Antibody Testing Is Not Currently Recommended to Assess Immunity After COVID-19 Vaccination: FDA Safety Communication

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The U.S. Food and Drug Administration (FDA) is reminding the public and health care providers that results from currently authorized SARS-CoV-2 antibody tests should not be used to evaluate a person's level of immunity or protection from COVID-19 at any time, and especially after the person received a COVID-19 vaccination.

While a positive antibody test result can be used to help identify people who may have had a prior SARS-CoV-2 infection, more research is needed in people who have received a COVID-19 vaccination. Currently authorized SARS-CoV-2 antibody tests have not been evaluated to assess the level of protection provided by an immune response to COVID-19 vaccination. If antibody test results are interpreted incorrectly, there is a potential risk that people may take fewer precautions against SARS-CoV-2 exposure. Taking fewer steps to protect against SARS-CoV-2 can increase their risk of SARS-CoV-2 infection and may result in the increased spread of SARS-CoV-2.

The FDA is providing additional information and recommendations to the public and health care providers about the use of antibody tests in people who received a COVID-19 vaccination.

Recommendations for People Who Had or May Have a SARS-CoV-2 Antibody Test

- Be aware that SARS-CoV-2 antibody tests help health care providers identify whether someone has antibodies to SARS-CoV-2, the virus that causes COVID-19, indicating a prior infection with the virus. However, more research is needed to understand the meaning of a positive or negative antibody test, beyond the presence or absence of antibodies, including in people who received a COVID-19 vaccination, in people who have been exposed and have SARS-CoV-2 antibodies, and in people who are not fully vaccinated.
- **If you have not been vaccinated:** Be aware that a positive result from an antibody test does not mean you have a specific amount of immunity or protection from SARS-CoV-2 infection. If you have a positive test result on a SARS-CoV-2 antibody test, it

means that it is possible you were previously infected with the SARS-CoV-2 virus. Talk with your health care provider about the meaning of your SARS-CoV-2 antibody test results.

- **If you received a COVID-19 vaccination:** Continue to follow the CDC's recommendations for fully vaccinated people (https://www.cdc.gov/coronavirus/2019-ncov/vaccines/fully-vaccinated.html). Be aware that if you have a positive test result on a SARS-CoV-2 antibody test, it is possible you were previously infected with SARS-CoV-2. A COVID-19 vaccination may also cause a positive antibody test result for some but not all antibody tests. You should not interpret the results of your SARS-CoV-2 antibody test as an indication of a specific level of immunity or protection from SARS-CoV-2 infection. Talk to your health care provider or your state and local health departments if you have questions about whether an antibody test is right for you.

Recommendations for Health Care Providers

- At this time, do not interpret the results of qualitative, semi-quantitative, or quantitative SARS-CoV-2 antibody tests as an indication of a specific level of immunity or protection from SARS-CoV-2 infection after the person has received a COVID-19 vaccination. While a positive antibody test can indicate an immune response has occurred (seroconversion), and failure to detect such a response may suggest a lack of immune response, more research is needed. Currently authorized SARS-CoV-2 antibody tests (/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-serology-and-other-adaptive-immune-response-tests-sars-cov-2) are not validated to evaluate specific immunity or protection from SARS-CoV-2 infection. SARS-CoV-2 antibody tests should be ordered only by health care providers who are familiar with the use and limitations of the test. For more information about antibody tests for SARS-CoV-2, see Serology/Antibody Tests: FAQs on Testing for SARS-CoV-2 (/medical-devices/coronavirus-covid-19-and-medical-devices/serologyantibody-tests-faqs-testing-sars-cov-2).
- Be aware that vaccines trigger antibodies to specific viral protein targets. For example, currently authorized COVID-19 mRNA vaccines induce antibodies to the spike protein and not to nucleocapsid proteins that are likely detected only after natural infections. Therefore, COVID-19 vaccinated people who have not had previous natural infection will receive a negative antibody test result if the antibody test does not detect the antibodies induced by the COVID-19 vaccine. If you are considering antibody testing in vaccinated individuals, follow the Centers for Disease Control and Prevention's guidelines (https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antibody-tests-guidelines.html) for antibody testing. For more information about antibody test performance visit EUA Authorized Serology Test Performance (/medical-devices

/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/eua-authorized-serology-test-performance).

Potential Risks of Improperly Using SARS-CoV-2 Antibody Test Results

Antibodies are proteins created by your body's immune system soon after you have been infected or vaccinated. SARS-CoV-2 antibody or serology tests look for antibodies in a blood sample to determine if an individual has had a past infection with the virus that causes COVID-19. These types of tests cannot be used to diagnose a current infection. For more information about antibody testing, see Antibody (Serology) Testing for COVID-19: Information for Patients and Consumers (/medical-devices/coronavirus-covid-19-and-medical-devices/antibody-serology-testing-covid-19-information-patients-and-consumers).

Test results from currently authorized SARS-CoV-2 antibody tests should not be used to evaluate a person's level of immunity or protection from COVID-19. If the results of the antibody test are interpreted as an indication of a specific level of immunity or protection from SARS-CoV-2 infection, there is a potential risk that people may take fewer precautions against SARS-CoV-2 exposure. Taking fewer precautions against SARS-CoV-2 exposure can increase their risk of infection and may result in increased spread of SARS-CoV-2.

FDA Actions

The FDA will continue to monitor the use of authorized SARS-CoV-2 antibody tests for purposes other than identifying people with an immune response to SARS-CoV-2 from a recent or prior infection.

The FDA provided updated information about SARS-CoV-2 antibody tests (/medical-devices/coronavirus-covid-19-and-medical-devices/serologyantibody-tests-faqs-testing-sars-cov-2) and will continue to keep health care providers and the public informed if new additional information becomes available. The FDA also provides information on Antibody (Serology) Testing for COVID-19: Information for Patients and Consumers (/medical-devices/coronavirus-covid-19-and-medical-devices/antibody-serology-testing-covid-19-information-patients-and-consumers) and will update the page if new additional information becomes available.

Reporting Problems

If you think you had a problem with a SARS-CoV-2 antibody test, the FDA encourages you to report the problem through the MedWatch Voluntary Reporting Form (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home).

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.

Questions?

If you have questions, email the Division of Industry and Consumer Education (DICE) at DICE@FDA.HHS.GOV (mailto:DICE@FDA.HHS.GOV) or call 800-638-2041 or 301-796-7100.