

Frequently Asked Questions: Laboratory Data Reporting for COVID-19 Testing

I am a laboratory performing COVID-19 testing. Do I need to report COVID-19 test results to public health authorities?

Laboratories are required to report to state and local public health authorities in accordance with applicable state or local law.

In addition, under section 18115 of the Coronavirus Aid, Relief, and Economic Security (CARES) Act (Public Law 116-136), laboratories, including those in patient care settings operating under a Clinical Laboratory Improvement Amendments (CLIA) Certificate of Waiver, Certificate of Compliance or Certificate of Accreditation, must report the results of COVID-19 tests to the Department of Health and Human Services (HHS) or its designee, in such form and manner as the Secretary may prescribe, during the declared public health emergency. The implementing [guidance](#), published on June 4, 2020, identifies the laboratories subject to the reporting requirement, the information that must be reported, and methods for reporting, among other things. This reporting is important to protect public health; for example, comprehensive laboratory testing data can contribute to understanding disease incidence and trends and inform mitigation and control activities.

When the HHS Food and Drug Administration (FDA) issues an Emergency Use Authorization (EUA) for a COVID-19 test, the letter of authorization includes a condition that requires authorized laboratories performing COVID-19 testing to have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate. FDA considers this condition to include authorized laboratories reporting test results to HHS in accordance with section 18115 of the CARES Act.

Which entities are required to report?

All laboratories—defined as laboratories, non-laboratory testing locations, and other facilities or locations offering point-of-care testing or in-home testing related to SARS-CoV-2¹—shall report data for all testing completed, for each individual tested, within 24 hours of results being known or determined, on a daily basis to the appropriate state or local public health department based on the individual’s residence.

What data and demographic elements must be reported?

Test ordered – use harmonized [LOINC codes provided by CDC](#), Device Identifier, 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](#), Test Result date (date

¹ The CARES Act authorizes the Secretary to prescribe the laboratories which must submit the required reports. This definition of laboratories is consistent with Clinical Laboratory Improvement Amendments (CLIA), under which a laboratory is defined as a facility that performs applicable testing on materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or assessment of the health of, human beings. The reference to “facilities offering . . . in-home testing” is not intended to suggest that an individual who utilizes an in-home test to determine if he or a member of his family has COVID-19 is a laboratory required to report his/her family’s test results.

format), Accession #/Specimen ID, Patient age, Patient race, Patient ethnicity, Patient sex, Patient residence zip code, Patient residence county or territory, Ordering provider name and NPI (as applicable), Ordering provider zip, Performing facility name and/or CLIA number, if known, Performing facility zip code, Specimen Source - use appropriate LOINC, SNOMED-CT, or SPM4 codes, or equivalently detailed alternative [codes](#), Date test ordered (date format), Date specimen collected (date format).

Additional information that must be provided includes: If this is a patient's first test, is the patient employed in healthcare, is the patient symptomatic as defined by [CDC](#)? , if yes, then state of symptoms sunset, is the patient Hospitalized, or in the ICU, is the patient a resident in a congregate care setting (including nursing homes, residential care for people with intellectual and developmental disabilities, psychiatric treatment facilities, group homes, board and care homes, homeless shelter, foster care or other setting), and is the patient pregnant.

The following additional demographic data elements should also be collected and reported to state or local public health departments but these data will not be collected by CDC or the Secretary's designee: Patient name (Last name, First name, Middle Initial), Patient street address, Patient phone number with area code, Patient date of birth, Ordering provider address, Ordering provider phone number.

Note: State and local privacy standards apply to the collection of these data elements and additional data elements may be requested by state, local or federal health departments at any time.

What should we do if we are unable to capture all of the requested data?

When information is not available, ordering health care providers (or their designees), laboratories performing SARS-CoV-2 and associated tests, and state public health departments should consider leveraging resources like state or regional HIEs and national Health Information Networks (HIN) to obtain missing, required information. These exchanges and networks have significant capacity to identify missing information as they typically work with a wide range of health care provider electronic health record (EHR) generated data, as well as a broader array of ADT (admit, discharge, transfer) feeds from local or regional stakeholders.

What are the methods of submission?

1. Submission of laboratory testing data directly to state or local public health departments, as required by state and/or local law or policy. These entities will then submit de-identified data to the CDC, as the HHS designee, on a daily basis using either Health Level 7 (HL7) messaging or the CDC-provided CSV format.
2. Submission of 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 such data will then be routed to the appropriate state and local authorities and routed to CDC after removal of elements to achieve de-identification according to applicable rules and regulations.

3. Submission of laboratory testing data through a state or regional Health Information Exchange (HIE) to the appropriate state or local public health department or to CDC as directed by the state.

When and how often will we be required to begin submitting testing data?

Reporting of these data elements should begin as soon as possible but must be reported no later than August 1, 2020. Reporting should occur within 24 hours of results being known or determined, on a daily basis, to the appropriate state or local public health department based on the individual's residence. *Note: Additional data elements may be requested at a future date.*

Will the required data be integrated into our electronic health record?

Some data elements specific to SARS-CoV-2 are considered "ask on order entry" (AOE) questions for traditional Electronic Health Records or Laboratory Information Management Systems. These elements should be collected and be conformant with the [HL7 Version 2.5.1 Lab Order Interface Implementation Guide](#) and associated standards, comprehensive of the above data fields.

When possible, all information should be collected using health information technology certified to the Office of the National Coordinator (ONC) 2015 Edition certification criteria, and all information should be structured in accordance with the US Core Data for Interoperability (USCDI) when available or when possible. All data transmission should occur electronically using HL7 electronic laboratory reporting (ELR) implementation guides when possible but a predefined flat file format may also be acceptable. In addition, clinical/point-of-care testing facilities using EHRs are encouraged to use electronic case reporting (eCR) standards to report laboratory testing data, at the receiver's discretion, provided the above data elements and timeliness requirements can be met.

For entities that do not currently have Electronic Health Records systems or Lab Information Systems, every effort should be made to comply with the standards referenced above. Reporting should occur electronically.