FDA STATEMENT

Coronavirus (COVID-19) Update: Serological Tests

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Statement From:

Commissioner of Food and Drugs - Food and Drug Administration
Stephen M. Hahn M.D.

Serological tests measure the amount of antibodies or proteins present in the blood when the body is responding to a specific infection, like COVID-19. In other words, the test detects the body's immune response to the infection caused by the virus rather than detecting the virus itself. In the early days of an infection when the body's immune response is still building, antibodies may not be detected. This limits the test's effectiveness for diagnosing COVID-19 and why it should not be used as the sole basis to diagnose COVID-19.

Serological tests can play a critical role in the fight against COVID-19 by helping healthcare professionals to identify individuals who have overcome an infection in the past and have developed an immune response. In the future, this may potentially be used to help determine, together with other clinical data, that such individuals are no longer susceptible to infection and can return to work. In addition, these test results can aid in determining who may donate a part of their blood called convalescent plasma, which may serve as a possible treatment for those who are seriously ill from COVID-19. This is why Vice President Mike Pence called on the laboratory community to develop serological tests for COVID-19.

In March, the FDA issued a policy to allow developers of certain serological tests to begin to market or use their tests once they have performed the appropriate evaluation to determine that their tests are accurate and reliable. This includes allowing developers to market their tests without prior FDA review if certain conditions outlined in the guidance document are met. The FDA issued this policy to allow early patient access to certain serological tests with the understanding that the FDA has not reviewed and authorized them.

The FDA can also authorize tests for COVID-19 under an Emergency Use Authorization (EUA). To date, FDA has authorized one EUA (https://www.fda.gov/media/136622/download) for a serological test that is intended for use by clinical laboratories.

Since the FDA issued the policy, over 70 test developers have notified the agency that they have serological tests available for use. However, some firms are falsely claiming that their serological tests are FDA approved or authorized, or falsely claiming that they can diagnose COVID-19. The

FDA will take appropriate action against firms making false claims or marketing tests that are not accurate and reliable.

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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Inquiries

Media:

Stephanie Caccomo (mailto:stephanie.caccomo@fda.hhs.gov)

301-348-1956

Consumer:

888-INFO-FDA

Related Information

- Coronavirus Disease 2019 (COVID-19) (/emergency-preparedness-and-response/counterterrorism-and-emerging-threats/coronavirus-disease-2019-covid-19)
- FAQs on Diagnostic Testing for SARS-CoV-2 (/medical-devices/emergency-situations-medical-devices/faqs-diagnostic-testing-sars-cov-2)
- Emergency Use Authorizations for COVID-19 (https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations#covid19ivd)

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