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

March 8, 2022

Effective date: April 4, 2022

Introductory Information

Public Law 116-136, § 18115(a), the Coronavirus Aid, Relief, and Economic Security (CARES) Act, requires "[e]very 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). The statute authorizes the Secretary to prescribe the form and manner, and timing and frequency, of such reporting. This updated guidance outlines 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 data elements be reported through existing public health data reporting methods, namely through reporting to state, territorial, local, and Tribal (STLT) public health departments as described in this guidance. As a guiding principle, data must be sent to STLT health departments using existing reporting channels to ensure rapid public health response by those departments (in accordance with STLT law, policies, and procedures). This reporting should be conducted concurrent to test results being shared with an ordering provider or patient, as applicable. HHS acknowledges that reporting laboratories rely on information they receive from ordering health care providers with patient specimens, as laboratories do not typically interact with patients. To enable and effectuate the purpose of § 18115(a), HHS strongly encourages ordering providers to collect and transmit the required data elements to laboratories with test orders.

This guidance outlines federal HHS laboratory reporting requirements under Section 18115 of the CARES Act; STLT jurisdictions may have additional laboratory reporting requirements applicable to testing entities subject to their jurisdiction. Part A, Section 2 of this guidance requires laboratories and testing entities to comply with applicable STLT test reporting requirements. Nothing in this guidance limits or prohibits STLT health departments from requesting or requiring additional SARS-CoV-2 result and/or data element reporting.

Part A of this guidance specifies:

- Laboratory reporting requirements, including reporting requirements by entity and type of testing (Section 1);
- Reporting results required by STLT health departments (Section 2);
- Timing, frequency, and methods of submission (Section 3);
- Minimum required data elements (Section 4);
- Data reporting and transmission requirements (Section 5); and
- Guidance on laboratory reporting and electronic health records (Section 6).

Part B of this guidance provides recommendations for developers and manufacturers of SARS-CoV-2 self-administered tests to facilitate improved capture and reporting of high quality testing data and inform national efforts at the prevention and control of COVID-19.

Note on viral genomic sequencing and variant surveillance
Viral genomic sequencing and variant surveillance are outside the scope of this guidance but are recognized as vital parts of the COVID-19 response and have become increasingly important as the response evolves. While deidentified viral genomic sequencing data has additional complexities compared with other laboratory test result reporting, laboratories that perform sequencing should engage with STLT health departments to identify means of variant surveillance reporting to effectively facilitate public health action by STLT health departments, including responding to specific outbreaks. Timelines and processes for reporting lineages determined through viral genomic sequencing to STLT health departments should be established in accordance with relevant STLT laws or regulations. Additional information on reporting SARS-CoV-2 sequencing results can be found at Guidance for Reporting SARS-CoV-2 Sequencing Results.

Contents

A. Reporting Requirements

The sections below outline HHS SARS-CoV-2 laboratory reporting requirements.

Section 1: Reporting Requirements by Entity and Type of Testing

Federal HHS SARS-CoV-2 laboratory reporting requirements are based on (1) the entity that performs the testing and (2) the type of test being performed.

Guidance for tests that are entirely self-administered are addressed in Part B of this guidance.

i. SARS-CoV-2 Nucleic Acid Amplification Test (NAAT) testing conducted in a facility certified under CLIA to perform moderate- or high-complexity tests
Clinical Laboratory Improvement Amendments (CLIA)-certified laboratories that are certified to perform moderate- or high-complexity testing ***must report all test results (i.e., positive, negative, inconclusive) from NAAT testing (e.g., RT-PCR)***.

This includes, but is not limited to, NAAT testing performed for SARS-CoV-2 by clinical laboratories, including public health, commercial, healthcare system, and academic laboratories.

ii. All other SARS-CoV-2 testing (except antibody and self-administered testing)
Entities conducting all other SARS-COV-2 testing (e.g., testing conducted in a setting operating under a CLIA certificate of waiver, non-NAAT testing conducted in a facility certified under CLIA to perform moderate- or high-complexity tests) except antibody and self-administered testing, ***must report positive test results***. Reporting of negative results, either individual test results or in aggregate, is optional. This includes rapid testing conducted in many settings (e.g., screening testing at schools, correctional facilities, employee testing programs, long-term care facilities, and point-of-care testing performed in pharmacies, medical provider offices, and drive-through testing sites). Negative result reporting may still be required by applicable state or local law, and entities should check with the applicable STLT jurisdiction for specific reporting requirements.

Note, entities that are using digitally enabled diagnostic tests or automated devices are encouraged to identify potential avenues for reporting aggregate negative totals and/or individual negative test results in collaboration with STLT jurisdictions and public health authorities.

iii. SARS-CoV-2 antibody testing
This guidance does not require entities to report SARS-CoV-2 antibody test results unless required by applicable STLT law or regulation.

Table 1. Reporting Requirements by Entity and Type of Testing			
	Is Reporting Required Under this Guidance?		**Examples**
	Positive Results	**Negative & Inconclusive Results**	
NAAT-testing conducted in a facility certified under CLIA to perform moderate- or high-complexity tests	**Required**	**Required**	• Laboratory-based Nucleic Acid Amplification Test (NAAT) testing, including RT-PCR, TMA, LAMP, and SDA tests • See https://www.cdc.gov/coronavirus/2019-ncov/lab/naats.html for more information
All other testing (except antibody)	**Required**	**Optional***	• Testing conducted in a setting operating under a CLIA certificate of waiver such as rapid tests used in many settings (e.g., screening testing at schools, correctional facilities, employee testing programs, long-term care facilities, and point-of-care testing performed in pharmacies, medical provider offices, and drive-through and pop-up testing sites) • Non-NAAT (e.g., high throughput antigen) testing conducted in a facility certified under CLIA to perform moderate or high-complexity tests
Antibody testing	**Optional***	**Optional***	• Tests used to determine previous infection with SARS-CoV-2 in any setting

* State, local, territorial, and Tribal jurisdictions may have additional laboratory reporting requirements applicable to testing entities subject to their jurisdiction. Refer to the applicable jurisdiction's reporting requirements.

Section 2: Reporting Results Required by STLT Health Departments

Generally, this guidance is intended to provide minimum test result and diagnostic data reporting requirements as set by HHS consistent with the CARES Act. **However, testing entities must follow all SARS-CoV-2 test-result reporting requirements issued by STLT health departments in addition to the minimum reporting requirements in Section 1.**

Section 3. Timing, Frequency, and Methods of Submission

For test results that are required to be reported under Section 1, entities must report:

(1) information for each individual test,
(2) within 24 hours of results being known or determined,
(3) at least on a daily basis, and
(4) to the appropriate STLT health department based on the individual's residence.

Entities required to report results under Section 1 of this guidance must submit test results to STLT health departments using one of the existing reporting channels below:

i. **Submission directly to a STLT health department**: Submission of laboratory testing data as set forth in this guidance directly to STLT health departments. These health departments will then submit deidentified data to the Centers for Disease Control and Prevention (CDC) on a daily basis using either Health Level 7 (HL7®) messaging or the CDC-provided CSV format.

ii. **Submission to STLT health agency via a centralized platform:** Submission of laboratory testing data to STLT health departments through a centralized platform, for example through APHL Informatics Messaging Services (AIMS) or the CDC-provided ReportStream tool. These health departments will then submit deidentified data to the CDC on at least a daily basis using either Health Level 7 (HL7®) messaging or the CDC-provided CSV format.

iii. **Submission through state or regional health information exchange**: Submission of laboratory testing data through a state or regional health information exchange (HIE) to the appropriate STLT health department and to the CDC, as directed by the state.

iv. **Submission through the National Healthcare Safety Network (long-term care facilities only):** Centers for Medicare & Medicaid Services (CMS)-certified long-term care (LTC) facilities may submit point-of-care SARS-CoV-2 testing data, including antigen testing data, to CDC's National Healthcare Safety Network (NHSN). This CDC- and CMS-preferred pathway to submit data to CDC's NHSN applies only to CMS-certified LTC facilities. Test data submitted to NHSN will be reported to appropriate STLT health departments using standard electronic laboratory messages. Other types of LTC facilities may also report testing data in NHSN for self-tracking or to fulfill STLT reporting requirements, if any.

Section 4. Minimum Required Data Elements

Required Data Elements and Data Harmonization

The following data elements must be collected and reported for SARS-CoV-2 laboratory tests (as required under Section 1) for the transmission of complete laboratory testing data to the appropriate STLT health departments. STLT health departments may vary in their reporting requirements. Technical Specifications for Implementation for COVID-19 Data Reporting for Laboratory-Based Testing are available to support stakeholder adoption of standardized and harmonized coding for diagnostic data elements. STLT health departments will send deidentified data to CDC or the Secretary's designee. (Note: Additional data elements may be requested at a future date).

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. Patient age
6. Patient race
7. Patient ethnicity
8. Patient sex
9. Patient residence zip code
10. Patient residence county
11. a) Test ordered and b) test resulted– use appropriate LOINC codes, as defined by the Laboratory In Vitro Diagnostics (LIVD) Test Code Mapping for SARS-CoV-2 Tests provided by CDC
12. Device identifier
13. Test result (values) – use appropriate SNOMED-CT codes, as defined by the Laboratory In Vitro Diagnostics (LIVD) Test Code Mapping for SARS-CoV-2 Tests provided by CDC
14. Test result date (date format)
15. Date specimen collected (date format)
16. Accession #/Specimen ID
17. Ordering organization or ordering provider name and NPI (as applicable), address, phone number, zip code along with affiliated organization (specific facility)
18. Performing facility name and CLIA number, address, phone number, code
19. Specimen Source - use appropriate SNOMED-CT, LOINC, or SPM4 codes, or equivalently detailed alternative codes
20. Reporting entity name and CLIA number (or appropriate ID), and address.

*Personally identifiable information (PII) is suppressed before data transmission to CDC.

In order for all of these data elements to be available for laboratories to report, it is critical that these data be collected at the time the test is ordered and provided by the submitter to the laboratory performing the test. **Any person or entity ordering a test, registering an individual to be tested, collecting a specimen, or performing a test subject to the guidance and these reporting**

requirements 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 STLT health departments and to comply with this guidance.

To protect patient privacy, any data that STLT health departments send to CDC will not include some patient-level information. The data shared with CDC will contribute to understanding COVID-19's impact, positivity trends for NAAT testing, testing coverage, and will help identify supply chain issues for reagents and other materials. Additional data elements, including "ask on entry" questions, are no longer requested, given the volume of COVID-19 testing in the United States.

Section 5. Data Reporting and Transmission Requirements

When possible, all information and elements set out above should be collected using health information technology certified to the Office of the National Coordinator for Health Information Technology (ONC) 2015 Edition certification criteria, and all information and elements set out above should be structured in accordance with the US Core Data for Interoperability (USCDI) when available or when possible. All data transmission in furtherance of the reporting set out above should occur electronically using Health Level 7 (HL7®) electronic laboratory reporting (ELR) implementation guides when possible, but a pre-defined 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 specimens that are sent to a laboratory for testing, the laboratory must be able to collect the required information to comply with required reporting. To accommodate this required reporting, the process for specimen collection should include collection and submission of all the data elements above (along with the specimen) to the laboratory performing the test, which will then report to the STLT health department consistent with this guidance. For point-of-care testing, the laboratory (including a facility or setting with a CLIA certificate of waiver) must ensure the test is set up and operational to deliver timely and complete electronic results (with identifiers) per the methods of submission.

Links to the relevant applicable standards:

- Guidance for mapping to SARS-CoV-2 LOINC terms – LOINC
- LOINC In Vitro Diagnostic (LIVD) Test Code Mapping for SARS-CoV-2 Tests | CDC
- PHIN VADS - Search All Vocabulary (cdc.gov)
- Transmission to public health agencies — reportable laboratory tests and value/results | HealthIT.gov
- HL7 Standards Product Brief - HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1 (US Realm) | HL7 International
- ELR Validation Tool @ NIST
- COVID-19 Novel Coronavirus Pandemic | Interoperability Standards Advisory (ISA) (healthit.gov)

Additional Resources provided by CDC and FDA:

- In vitro diagnostic commercial 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.

Section 6. Guidance on Laboratory Data Reporting and Electronic Health Records

To ensure that data are captured in the 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 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® (Fast Healthcare Interoperability Resources) (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 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 HHS 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 HHS Office of Civil Rights' (OCR) 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.

B. Self-Administered Tests

Self-administered SARS-CoV-2 home use tests (not including self-collected specimens where the test is performed at a laboratory)

Home use tests that are entirely self-administered (i.e., a test that allows for self-collection and testing at home, also known as home use or over the counter tests) have been authorized for emergency use by the federal Food and Drug Administration (FDA), and tests from additional test developers may be authorized in the future. While self-administered tests are outside the reporting requirements for laboratories in Section 18115 of the CARES Act as articulated in this guidance, these tests are of enormous potential public health and clinical value and utility.

Developers of self-administered tests are strongly encouraged to consider ways in which the data elements and information described in this guidance could be enabled to be collected and reported to public health authorities given their importance to current and future 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. Manufacturers working to enable automated, digital and/or wireless reporting from these at home or point-of-care technologies are strongly recommended to ensure the collection of all the data elements in Section 4 is enabled and data systems have the capacity to securely transfer data to a centralized platform as described in Section 3. Technical specifications for implementation for COVID-19 data reporting for non-laboratory-based testing are available to support stakeholder adoption of standardized and harmonized coding for diagnostic data elements.