Fact Sheet for Healthcare Providers

Mobility Health SARS-CoV-2 Antibody Response Test

MOBILITY HEALTH

This Fact Sheet informs you of the significant known and potential risks and benefits of ordering a test for your patient(s) 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.

The Mobility Health SARS-CoV-2 Antibody Response Test is a duplex immunoassay that provides a semi-quantitative measure of both SARS-CoV-2 nucleocapsid (NP) and spike proteins (SP) in human saliva, serum, and plasma samples. The assay is intended to differentiate immune response from individuals who have been exposed to SARS-CoV-2 (NP & SP) from individuals vaccinated with mRNA vaccines (SP). The assay can also be used to monitor the presence of NP and levels of neutralizing SP antibodies over time as an aid to physicians in treatment or risk prediction of patients post-infection.

You should not interpret the results of this test as an indication or degree of immunity or protection from infection.

The Mobility Health SARS-CoV-2 Antibody Response Test is provided for the qualitative and semi-quantitative detection of IgG antibodies to SARS-CoV-2 in human saliva.

All individuals whose specimens are tested with this test will receive the *Fact Sheet for Recipients: Mobility Health SARS-CoV-2 Antibody Response Test*

WHAT ARE THE SYMPTOMS OF COVID-19?

Many patients with COVID-19 have developed fever and/or symptoms of acute respiratory illness (e.g., cough, dyspnea), although some individuals experience only mild symptoms or no symptoms at all. The current information available to characterize the spectrum of clinical illness associated with COVID-19 suggests that, when present, symptoms include cough, shortness of breath or dyspnea, fever, chills, myalgias, headache, sore throat, new loss of taste or smell, nausea or vomiting or diarrhea. Signs and symptoms may appear any time from 2 to 14 days after exposure to the virus, and the median time to symptom onset is approximately 5 days. For further information on the symptoms of COVID-19 please see the link provided in "Where can I go for updates and more information?" section.

WHAT DO I NEED TO KNOW ABOUT COVID-19 ANTIBODY TESTING?

Current information on COVID-19 for healthcare providers is available at CDC's webpage, Information for Healthcare Professionals (see links provided in "Where can I go for updates and more information?" section).

- The Mobility Health SARS-CoV-2 Antibody Response Test should not be used to diagnose or exclude acute infection and should not be used as the sole basis for treatment or patient management decisions. Direct testing for SARS-CoV-2 should be performed if acute infection is suspected.
- The Mobility Health SARS-CoV-2 Antibody Response Test provides a semi-quantitative result. The clinical applicability of a semi-quantitative result is currently unknown and cannot be interpreted as an indication or degree of immunity or protection from infection. Because semi-quantitative SARS-CoV-2 antibody assays are not standardized, and the performance characteristics of each semi-quantitative SARS-CoV-2 antibody test is uniquely established, results from different semi-quantitative SARS-COV-2 antibody assays are not comparable.

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 you make informed recommendations about your patient's care.

WHAT DOES MY PATIENT'S 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 patient's 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 antibody until more than 21 days after symptom onset.

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]

The low, medium, or high range is helpful to you as a physician wanting to set a baseline measure of your patient's current antibody levels to benchmark against future tests.

As per CDC guidelines, the Mobility Health SARS-CoV-2 Antibody Response Test will provide three main results for recipients as follows:

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 your patient 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.

Laboratory test results should always be considered in the context of clinical observations and epidemiological data in making patient management decisions.

The performance of this test was established based on the evaluation of a limited number of clinical specimens. The clinical performance has not been established in all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS- CoV-2 and their prevalence, which change over time.

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.

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.

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