

# CORD

## Overview of COVID-19 Testing Efforts

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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.](#)



March 30, 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

- **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](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 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](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 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.](#)



March 24, 2020

## UPDATED Overview of COVID-19 Testing Efforts

### COMMITTEE ON ENERGY & COMMERCE

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#### LATEST DEVELOPMENTS

- The Administration notes that over 18 million tests have now been sent out, but only **313,000 tests have been run**. 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 to 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.
- **The Administration expects that the public health laboratories and other major laboratories will soon be able to run tens of thousands of tests per day**, and as a result, issues with testing high-priority individuals (e.g., symptomatic hospitalized patients and health care workers) will be resolved within 3-5 days. However, **the Administration estimates it will likely be June or July before everyone who wants to be tested can receive one**.
- **This week, the Food and Drug Administration (FDA) approved two rapid point-of-care tests that can be used in laboratories and certain patient settings, providing results in 45 minutes.**
- **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 6-7 million of these swabs in the supply chain.**

#### PRIORITIES FOR WHO SHOULD BE TESTED FOR COVID-19

- According to guidance from the Centers for Disease Control and Prevention (CDC), while health care providers should use their judgment on which patients should be tested, [CDC has indicated the following as priorities for testing](#):
  - Hospitalized patients with signs and symptoms compatible with COVID-19;
  - Other symptomatic individuals, such as older adults and individuals with chronic medical conditions and/or an immunocompromised state that may put them at higher risk; and
  - Any individuals, including health care personnel, who have had exposure to COVID-19 or who have a history of travel from affected geographic areas within 14 days of their symptom

onset.

## **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 to protect you and to keep your community safe.
- CDC has compiled a [one pager](#) with links to all state and territorial health department websites.

## **HOW IN VITRO DIAGNOSTIC TESTING WORKS FOR COVID-19**

- If you are a patient needing to be tested, a specimen will be collected, typically from the back of your throat or your nose, using a long swab. That specimen is then transferred to a collection device that will be sent to a qualified lab for processing.
- At the lab, technicians will amplify viral genetic material to determine whether the SARS-CoV-2 virus is present. If found, the patient will receive a positive result. Processing time of these samples varies based on the technology of the diagnostic test and the capacity of the lab.

## **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](#), 91 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, DC, 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).

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- 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](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 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 24th, in addition to the test offered by CDC, FDA has [authorized 11 commercial in vitro diagnostic products, two commercial lab tests, and a test offered by the New York State Department of Health. \[Four states are authorizing their own tests, and separately FDA has authorized nearly 40 laboratory developed tests.\]\(#\)](#)**
- 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.](#)

## **INVOKING THE DEFENSE PRODUCTION ACT**

- The [Defense Production Act \(DPA\)](#) was first enacted in 1950 as a national response to the Cold War. The DPA confers broad presidential authorities to mobilize domestic industry in service of the national defense, defined in statute as various military activities and [“homeland security, stockpiling, space, and any directly related activity”](#) including emergency preparedness activities under the Stafford Act, which has been used for public health emergencies.
- As the DPA’s definition of national defense encompasses homeland security issues, the DPA can be used to respond to public health emergencies, though this has not occurred before.
- President Trump issued an [executive order](#) on March 18th invoking DPA. This executive order delegated authority to HHS Secretary Azar to order production and distribution of health care supplies if necessary and as needed. The executive order allows Secretary Azar to consult with the heads of other departments and agencies on nationwide priorities and allocation of all health and medical resources, including controlling the distribution of such materials.