



CDC Newsroom

HHS Announces New Laboratory Data Reporting Guidance for COVID-19 Testing

Press Release

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Contact: [Media Relations](#)

(404) 639-3286

Today, the U.S. Department of Health and Human Services (HHS) announced new Guidance that specifies what additional data must be reported to HHS by laboratories along with Coronavirus Disease 2019 (COVID-19) test results. The Guidance standardizes reporting to ensure that public health officials have access to comprehensive and nearly real-time data to inform decision making in their response to COVID-19. As the country begins to reopen, access to clear and accurate data is essential to communities and leadership for making decisions critical to a phased reopening.

“HHS and the entire Trump Administration are deeply concerned that COVID-19 is having a disproportionate impact on certain demographics, including racial minorities and older Americans,” said HHS Secretary Alex Azar. “High quality data is at the core of any effective public health response, and standardized, comprehensive reporting of testing information will give our public health experts better data to guide decisions at all levels throughout the crisis.”

The new reporting requirements will provide information needed to better monitor disease incidence and trends by initiating epidemiologic case investigations, assisting with contact tracing, assessing availability and use of testing resources, and anticipating potential supply chain issues.

“The requirement to include demographic data like race, ethnicity, age, and sex will enable us to ensure that all groups have equitable access to testing, and allow us to accurately determine the burden of infection on vulnerable groups,” said ADM Brett P. Giroir, MD, Assistant Secretary for Health. “With these data we will be able to improve decision-making and better prevent or mitigate further illnesses among Americans.”

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 impact on socially vulnerable populations. Laboratory testing data, in conjunction with case reports and other data, also provide vital guidance for mitigation and control activities.

In addition, Health Information Exchanges can have a valuable role in this process and 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.

[Read the laboratory data reporting guidance.](#) – PDF   *

[Read the laboratory data reporting FAQs.](#) – PDF   *

The Guidance is being issued pursuant to the Coronavirus Aid, Relief, and Economic Security (CARES) Act

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). 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.

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