

Coronavirus (COVID-19) Update: FDA Provides More Regulatory Relief During Outbreak, Continues to Help Expedite Availability of Diagnostics

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Statement From:

Commissioner of Food and Drugs - Food and Drug Administration

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Today, as part of our ongoing and aggressive commitment to address the coronavirus outbreak, the FDA updated a [policy](#) originally issued on Feb. 29 on diagnostic testing for coronavirus (COVID-19) in order to achieve more rapid testing capacity in the U.S. We believe the unprecedented policy set forth in today's updated guidance, which addresses laboratories and commercial manufacturers, will help address these urgent public health concerns by helping to expand the number and variety of diagnostic tests, as well as available testing capabilities in health care settings, and reference and commercial laboratories.

This action demonstrates the FDA's ability to pivot and adapt as the situation warrants in light of a public health emergency. We are taking steps to support diagnostic development considering the urgent need. We urge state authorities and commercial developers to take all necessary steps to ensure the availability of accurate tests. Inaccurate diagnoses during a pandemic can impair prevention efforts and delay appropriate treatment for sick patients.

Our guidance provides more specific details for the laboratory and commercial manufacturer communities, but I want to highlight three key elements of the update we are issuing today.

First, we are putting in place a policy for states to take responsibility for tests developed and used by laboratories in their states, similar to the action the FDA granted to the New York State Department of Health last week. States can set up a system in which they take responsibility for authorizing such tests and the laboratories will not engage with the FDA. As stated in the guidance, the system does not need to mirror that of New York. Laboratories developing tests in these states can engage directly with the appropriate state authorities, instead of with the FDA. Nor will these laboratories pursue an Emergency Use Authorization (EUA) with the FDA.

Second, we are expanding who the policy outlined in the Feb. 29 guidance applies to. The policy was originally applicable only to laboratories that are certified to perform high-complexity testing consistent with requirements under the Clinical Laboratory Improvement Amendments. Under the update published today, the agency does not intend to object to commercial manufacturers distributing and labs using new commercially developed tests prior to the FDA granting an EUA, under certain circumstances. The FDA is aware that numerous commercial manufacturers are developing tests for coronavirus with the intention of submitting an EUA to the FDA. During this public health emergency, the FDA does not intend to object to the distribution and use of these tests for specimen testing for a reasonable period of time after the manufacturer's validation of the test and while the manufacturer is preparing its EUA request where the manufacturer provides instructions for use of the test and posts data about the test's performance characteristics on the manufacturer's website. As noted in the guidance, the FDA believes that 15 business days is a reasonable period of time to prepare an EUA submission for a test whose performance characteristics have already been validated by the manufacturer.

Finally, our updated policy provides recommendations for test developers who may wish to develop serological tests for use during this coronavirus outbreak. Serological tests measure the amount of antibodies or proteins present in the blood when the body is responding to a specific infection. We recognize that serology tests are less complex than molecular tests and are solely used to identify antibodies, which limits their effectiveness for diagnosis; however, as stated in the updated guidance, the FDA does not intend to object to the distribution and use of serology tests to identify antibodies to SARS-CoV-2 where the test has been validated, notification is provided to the FDA, and warning statements are included with the tests, for example, noting the test has not been reviewed by the FDA and results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status.

FDA Support of Diagnostics

The FDA has engaged with more than 100 test developers since the end of January, providing templates and advice about the EUA process. More than 80 developers have sought our assistance with development and validation of tests they plan to bring through the EUA process. We've granted multiple diagnostic EUAs during this outbreak.

We are updating frequently asked questions for labs and test developers, providing information on alternative sources of reagents, extraction kits, swabs and more.

We've also set up a toll-free line, 1-888-INFO-FDA, to help labs with any questions they may have about the EUA process, our policies or getting supplies.

We know that people want to know the current numbers of tests in the field and how many patients are being tested. This number fluctuates daily as more and more test developers get their tests in the field and start testing patients. At this time, the FDA is focused on making sure tests are distributed and that test developers and labs have the materials they need to run the tests.

The FDA continues to maintain operations 24/7 and we are here to support laboratories and test developers as they distribute tests through the country during this time of urgent need.

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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