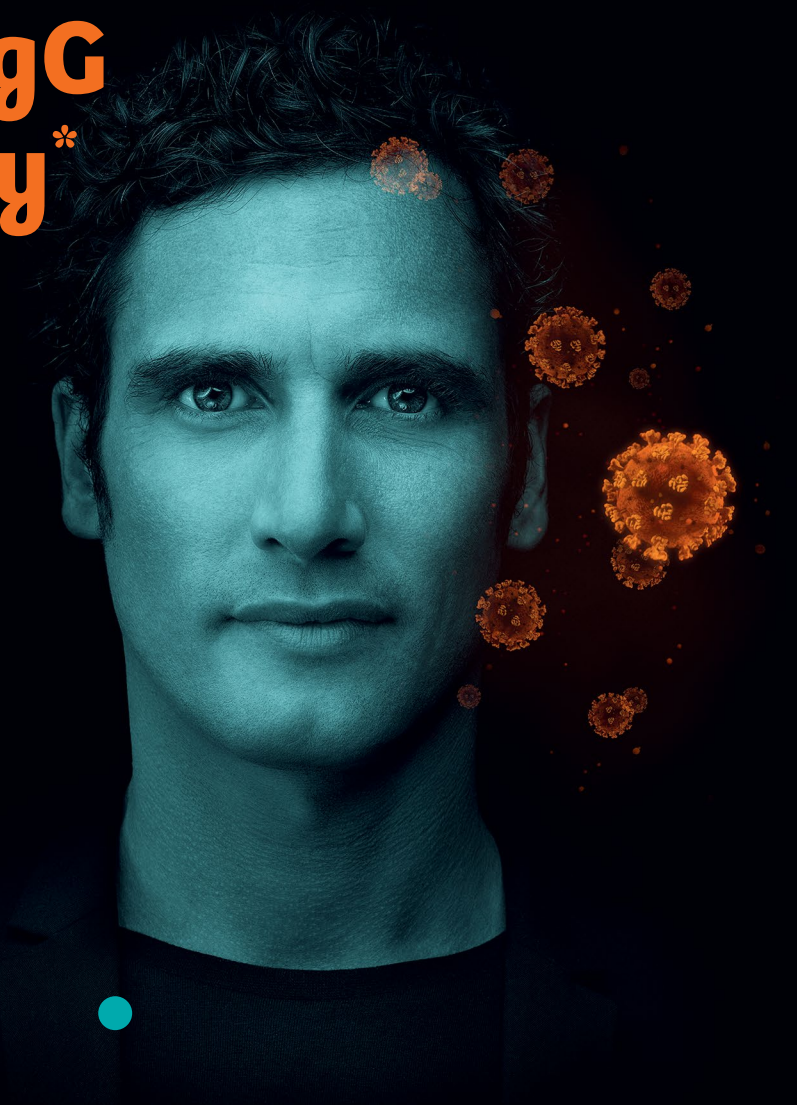
SARS-CoV-2 IgG (sCOVG) Assay*

Atellica® IM Analyzer and
ADVIA Centaur® XP/XPT/CP
Immunoassay System

siemens-healthineers.us



The COVID-19 pandemic has profoundly disrupted the world and tools that can help address the full spectrum of challenges to help secure communities and combat this pandemic are needed. Testing large numbers of individuals for immune response/antibody status against the SARS-CoV-2 virus is likely to be critical for re-opening society, as well as for managing the potential threat of a second wave of infections and for vaccine and immune response monitoring.

For U.S. use only

**This test has not been reviewed by the FDA. In the US, use of this test is limited to laboratories that are certified under Clinical Laboratory Improvement Amendments of 1988 (CLIA) to perform high-complexity testing. Product availability may vary by country and is subject to regulatory requirements.*

SIEMENS Healthineers

SARS-CoV-2 IgG Assay

Clinical Utility

The presence of antibodies to SARS-CoV-2 after natural infection indicates that the patient, whether symptomatic or asymptomatic, had an immune response to the virus. The immune system develops IgM and IgG antibodies as a response to SARS-CoV-2 infection. Over time it is IgG that remains the detectable antibody. Testing for IgG is vital for the assessment of antibodies to SARS-CoV-2 produced by recent or past infection. These antibodies are associated with potential immunity after infection (which is still under investigation) and may play a role in assessing need for and response to vaccination.

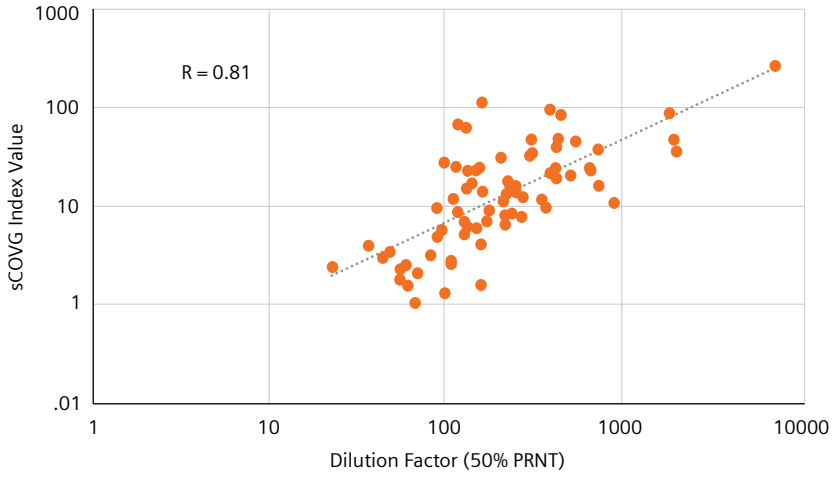
The Siemens Healthineers SARS-CoV-2 IgG (sCOVG) assay is used for the qualitative and semi-quantitative detection of IgG antibodies to SARS-CoV-2, including neutralizing antibodies, in human serum and plasma (lithium heparin).[1] This assay utilizes the spike protein receptor binding domain (S1 RBD) antigen to detect antibodies that block the virus entry into cells. This antigen selection is aligned with the multiple vaccines in use and development that target or include the SARS-CoV-2 S1 RBD with the goal of producing protective antibody.

With the ability to semi-quantitatively measure the level of IgG antibodies, including neutralizing antibodies in the blood, this assay can help clinicians assess and track patients' immune response. The correlation of neutralization titer using a PRNT assay was evaluated by testing samples from 74 subjects with a clinical diagnosis of COVID-19 based on a positive SARS-CoV-2 PCR method. Atellica IM sCOVG assay results generated on the Atellica IM Analyzer provided a Pearson correlation coefficient of 0.81, demonstrating a strong relationship between the Atellica IM sCOVG assay index value and neutralization titer.[1]

sCOVG Assay Benefits

- Accurate identification of immune response to support long term COVID-19 management.
- Smart selection of the S1RBD antigen to detect IgG antibodies, including neutralizing antibodies that block the virus entry into cells.
- Reliable and rapid SARS-CoV-2 antibody testing on a large scale for both reference labs and acute care settings.

Atellica IM sCOVG Assay Comparison to 50% PRNT[1]



Assay Characteristics[1,†]

System	Sample Types	Sample Volume	Calibration Interval	Cutoff (Index)	Measuring Interval (Index)	Onboard Stability	Detection Capability (Index)	Negative Percent Agreement	Time to First Result
Atellica IM Analyzer	Serum, plasma (lithium heparin)	40 µL	Lot: 28 days Pack: 14 days	<1.0 nonreactive ≥1.0 reactive	0.50–150.00	28 days	LoB: 0.40 LoD: 0.50 LoQ: 0.50	99.90%	25 min
ADVIA Centaur XP/XPT/CP Systems	Serum, plasma (lithium heparin)	40 µL	14 days	<1.0 nonreactive ≥1.0 reactive	0.50–150.00	28 days	LoB: 0.40 LoD: 0.50 LoQ: 0.50	99.90%	XP/XPT: 58 min CP: 50 min

Positive Percent Agreement[†]

Samples Tested	Days Post PCR Positive	Number Tested	Reactive	Nonreactive	Positive Percent Agreement	95% Confidence Interval
836	0–6	368	187	181	50.82%	45.58%–56.03%
	7–13	194	160	34	82.47%	76.38%–87.55%
	14–20	79	72	7	91.14%	82.59%–96.36%
	≥21	195	188	7	96.41%	92.74%–98.54%

[†]Negative percent agreement and positive percent agreement were determined on Atellica IM.

Atellica IM sCOVG Assay Ordering Information

Catalog No.	Contents	Quantity
11207387	5 Atellica IM sCOVG ReadyPack® primary reagent packs 5 Atellica IM sCOVG DIL ReadyPack Ancillary reagent packs 2 vials Atellica IM sCOVGG CAL low calibrator (CAL L), 1.0 mL per vial 2 vials Atellica IM sCOVG CAL high calibrator (CAL H), 1.0 mL per vial	500 tests
11207388	Atellica IM sCOVG QC Kit: 2 vials x 2.0 mL negative control, 2 vials x 2.0 mL positive control	1 set with 4 vials total
Optional Item: 11207587	Atellica IM MCM Set	1 set

ADVIA Centaur sCOVG Assay Ordering Information

Catalog No.	Contents	Quantity
11207377	5 ADVIA Centaur sCOVG ReadyPack primary reagent packs 5 ADVIA Centaur sCOVG DIL ReadyPack Ancillary reagent packs 2 vials of ADVIA Centaur sCOVG low calibrator (CAL L), 1.0 mL per vial 2 vials of ADVIA Centaur sCOVG high calibrator (CAL H), 1.0 mL per vial ADVIA Centaur sCOVG master curve card ADVIA Centaur sCOVG calibrator assigned value sheet and bar-code labels	500 tests
11207378	ADVIA Centaur sCOVG QC Kit: 2 vials x 2.0 mL negative control, 2 vials x 2.0 mL positive control	1 set with 4 vials total
Optional Item: 11207586	ADVIA Centaur MCM Set	1 set

At Siemens Healthineers, our purpose is to enable healthcare providers to increase value by empowering them on their journey toward expanding precision medicine, transforming care delivery, and improving patient experience, all enabled by digitalizing healthcare.

An estimated 5 million patients globally benefit every day from our innovative technologies and services in the areas of diagnostic and therapeutic imaging, laboratory diagnostics, and molecular medicine, as well as digital health and enterprise services.

We're a leading medical technology company with over 120 years of experience and 18,500 patents globally. With about 50,000 dedicated colleagues in over 70 countries, we'll continue to innovate and shape the future of healthcare.

On account of certain regional limitations of sales rights and service availability, we cannot guarantee that all products included in this brochure are available through the Siemens Healthineers sales organization worldwide. Availability and packaging may vary by country and is subject to change without prior notice. Some/All of the features and products described herein may not be available in the United States.

The information in this document contains general technical descriptions of specifications and options as well as standard and optional features, which do not always have to be present in individual cases.

Siemens Healthineers reserves the right to modify the design, packaging, specifications, and options described herein without prior notice. For the most current information, please contact your local sales representative from Siemens Healthineers.

Note: Any technical data contained in this document may vary within defined tolerances. Original images always lose a certain amount of detail when reproduced.

[1]Atellica IM SARS-CoV-2 IgG (sCOVG) Instructions for Use, 11207499_EN Rev. 01, 2021-01, ADVIA Centaur SARS-CoV-2 IgG (sCOVG) Instructions for Use, 11207910_EN Rev. 01, 2021-01

Siemens Healthineers Headquarters
Siemens Healthcare GmbH
Henkestr. 127
91052 Erlangen, Germany
Phone: +49 9131 84-0
siemens-healthineers.com

USA
Siemens Healthcare Diagnostics Inc.
Laboratory Diagnostics
511 Benedict Avenue
Tarrytown, NY 10591-5005, USA
Phone: +1-914-631-8000
siemens-healthineers.us

Published by Siemens Healthcare Diagnostics Inc. · Order No. LD-21-NAM-1906 · Online · 01.2021 · ©Siemens Healthcare Diagnostics Inc., 2021