

COVID-19 Pandemic Response, Laboratory Data Reporting: CARES Act Section 18115

June 4, 2020

Assuring a rapid and thorough public health response to the COVID-19 pandemic necessitates complete and comprehensive laboratory testing data, including standardized test results, relevant demographic details, and additional information that can improve both the public health response to SARS-CoV-2 and COVID-19. These data contribute to understanding disease incidence and trends: initiating epidemiologic case investigations, assisting with contact tracing, assessing availability and use of testing resources, and identifying supply chain issues for reagents and other material. Laboratory testing data, in conjunction with case reports and other data, also provide vital guidance for mitigation and control activities. As the country begins to reopen its doors, access to clear and accurate data is essential to communities and leadership as they use data to make decisions for a phased reopening. For individuals, access to personal test results improves feelings of safety, security, and awareness, and empowers them to take action, if necessary, to protect themselves, their families, and their communities.

Public Law 116-136, § 18115(a), the Coronavirus Aid, Relief, and Economic Security (CARES) Act, requires “every laboratory that performs or analyzes a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19” to report the results from each such test to the Secretary of the Department of Health and Human Services (HHS). In addition, the statute authorizes the Secretary to prescribe the form and manner, and timing and frequency, of such reporting. This document outlines the requirements for data submission to HHS as authorized under this law.

In an effort to receive these data in the most efficient and effective manner, the Secretary is requiring that all data be reported through existing public health data reporting methods, described below. As a guiding principle, data should be sent to state or local public health departments using existing reporting channels (in accordance with state law or policies) to ensure rapid initiation of case investigations by those departments, concurrent to laboratory results being shared with an ordering provider, or patient as applicable.

Entities Required to Report

All laboratories—including laboratories, testing locations operating as temporary overflow or remote locations for a laboratory, and other facilities or locations performing testing at point of

care or with at-home specimen collection 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.

Methods for Submission

The required data elements related to Laboratory Data Reporting to HHS may be reported through the following avenues:

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 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 and to the CDC as directed by the state.

Required Data Elements

The following data elements **must** be collected and reported for SARS-CoV-2 laboratory tests, for the transmission of complete laboratory testing data to the CDC or the Secretary’s designee. (Note: additional data elements may be requested at a future date.)

1. Test ordered – use harmonized [LOINC codes provided by CDC](#)
2. Device Identifier

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 CLIA regulations provide that “facilities only collecting or preparing specimens (or both) or only serving as a mailing service and not performing testing are not considered laboratories.” However, facilities collecting specimens may be directed by laboratories to provide the information required to be reported by the laboratories.

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/or CLIA number, if known
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 but these data will not be collected by CDC or the Secretary's designee. State and local privacy standards apply to the collection of these data elements. (Note: additional data elements may be requested by state, local or federal health departments at any time.)

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

In order to meet this requirement, 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. 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 EHR generated data, as well as a broader array of ADT (admit, discharge, transfer) feeds from local or regional stakeholders.

The following data fields are specific to SARS-CoV-2 and 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, and comprehensive of the above data fields.

1. First test (Y/N/U)
2. Employed in healthcare? Y/N/U
3. Symptomatic as defined by [CDC](#)? Y/N/U; if yes, then Date of Symptom Onset mm/dd/yy
4. Hospitalized? Y/N/U
5. ICU? Y/N/U
6. 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): (Y/N/U)
7. Pregnant? Y/N/U

Data Reporting and Transmission Requirements

Recognizing that the data elements requested go above and beyond what has been historically requested, this information should be made available in all reporting (including through methods using existing technical infrastructure such as an HIE) to state and local public health departments and subsequently the CDC as soon as possible, but no later than August 1, 2020.

When possible, all information should be collected using health information technology certified to the 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 Health Level 7 (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 electronic health records (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 home-based collection of samples that are sent to a laboratory for testing, the laboratory must be able to collect the required information for reporting, so the process for sample collection should include submission of the data elements above (along with the specimen) to the lab performing the test, which will then report to the state and/or local public health department and

subsequently HHS or entity designated by the Secretary. For point of care testing, the laboratory (including a facility or setting with a certificate of waiver) must ensure the test is set up and operational to deliver timely and complete electronic results (with identifiers) as per the methods of submission.

Tests that are performed entirely in the home with test results delivered on the testing device within the home are being developed and may be authorized in the future. Developers of such tests are encouraged to consider ways in which the data elements and information described above could be collected and reported given its critical importance to public health efforts. This might be accomplished through applications on a personal smartphone or tablet, a patient portal, direct transmission from the test platform itself, or other innovative technologies.

Links to the relevant applicable standards are available here:

- <https://loinc.org/sars-coronavirus-2/>
- <https://confluence.ihtsdotools.org/display/snomed/SNOMED%2BCT%2BCOVID-19%2BRelated%2BContent>
- <https://www.cdc.gov/csels/dls/sars-cov-2-livd-codes.html>
<https://phinvads.cdc.gov/vads/SearchVocab.action>
- <https://www.healthit.gov/test-method/transmission-public-health-agencies-reportable-laboratory-tests-and-valueresults#ccg>
- http://www.hl7.org/implement/standards/product_brief.cfm?product_id=98
- <https://hl7v2-elr-testing.nist.gov/mu-elr/#>
- <https://www.healthit.gov/isa/covid-19>

Additional Resources provided by CDC and FDA:

Test developers with questions about coding can send questions to:
SHIELD-LabCodes@fda.hhs.gov.

Test users (e.g., laboratories/healthcare providers) can send questions to: dlsinquiries@cdc.gov.

Laboratory Data Reporting and Electronic Health Records

Laboratory data serves not only as important information to support decision making related to the public health emergency, but also as a critical piece to better understanding the performance of tests in real-world conditions, the effectiveness of clinical interventions, and patient outcomes and interventions. Better understanding the characteristics and performance of tests can help ensure that healthcare providers are equipped with the maximum information necessary to make clinical decisions, develop recommendations, and provide the most appropriate care for their patients. Additionally, with widespread use of electronic health records (EHR), incorporating information related to laboratory testing can ensure completeness for future clinical research on

treatments, outcomes, quality and performance of diagnostic tests, and our clinical understanding of COVID-19.

To ensure that data can be captured in the electronic health record (EHR), HHS also recommends, but does not require, that the transmission of laboratory results back to the ordering provider (whenever possible) include the following information.

1. 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](#)
2. Test result date (date format)
3. Unique patient identifier
4. Test ordered – use appropriate LOINC codes
5. Device Identifier
6. Accession #/Specimen ID

These data fields represent the minimum information and any data transmission should be in accordance with the [HL7 Lab Results Interface \(LRI\) implementation guide](#) and standard. To ensure that patients receive timely and critical information regarding their own health condition and status, HHS also recommends, but does not require, the transmission of laboratory results be sent directly to the patient (or parent/guardian), either by mail (in writing), email (electronically), and/or via a patient portal or [secure standard-based application programming interface](#) (electronically), using commonly available standards such as FHIR (for instance, the [Argonaut Data Query Implementation Guide](#).)

LOINC and SNOMED-CT codes, as defined by the Laboratory In Vitro Diagnostics (LIVD) Test Code Mapping for SARS-CoV-2 Tests provided by CDC, should be used when possible to help ensure normalization and harmonization of data elements related to laboratory test and results.

Laboratories that meet the definition of a covered entity under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) regulations are permitted to disclose this protected health information (*i.e.*, laboratory results and other data elements described above) as provided in this guidance under the [HIPAA Privacy Rule](#). A laboratory's business associate also is permitted to disclose this protected health information if their business associate agreement allows the disclosure, or if the disclosure is pursuant to OCR's [Notification of Enforcement Discretion for Business Associates](#). Nothing in this guidance changes the existing requirements for HIPAA covered entities and business associates to comply with the applicable HIPAA Privacy, Security, and Breach Notification Rules.