Data Reporting for COVID-19 Testing

Information and Resources for Providers

Overview

Since the start of the COVID-19 public health emergency, clinical laboratories have worked closely with the provider community and public health officials to ensure relevant patient information is included in COVID-19 test orders.

This critical data helps inform prevention, surveillance and mitigation efforts across the country, including identifying patients at higher risk for infection, hospitalization and death from COVID-19. Further, this information provides important insight to better understand the disproportionate impact of COVID-19 on older Americans, people of color and other marginalized and minoritized communities to ensure that these high-risk populations are protected.

[Recent guidance](#) released by the U.S. Department of Health and Human Services (HHS) takes an important step in setting a national standard for data elements and patient demographic information that must be collected and reported for COVID-19 testing. Clinical laboratories rely on physicians, nurse practitioners, pharmacists, physician assistants and other health care providers to include demographic information from patients on every test order. Clinical labs do not typically interact directly with patients, making their ability to collect patient information limited to the data they receive from the ordering provider.

If we are to make progress on addressing the disproportionate impact of COVID-19 on marginalized and minoritized communities, we must work collaboratively to address gaps in our data reporting system. First and foremost, providers and laboratories must be committed to adhering to their respective reporting requirements and work together to close any data gaps in the least burdensome way possible. Furthermore, it is critical that we modernize our country's health IT systems to provide clinicians and laboratories with the tools and information they need to accurately and efficiently capture data on testing orders, not just for COVID-19, but for public health surveillance broadly.

Addressing the current patchwork reporting system across the states as well as the ongoing technical challenges will require strong federal coordination and leadership, and clinical labs are committed to supporting these important reporting efforts as part of our robust response to the COVID-19 pandemic.

Below are Frequently Asked Questions regarding COVID-19 data reporting. For additional questions, please reach out to Liz Thomas (lthomas@acla.com).

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Frequently Asked Questions

1. **Why has HHS expanded the kinds of information that must be reported by laboratories and other entities that conduct COVID-19 testing?**

   HHS developed this guidance in response to the recently enacted CARES Act, which requires that "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" reports the results from each such test in a manner determined by HHS. Although state and local public health departments have required testing results reporting since the beginning of the COVID-19 public health emergency, the requirements for patient information and other data elements have varied across states. The recent HHS guidance creates a national standard for the data fields required so that this critical information can inform real-time clinical interventions and mitigation strategies across the U.S.

2. **What information must be collected and reported for COVID-19 testing?**

   Beginning August 1, 2020, HHS will require that laboratories and other entities that conduct COVID-19 testing immediately begin reporting the following information:

   1. Test ordered
      a. Use harmonized LOINC codes provided by CDC.
   2. Device Identifier
   3. Test result
      a. 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 or DOB
   7. Patient race
   8. Patient ethnicity
   9. Patient sex
   10. Patient Street address
   11. Patient residence zip code
   12. Patient residence county
   13. Ordering provider name and NPI (as applicable)
   14. Ordering provider zip
   15. Ordering Provider phone number
      a. This is a critical element to assist public health authorities in follow up.
   16. Performing facility name and/or CLIA number, if known
   17. Performing facility zip code
   18. Specimen Source
      a. Use appropriate LOINC, SNOMED-CT, or SPM4 codes, or equivalently detailed alternative codes.
   19. Date test ordered (date format)
   20. Date specimen collected (date format)
   21. First test (Y/N/U)

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a. Indicates whether this is the patient's first test for the condition of interest.

22. Employed in healthcare? (Y/N/U)
    a. Indicates whether patient is employed in a healthcare setting, particularly those who work in a high-risk setting with patients.
23. Symptomatic? (Y/N/U)
    a. This is defined per current CDC guidance at time of order for the reportable condition/illness.
    b. If yes, then Date of Symptom Onset (mm/dd/yyyy).
24. Hospitalized? (Y/N/U)
    a. Indicates whether the patient has been hospitalized for the reportable illness/condition that this order has been placed for (suspected or diagnosed).
25. ICU? (Y/N/U)
    a. Indicates if patient has been admitted/transferred to the ICU at any time during the encounter for the reportable illness/condition that the order has been placed for (suspected or diagnosed).
26. Resident in a congregate care setting? (Y/N/U)
    a. This includes 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 at time of exposure where they normally live.
27. Pregnant?
    a. If the patient is female, expected answers are: Patient currently pregnant or possibly pregnant (Y); Not pregnant (N); or Unknown (U).

3. **For which kinds of tests is public health reporting required?**

   Federal guidance and state laws require public health reporting of patient information for **all** COVID-19 tests conducted at a lab or other entity with a certificate under the Clinical Laboratory Improvement Amendments (CLIA). Reporting is required for all diagnostic tests to detect infection with SARS-CoV-2 and antibody tests to detect immune response, regardless of the outcome of the test. It is critical that clinicians collect patient demographic information when ordering a COVID-19 test and include that information when the specimen and test order are sent to a lab. Laboratories are then required to report the patient data they receive from the clinician for each individual tested for COVID-19 within 24 hours of receiving results. In the case of point-of-care (POC) testing, clinicians performing POC tests are also required to report required patient data with all test results to public health departments beginning August 1. Reporting must happen on a daily basis to the appropriate state or local public health department based on where the individual resides or where the provider is located if the patient is out-of-state.

4. **Who is obligated to participate in public health reporting for COVID-19 test results, and how should patient information be collected?**

   Laboratories and other entities with CLIA certificates that conduct COVID-19 testing are required to report test results and patient information to local or state public health departments. Clinicians that order COVID-19 tests are required to collect all required patient information (noted in Question 2 and listed here) when ordering the test. Clinicians must share this information with laboratories when submitting the test order, or

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in the case of POC testing, clinicians conducting POC tests must report results with patient information, including the expanded data elements to the local and/or state public health department directly.

[Federal guidance specifies that entities conducting testing should utilize one of the following methods of submission](#):

- Submission of laboratory testing data directly to state or local public health departments, as required by state and/or local law or policy, followed by submission of 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.
- 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.
- 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.

5. **To which state public health departments should clinicians and labs report patient information and test results, and where can providers find more information about reporting requirements?**

   The reporting obligation is based on the patient's residence or the provider location for cases when a patient is out-of-state. Clinicians and labs should contact their local and/or state departments of health directly for more information on reporting requirements and the method for reporting.

6. **What happens if the provider who is caring for the patient being tested does not provide the required patient information – how can the laboratory secure the necessary information?**

   Ordering providers should make every effort to collect this critical information from patients during ordering and/or the specimen collection process. If ordering providers do not collect this information from patients, labs lose the opportunity to provide robust data to public health authorities to inform COVID-19 response efforts.

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