



March 30, 2020

UPDATED Overview of COVID-19 Testing Efforts

COMMITTEE ON ENERGY & COMMERCE

PURPOSE

- This document addresses issues related to COVID-19 testing. The information in this document is based on information provided by the Trump Administration. This document is intended to provide Members with the latest reported information during this unprecedented pandemic. The Committee continues to receive updates from Administration officials and will update Members as new information becomes available.

LATEST DEVELOPMENTS

- **Approximately 100,000 patients are now being tested each day, but the Administration estimates it will likely be June or July before everyone who wants to be tested can receive one.** Limitations in testing capability may be due to testing supply access, as well as personal protective equipment (PPE) supply. Some areas are preserving their test kits for high-priority patients or limiting tests at certain sites to ensure they do not run out of testing supplies or PPE.
- Laboratories have different platforms that are not interchangeable, so not all tests can be performed everywhere, and some are experiencing shortages of testing supplies and chemical reagents. Health care entities are also trying to preserve PPE necessary to administer tests. For entities with limited supplies of PPE, utilizing PPE for testing may mean that PPE would not be available for health care professionals needing to treat high-risk, sick patients.
- **Last week, the Food and Drug Administration (FDA) issued an [Emergency Use Authorization](#) of a [point-of-care \(POC\) test by Abbott](#) that can reportedly deliver positive results in as little as five minutes and negative results in 13 minutes. The company has stated that it is ramping up production to deliver 50,000 tests each day starting this week. This is in addition to the authorization of two rapid POC tests, by Cepheid and Mesa, that can be used in laboratories and certain patient settings, providing results in up to 45 minutes.**
- **The Centers for Disease Control and Prevention (CDC) also partnered with Apple to release an app and [website](#) that helps guide individuals through a series of questions to determine if they should seek care for COVID-19.**

PRIORITIES FOR WHO SHOULD BE TESTED FOR COVID-19

- CDC has noted that health care providers should use their best judgment on which patients should be tested; however, last week CDC [issued updated criteria for testing priorities](#):
 - **Priority 1: Hospitalized patients with signs and symptoms compatible with COVID-19**

and symptomatic health care workers;

- **Priority 2: Symptomatic individuals who are at highest risk, which includes patients in long-term care facilities, older adults, individuals with chronic medical conditions and/or an immunocompromised state that may put them at higher risk, and first responders; and**
- **Priority 3: As resources allow, testing of individuals in communities with rapidly increasing hospital cases, including symptomatic critical infrastructure workers, symptomatic individuals not in priority 1 or priority 2, health care workers and first responders, and individuals with mild symptoms in communities experiencing high COVID-19 hospitalizations.**

WHAT SOMEONE SHOULD DO IF THEY THINK THEY MAY HAVE COVID-19

- Call ahead! If you are experiencing symptoms of COVID-19 (fever, cough, shortness of breath), and may have had contact with a person with COVID-19, or recently traveled outside the country, call your health care provider first before seeking medical care. This is important for your protection and for ensuring the safety of your community.
- CDC has compiled a [one pager](#) with links to all state and territorial health department websites.

PUBLIC HEALTH LAB TESTING

- For public health labs, [CDC provides the necessary test kits](#). Clinicians looking to access these tests should work with either their public health laboratory or the laboratories they routinely work with to see how best to access validated tests for COVID-19.
- According to [CDC](#), 93 public health labs currently have the capacity to administer a COVID-19 test. This includes at least one public health lab in each of the 50 states, Washington, D.C., Guam, and Puerto Rico.
- Additional information can be found at [APHL's website](#). State and local questions can be directed to the Emergency Operations Center at eoc@aphl.org.

FDA OVERSEES DIAGNOSTIC TESTING

- FDA has regulatory authority over in vitro diagnostics that are used to diagnose a disease or condition, including COVID-19. FDA states that it has actively been working with CDC, interested states, labs, and commercial developers to [provide guidance](#) on how to expand access to diagnostic tests, while also ensuring accurate tests.
- To assist labs and test developers, FDA has released templates detailing the information FDA will need in order to authorize a lab test under an emergency use authorization (EUA). Those templates are available [at this link](#).

- FDA has released a [frequently asked questions page](#) to assist labs and developers pursuing an EUA. If labs and developers have additional questions, they can reach FDA 24 hours a day, seven days a week by calling 1-888-INFO-FDA (1-888-463-6332) and pressing *, or they can email CDRH-EUA-Templates@fda.hhs.gov.
- FDA has issued guidance to allow laboratory test kit manufacturers and laboratories certified to perform high complexity testing to begin testing of individuals following a notification to FDA and demonstration of validation.
 - Under this guidance, a submission of an EUA application should be made within 15 business days of notification. A new FDA policy also allows states to work with the agency to set up a system in which the state takes responsibility for authorizing lab tests.
- **As of March 29, in addition to the test offered by CDC, FDA has [issued EUAs](#) for 15 commercial in vitro diagnostic products, three commercial lab tests, and a test offered by the New York State Department of Health. [Four states are authorizing their own tests, and FDA has authorized nearly 50 laboratory-developed tests.](#)**
- To help mitigate shortages of testing supplies, FDA has [issued guidance](#) for laboratories to consider using an alternative foam swab. A senior official has reported to the Committee that there are currently six-to-seven million of these swabs in the supply chain. **This foam swab is also useful because it does not require health care providers to change their PPE after each sample is taken, helping to administer more widespread testing without sacrificing valuable PPE.**
- On March 24, the Federal Emergency Management Agency (FEMA) announced it would be [utilizing the Defense Production Act \(DPA\) to allocate 60,000 test kits](#) where they are needed though later stated the agency was able to secure the test kits without evoking the DPA.
- For laboratories experiencing difficulty in accessing the necessary materials to run diagnostic tests for COVID-19, [FDA has identified acceptable alternatives that can be used.](#)