FDA STATEMENT

Coronavirus (COVID-19) Update: FDA expedites review of diagnostic tests to combat COVID-19

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Statement From:

Commissioner of Food and Drugs - Food and Drug Administration
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Español (/news-events/press-announcements/actualizacion-del-coronavirus-covid-19-la-fda-acelera-la-revision-de-las-pruebas-de-diagnostico-para)

The U.S. Food and Drug Administration has been providing unprecedented flexibility to labs and manufacturers to develop and offer COVID-19 tests across the U.S. The FDA's regulations have not hindered or been a roadblock to the rollout of tests during this pandemic. Every action the FDA has taken during this public health emergency to address the COVID-19 pandemic has balanced the urgent need to make diagnostic tests available with providing a level of oversight that ensures accurate tests are being deployed. Moreover, as in previous emergencies, the FDA has been extremely proactive and supportive of test development by all comers—laboratories, and large and small commercial manufacturers—offering our expertise and support to speed development and to quickly authorize tests that the science supports.

It is not the FDA's role to develop tests or decide what tests a health care professional uses. Our role is to determine if the tests developed by others provide accurate and reliable results, even when some would prefer that we let tests on the market without evidence that they work. It's critical that the tests used work. False results can also contribute to the spread of COVID-19. We want our treatments to be tested for effectiveness and reviewed by the FDA. We want the same for our tests—assurances that they are accurate and effective.

Developing a test:

- Typically, with an emerging health threat, the Centers for Disease Control and Prevention (CDC) is the first developer of a diagnostic test in the U.S. - Samples of the virus are crucial to confirming the accuracy of the test.
- CDC has first access to viral samples that other test developers do not. CDC also manufactures their own tests for distribution to their national network of public health labs. In this pandemic, CDC encountered problems manufacturing their test. FDA assisted CDC in their work to resolve the issue and utilize a commercial manufacturer to make tests for any laboratory, not only public health labs.
- Viral samples became commercially available to private sector test developers in later February, when the National Institutes of Health's partner BEI Resources began selling vials of the virus grown from material provided by CDC.
- Laboratories have always had the ability to develop their own tests in the U.S.; the COVID-19 outbreak did not change this. Once a developer has a viral sample, they can confirm the accuracy of their test very quickly, usually in two to three days.
- In the future, making viral samples available earlier to commercial developers will be crucial to deploying tests quickly. Moreover, CDC's test should be manufactured by a commercial entity with the requisite

expertise.

Timeline of FDA support for test developers:

- Since the beginning of January, the FDA has worked with more than 230 test developers who have or are expected to submit requests for FDA emergency authorization of their tests; to date, 20 authorizations have been granted.
- In addition, more than 110 laboratories have notified the FDA that they have begun using their own tests.
- For interested developers, the FDA provided recommendations for how to check a test for accuracy as well as a short form to make it easy to share their test information quickly in support of an Emergency Use Authorization (EUA).

Emergency Use Authorization authorities:

- An EUA, put into place by Congress, is a relaxed standard that allows tests to be made available based on less data than in non-urgent circumstances and allows for expedited FDA review.
- In many cases, the FDA can do this review in as little as a day, which it has done repeatedly.
- EUA authority is not a barrier to test availability.

FDA policy updates:

- The FDA recognized the urgent need for even faster testing availability. Although laboratories could use the EUA pathway, many were hesitant or didn't know the pathway was available to them.
- To respond to this need, the FDA revised the process to allow labs to begin testing prior to FDA review of their validation data. This policy change was an unprecedented action to expand access to testing. Nevertheless, in the first week, only six laboratories took advantage of this further streamlined process because many laboratories did not have a test, or did not have the viral samples to check the accuracy of their test.
- In addition, the FDA implemented another change to empower states to take responsibility for tests developed and used by laboratories in their states without FDA review.

The FDA has and will continue to play a pivotal role in this emergency response.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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