Important Information on the Use of Serological (Antibody) Tests for COVID-19: Letter to Health Care Providers

The U.S. Food and Drug Administration (FDA) recommends that health care providers continue to use serological tests intended to detect antibodies to SARS-CoV-2 to help identify people who may have been exposed to the SARS-CoV-2 virus or have recovered from the COVID-19 infection. Health care providers should also be aware of the limitations of these tests and the risks to patients and the community if the test results are used as the sole basis to diagnose COVID-19.

The FDA is not aware of an antibody test that has been validated for diagnosis of SARS-CoV-2 infection. While the FDA remains open to receiving submissions for these tests for such uses, based on the underlying scientific principles of antibody tests, the FDA does not expect that an antibody test can be shown to definitively diagnose or exclude SARS-CoV-2 infection.

Recommendations

The FDA recommends health care providers:

- Continue to use serological (antibody) tests, as appropriate, and be aware of their limitations.
- Do not use serological (antibody) tests as the sole basis to diagnose COVID-19 but instead as information about whether a person may have been exposed.
- Be aware that not all marketed serological tests have been evaluated by the FDA. The FDA's authorized tests, including serological tests, are listed on the Emergency Use Authorization (EUA) page. Tests being offered under a policy outlined in the FDA's COVID-19 Diagnostic Policy Guidance are listed on our FAQ page. Such tests have not been reviewed by the FDA, unless an EUA has also been submitted and reviewed by FDA.

Background

Serological tests detect antibodies present in the blood when the body is responding to a specific infection, like COVID-19. They detect the body's immune response to the infection caused by the virus rather than detecting the virus itself. Experience with other viruses suggests that individuals whose blood contains antibodies associated with SARS-CoV-2 infection—provided they are recovered and not currently infected with the virus—may be able to resume work and other daily activities in society. They may also be eligible to serve as potential donors of convalescent plasma.

In the early days of an infection, when the body's immune response is still building, antibodies may not be present in detectable levels. This limits the test's effectiveness for diagnosing COVID-19 and is why it should not be used as the sole basis to diagnose COVID-19. Currently authorized serological tests for SARS-CoV-2 measure IgM and/or IgG antibodies. Since IgM antibodies may not develop early, or at all, in infected patients, this type of antibody test is not used to rule out SARS-CoV-2 in an individual. Since IgG antibodies generally do not develop until later, this type of antibody test, even though it is more specific to SARS-CoV-2, is not used to rule-out SARS-CoV-2 infection in an individual. We also do not know how long IgM or IgG antibodies to SARS-CoV-2 will remain present in the body after the infection has been cleared.

While antibody tests by themselves are of limited value in the immediate diagnosis of a patient where COVID-19 infection is suspected, using this type of test on many patients may help the medical community better understand how the immune response against the SARS-CoV-2 virus develops in patients over time and how many people may have been infected. While there is a lot of uncertainty with this new virus, it is also possible that, over time, broad use of antibody tests and clinical follow-up will provide the medical community with more information on whether or not and how long a person who has recovered from the virus is at lower risk of infection if they are exposed to the virus again.

Serological tests can play a critical role in the fight against COVID-19 by helping health care professionals identify individuals who may have been exposed to SARS-CoV-2 virus and may have developed an immune response. In the future, this may potentially be used to help determine, together with other clinical data, whether these individuals are less susceptible to infection.

Serological test results may also aid in determining who may qualify to donate blood that can be used to manufacture convalescent plasma as a possible treatment for those who are seriously ill from COVID-19.

Under the FDA's March 16 policy for serological tests, the FDA provided regulatory flexibility for developers offering such tests without FDA review and without an EUA where they have notified FDA that they have validated their tests and provide disclaimers about the limitations of the tests with any results generated by their tests, as outlined in the policy. The FDA does not review the validation, or accuracy, data for these tests unless an EUA is submitted. Test for which developers have provided a notification are listed on the FDA's COVID-19 Diagnostics FAQ page.

Serological test developers may pursue an EUA by submitting information about their test, including their validation data, to the FDA for review. Tests that are issued an EUA are listed on the FDA's EUA web page.

FDA Actions

To help ensure that health care providers have access to accurate tests, the FDA is working with the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC) on a validation project to help identify the most promising serological tests. This validation project is ongoing, and we hope to have additional information to share in the future.

The FDA will continue to keep health care providers and the public informed if new or additional information becomes available.

Reporting Problems to the FDA

Some firms are falsely claiming that their serological tests are FDA approved or authorized, or falsely claiming that these tests can diagnose COVID-19. The FDA will take appropriate action against firms making false claims or marketing tests that are not accurate and reliable.

In addition, the FDA encourages health care providers to report any adverse events or suspected adverse events experienced with serological tests.

- Voluntary reports can be submitted through MedWatch, the FDA Safety Information and Adverse Event Reporting program.

- Device manufacturers and user facilities must comply with any applicable Medical Device Reporting (MDR) regulations.
- Health care personnel employed by facilities that are subject to the FDA's user facility reporting requirements should follow the reporting procedures established by their facilities.
- The sale of fraudulent COVID-19 products is a threat to the public health. Consumers and health care professionals can help by reporting suspected fraud to the FDA's Health Fraud Program or the Office of Criminal Investigations. You can also email FDA-COVID-19-Fraudulent-Products@fda.hhs.gov

Prompt reporting of adverse events can help the FDA identify and better understand the risks associated with medical devices.

Contact Information

If you have questions about this letter, contact the Division of Industry and Consumer Education. For specific questions about COVID-19 diagnostic development, contact CDRH-EUA-Templates@fda.hhs.gov.

Additional resources:

- Serological/Antibody Tests in FAQs on Diagnostic Testing for SAR-CoV-2