Siemens Healthineers SARS-CoV-2 Total Assay*

FAQs for SARS-CoV-2 Total Antibody Testing

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What is SARS-CoV-2 and What is COVID-19?

Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) is the official name of the novel coronavirus that is currently causing a worldwide pandemic. COVID-19 is the official name of the respiratory disease caused by SARS-CoV-2. SARS-CoV-2 is highly contagious and is transmitted through respiratory droplets. More information about COVID-19 can be found at the U.S. Center for Disease Control and Prevention (CDC) website: https://www.cdc.gov/coronavirus/2019-nCoV/index.html or https://www.coronavirus.gov/.

What Siemens Healthineers systems does the SARS-CoV-2 Total assay run on?

The assay is available on our Atellica® IM analyzers and ADVIA Centaur® XP/XPT Immunoassay Systems.* A comparable total antibody assay is also available on our Dimension Vista® and Dimension® EXL™ systems.* The assay is under development for the ADVIA Centaur® CP system.†

Does Siemens Healthineers offer Quality Control material for the SARS-CoV-2 Total assay?

Yes, QC material is available and sold separately for all analyzers offering the SARS-CoV-2 Total assay. The QC material is manufactured by Siemens Healthineers and is tested prior to release using the same analyzers and reagents that labs use for their testing.

Why did Siemens Healthineers choose the S1RBD antigen instead of the nucleocapsid antigen?

Growing evidence indicates that spike protein antibodies are neutralizing, based on in-vitro data.[1] Evidence for neutralization antibodies to the N protein is currently sparse. Siemens Healthineers smartly selected the receptor-binding domain (RBD) of the S1 spike protein to detect antibodies that block the virus entry into the cells. This selection is aligned with current vaccinations in development that are targeting the spike protein.

**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 he 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 emergency use of in vitro diagnostics 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. Product availability may vary by country and is subject to regulatory requirements.*

†This test has not been reviewed by the FDA. In the U.S., use of this test is limited to laboratories that are certified under Clinical Laboratory Improvement Amendments of 1988 (CLIA) to perform high-complexity testing. Product availability may vary by country and is subject to regulatory requirements.

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What are the benefits of a Total Antibody SARS-CoV-2 assay as opposed to IgG or IgM specific assays?

Studies indicate that the total assay has higher levels of sensitivity the closer you get to the date of the first positive PCR than IgG or IgM alone, and therefore it can help identify those individuals with both prior exposure and recent infection, reducing the potential for false negative results.[2] In contrast, an IgG-only test is better for surveillance of people who are in the later, convalescent stage of the virus. IgG assays will be very valuable for identifying people who are immunocompetent after a vaccine comes out, detecting when they've generated IgG antibodies against the vaccine. Today, the total assay is a better assay for identifying people exposed to the virus than an IgG-only assay. For example, the CDC states that the use of a total antibody assay may increase sensitivity to people who have been recently infected.[3]

Is the Siemens Healthineers SARS-CoV-2 Total assay capable of detecting IgA antibodies?

Several publications have shown the presence of IgA, IgM and IgG antibodies to S1RBD Ag of SARS-CoV-2 in the serum of COVID-19 patients.[4,5,6] In the total assay we use S1RBD Ag for both capture and detection of the antibodies to SARS-CoV-2 and so theoretically the assay detects all these classes of antibodies.

Is Siemens Healthineers developing an IgG assay to address the need for a possible "immunity passport" once a vaccination is available?

Yes. Siemens Healthineers is in the process of developing an IgG-only assay to address this and other needs.

What sample types can be used with the Siemens Healthineers SARS-CoV-2 Total assay?

The assay can be run on serum, and plasma (EDTA and lithium heparin additive tubes).

What does it mean if the result is positive?

If you test positive:

A positive test result shows you have antibodies that likely resulted from an infection with SARS-CoV-2, or possibly a related coronavirus.

- At this time, it's unclear if those antibodies can provide protection (immunity) against getting infected again. This means that we do not know at this time if antibodies make you immune to the virus.
- If you have symptoms and meet other guidelines for testing, you would need another type of test called a nucleic acid test (molecular test), or viral test. This test uses respiratory samples, such as a swab from inside your nose, to confirm COVID-19. An antibody test alone cannot tell if you definitely have active COVID-19.
- It's possible you might test positive for antibodies and you might not have or have ever had symptoms of COVID-19. This is known as having an asymptomatic infection, or an infection without symptoms.

What does it mean if the result is negative?

If you test negative:

- If you test negative for COVID-19 antibodies, you probably did not have a previous infection. However, you could have an early current infection. It's possible you could still get sick if you have been exposed to the virus recently, since antibodies don't show up for 1 to 3 weeks after infection. This means you could still spread the virus.[6]
- Some people who were infected may take even longer to develop antibodies, and some people may not develop antibodies.
- If you have symptoms and meet other guidelines for testing, you would need another type of test called a molecular test. This test uses respiratory samples, such as a swab from inside your nose, to confirm COVID-19. An antibody test alone cannot tell if you definitely do not have COVID-19.

How do you interpret the PCR and antibody test results?

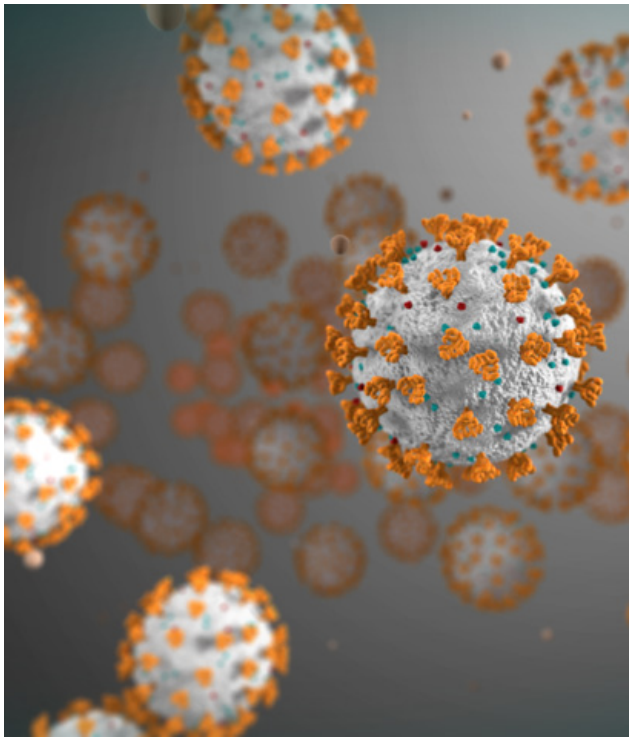
SARS-CoV-2 Total Assay Result	SARS-CoV-2 RT-PCR Result	Interpretation
Reactive	Unavailable	Indicates an immune response to a current or past infection with SARS-CoV-2 virus. Additional testing needed to distinguish if current or past infection. May be a false reactive result due to cross-reactivity from pre-existing antibodies or other possible causes.
	Positive	Indicates current infection by SARS-CoV-2 virus.
	Negative	Indicates an immune response to a past or recent infection with SARS-CoV-2 virus, or a false negative PCR result. May be a false reactive result due to cross-reactivity from pre-existing antibodies or other possible causes.
Nonreactive	Unavailable	Indicates no SARS-CoV-2 infection, or no immune response to a current infection with SARS-CoV-2. Additional testing needed to detect possible early current infection.
	Positive	Indicates early current infection by SARS-CoV-2 virus. Antibody testing should be repeated with a later sample draw.
	Negative	Indicates no current or past infection with SARS-CoV-2 virus, or a false negative PCR result during early infection.

What are the cross-reactive profiles and interferences of the Atellica IM and ADVIA Centaur SARS-CoV-2 Total Assay?

The assay was evaluated for potential cross-reactivity in specimens with other viral and microbial antibodies and other disease states. No inteference was found from common interfering substances. [See IFU for additional details].

What can be said about the specificity of this assay in the presence of other coronaviruses like SARS and MERS?

Cross-reactivity with SARS-CoV is expected. However, SARS-CoV has not circulated in the human population since 2003 and an earlier study reported undetectable SARS-CoV-specific antibodies in serum samples of 91% (21/23) of samples tested 6 years following infection.[7] Our specificity study included samples from >1000 individuals in the pre-COVID-19 time period, with resulting specificity of 99.8%.



At Siemens Healthineers, our purpose is to enable healthcare providers to increase value by empowering them on their journey toward expanding precision medicine, transforming care delivery, and improving patient experience, all made possible by digitalizing healthcare.

An estimated 5 million patients globally benefit every day from our innovative technologies and services in the areas of diagnostic and therapeutic imaging, laboratory diagnostics, and molecular medicine, as well as digital health and enterprise services.

We are a leading medical technology company with over 120 years of experience and 18,000 patents globally. Through the dedication of more than 50,000 colleagues in 75 countries, we will continue to innovate and shape the future of healthcare.

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Product availability may vary from country to country and is subject to varying regulatory requirements. Please contact your local representative for availability.

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