

FDA FACT SHEET

ANTIBODY TEST OVERSIGHT AND USE FOR COVID-19

What is an antibody test and how is it used?

Antibody tests, a type of serological test, detect antibodies present in the blood when the body is responding to or has responded to a specific infection, such as COVID-19. Antibody tests detect the body's immune response to the infection caused by the virus rather than detecting the virus itself. This is why they should not be used to diagnose current SARS-CoV-2 infection.

Antibody tests can be used to determine if individual patients may have been exposed to and infected with a virus, and also can be used to understand to understand how many people in a population have antibodies (known as "surveillance tests," or sero-surveys).

- Testing individuals may help identify who has developed antibodies against SARS-CoV-2. The result of ongoing research are needed before it is know whether these antibodies are associated with protection from future infection. Current results can help inform who may qualify to donate blood that can be used to manufacture [convalescent plasma](#), an investigational product for use with those who are seriously ill from COVID-19.
- When used for surveillance, the results can help determine how widely the virus has spread in communities. Results from tests used for surveillance only are generally not shared with individual patients.

Who regulates antibody tests?

FDA: The U.S. Food and Drug Administration (FDA) regulates, among other products, tests intended for the diagnosis of a disease or condition (a type of "device") under the Federal Food, Drug, and Cosmetic Act. Outside of a declared public health emergency, serological tests generally require FDA premarket review through one of the established premarket pathways (de novo, 510(k) or PMA). The FDA has issued emergency use authorizations (EUAs), an authorization available to certain products in a declared public health emergency, for some antibody tests based on the data submitted to the Agency after determining that the applicable statutory criteria had been met. FDA has also announced a policy of enforcement discretion for certain laboratories certified under the Clinical Laboratory Improvement Amendments (CLIA) for performing high-complexity testing to develop and validate their own serological tests (called laboratory-developed tests, or LDTs), as outlined in the FDA's COVID-19 Testing Guidance. The FDA does not generally regulate antibody tests that are used for surveillance purposes only, where test results are not returned to patients or healthcare providers.

CMS: The Centers for Medicare & Medicaid Services (CMS) regulates all laboratory testing (except research) performed on humans in the U.S. through the Clinical Laboratory Improvement Amendments (CLIA), part of the Public Health Service Act. In total, CLIA covers approximately 260,000 laboratory entities. The CLIA program regulates laboratories that perform testing on patient specimens in order to ensure accurate and reliable test results. When a laboratory develops a test system such as an LDT, and FDA has not yet categorized the test (e.g., because the test has not been categorized in an EUA), the law requires that the test be performed only in a lab certified under CLIA to perform high-complexity testing. The laboratory must establish the performance characteristics of the test, including analytical validity, for

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the use of that test system in the laboratory's own environment prior to reporting patient results. In other words, if a test has not been reviewed by FDA, and thus has not been categorized by FDA, under CLIA, that test must only be used by laboratories certified under CLIA to perform high-complexity testing; this is another measure that helps to ensure the test performance is validated.

CDC: The U.S. Centers for Disease Control and Prevention (CDC) develops guidelines on the use of different tests, including for surveillance.

States: Under FDA's current policy, States or territories may also take responsibility for certain COVID-19 testing by high-complexity CLIA-certified laboratories (using LDTs) in that State/territory during the COVID-19 outbreak to expedite testing. A State or territory choosing to authorize laboratories within that State or territory to develop and perform a test for COVID-19 does so under authority of its own State law, and under a process that it establishes. Some States have done this, and they are listed on [FDA's website](#). As stated in Section IV.B of the guidance, the FDA will not be reviewing the process adopted by the State or territory under this policy. The FDA has provided technical assistance to States on test validation measures under this policy.

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