demographic information when conducting COVID-19 testing?

HHS developed this guidance in response to the CARES Act, which requires every testing site to report every test it performs to detect SARS-CoV-2 or to diagnose a possible case of COVID-19. State and local public health departments have required laboratories to report COVID-19 testing results since the beginning of the COVID-19 public health emergency; however, the requirements for patient information and other data elements have varied across states. The new HHS guidance aims to increase the reporting of important data elements, (e.g., patient age and residence zip code) to inform COVID-19 control and mitigation efforts.

2. 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 de-identified 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

3. Are laboratories required to report to *both* state or local public health departments and HHS?

Laboratories are not required to report to both state or local health departments and HHS. The CARES Act requires laboratories to report all data to state or local public health departments using existing public health data reporting channels (in accordance with state law or policies). The state health departments will provide this data to HHS.

4. Are *all* data elements in the HHS guidance required to be reported by the August 1, 2020 deadline?

Starting on August 1, 2020, laboratories are expected to make every reasonable effort to report data to the appropriate state or local public health department, as required by HHS guidance.

5. What happens if a laboratory cannot report *all* elements starting on August 1, 2020?

Anyone who orders a COVID-19 test, collects a specimen, or performs a laboratory test should make every reasonable effort to collect complete demographic information and responses to the "ask on order entry" (AOE questions). Ordering providers should make every effort to collect this critical information from patients during the specimen collection process and provide it to the laboratories performing the test.

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

6. Does HHS require the reporting of all laboratory tests, including antibody and antigen tests and negative test results?

Yes, the CARES Act requires 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., molecular, antigen, antibody)**,** not just positive tests, to state or local public health departments. Results from surveillance testing for SARS-CoV-2 should not be reported to state or local public health departments.

7. My laboratory is testing samples from multiple states. Can this data be sent to the state in which the testing facility is located?

Laboratories must report results to the appropriate state or local health department based on the individual's residence or the provider location when a patient is out-of-state.

8. Which laboratory is responsible for reporting — the testing lab, referring facility, or both?

The laboratory that performs the COVID-19 test is responsible for reporting to the appropriate state or local public health department.

9. What are the reporting requirements for samples from individuals from other countries?

Laboratories need to report test results to the state where the individual is temporarily living or visiting.

10. Where can clinicians and laboratories find more information about reporting requirements?

Clinicians and laboratories should contact their state or local public health department directly for more information on reporting requirements and the method for reporting.

Technical aspects of reporting

1. Have Logical Observation Identifiers Names and Codes (LOINC) been assigned to COVID-19 tests?

Yes, information about LOINC codes and the specific harmonized LOINC codes for COVID-19 tests can be found on CDC's website: LOINC In Vitro Diagnostic (LIVD) Test Code Mapping for SARS-CoV-2 Tests.

2. How can laboratories obtain a LOINC code for the Emergency Use Authorization (EUA) assay their laboratory is using?

CDC's LOINC In Vitro Diagnostic (LIVD) Test Code Mapping for SARS-CoV-2 Tests website has a mapping catalogue coded for the data elements associated with COVID-19 tests, including the LOINC test order, LOINC test result, SNOMED-CT test description and SNOMED-CT specimen source. Test developers and manufacturers of new tests should contact FDA at SHIELD-LabCodes@fda.hhs.gov for information about obtaining new codes.

3. Will state or local health departments accept COVID-19 electronic laboratory reporting (CELR) extracts if they do not include all required data elements?

Yes, state or local health departments will still accept the data. Public health recognizes this information is not always provided in test orders.

4. Does CDC have the CSV format for reporting?

Laboratories should contact their state or local health department for the CSV format for reporting.

5. What is the device identifier (DI)?

The DI for some tests can be found in the National Institute of Health's (NIH) Access GUDID Database. For a specific DI not located in the Access GUDID Database, contact the device manufacturer to obtain the DI. If the manufacturer does not yet have the DI for the device you are using, contact SHIELD-LabCodes@fda.hhs.gov for assistance.

"Ask on order entry" (AOE) questions and other data elements

1. How should laboratories collect data for AOE questions in the HHS guidance?

If test orders *are placed* electronically, healthcare facilities and laboratories should ensure that the laboratory test order interface can collect or transfer complete demographic data and answers to AOE questions. Healthcare facilities and laboratories should work with their electronic health record or laboratory information management system vendors to improve the order processes and information exchange between the healthcare provider and the laboratory.

If test orders *are not placed* electronically, submission forms (web based or paper) should be updated to include the data elements described in the CARES Act Section 18115 guidance.

2. Will facilities or healthcare providers that order COVID-19 tests be requested to collect the AOE questions?

Every effort should be made to collect this information because these data are critical for state and local public health departments to plan and execute COVID-19 control and mitigation efforts. These elements should 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 related to the AOE questions should be collected and reported to state and local public health departments in the electronic laboratory report messages.

Clinical research trial reporting

1. For an Institutional Review Board (IRB) approved clinical research trial, are laboratories required to report laboratory testing data from CLIA-certified COVID-19 testing (molecular, 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.

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

The reporting requirements differ for laboratories and research clinicians:

Laboratories

Laboratories are not responsible for reporting these data since they do not have the patient-identifying information required to comply 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.

Last Updated Aug. 17, 2020
Content source: National Center for Immunization and Respiratory Diseases (NCIRD), Division of Viral Diseases