

Evaluation of the OPTI SARS-CoV-2 Total Antibody Test at Iowa State University in the USA

Studies prove high performance of the OPTI SARS-CoV-2 Total Antibody Test

The OPTI* SARS-CoV-2 Total Antibody Test is an enzyme-linked immunosorbent assay (ELISA) that detects antibodies for SARS-CoV-2, the virus that causes COVID-19. The test detects IgM, IgG, and IgA antibodies and can be run manually or by using automation.

The OPTI SARS-CoV-2 Total Antibody Test was evaluated and compared against another ELISA for SARS-CoV-2 antibody detection at Iowa State University, USA.

A total of 389 blood samples were tested, including 287 known negative samples (collected in 2016 before the COVID-19 pandemic), 72 presumed negative samples, and 30 known positive samples. In addition, a proficiency panel consisting of positive and negative samples was tested. All samples were confirmed by at least one other commercial SARS-CoV-2 antibody test. In the case of discrepant results, confirmatory testing was done.

The OPTI SARS-CoV-2 Total Antibody Test performed with 99.7% diagnostic specificity and 100% diagnostic sensitivity. The test correctly identified all reference panel samples.



		Confirmed status		
		Positive	Negative	Total
OPTI SARS-CoV-2 Total Antibody Test	Positive	30	1	31
	Negative	0	358	358
	Total	30	359	389

The OPTI SARS-CoV-2 Total Antibody Test met the expectations of Iowa State University for the performance of a SARS-CoV-2 total antibody test.

“The OPTI SARS-CoV-2 Total Antibody Test had a high diagnostic sensitivity and specificity in our studies.”

Luis Gimenez-Lirola, Associate Professor, ISU

Ordering information

Product number: 99-41609

Name: OPTI SARS-CoV-2 Total Antibody Test

Units: 5 96-well tests



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.

covid19@optimedical.com

IDEXX USA +1 800 548 9997

IDEXX Europe +800 727 43399