

Using the OPTI SARS-CoV-2 Total Antibody Test to determine vaccine-elicited antibody uptake

In this study, the OPTI* SARS-CoV-2 Total Antibody Test was used to detect antibodies to the receptor-binding domain (RBD) of the SARS-CoV-2 spike protein before, during, and after a complete COVID-19 vaccination regimen.

Thirty individuals were tested before vaccination, 3 weeks after the first vaccination, and 2 weeks after the second vaccination with the Moderna vaccine, an mRNA vaccine that encodes the RBD. The samples, acquired through Access Biologicals, represented a wide distribution of age and gender (19–73 years, 9 male, 21 female). The test was used according to the manufacturer's guidelines. The results are shown in figure 1.

Prevaccine antibody levels were measurable in eight individuals, presumably caused by an immune response to a previous SARS-CoV-2 exposure. All samples were strongly positive for

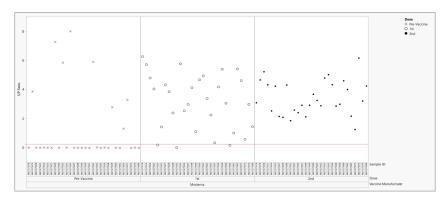


Figure 1. Total antibody levels determined using the OPTI SARS-CoV-2 Total Antibody Test before vaccination, 3 weeks after first vaccination, and 2 weeks after second vaccination with the Moderna vaccine.

RBD antibodies after the second vaccination, and all but three samples were positive after the first vaccination.

The same samples were tested on a predicate platform (DiaSorin* Liaison*). The results showed perfect agreement between the two tests for all samples after the second vaccination. However, the OPTI SARS-CoV-2 Total Antibody Test was able to detect antibodies in 27 individuals after the first vaccination, while the predicate test detected antibodies in only 26 individuals, highlighting the greater sensitivity of the OPTI SARS-CoV-2 Total Antibody Test.

In conclusion, this study demonstrates that the OPTI SARS-CoV-2 Total Antibody Test is an extremely sensitive test for evaluating antibody responses in people who have had one or both Moderna vaccinations. We expect that the results would be similar with other vaccines that use the RBD subunit of the spike protein (e.g., Pfizer*-BioNTech*, Johnson & Johnson, and AstraZeneca* vaccines). While this test, by itself, cannot discern whether antibodies are from natural infection or vaccination, it can effectively differentiate individuals who have protective antibodies from those who do not have antibodies. In addition, the test sensitivity makes it an effective monitoring tool for determining how long an individual maintains protective antibodies after vaccination.

Ordering information

Product number: 99-41609

Name: OPTI SARS-CoV-2 Total Antibody Test

Units: 5 96-well tests

CE

This CE mark certification represents OPTI Medical Systems' assurance that its test complies with the European Union's In Vitro Diagnostic Directive, which applies to products that are manufactured in or designed to be sold in the European Economic Area and Switzerland. The European Economic Area includes the European Union (Austria, Belgium, Bulgaria, Croatia, Republic of Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, and Sweden) and the following countries: Iceland, Liechtenstein, Norway, and United Kingdom.

The test is sold for Research Use Only in the United States. The test is not FDA approved

For more information on the OPTI* SARS-CoV-2 Total Antibody Test. contact your area manager or distributor, or visit optimedical.com.

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