



Denver Family Medicine

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LabCorp's COVID-19 Serological Antibody Tests

LabCorp's serological testing for COVID-19 is now available for ordering by hospitals and healthcare organizations.

Serological tests for SARS-CoV-2 are intended for individuals who may have had COVID-19 symptoms but are no longer symptomatic. **The tests determine the presence of antibodies to the virus and can help to identify individuals who have been exposed to the virus.** Understanding if an individual has developed antibodies and a potential immune response can be useful in the determination of important decisions such as the ability for hospital staff to care for patients.

Serological tests use serum in blood samples from individuals who are being evaluated or have been exposed to the virus. LabCorp offers separate tests for each of the three major classes of SARS-CoV-2 antibodies (IgG, IgA, and IgM).

A positive serologic result indicates that an individual has likely produced an immune response to the SARS-CoV-2 virus. A negative serologic result indicates that an individual has not developed detectable antibodies at the time of testing. While contingent on a variety of factors, this could be due to testing too early in the course of COVID-19, the absence of exposure to the virus, or the lack of an adequate immune response, which can be due to conditions or treatments that suppress immune function.

Confirmation of infection with SARS-CoV-2 must be made through a combination of clinical evaluation and other applicable tests. Decisions about ongoing monitoring, treatment or return to normal activities for patients being treated for suspected infection with SARS-CoV-2 should also be made in accordance with guidance from public health authorities.

These tests have not been reviewed by the FDA, but are being offered by LabCorp in accordance with the public health emergency guidance issued by the FDA on March 16. As this is a new test, the cost is still unknown. We will be submitting through your insurance. If it is not covered you will receive a bill directly from LabCorp.

"Current data suggest that IgM antibodies against SARS-CoV-2 develop in the circulation after the first week of COVID-19, while IgG antibodies become detectable sometime beyond 14 days of infection. Detection of specific antibodies (IgM, IgG, or both) against SARS-CoV-2 would therefore suggest that a person has been infected with the virus at some time in the past. It is unclear at this point what role the IgA antibody plays other than that the immune system may develop this type of antibody also. Antibody tests will be most useful to help estimate relative proportions that different population groups have been exposed to SARS CoV-2. They will have less utility as diagnostic tools for individual patient assessment."



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For **Positive** results:

- A + result means that the patient was exposed in the past and has developed the detected antibody.
- A + result does not prove that a patient is immune to the virus.
- A + result does not indicate that the patient is not currently infectious to others.
- A + positive result does not indicate that the patient currently has the virus in his/her system.
- There may be a false positive if a patient was exposed to another non-SARS-CoV-2 coronavirus strain. These non-SAS-CoV-2 strains are common and are one cause of the common cold. We don't have the numbers today on how often the false positives due to cross reactivity may occur.

For **Negative** results:

- A negative result means that no antibody to the virus was detected in the sample tested or if low level of antibody is present, it is present at a level below the assay's detection limit
- A negative result does not mean that the patient is free of the virus.
- A negative result does not mean that the patient is not currently infected and infectious to others, especially if the individual has come in contact with the virus. Follow-up testing with a molecular diagnostic should be performed in these individuals.
- Individuals who are immunosuppressed or who are on drugs that suppress the immune system may test negative despite being exposed to SARS-CoV-2.

For questions regarding a LabCorp bill you will need to contact them directly at 800.845.6167.