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Date: **June 7, 2021**
To: Local Health Departments, Primary Care Providers, Pharmacies, Hospitals, Urgent Care Centers, and other COVID-19 vaccination sites

Informational Message: FDA Advises Against Use of SARS-CoV-2 Antibody Test Results to Evaluate Immunity or Protection From COVID-19 After Vaccination

Please distribute immediately to:
Vaccinators, Medical Directors, Nursing Directors, Nurse Educators, Pharmacists and Occupational Health

Summary

- On May 19, 2021, the U.S. Food and Drug Administration (FDA) issued a safety communication to healthcare providers and the public, advising against use of SARS-CoV-2 antibody test results to evaluate immunity or protection from COVID-19 after 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.
- A positive result from a SARS-CoV-2 IgG antibody test in a person who is not fully vaccinated against COVID-19 does not necessarily indicate long-term immunity or protection from COVID-19; such persons should still receive a complete COVID-19 vaccine series as per current CDC guidance.
- A negative or low result from a SARS-CoV-2 IgG antibody test in a person who is fully vaccinated against COVID-19 does not indicate insufficient vaccine-induced immunity. No further doses of COVID-19 vaccine are recommended on the basis of post-vaccination serologic tests for persons who have received a complete COVID-19 vaccine series.
- The FDA's May 19, 2021 communication is consistent with existing U.S. Centers for Disease Control and Prevention (CDC) interim guidelines for COVID-19 antibody testing and for COVID-19 vaccines.

Background

SARS-CoV-2 antibody tests play an important role in assessing whether patients have had a current or recent COVID-19 infection. However, currently available SARS-CoV-2 antibody tests have not been evaluated to assess the immunity induced by COVID-19 vaccination.

The CDC recommends against use of SARS-CoV-2 antibody testing to evaluate immunity following COVID-19 vaccination or to assess the need for vaccination in an unvaccinated person. If antibody testing is nonetheless performed following vaccination, the CDC does not recommend additional doses of the same or different COVID-19 vaccines based on antibody test results.

On May 19, 2021, the FDA issued a safety communication to healthcare providers and the public, advising against use of SARS-CoV-2 antibody test results to evaluate immunity or protection from COVID-19 after vaccination, consistent with CDC guidance. The full text of the

May 19, 2021 FDA safety communication is available at: https://www.fda.gov/medical-devices/safety-communications/antibody-testing-not-currently-recommended-assess-immunity-after-covid-19-vaccination-fda-safety.

Recommendations for Assessment of COVID-19 Immunity

- A person is considered fully vaccinated against COVID-19 ≥2 weeks after receipt of the second dose in a 2-dose series (Pfizer-BioNTech and Moderna) or ≥2 weeks after receipt of the single dose of the Janssen vaccine.
- People with a history of prior COVID-19 infection should be offered COVID-19 vaccine regardless of the results of pre-vaccination serologic tests.
    - However, vaccination of people with known current SARS-CoV-2 infection should be deferred until the person has recovered from the acute illness and has met criteria to discontinue isolation. This recommendation applies to people who experience SARS-CoV-2 infection before receiving any vaccine dose and those who experience SARS-CoV-2 infection after the first dose of an mRNA vaccine but before receipt of the second dose.
- People with an incomplete COVID-19 vaccine series (i.e., receipt of a single dose of a 2-dose series) should complete the vaccine series as recommended by the CDC, regardless of the results of post-vaccination serologic testing.
- No additional doses of COVID-19 vaccine are recommended on the basis of post-vaccination serologic test results for people who are fully vaccinated against COVID-19.

References

- Antibody Testing Is Not Currently Recommended to Assess Immunity After COVID-19 Vaccination: FDA Safety Communication, May 19, 2021: https://www.fda.gov/medical-devices/safety-communications/antibody-testing-not-currently-recommended-assess-immunity-after-covid-19-vaccination-fda-safety
- FDA In Brief: FDA Advises Against Use of SARS-CoV-2 Antibody Test Results to Evaluate Immunity or Protection From COVID-19, Including After Vaccination, May 19, 2021: https://www.fda.gov/news-events/press-announcements/fda-brief-fda-advises-against-use-sars-cov-2-antibody-test-results-evaluate-immunity-or-protection
- CDC Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States: https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html
- CDC Interim Guidelines for COVID-19 Antibody Testing: https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antibody-tests-guidelines.html