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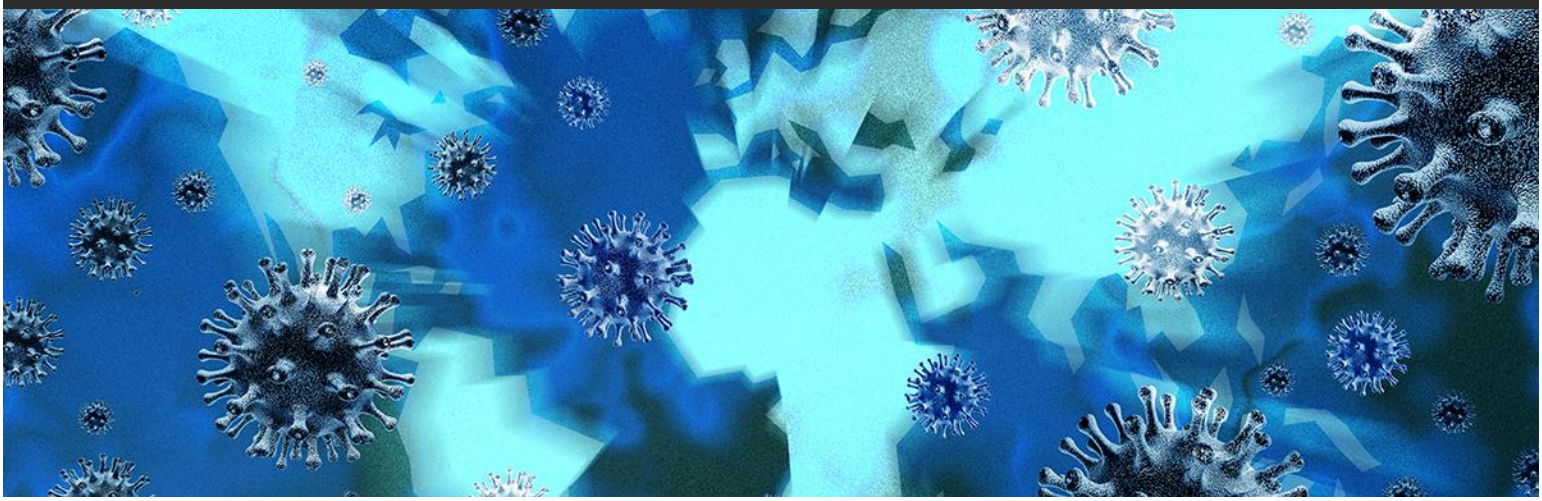
Alert | Health Emergency Preparedness Task Force: Coronavirus Disease 2019



March 20, 2020

COVID-19 Testing: Access Continues to Present Challenges Despite Recent Advances

The development of laboratory assays to test for the novel coronavirus that causes coronavirus disease 2019 ("COVID-19") has been moving at an accelerated pace, with medical device manufacturers and clinical laboratories working tirelessly to develop and validate. Federal, state, and local public health authorities have taken unprecedented steps to promote the development of COVID-19 testing, expand access to tests, and provide vital information to the public. The U.S. Food and Drug Administration (FDA) is working quickly to authorize new diagnostic tests to the market to meet the demand for both testing and screening. Also, the Centers for Medicare and Medicaid Services (CMS), state health programs, and commercial health insurers have helped to expand access to testing by ensuring coverage for COVID-19 testing to avoid potential impediments to accessing needed care. Nevertheless, it remains difficult for many to get tested due to the current number of laboratories able to offer COVID-19 testing, as well as the issues surrounding specimen collection and eligibility for testing. These challenges continue to hinder access to COVID-19 testing and remain key areas for government regulators and the health care industry to work together to address.

Further innovations are anticipated from medical device and clinical laboratory companies working to develop COVID-19 testing that simplifies specimen collection or uses different specimen types for heightened accuracy. In the meantime, greater flexibility by government regulators to permit at-home, self-collection of specimens could significantly enhance access to testing and reduce risks of transmission. COVID-19 testing currently relies on the collection of an upper respiratory nasopharyngeal swab, oropharyngeal swab, and potentially the collection of sputum. The Centers for Disease Control and

Prevention (CDC) has issued guidelines related to specimen collection (*see* Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons for Coronavirus Disease 2019 and Interim Guidance for Public Health Personnel Evaluating Persons Under Investigation (PUIs) and Asymptomatic Close Contacts of Confirmed Cases at Their Home or Non-Home Residential Settings). The specimen-collection process can induce coughing and sneezing and presents real risks of transmission to health care professionals if precautions are not followed. Some of those precautions involve the use of personal protective equipment, which can be in short supply. Concerns about transmission and shortages of protective equipment have prompted many health care providers not to offer sample collection or access to testing. This problem could potentially be addressed if patients are permitted to collect specimens from their homes and securely send them to an authorized laboratory for analysis, but currently self-collection is not allowed for the tests authorized by FDA.

Another impediment to testing access is the criteria for eligibility. Although the eligibility criteria to be tested has expanded since the early days of COVID-19 testing and now includes consideration of clinical symptoms as well as exposure to individuals with COVID-19 and travel history, it may still be too narrow. Further, many providers willing to perform specimen collection for COVID-19 testing may misunderstand the CDC's criteria, rely on outdated information, or otherwise unduly restrict test access. Some physicians, for instance, will still only order testing for those who have traveled to countries with heightened risks or who have had contact with an individual who has been diagnosed with COVID-19. Reliance on the latter factor, however, can be particularly constraining, given that many individuals with COVID-19 likely have not been diagnosed or even tested. Further clarification, expansion, or even elimination of eligibility criteria could prove valuable in enhancing access, particularly as testing capability continues to increase.

Despite these challenges, because of the efforts of dedicated public servants at the federal, state, and local level, there are numerous resources available to medical device manufacturers, clinical laboratories, and health care providers who are part of the effort to make COVID-19 testing more widely available.

The FDA's emergency use authorization (EUA) has allowed clinical laboratories to obtain expedited authorization to market and use diagnostic tests for COVID-19. FDA has also issued and recently updated FAQs on Diagnostic Testing for SARS-CoV-2 to clarify common issues related to the development and performance of diagnostic tests, and the Agency has provided templates for EUA submissions to facilitate requests for emergency authorization. In addition to the resources made available by FDA, CDC has developed a page providing Information for Laboratories, which provides guidance and recommendations related to CDC's EUA-authorized COVID-19 test, as well as other testing.

On Monday, March 16, FDA expanded its policy related to the Emergency Use Authorization ("EUA") of COVID-19 testing to permit states and territories to authorize laboratories to conduct validated COVID-19 testing without the submission of an EUA request to FDA. Under the FDA's revised policy, commercial test-kit manufacturers may now also distribute COVID-19 test kits prior to the submission of an EUA, provided that certain criteria are met. However, this policy specifically excludes at-home testing, as does a new policy allowing greater flexibility regarding the development and use of serology tests.

CMS has issued numerous resources that are helpful to clinical laboratories regarding coverage and reimbursement of COVID-19 testing:

- Medicare Administrative Contractor COVID-19 Test Pricing
- COVID-19 Frequently Asked Questions (FAQs) for State Medicaid and Children's Health Insurance Program (CHIP) Agencies

- Memorandum to All Medicare Advantage Organizations, Part D Sponsors, and Medicare-Medicaid Plans
- COVID-19 FAQs
- Press Release: CMS Develops Additional Code for Coronavirus Lab Tests
- Information Related to COVID-19 Individual and Small Group Market Insurance Coverage

Further, multiple large and small commercial health insurers have taken steps to expand access to COVID-19 testing by increasing coverage, eliminating the need for prior authorizations, and waiving patient cost-sharing obligations.

For more information and updates on the developing COVID-19 situation, visit GT's Health Emergency Preparedness Task Force: Coronavirus Disease 2019.

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