



## COVID-19 Antibody Test Information

### What is a COVID-19 antibody test?

COVID-19 antibody tests use a blood sample to check for proteins in the immune system, known as antibodies. If these antibodies are present, then it means that a person was exposed to the virus and developed antibodies against it, suggesting that the patient has some sort of an immunity at the time of the test. **Our test looks for the IgM, IgA, and IgG antibodies.** The IgM antibody typically appears about 7 days after the initial infection, and the IgG antibody appears after 14 days.

Studies have not confirmed how long that immunity lasts, and *COVID-19 antibody tests do not diagnose the active virus.*

<b>Test Laboratory:</b>	PathGroup
<b>Test Manufacturer:</b>	Roche Diagnostics
<b>Test Name:</b>	Elecsys Anti-SARS-CoV-2
<b>Sensitivity:</b>	100%
<b>Specificity:</b>	99.8%

\* with no reported cross-reactivity to other similar coronaviruses that could generate a false positive result and thus wrongly infer potential immunity.

**Roche Fact Sheet:** <https://www.fda.gov/media/137604/download>

<b>Sensitivity</b> measures how often a test correctly generates a positive result for people who have the condition that's being tested for (also known as the "true positive" rate). A test that's highly sensitive will flag almost everyone who has the disease and not generate many false-negative results.	<b>Specificity</b> measures a test's ability to correctly generate a negative result for people who don't have the condition that's being tested for (also known as the "true negative" rate). A high-specificity test will correctly rule out almost everyone who doesn't have the disease and won't generate many false-positive results.
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### FDA Status:

- On May 3, 2020, the U.S. Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for the Roche Elecsys® SARS-CoV-2 antibody test.

### Note:

- To date, no study has provided conclusive evidence that the presence of antibodies confers immunity to subsequent infection by the same or other strains of SARS-CoV-2 in humans. In addition, a nonreactive (negative) test result does not rule out the possibility of SARS-CoV-2 infection as negative results may be obtained prior to seroconversion. Therefore, this test is not intended for use to diagnose an acute infection.