
COVID-19 IgG Serology (Antibody) Testing

FACT SHEET FOR PATIENTS

You are being given this fact sheet to help you understand the risk and benefits of having this test.

For the most up to date information on COVID-19 please visit the CDC Coronavirus Disease 2019 (COVID-19) webpage <https://www.cdc.gov/COVID19>

What is COVID-19 Serologic Testing?

IgG is a type of antibody produced by our immune system to fight antigens like bacteria and viruses. IgG represents a past infection.

The test being offered is NOT an FDA approved test. It does carry Emergency Use Authorization by the FDA, which means the FDA has said it is ok to use, but it has not undergone any significant or typical FDA review process.

The makers of this test took serum specimens they had stored from mid-year 2019 (pre COVID). They ran the test on 1022 specimens. The expected result was negative, and 99.6% were negative, giving this test a false positive rate of 0.4%.

They then took regular specimens from symptomatic COVID positive patients (by PCR nasal swab testing) various numbers of days after the positive PCR tests. The expected result was positive. On days 8 to 13, 91% tested positive. This gives a false negative rate of 0% at 14 days after a positive PCR test.

While the test was compared against several other conditions (such as CMV, mono, pregnancy, lupus, influenza and several others) it was not compared against other coronaviruses, some of which are quite mild and can cause common cold symptoms. The tests done against each condition were very small (5 tests per condition).

This means that a positive IgG test DOES NOT CONFIRM IMMUNITY against COVID-19.

How are COVID-19 serology results reported?

POSITIVE: Antibodies to COVID-19 detected, which may be due to a past or current infection.

NEGATIVE: No COVID-19 antibodies detected. Patients within 10 days of symptom onset for COVID-19 may not produce sufficient levels of detectable antibodies.

EQUIVOCAL: Patients within 10 days of symptom onset for COVID-19 may not produce sufficient levels of detectable antibodies. Immunocompromised COVID-19 patients may take longer to develop antibodies. Repeat testing in 14 days with additional blood sample is recommended if clinically indicated.

Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform of infection status. COVID-19 PCR test should be ordered if current infection is suspected.

It is not known whether the presence of SARS-COV-2 antibodies will confer future protection from COVID-19 infection. At this time, it is presumed that all persons, regardless of COVID-19 serology results, could develop COVID-19 infection.

It is not known whether the presence or absence of SARS-C-V-2 antibodies correlates with disease severity in COVID-19.