

Fact Sheet for Recipients

Mobility Health SARS-CoV-2 Antibody Response Test



You are being given this Fact Sheet because your saliva sample is being tested or was tested for antibodies to the virus that causes

Coronavirus Disease 2019 (COVID-19) using the Mobility Health SARS-CoV-2 Antibody Response Test - a test that separately detects antibodies from vaccines and SARS-CoV-2 infection in one 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>

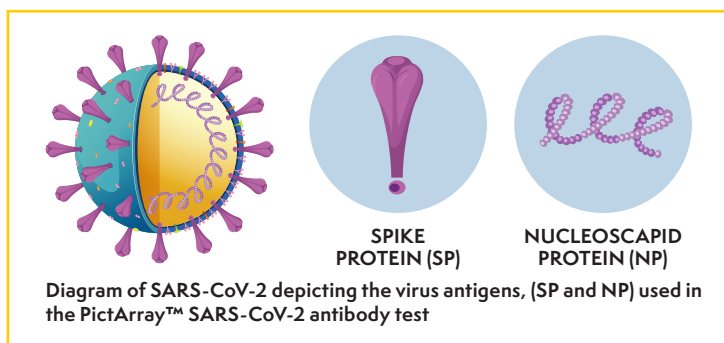
HOW ARE PEOPLE TESTED FOR COVID-19?

Two kinds of tests are currently available for COVID-19:

- A diagnostic test tells you if you have a current infection.
- An antibody test tells you if you have an immune response to a previous infection, or vaccination, or both.

SARS-COV-2

COVID-19 is caused by the B coronavirus, SARS-CoV-2, a spherical virus comprising four main proteins, nucleocapsid protein (NP), spike protein (SP), membrane protein (MP), and the envelope protein (EP).



WHAT IS THE DIFFERENCE BETWEEN THE SPIKE AND NUCLEOCAPSID PROTEINS?

Nucleocapsid and Spike are viral structural proteins. The nucleocapsid helps organize viral RNA while the Spike protein mediates viral entry into human cells. Antibodies to the SARS-CoV-2 viral spike protein have been shown to have neutralizing effects. Current vaccines were designed to elicit antibodies to the spike protein.

Spike (S): Antibodies to the spike protein are produced after vaccination or prior infection.

Nucleocapsid (N): Antibodies to the nucleocapsid protein identify individuals who have had a recent or prior COVID-19 infection, but are not useful for detecting antibodies elicited by currently available SARS-CoV-2 vaccines.

WHAT IS COVID-19 AND WHAT ARE ANTIBODIES?

Antibodies are proteins made by your body's immune system to help fight off infections, including those caused by viruses. Some antibodies in your body may protect you from getting those infections. Your immune system can also safely learn to make antibodies through vaccination. If antibodies give you this protection and how long this protection lasts can be different for each disease and each person.

NEUTRALIZING ANTIBODIES

Neutralizing antibodies provide protection from virus infections by preventing the virus from replicating and are produced by the body as part of the immune response triggered by both infections and vaccinations. Some antibodies produced by the body in response to infection or vaccination are not neutralizing.

SARS-CoV-2 Neutralizing Antibodies have been shown to be highly predictive of immune protection from symptomatic SARS-CoV-2 infection.^{1,2,3}

<https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/antibody-serology-testing-covid-19-information-patients-and-consumers#results>

Need more information?

The most up-to-date information on COVID-19 is available at <https://www.cdc.gov/COVID19>. Please also contact your healthcare provider with any questions/concerns.

INTERPRETATION OF SP AND NP ANTIBODY RESULTS

SP Antibody	NP Antibody	Interpretation*
+	+	Previously infected, may or may not have been vaccinated
+	-	Vaccinated with no previous infection
-	-	Not previously vaccinated or infected

*Potential false positive or false negative results, failure to develop detectable antibodies after vaccination or infection, and the waning of antibodies with time after infection or vaccination should be considered when interpreting antibody test results.

<https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antibody-tests-guidelines.html>

As this test is semi-quantitative, it will give you a numerical result, but you should not interpret the number to mean that having any measurement of antibodies to SARS-CoV-2 will protect you from getting infected again or help reduce the severity or duration of future COVID-19 symptoms. This topic is being studied, but the information is unknown. It is also not known how long antibodies to SARS-CoV-2 will remain present in the body after infection.

The numerical result and range is helpful if your physician is wanting to set a baseline measure of your current antibody levels to benchmark against future use with this test.

Your healthcare provider will work with you to determine how best to care for you based on the test results along with other factors of your medical history, your symptoms, possible exposures, and the geographic location of places you have recently traveled.

HOW CAN I GET TESTED?

Talk to your physician to determine if this test is right for you. They can then order the test if deemed clinically appropriate.

WHO CAN GET TESTED?

This antibody test is currently available for patients aged 18 years or older. The test must be ordered by a physician.

HOW LONG WILL IT TAKE TO GET MY RESULTS?

3-5 days of laboratory sample receipt.

WHAT ARE THE KNOWN AND POTENTIAL RISKS AND BENEFITS OF THE TEST?

Potential risks include:

- Possible challenges in producing saliva in instances where a patient has a dry mouth or is taking a medication/s that reduce saliva production and cause a dry mouth.

Potential benefits include:

- The results, along with other information, can help your healthcare provider make informed recommendations about your care.

WHAT WILL MY RESULTS MEAN?

A semi-quantitative antibody test can help identify individuals who have developed an immune response after exposure to COVID-19 or vaccination.

The Mobility Health SARS-CoV-2 Antibody Response Test indicate the presence or absence of IgG antibodies towards the SARS-CoV-2 SP and NP proteins, enabling the differentiation between recent infection with the SARS-CoV-2 virus (SP and NP) and an immune response following vaccination (SP only).

A positive test result indicates IgG antibodies have been found during screening.

Your neutralizing antibody score is calculated from the level of Spike IgG detected in your test.

A negative test result means no antibodies have been detected.

Testing for antibodies induced by vaccination should be performed at least two weeks after the second vaccine dose.

Negative antibody results in persons collected earlier than 21 days after symptom onset may be negative due to the kinetics of seroconversion, specifically, some patients will not have measurable antibodies until more than 21 days after symptom onset.

References:

1. Khoury, D.S., et al., Neutralizing antibody levels are highly predictive of immune protection from symptomatic SARS-CoV-2 infection. *Nat Med*, 2021. **27**(7): p. 1205-1211.
2. Earle, K.A., et al., Evidence for antibody as a protective correlate for COVID-19 vaccines. *Vaccine*, 2021. **39**(32): p. 4423-4428.
3. Bruel, T., et al. Neutralising antibody responses to SARS-CoV-2 omicron among elderly nursing home residents following a booster dose of BNT162b2 vaccine: A community-based, prospective, longitudinal cohort study. *eClinicalMedicine*. Jul 2022; 51:101576.



Ask your Healthcare Provider if this test is right for you.



Mobility Health is a CLIA-certified lab located in Mason, Ohio 5155 Financial Way, Suite 15 Mason, OH 45040
Contact us at 513-972-4621 | info@mobilityhealthlab.com ©2023 by Mobility Health, CLIA #: 36D2194362.