



April 15, 2020

## UPDATED - Overview of COVID-19 Testing Efforts

### COMMITTEE ON ENERGY & COMMERCE

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#### 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

- To date, Centers for Disease Control and Prevention (CDC), public, and commercial laboratories have tested over 2.39 million samples.
- On average, between 110,000–130,000 diagnostic tests are now conducted each day. The Administration has stated that it anticipates scaling up testing over the next four to six weeks, and that it eventually expects increasing the number of tests run each day to four to five times the current average.
- Serological tests, which detect the body's immune response to infections, such as COVID-19, rather than diagnostic tests, which detect the virus itself, can be used to help determine whether a person has previously contracted COVID-19 and developed antibodies. Because serological tests are believed to be less complex than diagnostic tests, the Food and Drug Administration (FDA) has said it will not object to these tests being developed and distributed for use in laboratories or by health care workers at point of care, as long as the test has been validated, the manufacturer has notified FDA, and the test includes warnings, including one noting that the test has not been reviewed by FDA. Nevertheless, FDA has encouraged serological test manufacturers to request an emergency use authorization (EUA) for their tests and [has granted one such serology test EUA](#). A list of tests that have received an EUA is available [here](#) and a list of manufacturers who have notified FDA that they intend to market a test without FDA authorization is available [here](#).
- The scientific community is working hard to determine parameters of use for serological tests; we currently know that the presence of specific antibodies means an individual has been exposed to the COVID-19 virus, but it is not fully understood how much protective immunity this confers to an individual. The Administration has stated that it expects to have approximately 20 million serological tests available each month in the future.
- The Federal Emergency Management Agency (FEMA) announced that the 41 Community-Based Testing Sites (CBTS) would be transitioned to state and local oversight on April 10, later [issuing an advisory](#) to clarify that states needed to confirm whether they would seek to

transition to full state control with federal supply assistance, or to continue under current operations. Those states that have requested continued FEMA presence at their CBTS have been asked to notify FEMA by May 30 if they are still not ready to transition.

- On March 27, FDA issued an EUA 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. Abbott currently has 18,000 machines in place across the country in different health facilities producing 50,000 tests per day in prioritized high-risk areas and is working to increase production to 100,000 tests per day. The Department of Health and Human Services (HHS) announced on April 6 that it has purchased 1,200 Abbott POC tests for distribution to state, territorial, and tribal public health labs. 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. Cepheid is working to eventually produce up to ten million tests per month.
- Most COVID-19 diagnostic tests rely on a nasopharyngeal or oropharyngeal swab to collect a sample from a patient. On April 13, FDA issued an EUA to Rutgers RUDCR Infinite Biologics for a test that uses saliva, the first such authorization for COVID-19. While this test will still need to be conducted in a health care setting, this development is promising because health care providers will not be required to directly handle swabs and risk further exposure to coronavirus.
- 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.
- Ongoing limitations in testing capability may be due to testing supply access, including personal protective equipment (PPE) supply. For instance, 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 also have different platforms that are not interchangeable, so not all tests can be performed everywhere, and some continue to experience shortages of testing supplies, including swabs and reagents. There are also reports of lack of plastic materials for use by manufacturers for their test kits, harming capacity of making these kits. Lab workforce capacity may be another reason for limitations in testing capabilities.

## **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. On March 24, [CDC issued an additional revision to its testing priorities criteria](#). These [include](#):
  - Priority 1: Hospitalized patients with 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.
- If someone is experiencing symptoms of COVID-19 (fever, cough, shortness of breath), and may have had contact with a person with COVID-19, they should call a health care provider first before seeking medical care.
- CDC has compiled a [one pager](#) with links to all state and territorial health department websites. In addition, some states have put forward a list of available sites for where an individual can be tested.

## **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](#), 98 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](mailto: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 EUA.
- 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 email [CDRH-EUA-Templates@fda.hhs.gov](mailto: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 individuals following a notification to FDA, and submission of an EUA application and demonstration of validation within 15 days. 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 April 13, in addition to the test offered by CDC, FDA has [issued EUAs](#) for 34 in vitro diagnostic products, including two rapid POC tests. [Seven states are authorizing the use of tests conducted by labs within their state boundaries, and FDA has authorized nearly 90 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 utilizing additional PPE.
- On March 24, 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.](#)