

Certain COVID-19 Serology/Antibody Tests Should Not Be Used - Letter to Clinical Laboratory Staff and Health Care Providers

The U.S. Food and Drug Administration (FDA) recommends that clinical laboratories and health care providers stop using COVID-19 antibody tests that are listed on FDA's "removed" test list (<https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-testing-sars-cov-2#nolonger-ivd>), found on the FDA's FAQs on Testing for SARS-CoV-2 webpage (</medical-devices/emergency-situations-medical-devices/faqs-testing-sars-cov-2>). The "removed" test list includes tests where significant clinical performance problems were identified that cannot be or have not been addressed by the commercial manufacturer in a timely manner, tests for which an Emergency Use Authorization request has not been submitted by a commercial manufacturer of a serology test within a reasonable period of time as outlined in FDA's guidance, and tests voluntarily withdrawn by the respective commercial manufacturers.

Although tests on the "removed" test list should no longer be distributed, laboratories and health care providers may still have these tests within their stock, or may have used these tests in the past. The FDA is therefore providing additional information and recommendations to laboratories and health care providers regarding these tests.

Recommendations

The FDA recommends laboratories and health care providers:

- Stop using the antibody tests listed on FDA's "removed" test list (<https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-testing-sars-cov-2#nolonger-ivd>).
- Evaluate, given the patient's clinical presentation and medical history, whether prior test results generated using these tests may have been incorrect, and whether the patient should be retested using an FDA-authorized test.
- Remove from your stock any remaining tests that are listed on FDA's "removed" test list (<https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-testing-sars-cov-2#nolonger-ivd>).
- Report (</safety/medwatch-fda-safety-information-and-adverse-event-reporting-program>) any issues with using COVID-19 tests to the FDA.

Background

SARS-CoV-2 serology, or antibody, tests are designed to detect antibodies, typically IgG and/or IgM, to the SARS-CoV-2 virus in whole blood, serum, or plasma specimens. SARS-CoV-2 antibody tests are intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection, by detecting antibodies to SARS-CoV-2 in human blood specimens. Because the antibodies are part of the body's immune response to exposure and not the virus itself, such testing cannot be used for diagnosis of infection. SARS-CoV-2 serology tests should be ordered only by clinicians who are familiar with the use and limitations of the test.

Under policies outlined in the *Policy for Coronavirus Disease-2019 Tests* ([/regulatory-information/search-fda-guidance-documents/policy-coronavirus-disease-2019-tests-during-public-health-emergency-revised](#)), some commercial manufacturers' antibody tests were placed on FDA's "notification" list and distributed prior to FDA's review of the manufacturer's validation data. On May 4, 2020, the FDA updated its policies to include the agency's expectation that commercial manufacturers of antibody tests submit an EUA request within 10 business days from the date they notified FDA of their test validation or the date of publication of the revised policy, whichever was later.

In keeping with the FDA's commitment to transparency, on May 21, 2020 ([/news-events/press-announcements/coronavirus-covid-19-update-fda-provides-promised-transparency-antibody-tests](#)), the agency provided a list of antibody tests from commercial manufacturers that had been removed from the antibody test notification list. This "removed" test list (<https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-testing-sars-cov-2#nolonger-ivd>) includes tests where significant clinical performance problems were identified that cannot be or were not addressed by the commercial manufacturer in a timely manner, tests for which an EUA request was not submitted by a commercial manufacturer of a serology test within a reasonable period of time as outlined in FDA's guidance, and tests voluntarily withdrawn from the notification list by the respective commercial manufacturer. FDA will continue to update this "removed" test list.

The FDA is issuing this communication to ensure that laboratories and health care providers who may still have within their stock tests on the "removed" test list, or have used such tests, are aware that these tests may have demonstrated poor clinical performance or lack of adequate information to support clinical performance. Results for antibody tests that have been evaluated through the Department of Health and Human Services (HHS) National Institutes of Health (NIH) National Cancer Institute (NCI) independent evaluation program may be found on FDA's [Independent Evaluations of COVID-19 Serological Tests](#) (<https://open.fda.gov/apis/device/covid19serology/>) webpage.

False positive serology test results can lead to an incorrect assessment that the tested person had an immune response to SARS-CoV-2. Although it is unknown whether the presence of antibodies confers immunity, an individual with a false positive result may not take necessary precautions against virus exposure. This may increase the individual's risk of infection and may lead the person to not seek testing if later infected, which could potentially increase the spread of the disease.

False negative test results can lead to an incorrect assessment that the tested person has not had an adaptive immune response to SARS-CoV-2 and has not had recent or prior infection with SARS-CoV-2. An individual with a false negative result may restrict activities deemed acceptable for individuals with evidence of an antibody response to SARS-CoV-2. A false negative serology test result may also lead to additional unnecessary diagnostic evaluations. In the context of the current public health emergency, incorrect serological test results could negatively impact the effectiveness of infection control activities.

FDA Actions

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

The FDA encourages health care providers to report any adverse events or suspected adverse events experienced with COVID-19 tests.

- Voluntary reports can be submitted through MedWatch, the FDA Safety Information and Adverse Event Reporting program (</safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda>).
- Device manufacturers and user facilities must comply with any applicable Medical Device Reporting (MDR) regulations (</medical-devices/postmarket-requirements-devices/mandatory-reporting-requirements-manufacturers-importers-and-device-user-facilities>).
- Health care personnel employed by facilities that are subject to the FDA's user facility reporting requirements (</medical-devices/postmarket-requirements-devices/mandatory-reporting-requirements-manufacturers-importers-and-device-user-facilities>) 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 (</safety/report-problem-fda/reporting-unlawful-sales-medical-products-internet>) or the Office of Criminal Investigations (<https://www.accessdata.fda.gov/scripts/email/oc/oci/contact.cfm>). You can also email

FDA-COVID-19-Fraudulent-Products@fda.hhs.gov (mailto: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 (/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice). For specific questions about COVID-19 diagnostic development, contact CDRH-EUA-Templates@fda.hhs.gov (mailto:CDRH-EUA-Templates@fda.hhs.gov).

Additional resources:

- Serological/Antibody Tests (<https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-testing-sars-cov-2#serology>) in FAQs on Diagnostic Testing for SARS-CoV-2
- Independent Evaluations of COVID-19 Serological Tests (<https://open.fda.gov/apis/device/covid19serology/>)
- Emergency Use Authorizations for IVDs for COVID-19 (<https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations# covid19ivd>)