

FDA: Do not use antibody tests to assess immunity after COVID-19 vaccination

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Editor's note: For the latest news on COVID-19, visit <http://bit.ly/AAPNewsCOVID19>.

The Food and Drug Administration (FDA) is advising against the use of SARS-CoV-2 antibody tests to evaluate immunity or protection from COVID-19, especially after an individual has received a COVID-19 vaccine. The tests should be ordered only by health care providers familiar with their use and limitations, according to an [FDA safety communication](#) issued today.

Although antibody tests play a role in identifying individuals who may have been exposed to SARS-CoV-2 and developed an adaptive immune response, COVID-19 antibody testing has limitations, the FDA said.

Authorized SARS-CoV-2 antibody tests are not validated to evaluate immunity or protection from COVID-19 infection. And in vaccinated individuals, antibody test results will be negative if there is no history of natural infection and if the test does not detect the type of antibodies induced by the vaccine, the FDA said.

“The FDA will continue to monitor the use of authorized SARS-CoV-2 antibody tests for purposes other than identifying people with an adaptive immune response to SARS-CoV-2 from a recent or prior infection,” Tim Stenzel, M.D., Ph.D., director, Office of In Vitro Diagnostics and Radiological Health, FDA Center for Devices and Radiological Health, said in the safety communication.

For a list of tests that received emergency use authorization from the FDA, visit <http://bit.ly/fdaeuatests>.

