

Patient Guide To Roche's Elecsys® Anti-SARS-CoV-2 Antibody Test

What is the Roche Anti-SARS-CoV-2 antibody test?

The Anti-SARS-CoV-2 antibody test uses a simple blood sample to detect the presence of antibodies against SARS-CoV-2 in patients. Antibodies are proteins that the body's immune system develops to fight viruses.

Why should I get an antibody test?

There are several reasons to get an antibody test:

- 1. To determine if you have previously been exposed to SARS-CoV-2 and developed antibodies against it, that may or may not give future protection
- 2. After talking to your healthcare professional, the results may help you decide when and how to return to work, school, and other routine activities, knowing that antibodies may not prevent a second infection
- 3. The results can help healthcare professionals and researchers by giving better understanding on how common the virus is, how fatal the virus is, and who could potentially benefit from a future vaccine
- 4. To help identify recovered patients that could potentially donate convalescent plasma

What is the difference between a diagnostic test and an antibody test for COVID-19?

A diagnostic test shows if a patient currently has the virus in their body. An antibody test shows a patient was exposed to the virus in the past, and if their body has developed an immune response to the virus.

How accurate is the Roche antibody test?

Roche's test is highly accurate. The test has the largest set of clinical data among all manufacturers. Studies show that Roche's antibody test is 99.5% accurate (sensitivity) at detecting SARS-CoV-2 antibodies in the blood 14 days after a confirmed diagnostic test. The test also has a 99.8% accuracy (specificity) at ruling out SARS-CoV-2 antibodies in the blood. This was proven on over 10,000 patient samples.

What will getting my sample collected be like?

A healthcare professional will collect a blood sample from you through a venipuncture. No preparation or fasting is needed.

What does a positive test result mean?

A positive result means that you have likely been infected with SARS-CoV-2 in the past and developed antibodies against it. In many viruses, the presence of antibodies means some level of immunity, although this is still being studied for SARS-CoV-2. Talk with your healthcare provider about your test result as more COVID-19 data becomes available.

What does a negative test result mean?

A negative result means that you have likely not been exposed to SARS-CoV-2 in the past. A negative result is also possible early in the infection, before your body has developed antibodies that are able to fight the virus. Antibody tests should not be used to rule out current or recent infections. Discuss the meaning of your result with your healthcare provider.

- Not for screening of donated blood
- This test has not been FDA cleared or approved
- This test has been authorized by FDA under an EUA for use by authorized laboratories
- This test has been authorized only for detecting the presence of antibodies against SARS-CoV-2, not for any other viruses or pathogens
- This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of in vitro diagnostic tests for detection and/or diagnosis of COVID-19 under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb- 3(b)(1), unless the authorization is terminated or revoked sooner



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