



March 24, 2020

UPDATED Overview of COVID-19 Testing Efforts

COMMITTEE ON ENERGY & COMMERCE

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.

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 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 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.