# SARS-CoV-2 IgG (sCOVG) Assay*

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

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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 Use Outside the U.S.**

**Not available for sale in the U.S. Product availability varies from country to country and is subject to varying regulatory requirements.*

SIEMENS Healthineers

# SARS-CoV-2 IgG Assay

## Clinical Utility

The presence of antibodies to SARS-CoV-2 indicates that the patient, whether symptomatic or asymptomatic, had an immune response to the virus. The use of total antibody tests detecting both SARS-CoV-2 IgG and IgM in the blood can help to provide a clearer disease-state picture. Over time it is IgG that remains the primary 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, once vaccines become available.

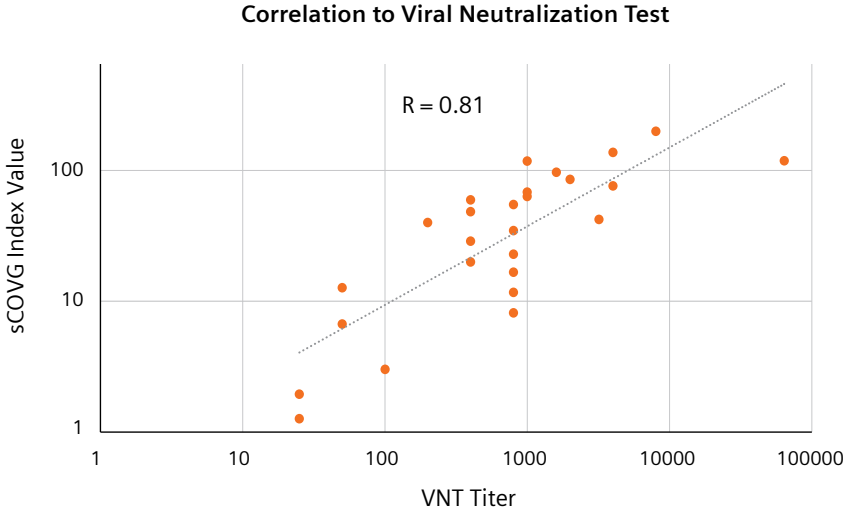
The Siemens Healthineers SARS-CoV-2 IgG (sCOVG) assay is used for the qualitative and quantitative detection of neutralizing IgG antibodies to SARS-CoV-2 in human serum and plasma (lithium heparin) obtained by venipuncture or capillary puncture. This assay utilizes the spike protein receptor binding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

With the ability to quantitatively measure the level of neutralizing antibodies in the blood, this assay can help clinicians assess and track patients' immune response. A correlation study using a viral neutralizing test demonstrated a strong correlation between the sCOVG assay index value and neutralizing antibody titers. This enables this assay to be potentially used for convalescent donor identification as well as determining vaccine response and monitoring post-vaccination neutralizing antibody levels.

The correlation to neutralization titer using a viral neutralization test (VNT) was evaluated by testing samples from 26 subjects with a clinical diagnosis of COVID-19 based on a positive SARS-CoV-2 PCR result. 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, as shown in the graph below.

## sCOVG Assay Benefits

- Accurate identification of immune response to support long term COVID-19 management.
- Smart selection of the S1 RBD antigen to detect 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.



## Assay Characteristics

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

*†Negative Percent Agreement*

## Clinical Sensitivity (Positive Percent Agreement)

| Samples Tested | Days Post PCR Positive | Number Tested | Reactive | Nonreactive | Clinical Sensitivity | 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% |

## Atellica IM sCOVG Assay Ordering Information

| Catalog No. | Contents | Quantity |
|---|---|---|
| 11207386 | 1 Atellica IM sCOVG ReadyPack® primary reagent pack<br>1 Atellica IM sCOVG DIL ReadyPack Ancillary reagent pack<br>1 vial Atellica IM sCOVG CAL low calibrator (CAL L), 1.0 mL per vial<br>1 vial Atellica IM sCOVG CAL high calibrator (CAL H), 1.0 mL per vial | 100 tests |
| 11207387 | 5 Atellica IM sCOVG ReadyPack primary reagent packs<br>5 Atellica IM sCOVG DIL ReadyPack Ancillary reagent pack<br>2 vials Atellica IM sCOVGG CAL low calibrator (CAL L), 1.0 mL per vial<br>2 vials Atellica IM sCOVG CAL high calibrator (CAL H), 1.0 mL per vial | 500 tests |
| 11207388 | Atellica IM sCOVG QC Kit:<br>2 vials x 2.0 mL negative control, 2 vials x 2.0 mL positive control | 1 set with 4 vials total |

## ADVIA Centaur sCOVG Assay Ordering Information

| Catalog No. | Contents | Quantity |
|---|---|---|
| 11207376 | 1 ADVIA Centaur sCOVG ReadyPack primary reagent pack<br>1 ADVIA Centaur sCOVG DIL ReadyPack Ancillary reagent pack<br>1 vial of ADVIA Centaur sCOVG low calibrator (CAL L), 1.0 mL per vial<br>1 vial of ADVIA Centaur sCOVG high calibrator (CAL H), 1.0 mL per vial<br>ADVIA Centaur sCOVG master curve card<br>ADVIA Centaur sCOVG calibrator assigned value sheet and bar-code labels | 100 tests |
| 11207377 | 5 ADVIA Centaur sCOVG ReadyPack primary reagent packs<br>5 ADVIA Centaur sCOVG DIL ReadyPack Ancillary reagent pack<br>2 vials of ADVIA Centaur sCOVG low calibrator (CAL L), 1.0 mL per vial<br>2 vials of ADVIA Centaur sCOVG high calibrator (CAL H), 1.0 mL per vial<br>ADVIA Centaur sCOVG master curve card<br>ADVIA Centaur sCOVG calibrator assigned value sheet and bar-code labels | 500 tests |
| 11207378 | ADVIA Centaur sCOVG QC Kit:<br>2 vials x 2.0 mL negative control, 2 vials x 2.0 mL positive control | 1 set with 4 vials total |

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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 are a leading medical technology company with over 120 years of experience and 18,000 patents globally. Through the dedication of more than 50,000 colleagues in 75 countries, we will continue to innovate and shape the future of healthcare.



Product availability may vary from country to country and is subject to varying regulatory requirements. Please contact your local representative for availability.

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