SARS-CoV-2 IgG Assay*

Atellica IM Analyzer and
ADVIA Centaur XP/XPT
Immunoassay System

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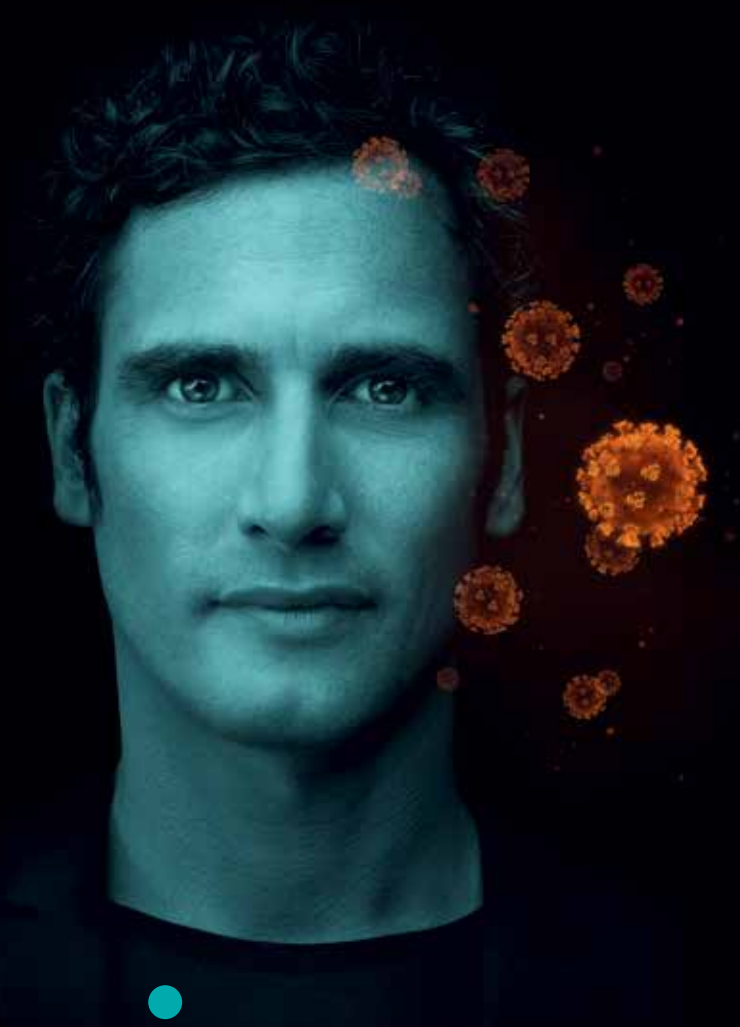

The COVID-19 pandemic has profoundly disrupted the world and tools that can help address the full spectrum of challenges to help secure communities and combat this pandemic are needed. Testing large numbers of individuals for immune response/antibody status against the SARS-CoV-2 virus is likely to be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

**This test has not been FDA cleared or approved. This test has been authorized by FDA under an EUA for use by authorized laboratories. This test has been authorized only for detecting the presence of antibodies against SARS-CoV-2, not for any other viruses or pathogens. This test is 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 by country and is subject to varying regulatory requirements.*

SIEMENS Healthineers

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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. Multiple vaccines in development target or include the SARS-CoV-2 spike protein receptor binding domain (S1 RBD) that is used in our assay, with the goal of producing protective antibody.

The Siemens Healthineers SARS-CoV-2 IgG (COV2G) assay is a chemiluminescent immunoassay intended for qualitative and semi-quantitative detection of IgG antibodies to SARS-CoV-2 in human serum and plasma (EDTA and lithium heparin) using the Atellica® IM Analyzer, ADVIA Centaur® XP and ADVIA Centaur® XPT Immunoassay Systems. The COV2G assay is intended as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection.

Cross-reactivity was determined in accordance with CLSI Document EP07-ed3.[1] The assay was evaluated for potential cross-reactivity using specimens containing antibodies to other pathogens and other disease states using the COV2G assay with the Atellica IM Analyzer and ADVIA Centaur XP System. No false positive results were observed with the potential cross-reactants.

COV2G Assay Benefits

- Accurate identification of immune response to support long term COVID-19 management.
- Smart selection of the S1RBD antigen to detect 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 (EDTA, lithium heparin)	10 µL	Lot: 28 days Pack: 14 days	<1.0 nonreactive ≥1.0 reactive	0.50–20.0	28 days	LoB: 0.40 LoD: 0.50 LoQ: 0.50	99.95%	25 min
ADVIA Centaur XP/XPT Systems	Serum, plasma (EDTA, lithium heparin)	10 µL	14 days	<1.0 nonreactive ≥1.0 reactive	0.50–20.0	28 days	LoB: 0.40 LoD: 0.50 LoQ: 0.50	99.89%	58 min

†Negative Percent Agreement

Clinical Sensitivity (Positive Percent Agreement)

System	Samples Tested	Days Post PCR Positive	Number Tested	Reactive	Nonreactive	Clinical Sensitivity	95% Confidence Interval
Atellica IM Analyzer	197	0–6	91	51	40	56.04%	45.25%–66.44%
		7–13	64	59	5	92.19%	82.70%–97.41%
		≥14	42	42	0	100.00%	91.59%–100.00%
ADVIA Centaur XP/XPT Systems	189	0–6	86	46	40	53.49%	42.41%–64.23%
		7–13	61	57	4	93.44%	84.05%–98.18%
		≥14	47	47	0	100.00%	91.59%–100.00%

Atellica IM COV2G Assay Ordering Information

Catalog No.	Contents	Quantity
11206997	1 Atellica IM COV2G ReadyPack® primary reagent pack 1 vial Atellica IM COV2G CAL low calibrator (CAL L), 1.0 mL per vial 1 vial Atellica IM COV2G CAL high calibrator (CAL H), 1.0mL per vial	100 tests
11206998	5 Atellica IM COV2G ReadyPack primary reagent packs 2 vials Atellica IM COV2G CAL low calibrator (CAL L), 1.0 mL per vial 2 vials Atellica IM COV2G CAL high calibrator (CAL H), 1.0 mL per vial	500 tests
11206999	Atellica IM COV2G QC Kit: 2 vials x 2.0 mL negative control, 2 vials x 2.0 mL positive control	1 set with 4 vials total

ADVIA Centaur COV2G Assay Ordering Information

Catalog No.	Contents	Quantity
11206992	1 ADVIA Centaur COV2G ReadyPack primary reagent pack 1 vial of ADVIA Centaur COV2G low calibrator (CAL L), 1.0 mL per vial 1 vial of ADVIA Centaur COV2G high calibrator (CAL H), 1.0 mL per vial ADVIA Centaur COV2G master curve card ADVIA Centaur COV2G calibrator assigned value sheet and bar-code labels	100 tests
11206993	5 ADVIA Centaur COV2G ReadyPack primary reagent packs 2 vials of ADVIA Centaur COV2G low calibrator (CAL L), 1.0 mL per vial 2 vials of ADVIA Centaur COV2G high calibrator (CAL H), 1.0 mL per vial ADVIA Centaur COV2G master curve card ADVIA Centaur COV2G calibrator assigned value sheet and bar-code labels	500 tests
11206994	ADVIA Centaur COV2G QC Kit: 2 vials x 2.0 mL negative control, 2 vials x 2.0 mL positive control	1 set with 4 vials total

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 made possible 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 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.

References:

1. Clinical and Laboratory Standards Institute. Interference Testing in Clinical Chemistry; Approved Guideline—Third Edition. Wayne, PA: Clinical and Laboratory Standards Institute; 2018. CLSI Document EP07-ed3.

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