Meet the COVID-19 testing needs of your patients and communities

Support the clinical and public health decisions needed to reopen safely and responsibly

Provide the most critical COVID-19 testing with a comprehensive portfolio that includes molecular (PCR) and serology solutions

Take advantage of in vitro tests that include semi-quantitative IgG antibody results to:

- Aid in diagnosis and monitor the level of immune response over time
- Help assess the antibody levels of at-risk patients and frontline healthcare workers
- Meet testing needs for seroprevalence studies
- Provide actionable results for your clinicians

Diagnosing Active Infections	Acute Immune Response Testing	Population Surveillance[1]	Employer Workforce Testing	Contact Tracing	Potential Measurement of Response to Vaccination	Identifying Recovered Infections[1]	Population Immune Response Assessment[2]	Identify Potential Convalescent Plasma Donors[3]
PCR Testing	**Total (IgM and IgG) Antibody Testing**							
		Total (IgM and IgG) Antibody Testing						

Molecular (PCR) Testing FTD SARS-CoV-2 Solution[4]

- Aid in diagnosis of SARS-CoV-2 infections
- Robust molecular assays with multiple target design to identify active infection
- Demonstrates 100% positive percent agreement (PPA) (91.8-100, 95% CI)[5]
- Demonstrates 100% negative percent agreement (NPA) (88.7-100, 95% CI)[5]

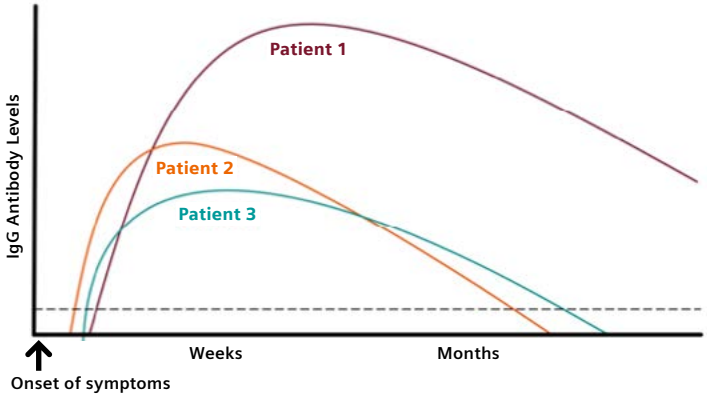
Serologic Antibody Testing SARS-CoV-2 Total and IgG Solution[4]

- Detect immune response to SARS-CoV-2
- High throughput with the ability to tests up to 440 tests/hour with the Atellica® IM[7]
- Highly accurate with a sensitivity of 100%[8] and a specificity of >99.8%

GenesisLabs
LABORATORY OF CHOICE

Assess the Strength of Immune Response in Crucial Populations with the First Semi-Quantitative SARS-CoV-2 IgG Antibody Assay

Individual patients can experience varying levels of immune response that progress differently over time. Qualitative serology assays do not measure changes in antibody levels over time. It is essential to have the most comprehensive test results to assess the antibody levels of at-risk patients and frontline healthcare workers.



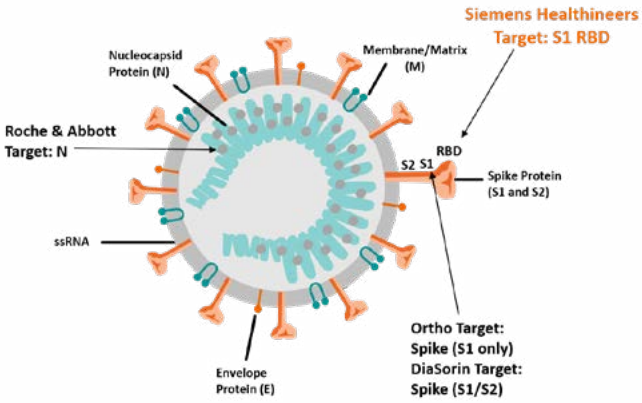
Advantages of semi-quantitative anti-RBD test results

- Detect the presence and level of S1 RBD antibodies.
- Support assessment for the degree of a patient's antibody-associated immune response and declining antibody levels over time
- Appraise potential convalescent plasma donors for the presence and level of IgG antibodies[3]
- Support the semi-quantitative evaluation of a successful immune response

Assay Specifications[9]	Performed at Genesis	Abbott IgG assay	DiaSorin IgG assay	Beckman Coulter IgG assay
Platforms	**Atellica IM 1300/1600**	Alinity i	Liaison	DxI/Access 2
Antigen	**S1 RBD**	N	S1/S2	S1 RBD
Result/Output	**Semi-Quantitative Index Value**	Qualitative	Qualitative	Qualitative with retesting zone
Sensitivity ≥ 14 days post positive PCR test	**100%**	96.77%†	97.60%	96.8%*
Specificity	**99.89%**	99.60%	99.30%	99.60%
Positive Predictive Value (PPV) at 5% prevalence	**98.00%**	84.00%	88.00%	93.40%

**> 15 days post positive PCR test*
†100% sensitivity when 5 patients were excluded from sampling

Are you targeting the right antigen with your antibody testing?



Why does the smart design of Siemens Healthineers SARS-CoV-2 IgG and Total Antibody assays include the S1 RBD Protein as the targeted antigen?[10-11]

- Most specific antigen that differentiates SARS-CoV-2 from other coronaviruses
- Growing evidence indicates that the spike protein antibodies are neutralizing, based on in vitro data[12]
- All vaccines SARS-CoV-2 target the spike protein

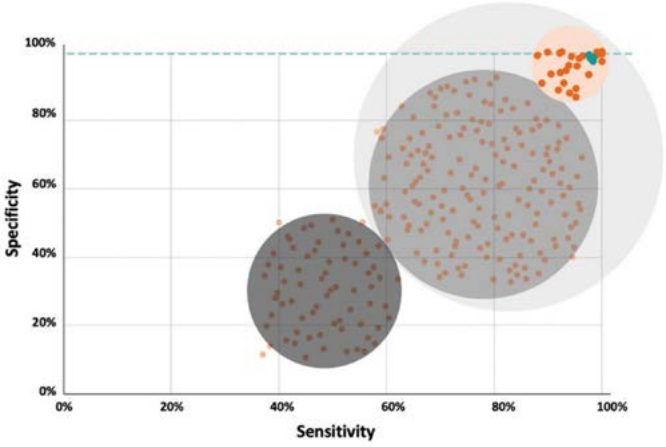
Testing accuracy is essential for minimizing risks to patients and providers

Are you using an accurate SARS-CoV-2 antibody assay?

An assay with analytical specificity of 99.5% or above yields a high positive predictive value (PPV) regardless of prevalence. As prevalence increases, so does the PPV of high-performing assays.[13]

The state of U.S. SARS-CoV-2 Antibody Testing

- More than 220 antibody tests on the market[14]
- Fewer than **1 out of 4** tests hold FDA EUA[15]
- Fewer than **1 out of 10** tests meet the CDC recommended >99.5% specificity[15]
- **6 of these high-performing assays are offered by Siemens Healthineers**



Antibody tests that hold FDA EUA

Siemens Healthineers antibody tests

Total antibody tests in the market[14]

Number of tests that should no longer be offered[15]

Tests in the market without FDA EUA

Data as of July 31, 2020

[1]Data limited on how IgG (N) compares to Total (N) for early detection when using highly sensitive and specific assays.

[2]At this time, it is unknown for how long antibodies persist following infection and if the presence of antibodies confers protective immunity

[3]Luchsinger LL et al. Serological Analysis of New York City COVID19 Convalescent Plasma Donors. https://doi.org/10.1101/2020.06.08.20124792

[4]These SARS-CoV-2 molecular and serology tests have not been FDA cleared or approved. These tests have been authorized by FDA under an EUA for use by authorized laboratories. The molecular test has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens. The serology tests have been authorized only for detecting the presence of antibodies against SARS-CoV-2, not for any other viruses or pathogens. These tests are 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 from country to country and is subject to varying regulatory requirements.

[5]FTD SARS-CoV-2 Instructions for Use.

[6]Laboratories that adopt the FTD SARS-CoV-2 assays are responsible for validation the assays as part of their workflow

[7]Throughput is dependent on test mix.

[8]100% positive percent agreement (sensitivity) at ≥14 days following a positive PCR test.

[9]https://www.fda.gov/medical-devices/emergency-situations-medical-devices/eua-authorized-serology-test-performance

[10]Premkuna, L. et al. Science Immunology 11 Jun 2020: Vol. 5, Issue 48, eabc8413, DOI: 10.1126/sciimunol.abc8413

[11]Ni et al., 2020, Immunity 52, 1–7, June 16, 2020. https://doi.org/10.1016/j.immuni.2020.04.023

[12]Chen X, et al. Cellular & Molecular Immunology. 2020 Apr. https://doi.org/10.1038/s41423-020-0426-7

[13]According to CDC

[14]https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-testing-sars-cov-2#offeringtests

[15]https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-testing-sars-cov-2#nolonger

Published by Siemens Healthcare Diagnostics Inc. · Order No. LD-20-NAM-1372 · Online · 08.2020 ·