March 19, 2020

Overview of COVID-19 Testing Efforts

COMMITTEE ON ENERGY & COMMERCE

THE ROLL-OUT OF TESTING IN THE UNITED STATES

- COVID-19 testing in the United States has faced challenges, delaying availability and access to tests, and hindering contact tracing in communities.

- Rather than utilizing the test distributed by the World Health Organization, the Centers for Disease Control and Prevention (CDC) developed its own test, but has struggled to make it widely available.

- After a possible contamination in CDC's test that resulted in inconclusive results, CDC had to roll-back faulty tests, causing delays. After complaints that some patients at high-risk were not eligible for tests, CDC expanded its testing criteria.

- The Administration has repeatedly stated that millions of tests would be available, but CDC, public health labs, and private diagnostic labs have collectively tested approximately 59,000 people since January, while other countries have conducted tens of thousands per day.

- Recent reports indicate that while more tests may be available, labs have limited capacity to conduct tests, and are experiencing shortages of supplies such as cotton swabs and other testing agents.

PRIORITIES FOR WHO SHOULD BE TESTED FOR COVID-19

- According to guidance from 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 the Association of Public Health Laboratories (APHL), 89 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 — and more are coming online each day.

- 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.

- As of March 17th, public health laboratories had reported out approximately 32,000 tests. Clinical laboratories have reported out about 27,000 tests, and 8,200 of the clinical laboratories' tests were reported out on March 16th alone.

FDA OVERSEES DIAGNOSTIC TESTING

- The Food and Drug Administration (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. More than 100 companies have requested and received these templates.

- 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 17th, in addition to the test offered by CDC, FDA has authorized three commercial in vitro diagnostic products, a commercial lab test, and a test offered by the New York State Department of Health. A number of other labs have notified FDA that they have validated their own diagnostic test and have started patient testing.

- 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.

- On March 18th, the President signed an executive order invoking DPA to address concerns over medical supplies shortages due to the COVID-19 outbreak. This executive order delegated this authority to the HHS Secretary Azar to order production and distribution of healthcare supplies if necessary and as needed. Prior to this announcement the Department of Defense announced they would be making available five million N95 respirator masks and other personal protective equipment, as well as 2,000 deployable ventilators.

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