SIEMENS

ADVIA Centaur®
Immunoassay Systems

SARS-CoV-2 IgG (sCOVG)

For Use Under Emergency Use Authorization Only

For *in vitro* diagnostic use.

For prescription use only.

The results of this semi-quantitative test should not be interpreted as an indication or degree of immunity or protection from infection.

Assay for the Detection of IgG Antibodies to SARS-CoV-2

Current Revision and Date[a]	Rev. 02, 2021-08	
Product Name	ADVIA Centaur SARS-CoV-2 IgG (sCOVG)	REF 11207376 (100 tests)
		REF 11207377 (500 tests)
Abbreviated Product Name	ADVIA Centaur sCOVG	
Test Name/ID	sCOVG	
Systems	ADVIA Centaur XP system ADVIA Centaur XPT system ADVIA Centaur CP system	
Materials Required but Not Provided	ADVIA Centaur sCOVG QC	REF 11207378
	ADVIA Centaur Ancillary Probe Wash 1	REF 03395373
	ADVIA Centaur Probe Wash 3	REF 03333963
	ADVIA Centaur Wash 1 (2 x 1500 mL)	REF 01137199 (112351)
	ADVIA Centaur Wash 1 (2 x 2500 mL)	REF 03773025
Optional Materials	ADVIA Centaur sCOVG DIL	REF 11208300 (2-pack)
	ADVIA Centaur Multi-Diluent 12	REF 04786546 (vial)
	ADVIA Centaur sCOVG MCM	REF 11207586
Specimen Types	Serum, lithium heparin plasma	

Sample Volume	40 µL
Measuring Interval	0.50–100.00 Index

[a] A vertical bar in the page margin indicates technical content that differs from the previous version.

Intended Use

The ADVIA Centaur® SARS-CoV-2 IgG (sCOVG) assay is a chemiluminescent immunoassay intended for qualitative and semi-quantitative detection of IgG antibodies to SARS-CoV-2 in human serum and plasma (lithium heparin) using the using the ADVIA Centaur® XP, ADVIA Centaur® XPT, and ADVIA Centaur® CP Immunoassay Systems. The ADVIA Centaur SARS-CoV-2 IgG (sCOVG) assay is intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection. At this time, it is unknown for how long antibodies persist following infection and if the presence of antibodies confers protective immunity. The ADVIA Centaur SARS-CoV-2 IgG (sCOVG) assay should not be used to diagnose or exclude acute SARS-CoV-2 infection. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C 263a, that meet requirements to perform moderate or high complexity tests.

Results are for the detection of SARS-CoV-2 IgG antibodies. IgG antibodies to SARS-CoV-2 are generally detectable in blood several days after initial infection, although the duration of time antibodies are present post-infection is not well characterized. Individuals may have detectable virus present for several weeks following seroconversion.

Laboratories within the United States and its territories are required to report all results to the appropriate public health authorities.

The sensitivity of the ADVIA Centaur SARS-CoV-2 IgG (sCOVG) assay early after infection is unknown. Negative results do not preclude acute SARS-CoV-2 infection. If acute infection is suspected, direct testing for SARS-CoV-2 is necessary.

False positive results for the ADVIA Centaur SARS-CoV-2 IgG (sCOVG) assay may occur due to cross-reactivity from pre-existing antibodies or other possible causes.

Samples should only be tested from individuals who are 15 days or more post symptom onset.

The ADVIA Centaur SARS-CoV-2 IgG (sCOVG) assay is only for use under the Food and Drug Administration's Emergency Use Authorization.

Summary and Explanation

COVID-19 (coronavirus disease 2019) is the illness resulting from infection with SARS-CoV-2 (severe acute respiratory syndrome coronavirus 2) virus.[1-5] The virus spreads readily from person to person or possibly from environmental exposure.[6] Evidence supports spread by both asymptomatic and symptomatic individuals.[7]

Antibodies appear approximately 1-3 weeks post-symptom onset in most patients and are produced in both symptomatic and asymptomatic infection.[8,9] Unlike typical seroconversion profiles, near-simultaneous production of both IgM and IgG has been observed in symptomatic patients with confirmed SARS-CoV-2. Titer of antibody may be higher in symptomatic disease, though additional data is needed to confirm this.[10,11]

Antibodies produced to structural proteins of the virus include spike antibody and nucleocapsid antibody. Data show both IgM and IgG antibodies for these structural proteins appear with seroconversion. IgM eventually disappears, but IgG remains detectable in most patients. Spike is a transmembrane glycoprotein comprised of two regions: S1 and S2. S1 mediates recognition and binding of the viral receptor (ACE2) on host cells, and S2 facilitates viral fusion and entry.[12,13] The majority of S1 is comprised of the receptor binding domain (RBD) that binds directly to ACE2 and is highly immunogenic. The S1 RBD in SARS-CoV-2 contains both unique and conserved sequences compared to other beta-coronaviruses.

Principles of the Procedure

The ADVIA Centaur sCOVG assay is a fully automated 2-step sandwich immunoassay using indirect chemiluminescent technology. The patient specimen is diluted with ADVIA Centaur sCOVG DIL and incubated with the Solid Phase Reagent. The Solid Phase contains a preformed complex of streptavidin-coated microparticles and biotinylated SARS-CoV-2 recombinant antigens. The antigen-coated particles subsequently capture SARS-CoV-2 specific antibodies in the specimen. The antibody-antigen complex is washed and Lite Reagent is added. The Lite Reagent consists of an acridinium-ester-labeled anti-human IgG mouse monoclonal antibody. The entire complex is washed and the signal is generated in the presence of Lite Reagent bound to the Solid Phase via the anti-SARS-CoV-2 IgG:SARS-CoV-2 antigen complex.

A direct relationship exists between the amount of SARS-CoV-2 IgG antibody present in the patient sample and the amount of relative light units (RLUs) detected by the system.

A result of reactive or nonreactive is determined according to the Index Value established with the calibrators. Refer to *Interpretation of Results*.

Reagents

Material Description	Storage	Stability
ADVIA Centaur sCOVG ReadyPack® primary reagent pack[a, b] **Lite Reagent** 10.0 mL/reagent pack Mouse monoclonal anti-human IgG antibody labeled with acridinium ester (~0.05 µg/mL); buffer; surfactant; bovine serum albumin (BSA); sodium azide (< 0.1%); preservative **Solid Phase** 10.0 mL/reagent pack Streptavidin-coated paramagnetic microparticles preformed with biotinylated SARS-CoV-2 S1 RBD antigen (~1.0 µg/mL); buffer; bovine serum albumin; horse serum; surfactant; preservative **Ancillary Well Reagent** 10.0 mL/reagent pack Buffer; surfactant; bovine serum albumin; horse serum; preservative	Unopened at 2–8°C Onboard	Until expiration date on product Refer to *Onboard Stability*
ADVIA Centaur sCOVG DIL ReadyPack ancillary reagent pack[a, b, c] 25.0 mL/reagent pack Potassium thiocyanate (~0.55 M); surfactant; sodium caseinate; BSA; preservatives	Unopened at 2–8°C Onboard	Until expiration date on product 28 days
ADVIA Centaur sCOVG CAL[a, b] **sCOVG CAL L**: 1.0 mL/vial Processed* human plasma nonreactive for SARS-CoV-2 antibodies; sodium azide (< 0.1%) **Processed plasma is defibrinated and filtered plasma.* **sCOVG CAL H**: 1.0 mL/vial Horse serum spiked with human monoclonal IgG antibodies to SARS-CoV-2; sodium azide (< 0.1%)	Unopened at 2–8°C Opened at 2–8°C At room temperature	Until expiration date on product 60 days 8 hours

Material Description	Storage	Stability
ADVIA Centaur Multi-Diluent 12[a, d] 20.0 mL/vial Human serum; detergents; glycerol; anti-foam; preservatives	At 2–8°C	Until expiration date on product
ADVIA Centaur Ancillary Probe Wash 1 ReadyPack ancillary reagent pack[a, e] 25.0 mL/pack 0.4 N sodium hydroxide	Unopened at 2–8°C Onboard	Until expiration date on product 14 days
ADVIA Centaur Probe Wash 3[a, e] 50.0 mL/pack Sodium hypochlorite (0.5%); sodium hydroxide (< 0.5%); pH 11.0	Unopened at 2–8°C Onboard	Until expiration date on product 100 days
ADVIA Centaur Wash 1[a, e] 1500 mL/pack Phosphate-buffered saline; sodium azide (< 0.1%); surfactant	Unopened at 2–25°C Onboard	Until expiration date on product 1 month
ADVIA Centaur Wash 1[a, e] 2500 mL/pack Phosphate-buffered saline; sodium azide (< 0.1%); surfactant	Unopened at 2–25°C Onboard	Until expiration date on product 1 month

[a] Store in an upright position.
[b] Prevent exposure to sunlight and heat.
[c] The diluent provided in this kit is also available as an optional material if additional diluent is needed. Refer to *Optional Materials*.
[d] Refer to *Optional Materials*.
[e] Refer to *Materials Required but Not Provided*.

Warnings and Precautions

For Use Under Emergency Use Authorization Only

For *in vitro* diagnostic use only.

For prescription use only.

This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories.

This product has been authorized only for detecting the presence of IgG antibodies to SARS-CoV-2, not for any other viruses or pathogens.

The emergency use of this product 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 Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

CAUTION

Federal (USA) law restricts this device to sale by or on the order of a licensed healthcare professional.

Safety data sheets (SDS) available on siemens-healthineers.com.

H317, H412
P273, P280, P302+P352, P333+P313, P362+P364, P501

Warning!
May cause an allergic skin reaction. Harmful to aquatic life with long lasting effects.
Avoid release to the environment. Wear protective gloves/protective clothing/eye protection/face protection. IF ON SKIN: Wash with plenty of soap and water. If skin irritation or rash occurs: Get medical advice/ attention. Take off contaminated clothing and wash it before reuse. Dispose of contents and container in accordance with all local, regional, and national regulations.
Contains: reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (in ADVIA Centaur sCOVG DIL)

H290, H319, H315
P264, P280, P305+P351+P338

Warning!
May be corrosive to metals. Causes serious eye irritation. Causes skin irritation.
Wash hands thoroughly after handling. Wear protective gloves/protective clothing/eye protection/face protection. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
Contains: sodium hydroxide (in ADVIA Centaur Ancillary Probe Wash 1)

CAUTION POTENTIAL BIOHAZARD

Contains human source material. Each donation of human blood or blood component was tested by FDA-approved methods for the presence of antibodies to human immunodeficiency virus type 1 (HIV-1) and type 2 (HIV-2), as well as for hepatitis B surface antigen (HBsAg) and antibody to hepatitis C virus (HCV). The test results were negative (not repeatedly reactive). No test offers complete assurance that these or other infectious agents are absent; this material should be handled using good laboratory practices and universal precautions.[14-16]

CAUTION

This device contains material of animal origin and should be handled as a potential carrier and transmitter of disease.

Contains sodium azide as a preservative. Sodium azide can react with copper or lead plumbing to form explosive metal azides. On disposal, flush reagents with a large volume of water to prevent buildup of azides. Disposal into drain systems must be in compliance with prevailing regulatory requirements.

Dispose of hazardous or biologically contaminated materials according to the practices of your institution. Discard all materials in a safe and acceptable manner and in compliance with prevailing regulatory requirements.

Storage and Stability

Store all reagents at 2–8°C in an upright position, away from light and heat. Do not use products beyond the expiration date printed on the product labeling.

For information about product storage and stability, refer to *Reagents*.

Onboard Stability

Discard products at the end of the onboard stability interval. Do not use products beyond the expiration date printed on the product labeling.

System	Onboard Stability Interval (days)
ADVIA Centaur XP/XPT system	28
ADVIA Centaur CP system	21

For further information about product onboard stability, refer to *Reagents*.

Specimen Collection and Handling

Serum and plasma (lithium heparin) are the recommended sample types for this assay. Do not use heat-inactivated specimens.

Collecting the Specimen

- Observe universal precautions when collecting specimens. Handle all specimens as if they are capable of transmitting disease.[16]
- Follow recommended procedures for collection of diagnostic blood specimens by venipuncture.[17]
- Follow the instructions provided with your specimen collection device for use and processing.[18]
- Allow blood specimens to clot completely before centrifugation.[15]
- Keep tubes capped at all times.[15]

Storing the Specimen

- Samples are stable for up to 24 hours onboard the system.
- Separated samples are stable for up to 7 days at room temperature, and for up to 14 days at 2–8°C.
- Thawed frozen specimens must be clarified by centrifugation prior to testing. Do not store in a frost-free freezer. Avoid more than 4 freeze-thaw cycles.
- Freeze samples, devoid of red blood cells, at ≤ -20°C for longer storage.

The handling and storage information provided here is based on data or references maintained by the manufacturer. It is the responsibility of the individual laboratory to use all available references and/or its own studies when establishing alternate stability criteria to meet specific needs.

Transporting the Specimen

Package and label specimens for shipment in compliance with applicable federal and international regulations covering the transport of clinical specimens and etiological agents.

If shipment is expected to exceed 4 days, ship specimens frozen. Store samples capped and upright at 2–8°C upon arrival.

Preparing the Samples

This assay requires 40 µL of sample for a single determination. This volume does not include the unusable volume in the sample container or the additional volume required when performing duplicates or other tests on the same sample. For a complete list of appropriate sample containers and information about determining the minimum required volume, refer to the system online help.

The sample volume required to perform onboard dilution differs from the sample volume required to perform a single determination on an undiluted sample. Refer to *Dilutions*.

Do not use samples with apparent contamination.

Before placing samples on the system, ensure that samples are free of:

- Bubbles or foam.
- Fibrin or other particulate matter.

Remove particulates by centrifugation according to CLSI guidance and the collection device manufacturer's recommendations.[15]

Procedure

Materials Provided

The following materials are provided:

REF	Contents	Number of Tests
11207376	1 ReadyPack primary reagent pack containing ADVIA Centaur sCOVG Lite Reagent, Solid Phase, and Ancillary Well Reagent 1 ReadyPack ancillary reagent pack containing ADVIA Centaur sCOVG DIL DIL ADVIA Centaur sCOVG master curve card 1 vial ADVIA Centaur sCOVG CAL low calibrator CAL L 1 vial ADVIA Centaur sCOVG CAL high calibrator CAL H ADVIA Centaur sCOVG CAL calibrator assigned value sheets and barcode labels	100
11207377	5 ReadyPack primary reagent packs containing ADVIA Centaur sCOVG Lite Reagent, Solid Phase, and Ancillary Well Reagent 5 ReadyPack ancillary reagent packs containing ADVIA Centaur sCOVG DIL DIL ADVIA Centaur sCOVG master curve card 2 vials ADVIA Centaur sCOVG CAL low calibrator CAL L 2 vials ADVIA Centaur sCOVG CAL high calibrator CAL H ADVIA Centaur sCOVG CAL calibrator assigned value sheets and barcode labels	500

Materials Required but Not Provided

The following materials are required to perform these assays, but are not provided:

REF	Description	
	ADVIA Centaur XP system[a] ADVIA Centaur XPT system[a] ADVIA Centaur CP system[a]	
11207378	ADVIA Centaur sCOVG QC (quality control material)	2 x 2.0 mL negative quality control, level 1 CONTROL - 1 2 x 2.0 mL positive quality control, level 2 CONTROL + 2 Quality control assigned value sheet
03395373	ADVIA Centaur Ancillary Probe Wash 1 (probe wash)	2 ReadyPack ancillary reagent packs containing 25.0 mL/ pack APW 1
03333963	ADVIA Centaur Probe Wash 3 (probe wash)	50.0 mL PW 3

REF	Description	
01137199 (112351)	ADVIA Centaur Wash 1 (wash)	2 x 1500 mL/pack WASH 1
03773025	ADVIA Centaur Wash 1 (wash)	2 x 2500 mL/pack WASH 1

[a] Additional system fluids are required to operate the system: ADVIA Centaur Acid Reagent, ADVIA Centaur Base Reagent, and ADVIA Centaur Cleaning Solution.

Optional Materials

The following materials may be used to perform this assay, but are not provided:

REF	Description	
11208300	ADVIA Centaur sCOVG DIL (diluent)	2 ReadyPack ancillary reagent packs containing 25.0 mL/pack DIL
04786546	ADVIA Centaur Multi-Diluent 12 (diluent)	20.0 mL/vial DIL
11207586	ADVIA Centaur sCOVG MCM (master curve material)	4 x 1.0 mL levels of master curve material MCM

Assay Procedure

The system automatically performs the following steps:

1. Dispenses 40 µL of sample into a cuvette.
2. Dispenses 160 µL of ADVIA Centaur sCOVG DIL into the cuvette with the sample.
3. Removes 10 µL of the diluted sample from the cuvette and dispenses it into a second cuvette.
4. Dispenses 100 µL of Solid Phase and 100 µL of Ancillary Well Reagent, then incubates for 18 minutes at 37°C.
5. Performs a wash sequence using ADVIA Centaur Wash 1.
6. Resuspends the washed particles in 150 µL of ADVIA Centaur Wash 1 on the ADVIA Centaur XP system.

   Resuspends the washed particles in 250 µL of ADVIA Centaur Wash 1 on the ADVIA Centaur CP system.
7. Dispenses 100 µL of Lite Reagent, then incubates for 18 minutes at 37°C.
8. Performs a wash sequence using ADVIA Centaur Wash 1.
9. Dispenses 300 µL each of ADVIA Centaur Acid Reagent and ADVIA Centaur Base Reagent to initiate the chemiluminescent reaction.
10. Reports results.

Preparing the Reagents

All reagents are liquid and ready to use. Before loading the packs onto the system, reagents require mixing. For information about mixing the reagents, refer to the system online help.

Preparing the System

Ensure that sufficient materials are loaded on the system. Refer to *Materials Provided* and *Materials Required but Not Provided* for guidance about required reagents.

For information about loading products, refer to the system online help.

Master Curve Definition

Before initiating calibration on each new lot of reagent, enter the assay master curve values by scanning the master curve card. For information about defining the master curve, refer to the system online help.

Performing Calibration

For calibration of the ADVIA Centaur sCOVG assay, use the calibrators provided with each kit.

Note Calibrators provided in an assay kit must only be used with the reagent lot provided in the same kit.

Calibration Frequency

Perform a calibration if one or more of the following conditions exist:

- At the end of the 14-day calibration interval.
- When changing lot numbers of primary reagent packs.
- When indicated by quality control results.
- After major maintenance or service, if indicated by quality control results.

Follow government regulations or accreditation requirements for calibration frequency. Individual laboratory quality control programs and procedures may require more frequent calibration.

Preparing the Calibrators

Calibrators are liquid and ready to use. Allow the calibrators to equilibrate to room temperature. Gently mix and invert the vials to ensure homogeneity of the material.

Use calibrators within the stability limits specified in *Reagents* and discard any remaining material.

Calibration Procedure

The calibrators are provided in dropper vials. Each dispensed drop is approximately 50 µL.

Perform the calibration procedure using the following steps:

1. Ensure that the appropriate master curve and calibrator assigned values are entered on the system. For information about defining the master curve and entering calibrator values, refer to the system online help.
2. Load the required reagents for the assay.
3. Schedule the calibrators.
4. Label two sample containers with barcode labels: one container for the low calibrator and one container for the high calibrator. Place the barcode labels on the sample containers with the readable characters oriented vertically.

   Note Barcode labels are lot-specific. Do not use barcode labels from one lot of calibrators with any other lot of calibrators.
5. Gently mix the product and dispense a sufficient volume of each calibrator into the appropriate sample containers. Avoid bubbles.

   The required sample volume for testing depends on several factors. For information about sample volume requirements, refer to the system online help.
6. Load the samples according to the system online help.

Note Dispose of any calibrator that remains in the sample container after 8 hours. Do not refill or reuse sample containers. Do not return any calibrator material back into the original container.

Performing Quality Control

For quality control of the ADVIA Centaur sCOVG assay, use the ADVIA Centaur sCOVG QC at least once during each day that samples are analyzed. Use the quality control material in accordance with the quality control instructions for use. For the assigned values, refer to the quality control assigned value sheet provided.

A satisfactory level of performance is achieved when the analyte values obtained are within the expected control interval for the system or within your interval, as determined by an appropriate internal laboratory quality control procedure. Follow your laboratory's quality control procedures if the results obtained do not fall within the acceptable limits. For information about entering quality control definitions, refer to the system online help.

Follow government regulations or accreditation requirements for quality control frequency. Individual laboratory quality control programs and procedures may require more frequent quality control testing.

Test quality control samples after a successful calibration.

Taking Corrective Action

If the quality control results do not fall within the expected control interval, do not report results. Perform corrective actions in accordance with established laboratory protocol. For suggested protocol, refer to the system online help.

Results

Calculation of Results

The system determines the result using the calculation procedure described in the system online help. Refer to *Interpretation of Results*.

For information about results outside the specified measuring interval, refer to *Analytical Measuring Interval*.

Dilutions

The analytical measuring interval is 0.50–100.00 Index. For information about dilution options, refer to the system online help.

Dilute and retest samples with values > 100.00 Index to obtain accurate results up to 2000 Index.

Note Due to the heterogeneity of SARS-CoV-2 antibodies, some patient samples may exhibit a non-linear dilution.

ADVIA Centaur XP/XPT System

For automated dilutions using the ADVIA Centaur XP/XPT system, perform the following activities.

- Load additional ADVIA Centaur sCOVG DIL, if needed.
- Ensure that sufficient sample volume is available. Refer to the table below.
- Select the appropriate dilution factor.

For automatic dilutions, enter a dilution setpoint ≤ 100 Index.

For additional instructions on running automatic dilutions, refer to the system online help.

Sample	Dilution	Sample Volume (µL)
Serum and plasma	1:5	40
Serum and plasma	1:10	40
Serum and plasma	1:20	40

ADVIA Centaur CP System

The ADVIA Centaur CP system does not perform onboard dilutions for the ADVIA Centaur sCOVG assay. If patient results exceed the upper limit of the analytical measuring interval of the assay, or if laboratory protocol requires manual dilution, manually dilute the patient sample.

Sample	Dilution	Sample Volume (µL)
Serum and plasma	1:5	40
Serum and plasma	1:10	40
Serum and plasma	1:20	40

For manual dilutions, perform the following actions:

- Use ADVIA Centaur Multi-Diluent 12 (vial) to prepare a manual dilution. Refer to *Optional Materials*.
- For information about ordering tests for manually diluted samples, refer to the system online help.
- Ensure that results are mathematically corrected for dilution. If a dilution factor is entered when scheduling the test, the system automatically calculates the result.

Interpretation of Results

The system reports ADVIA Centaur sCOVG assay results in Index Values and as Nonreactive or Reactive:

- **Nonreactive (negative):** < 1.00 Index. These samples are considered negative for SARS-CoV-2 IgG antibodies. Report nonreactive patient results as < 1.00 Index.
- **Reactive (positive):** ≥ 1.00 Index. These samples are considered positive for SARS-CoV-2 IgG antibodies. Report reactive results with the numeric Index Value within the measuring interval for semi-quantitative measurements.

Numeric results are reported for samples with values between 1.00 and 100.00 Index. Numeric results below 1.00 Index should not be reported outside of the laboratory. Results above 100.00 Index are reported as > 100.00 Index or > 2000 Index for diluted samples that exceeded the extended measuring interval.

Results of this assay should always be interpreted in conjunction with the patient's medical history, clinical presentation, and other findings.

Limitations

The following information pertains to limitations of the assay:

- Use of the ADVIA Centaur SARS-CoV-2 IgG (sCOVG) assay is limited to laboratory personnel who have been trained. Not for home use.
- False positive results may occur due to cross-reactivity from pre-existing antibodies or other possible causes.

- This assay has not been evaluated with fingerstick specimens. This test is not authorized for use with fingerstick whole blood.
- The performance of this test has not been established in individuals who have received a COVID-19 vaccine. The clinical significance of a positive or negative antibody result following COVID-19 vaccination has not been established, and the result from this test should not be interpreted as an indication or degree of protection from infection after vaccination.
- The performance of this test was established based on the evaluation of a limited number of clinical specimens. The samples for the positive percentage agreement were collected from the United States and Belgium between March 2020 to July 2020 and November 2020 to December 2020 (for additional 50 lithium heparin plasma specimens). The clinical performance has not been established in all circulating variants, but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.
- Samples should only be tested from individuals who are 15 days or more post symptom onset.
- The clinical applicability of a quantitative or semi-quantitative result is currently unknown and results cannot be interpreted as an indication or degree of immunity or protection from reinfection, nor be compared to the results from other SARS-CoV-2 antibody assays.
- This device should not be used to diagnose or exclude acute SARS-CoV-2 infection. Direct testing for SARS-CoV-2 with a molecular assay should be performed to evaluate acute infection in symptomatic individuals.
- Performance characteristics have not been established for the assay used in conjunction with other manufacturers' assays for specific SARS-CoV-2 serological markers. Laboratories are responsible for establishing their own performance characteristics.
- The performance of the assay has not been established with cord blood, neonatal specimens, cadaver specimens, or body fluids other than serum or plasma.
- Results obtained with the assay may not be used interchangeably with values obtained with different manufacturers' test methods.
- A positive result may not indicate previous SARS-CoV-2 infection. Consider other information, including clinical history and local disease prevalence, in assessing the need for a second, but different, serology test to confirm an immune response.
- A negative result for an individual subject indicates absence of detectable anti-SARS-CoV-2 antibodies. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. The sensitivity of this assay early after infection is unknown.
- A negative result can occur if the quantity of the anti-SARS-CoV-2 antibodies present in the specimen is below the detection limits of the assay, or the antibodies that are detected are not present during the stage of disease in which a sample is collected.
- Performance has only been established with the specimen types listed in the *Intended Use*. Other specimen types have not been evaluated and should not be used with this assay.
- Results are not intended to be used as the sole basis for patient management decisions. Test results should be interpreted in conjunction with clinical observations, patient history, epidemiological information, and other laboratory findings.

- The immune response may be depressed in elderly, immunocompromised, or immunosuppressed patients. Immunocompromised patients who have COVID-19 may have a delayed antibody response and produce levels of antibody which may not be detected as reactive by the assay.
- It is not known at this time if the presence of antibodies to SARS-CoV-2 confers immunity to infection.
- This test should not be used for donor screening to prevent SARS-CoV-2 transmission during blood, tissue, or organ donations.
- Numeric values obtained with ADVIA Centaur XP/XPT and ADVIA Centaur CP instruments may differ from numeric values obtained with the Atellica IM instrument when testing the same sample.

Conditions of Authorization for the Laboratory

The ADVIA Centaur SARS-CoV-2 IgG (sCOVG) assay Letter of Authorization, along with the authorized Fact Sheet for Healthcare Providers, the authorized Fact Sheet for Recipients, and authorized labeling are available on the FDA website:

https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas

Authorized laboratories using the ADVIA Centaur SARS-CoV-2 IgG (sCOVG) assay must adhere to the Conditions of Authorization indicated in the Letter of Authorization as listed below:

- Authorized laboratories[a] using the ADVIA Centaur SARS-CoV-2 IgG (sCOVG) assay must include with test result reports, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.
- Authorized laboratories using the ADVIA Centaur SARS-CoV-2 IgG (sCOVG) assay must use the product as outlined in the authorized labeling. Deviations from the authorized procedures, including the authorized instruments, authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to use the ADVIA Centaur SARS-CoV-2 IgG (sCOVG) assay are not permitted.
- Authorized laboratories that receive the ADVIA Centaur SARS-CoV-2 IgG (sCOVG) assay must notify the relevant public health authorities of their intent to run the assay prior to initiating testing.
- Authorized laboratories using the ADVIA Centaur SARS-CoV-2 IgG (sCOVG) assay must have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.
- Authorized laboratories must collect information on the performance of the ADVIA Centaur SARS-CoV-2 IgG (sCOVG) assay and report to DMD/OHT7-OIR/OPEQ/ CDRH (via email: CDRH EUA Reporting@fda.hhs.gov) and Siemens Healthineers Technical Support (https://www.siemens-healthineers.com/en-us/; tel: 1-877-229-3711) any suspected occurrence of false reactive (positive) or false nonreactive (negative) results and significant deviations from the established performance characteristics of the assay of which they become aware.

- All laboratory personnel using the ADVIA Centaur SARS-CoV-2 IgG (sCOVG) assay must be appropriately trained in automated immunoassay techniques and use appropriate laboratory and personal protective equipment when handling this kit, and use the ADVIA Centaur SARS-CoV-2 IgG (sCOVG) assay in accordance with the authorized labeling. All laboratory personnel using the assay must also be trained in and be familiar with the interpretation of results of the the ADVIA Centaur SARS-CoV-2 IgG (sCOVG) assay.
- Siemens Healthineers, authorized distributors, and authorized laboratories using the ADVIA Centaur SARS-CoV-2 IgG (sCOVG) assay must ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

[a] The letter of authorization refers to, "Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform moderate or high complexity tests" as "authorized laboratories".

Performance Characteristics

The ADVIA Centaur XP, ADVIA Centaur XPT, and ADVIA Centaur CP systems use the same reagent formulation as the Atellica® IM Analyzer. Performance characteristics information represent data from the Atellica IM Analyzer, unless otherwise noted.

Assay performance characteristics are representative data. Results obtained at individual laboratories may vary from the data presented.

Analytical Measuring Interval

0.50–100.00 Index is reported as Nonreactive (< 1.00 Index) or Reactive (≥ 1.00 Index).

The lower limit of the analytical measuring interval is defined by the LoQ (0.50 Index). However, report nonreactive patient results as < 1.00 Index. When sample results exceed the upper limit of the analytical measuring interval, refer to *Dilutions*.

Detection Capability

Detection capability was determined in accordance with CLSI Document EP17-A2.[19] The following results were obtained:

Method	Result (Index)
Limit of Blank (LoB)	0.30
Limit of Detection (LoD)	0.50
Limit of Quantitation (LoQ)	0.50

Results obtained at individual laboratories may vary from the data presented.

The LoB corresponds to the highest measurement result that is likely to be observed for a blank sample with a probability of 95%. The estimate of the LoB based on 2 reagent lots is 0.30 Index.

The LoD corresponds to the lowest concentration of IgG antibodies to SARS-CoV-2 that can be detected with a probability of 95%. The estimate of the LoD based on 2 reagent lots is 0.50 Index.

The LoQ corresponds to the lowest concentration of IgG antibodies to SARS-CoV-2 in a sample at which the within laboratory CV is ≤ 20%. The LoQ of the assay based on 2 reagent lots is 0.50 Index.

The lower limit of the analytical measuring interval is defined by the LoQ (0.50 Index). However, report nonreactive patient results as < 1.00 Index.

Seroconversion Sensitivity

A total of 68 specimens were collected serially from 10 subjects with a clinical diagnosis of COVID-19 based on a positive SARS-CoV-2 polymerase chain reaction (PCR) result. Of these, seroconversion was observed in 10 panels with 2 or more nonreactive blood draws and 2 or more reactive blood draws with the Atellica IM sCOVG assay using the Atellica IM Analyzer. The results are shown in the table below:

Panel	Number of Draws	Number of Reactive Draws	First Draw		Last Nonreactive Draw		First Reactive Draw		Last Draw	
			Days Post PCR Positive	Index	Days Post PCR Positive	Index	Days Post PCR Positive	Index	Days Post PCR Positive	Index
A	5	3	0	0.14	2	0.42	4	2.92	12	>150
B	6	3	0	0.00	4	0.57	8	58.42	12	>150
C	11	9	2	0.31	3	0.62	4	1.61	26	>150
D	11	9	0	0.07	2	0.09	4	1.27	27	>150
E	5	2	0	0.04	3	0.12	14	43.28	17	65.10
F	4	2	0	0.07	6	0.13	13	14.33	17	13.57
G	9	4	0	0.01	12	0.11	16	2.94	26	8.81
H	5	2	1	0.00	7	0.16	9	1.66	12	15.73
I	6	4	0	0.16	2	0.70	5	4.86	14	13.99
J	6	3	0	0.00	5	0.22	8	19.91	12	83.28

Clinical Agreement

Positive percent agreement and negative percent agreement were determined in accordance with CLSI Document EP12-A2.[20] The performance of the assay was determined by testing a total of 2706 prospective and retrospective samples using the Atellica IM Analyzer.

Positive Percent Agreement

Positive percent agreement was determined by testing 711 retrospective samples collected over the course of time from unique donor subjects with a clinical diagnosis of COVID-19 based on a positive SARS-CoV-2 polymerase chain reaction (PCR) method. The following table describes positive percent agreement by time of sampling following a positive PCR result:

Days After PCR Method	Number Tested	Reactive	Nonreactive	Positive Percent Agreement (95% CI)
0–7	324	165	159	50.93% (45.58%–56.03%)
8–14	138	108	30	78.26% (76.38%–87.55%)
≥ 15	249	238	11	95.58% (92.23%–97.77%)

Negative Percent Agreement

Negative percent agreement was determined by testing 1995 samples collected prospectively prior to the COVID-19 outbreak (before November 2019) from apparently healthy individuals and apparently healthy pregnant women in the United States. The results are shown in the table below:

Group	Number Tested	Nonreactive	Reactive	Negative Percent Agreement (95% CI)
Apparently Healthy	1952	1950	2	99.90% (99.63%–99.99%)
Apparently Healthy Pregnant Women	43	43	0	100% (91.78%–100%)
Total	**1995**	**1993**	**2**	**99.90% (99.64%–99.99%)**

Platform Comparison

ADVIA Centaur XP System versus Atellica IM Analyzer

Positive percent agreement was determined by comparing the ADVIA Centaur sCOVG assay using the ADVIA Centaur XP system to the Atellica IM sCOVG assay using the Atellica IM Analyzer.

A population of 478 Atellica IM sCOVG reactive samples was tested using the ADVIA Centaur XP system. The performance is shown in the following table:

Number	Nonreactive	Reactive	Positive Percent Agreement (%)	95% Confidence Interval
478	0	478	100% (478/478)	99.23%–100%

Negative percent agreement was determined by comparing the ADVIA Centaur sCOVG assay using the ADVIA Centaur XP system to the Atellica IM sCOVG assay using the Atellica IM Analyzer.

A population of 981 Atellica IM sCOVG nonreactive samples was tested using the ADVIA Centaur XP system. The performance is shown in the following table:

Number	Nonreactive	Reactive	Negative Percent Agreement (%)	95% Confidence Interval
981	981	0	100% (981/981)	99.62%–100%

Results obtained at individual laboratories may vary from the data presented.

ADVIA Centaur CP System versus Atellica IM Analyzer

Positive percent agreement was determined by comparing the ADVIA Centaur sCOVG assay using the ADVIA Centaur CP system to the Atellica IM sCOVG assay using the Atellica IM Analyzer.

A population of 109 Atellica IM sCOVG reactive samples was tested using the ADVIA Centaur CP system. The performance is shown in the following table:

Number	Nonreactive	Reactive	Positive Percent Agreement (%)	95% Confidence Interval
109	0	109	100% (109/109)	96.67%–100%

Negative percent agreement was determined by comparing the ADVIA Centaur sCOVG assay using the ADVIA Centaur CP system to the Atellica IM sCOVG assay using the Atellica IM Analyzer.

A population of 903 Atellica IM sCOVG nonreactive samples was tested using the ADVIA Centaur CP system. The performance is shown in the following table:

Number	Nonreactive	Reactive	Negative Percent Agreement (%)	95% Confidence Interval
903	902	1	99.89% (902/903)	99.38%–100%

Results obtained at individual laboratories may vary from the data presented.

Precision

Single-Site Precision

Single-site precision studies for the ADVIA Centaur sCOVG assay were conducted using the ADVIA Centaur XP system and the ADVIA Centaur CP system in accordance with CLSI Document EP05-A3.[21]

ADVIA Centaur XP System

Samples and assay controls (a Negative Control and a Positive Control) were assayed in duplicate, in 2 runs per day for 20 days using the ADVIA Centaur XP system. Results for the precision of the ADVIA Centaur sCOVG assay using the ADVIA Centaur XP system are presented in the following table:

			Repeatability		Within-Laboratory Precision	
Specimen Type	N[a]	Mean (Index)	SD[b] (Index)	CV[c] (%)	SD (Index)	CV (%)
Serum A	80	2.18	0.065	3.0	0.086	3.9
Serum B	80	3.64	0.149	4.1	0.244	6.7
Serum C	80	52.34	1.860	3.6	2.456	4.7
Serum D	80	88.69	2.777	3.1	4.377	4.9
Lithium Heparin Plasma A	80	1.02	0.038	3.7	0.050	4.9
Lithium Heparin Plasma B	80	3.23	0.114	3.5	0.145	4.5
Lithium Heparin Plasma C	80	3.59	0.208	5.8	0.241	6.7
Control 1	80	0.03	0.075	N/A[d]	0.075	N/A
Control 2	80	4.59	0.120	2.6	0.184	4.0

[a] Number of measurements.
[b] Standard deviation.
[c] Coefficient of variation.
[d] Not applicable.

ADVIA Centaur CP System

Samples and assay controls (a Negative Control and a Positive Control) were assayed in duplicate, in 2 runs per day for 12 days using the ADVIA Centaur CP system. Results for the precision of the ADVIA Centaur sCOVG assay using the ADVIA Centaur CP system are presented in the following table:

			Repeatability		Within-Laboratory Precision	
Specimen Type	N[a]	Mean (Index)	SD[b] (Index)	CV[c] (%)	SD (Index)	CV (%)
Serum A	48	2.41	0.128	5.3	0.132	5.5
Serum B	48	4.09	0.249	6.1	0.273	6.7
Serum C	48	71.93	1.948	2.7	3.484	4.8
Lithium Heparin Plasma A	48	1.16	0.073	6.3	0.077	6.7
Lithium Heparin Plasma B	48	3.64	0.182	5.0	0.184	5.0
Lithium Heparin Plasma C	48	4.06	0.219	5.4	0.328	8.1
Control 1	48	0.02	0.028	N/A[d]	0.038	N/A
Control 2	48	5.41	0.190	3.5	0.194	3.6

[a] Number of measurements.
[b] Standard deviation.
[c] Coefficient of variation.
[d] Not applicable.

Results obtained at individual laboratories may vary from the data presented.

Instrument and Lot Reproducibility

Reproducibility of the ADVIA Centaur sCOVG assay was evaluated using ADVIA Centaur XP and ADVIA Centaur CP instruments and the data were analyzed to calculate the following components of precision: repeatability, between-run, between-day, between-lot, between-instrument, and reproducibility (total).

ADVIA Centaur XP System

Reproducibility of the ADVIA Centaur sCOVG assay was evaluated on 2 ADVIA Centaur XP instruments using 2 reagent lots. Samples and assay controls (a Negative Control and a Positive Control) were assayed in duplicate in 2 runs per day for 5 days. The results are presented in the following table:

			Repeatability		Between-Run		Between-Day		Between-Lot		Between-Instrument		Reproducibility	
Sample	N[a]	Mean (Index)	SD[b] (Index)	CV[c] (%)	SD (Index)	CV (%)	SD (Index)	CV (%)	SD (Index)	CV (%)	SD (Index)	CV (%)	SD (Index)	CV (%)
Serum A	80	2.17	0.050	2.3	0.052	2.4	0.000	0.0	0.080	3.7	0.000	0.0	0.107	4.9
Serum B	80	3.61	0.139	3.9	0.140	3.9	0.000	0.0	0.149	4.1	0.000	0.0	0.247	6.8
Serum C	80	56.54	2.344	4.1	0.740	1.3	1.289	2.3	1.131	2.0	1.167	2.1	3.217	5.7
Serum D	80	99.03	4.163	4.2	2.707	2.7	0.000	0.0	2.483	2.5	7.736	7.8	9.522	9.6
Lithium Heparin Plasma A	80	1.01	0.033	3.3	0.033	3.3	0.000	0.0	0.024	2.4	0.000	0.0	0.052	5.1

			Repeatability		Between-Run		Between-Day		Between-Lot		Between-Instrument		Reproducibility	
Sample	N[a]	Mean (Index)	SD[b] (Index)	CV[c] (%)	SD (Index)	CV (%)	SD (Index)	CV (%)	SD (Index)	CV (%)	SD (Index)	CV (%)	SD (Index)	CV (%)
Lithium Heparin Plasma B	80	3.18	0.086	2.7	0.061	1.9	0.000	0.0	0.153	4.8	0.000	0.0	0.186	5.8
Lithium Heparin Plasma C	80	3.57	0.090	2.5	0.091	2.5	0.000	0.0	0.140	3.9	0.000	0.0	0.189	5.3
Control 1	80	0.01	0.029	N/A[d]	0.000	N/A	0.012	N/A	0.007	N/A	0.000	0.0	0.032	N/A
Control 2	80	4.80	0.081	1.7	0.101	2.1	0.000	0.0	0.141	2.9	0.000	0.0	0.191	4.0

[a] Number of measurements.
[b] Standard deviation.
[c] Coefficient of variation.
[d] Not applicable.

ADVIA Centaur CP System

Reproducibility of the ADVIA Centaur sCOVG assay was evaluated on 2 ADVIA Centaur CP instruments using 2 reagent lots. Samples and assay controls (a Negative Control and a Positive Control) were assayed in duplicate in 2 runs per day for 5 days. The results are presented in the following table:

			Repeatability		Between-Run		Between-Day		Between-Lot		Between-Instrument		Reproducibility	
Sample	N[a]	Mean (Index)	SD[b] (Index)	CV[c] (%)	SD (Index)	CV (%)	SD (Index)	CV (%)	SD (Index)	CV (%)	SD (Index)	CV (%)	SD (Index)	CV (%)
Serum A	80	2.43	0.115	4.7	0.000	0.0	0.078	3.2	0.221	9.1	0.000	0.0	0.261	10.7
Serum B	80	3.89	0.166	4.3	0.258	6.6	0.000	0.0	0.165	4.2	0.115	3.0	0.367	9.4
Serum C	80	63.40	3.084	4.9	1.344	2.1	0.930	1.5	7.253	11.4	3.668	5.8	8.845	14.0
Serum D	80	120.82	6.441	5.3	4.713	3.9	0.000	0.0	7.234	6.0	0.000	0.0	10.772	8.9
Lithium Heparin Plasma A	80	1.21	0.060	5.0	0.026	2.1	0.000	0.0	0.069	5.7	0.000	0.0	0.095	7.9
Lithium Heparin Plasma B	80	3.62	0.179	4.9	0.123	3.4	0.000	0.0	0.190	5.2	0.077	2.1	0.298	8.2
Lithium Heparin Plasma C	80	3.89	0.171	4.4	0.071	1.8	0.101	2.6	0.251	6.4	0.000	0.0	0.327	8.4
Control 1	80	0.06	0.024	N/A[d]	0.025	N/A	0.045	N/A	0.000	N/A	0.081	N/A	0.099	N/A
Control 2	80	5.20	0.215	4.1	0.045	0.9	0.000	0.0	0.337	6.5	0.000	0.0	0.402	7.7

[a] Number of measurements.
[b] Standard deviation.
[c] Coefficient of variation.
[d] Not applicable.

Specimen Equivalency

Matched sample sets (serum and lithium heparin plasma) from the same donors were used for the matrix comparison studies. Samples contained SARS-CoV-2 IgG levels distributed across the measuring interval. Specimen equivalency was determined by testing the samples with the Atellica IM sCOVG assay using the Atellica IM Analyzer in accordance with CLSI Document EP35-Ed1.[22]

Using a weighted Deming regression model, results from plasma samples were compared to serum results. The following results were obtained:

Plasma (y) vs. Serum (x)	N[a]	Sample Interval	Slope (95% CI)	Intercept (95% CI)	r[b]
Lithium heparin (plasma)	47	0.69–85.90 Index	1.02 (1.01–1.04)	0.004 (-0.033–0.040)	0.998

[a] Number of samples tested.
[b] Correlation coefficient.

Agreement of the specimen types may vary depending on the study design and sample population used. Assay results obtained at individual laboratories may vary from the data presented.

Interferences

Interference testing was performed in accordance with CLSI Document EP07-ed3.[23] The impact of potentially interfering substances on the detection of SARS-CoV-2 IgG antibodies with the Atellica IM sCOVG assay was evaluated with endogenous substances commonly found in serum and plasma specimens, including hemoglobin, conjugated bilirubin, unconjugated bilirubin, triglycerides, biotin, cholesterol, and protein. Serum samples were spiked with SARS-CoV-2 IgG at the following levels: unspiked, near cut-off (~1.0 Index), and low positive (~1.5 Index). Testing demonstrated a ≤ 10% change for each substance at the indicated concentration.

Substance	Substance Test Concentration
Hemoglobin	1000 mg/dL
Bilirubin, conjugated	40 mg/dL
Bilirubin, unconjugated	40 mg/dL
Triglycerides (Intralipid)	2000 mg/dL
Biotin	3500 ng/mL
Cholesterol	500 mg/dL
Protein, total	12 g/dL

Cross-Reactivity

Cross-reactivity was determined in accordance with CLSI Document EP07-ed3.[23] The assay was evaluated for potential cross-reactivity using specimens containing antibodies to other pathogens and other disease states using the Atellica IM sCOVG assay with the Atellica IM Analyzer. One specimen was found to be cross-reactive out of 310 specimens.

Clinical Category	Number Tested	Number Reactive with Atellica IM sCOVG Assay
Autoimmune diseases[a]	14	0
Candida albicans antibody	10	0
Chlamydia pneumoniae IgG	10	0
Chlamydia trachomatis IgM	4	0
Cytomegalovirus (CMV) IgG	5	0
Cytomegalovirus (CMV) IgM	5	0
Epstein Barr virus (EBV) IgG	5	0
Epstein Barr virus (EBV) IgM	5	0
Haemophilus influenzae b (Hib) IgG	20	0
Hepatitis A virus (HAV) IgM	4	0
Hepatitis B core (anti-HBc) IgM	5	0
Hepatitis C virus (HCV) antibody	5	0
Human anti-mouse antibody (HAMA)	2	0
Human coronavirus antibodies[b]	29	0
Human herpes virus (HHV) IgM	2	0
Human immunodeficiency virus (HIV) antibody	9	0
Human metapneumovirus (HMPV) IgG	5	1
Influenza antibody	29	0
Influenza A antibody	6	0
Influenza B antibody	10	0
Measles antibody	5	0
Middle East respiratory syndrome coronavirus (MERS-CoV) IgG	5	0
Mycoplasma pneumoniae IgG	19	0
Parvovirus B19 antibody	5	0
Respiratory pathogen antibodies[c]	23	0
Respiratory syncytial virus (RSV) antibody	20	0
Severe acute respiratory syndrome coronavirus (SARS-CoV-1) IgG	5	0
Streptococcus pneumoniae anti-PCP IgG	10	0

Clinical Category	Number Tested	Number Reactive with Atellica IM sCOVG Assay
Toxoplasma gondii antibody	10	0
Toxoplasma gondii IgG	20	0
Varicella zoster virus (VZV) antibody	4	0
Total	**310**	**1**

[a] This group consists of samples from 14 subjects with autoimmune disease states including anti-nuclear antibody (ANA; N = 5), Graves' disease (N = 5), and rheumatoid factor (RF; N = 4).

[b] This panel includes 29 subjects who had antibodies to multiple human coronaviruses, including coronavirus HKU (N = 24), coronavirus OC43 (N = 27), coronavirus 229E (N = 29), and coronavirus NL63 (N = 21).

[c] This panel consists of samples from 23 subjects with antibodies to multiple respiratory pathogens, including Adenovirus antibodies (N = 8), *Bordetella pertussis* IgG (N = 19), *Chlamydia pneumoniae* IgG (N =23), *Chlamydia psittaci* IgG (N = 3), *Chlamydia psittaci* IgM (N =1), *Haemophilus influenzae* b (Hib) IgG (N = 11), Influenza A IgG (N = 22), Influenza A IgM (N = 1), Influenza B IgG (N = 18), Influenza B IgM (N = 1), and *Mycoplasma pneumoniae* IgG (N = 6).

Results obtained at individual laboratories may vary from the data presented.

Linearity

Linearity testing was performed in accordance with CLSI Document EP06-A.[24]

Patient pools containing high levels of SARS-CoV-2 IgG (1 serum and 2 lithium heparin plasma) were diluted with negative basepool to prepare a dilution series comprised of nine (9) levels. Each level was tested in 3 replicates using the ADVIA Centaur XP system.

Patient pools containing high levels of SARS-CoV-2 IgG (1 serum and 1 lithium heparin plasma) were diluted with negative basepool to prepare a dilution series comprised of nine (9) levels. Each level was tested in 3 replicates using the ADVIA Centaur CP system.

Linearity was demonstrated for the analytical measuring interval of 0.50–100.00 Index using the ADVIA Centaur XP system and the ADVIA Centaur CP system with deviations from linearity within 15%.

Taking into consideration the estimates of LoB, LoD, LoQ, precision, and linearity, the analytical measuring interval of the ADVIA Centaur sCOVG assay is 0.50–100.00 Index.

Extended Measuring Interval (Dilutions)

ADVIA Centaur XP System

Three serum samples and three lithium heparin plasma samples in the range of 94.42–352.90 Index were diluted 1:5, 1:10, and 1:20 with ADVIA Centaur sCOVG DIL and assayed for recovery. The recoveries ranged from 94.7%–109.1%.

The extended measuring interval of the ADVIA Centaur sCOVG assay by automatic dilution with ADVIA Centaur sCOVG DIL using the ADVIA Centaur XP system is 100.00–2000 Index.

Sample	Dilution	Observed (Index)	Expected (Index)	Recovery (%)
Serum 1	—	329.76	—	—
	1:5	64.39	65.95	97.6
	1:10	31.80	32.98	96.4
	1:20	15.81	16.49	95.9
Serum 2	—	352.90	—	—

Sample	Dilution	Observed (Index)	Expected (Index)	Recovery (%)
	1:5	71.88	70.58	101.8
	1:10	35.69	35.29	101.1
	1:20	17.39	17.64	98.5
Serum 3	—	196.59	—	—
	1:5	41.15	39.32	104.7
	1:10	21.44	19.66	109.1
	1:20	9.70	9.83	98.7
Lithium heparin plasma 1	—	94.42	—	—
	1:5	18.55	18.88	98.2
	1:10	9.12	9.44	96.6
	1:20	4.68	4.72	99.0
Lithium heparin plasma 2	—	149.35	—	—
	1:5	28.28	29.87	94.7
	1:10	14.73	14.94	98.6
	1:20	7.10	7.47	95.1
Lithium heparin plasma 3	—	122.89	—	—
	1:5	25.16	24.58	102.4
	1:10	12.85	12.29	104.5
	1:20	6.25	6.14	101.7
Mean				**99.7**

ADVIA Centaur CP System

Three serum samples and four lithium heparin plasma samples were manually diluted 1:5 and five additional serum samples were diluted 1:10 and 1:20 in the range of 85.42–218.46 Index with ADVIA Centaur Multi-Diluent 12 and assayed for recovery. The recoveries ranged from 91.2%–107.6%.

The extended measuring interval of the ADVIA Centaur sCOVG assay by manual dilution with ADVIA Centaur Multi-Diluent 12 using the ADVIA Centaur CP system is 100.00–2000 Index.

Sample	Dilution	Observed (Index)	Expected (Index)	Recovery (%)
Serum 1	—	129.47	—	—
	1:5	24.47	25.89	94.5
Serum 2	—	128.57	—	—
	1:5	23.48	25.71	91.3
Serum 3	—	177.30	—	—

Sample	Dilution	Observed (Index)	Expected (Index)	Recovery (%)
	1:5	38.14	35.46	107.6
Serum 4	—	196.68	—	—
	1:10	17.93	19.67	91.2
	1:20	10.56	9.83	107.4
Serum 5	—	206.35	—	—
	1:10	20.74	20.63	100.5
	1:20	10.86	10.32	105.3
Serum 6	—	85.42	—	—
	1:10	8.35	8.54	97.7
	1:20	4.00	4.27	93.6
Serum 7	—	91.41	—	—
	1:10	8.93	9.14	97.6
	1:20	4.29	4.57	93.9
Serum 8	—	105.10	—	—
	1:10	10.37	10.51	98.7
	1:20	4.79	5.25	91.2
Lithium heparin plasma 1	—	187.58	—	—
	1:5	39.21	37.52	104.5
Lithium heparin plasma 2	—	175.72	—	—
	1:5	36.41	35.14	103.6
Lithium heparin plasma 3	—	108.87	—	—
	1:5	20.45	21.77	93.9
Lithium heparin plasma 4	—	218.46	—	—
	1:5	43.49	43.69	99.5
Mean				**98.4**

Traceability

The ADVIA Centaur sCOVG assay is traceable to an internal standard based on agreement with known positive and negative SARS-CoV-2 samples.

Technical Assistance

For customer support, contact your local technical support provider or distributor.

siemens-healthineers.com

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16. Clinical and Laboratory Standards Institute. *Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline—Fourth Edition*. Wayne, PA: Clinical and Laboratory Standards Institute; 2014. CLSI Document M29-A4.
17. Clinical and Laboratory Standards Institute. *Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture; Approved Standard—Sixth Edition*. Wayne, PA: Clinical and Laboratory Standards Institute; 2007. CLSI Document GP41-A6.

18. Clinical and Laboratory Standards Institute. *Tubes and Additives for Venous and Capillary Blood Specimen Collection; Approved Standard—Sixth Edition*. Wayne, PA: Clinical and Laboratory Standards Institute; 2010. CLSI Document GP39-A6.
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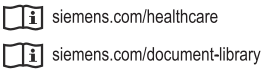
21. Clinical and Laboratory Standards Institute. *Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline—Third Edition*. Wayne, PA: Clinical and Laboratory Standards Institute; 2014. CLSI Document EP05-A3.
22. Clinical and Laboratory Standards Institute. *Assessment of Equivalence or Suitability of Specimen Types for Medical Laboratory Measurement Procedures—1st Edition*. Wayne, PA: Clinical and Laboratory Standards Institute; 2019. CLSI Document EP35-Ed1.
23. 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.
24. Clinical and Laboratory Standards Institute. *Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline*. Wayne, PA: Clinical and Laboratory Standards Institute; 2003. CLSI Document EP06-A.

Definition of Symbols

The following symbols may appear on the product labeling:

Symbol	Symbol Title and Description
	Consult instructions for use
	Version of instructions for use
	Internet URL address to access the electronic instructions for use
	Revision
	Caution Consult instructions for use or accompanying documents for cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device.
	Biological risks Potential biological risks are associated with the medical device.
	Corrosive
	Dangerous to environment

Symbol	Symbol Title and Description
	Irritant Oral, dermal, or inhalation hazard
	Inhalation hazard Respiratory or internal health
	Flammable Flammable to extremely flammable
	Oxidizing
	Explosive
	Toxic
	Compressed gas
	Keep away from sunlight Prevent exposure to sunlight and heat.
	Up Store in an upright position.
	Do not freeze
	Temperature limit Upper and lower limits of temperature indicators are adjacent to the upper and lower horizontal lines.
	Handheld barcode scanner
IVD	*In vitro* diagnostic medical device
Σ (n)	Contains sufficient for <n> tests Total number of IVD tests the system can perform with the IVD kit reagents appears adjacent to the symbol.
RxOnly	Prescription device (US only) Applies only to United States-registered IVD assays. CAUTION: Federal (USA) law restricts this device to sale by or on the order of a licensed healthcare professional.
	Mixing of substances Mix product before use.

Symbol	Symbol Title and Description
	Reconstitute and mix lyophilized product before use.
	Target
	Interval
	Legal Manufacturer
	Authorized Representative in the European Community
	Use-by date Use by the designated date.
	Batch code
	Catalog number
	Recycle
	Printed with soy ink
	CE Mark
	CE Mark with notified body ID number Notified body ID number can vary.
YYYY-MM-DD	Date format (year-month-day)
CHECKSUM	Variable hexadecimal number that ensures the Master Curve and Calibrator definition values entered are valid.
MC DEF	Master Curve Definition
LOT DTL	Lot Details
UNITS C	Common Units
UNITS SI	International System of Units
MATERIAL	Material
MATERIAL ID	Unique material identification number
CONTROL NAME	Name of control
CONTROL TYPE	Type of control

Legal Information

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SIEMENS

ADVIA Centaur®
Immunoassay Systems

SARS-CoV-2 IgG Quality Control (sCOVG QC)

Current Revision and Date[a]	Rev. 01, 2021-06	
Product Name	ADVIA Centaur SARS-CoV-2 IgG Quality Control (sCOVG QC)	
Abbreviated Product Name	ADVIA Centaur sCOVG QC	
	2 x 2.0 mL negative quality control, level 1 CONTROL 2 x 2.0 mL positive quality control, level 2 + 2 CONTROL Quality control assigned value sheet and barcode labels	REF 11207378
Systems	ADVIA Centaur systems	

[a] A vertical bar in the page margin indicates technical content that differs from the previous version.

FOR USA:
For Use Under Emergency Use Authorization Only For *in vitro* diagnostic use only.
For Prescription Use Only.

Intended Use

The ADVIA Centaur® SARS-CoV-2 IgG Quality Control (sCOVG QC) is for *in vitro* diagnostic use in monitoring the precision and accuracy of the ADVIA Centaur® SARS-CoV-2 IgG (sCOVG) assay using the ADVIA Centaur® systems.

Material Description

Material Description	Storage	Stability
ADVIA Centaur sCOVG QC[a, b] **Control 1**: 2.0 mL/vial	Unopened at 2–8°C	Until expiration date on product
Processed* human plasma nonreactive for SARS-CoV-2	Opened at 2–8°C	60 days
antibodies; sodium azide (< 0.1%)	At room temperature	8 hours
**Processed plasma is defibrinated and filtered plasma.*		
ADVIA Centaur sCOVG QC[a, b] **Control 2**: 2.0 mL/vial	Unopened at 2–8°C	Until expiration date on product
Horse serum spiked with human monoclonal IgG	Opened at 2–8°C	60 days
antibodies to SARS-CoV-2; sodium azide (< 0.1%)	At room temperature	8 hours

[a] Store in an upright position.

[b] Prevent exposure to sunlight and heat.

Warnings and Precautions

FOR USA:
For Use Under Emergency Use Authorization Only

For *in vitro* diagnostic
use. For Prescription
Use Only.

This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories.

This product is for use with a test authorized only for detecting the presence of IgG antibodies to SARS-CoV-2, not for any other viruses or pathogens.

The emergency use of this product 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 Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

CAUTION

Federal (USA) law restricts this device to sale by or on the order of a licensed healthcare professional.

Safety data sheets (SDS) available on siemens-healthineers.com.

CAUTION POTENTIAL BIOHAZARD

Contains human source material. Each donation of human blood or blood component was tested by FDA-approved methods for the presence of antibodies to human immunodeficiency virus type 1 (HIV-1) and type 2 (HIV-2), as well as for hepatitis B surface antigen (HBsAg) and antibody to hepatitis C virus (HCV). The test results were negative (not repeatedly reactive). No test offers complete assurance that these or other infectious agents are absent; this material should be handled using good laboratory practices and universal precautions.[1-3]

CAUTION

This device contains material of animal origin and should be handled as a potential carrier and transmitter of disease.

Contains sodium azide as a preservative. Sodium azide can react with copper or lead plumbing to form explosive metal azides. On disposal, flush reagents with a large volume of water to prevent buildup of azides. Disposal into drain systems must be in compliance with prevailing regulatory requirements.

Dispose of hazardous or biologically contaminated materials according to the practices of your institution. Discard all materials in a safe and acceptable manner and in compliance with prevailing regulatory requirements.

Storage and Stability

Store quality control materials in an upright position. Quality control materials are stable until the expiration date on the product when stored at 2–8°C. Discard products at the end of the onboard stability interval. Do not use products beyond the expiration date printed on the product labeling.

For information about product storage and stability, refer to *Material Description*.

Performing Quality Control

Perform the quality control procedure at least once during each day that samples are analyzed. Test quality control samples after a successful calibration.

Follow government regulations or accreditation requirements for quality control frequency. Individual laboratory quality control programs and procedures may require more frequent quality control testing.

Treat all quality control samples the same as patient samples.

Preparing the Quality Control Materials

Quality control materials are liquid and ready to use. Gently mix and invert the vials to ensure homogeneity of the material.

Note Use quality control material within the stability limits specified in *Material Description*

and discard any remaining material.

Quality Control Procedure

The quality control material is provided in dropper vials. Each dispensed drop is approximately 50 µL.

The required sample volume for testing depends on several factors. For information about sample volume requirements, refer to the system online help. Perform the quality control procedure using the following steps:

1. Ensure that the quality control definitions are defined, and that the quality control values are entered on the system using the assigned value sheet provided.
2. Ensure that the required reagents are loaded for the assay.
3. Schedule the quality control samples to the worklist.
4. Label two sample containers with barcode labels: one sample container for the positive control, and one sample container for the negative control.

   Note Barcode labels are lot-specific. Do not use barcode labels from one lot of controls with any other lot of controls.
5. Gently mix each vial of quality control material and dispense at least 5-6 drops into the appropriate sample container. Avoid bubbles.

   Note This procedure uses sufficient volumes to test each product in duplicate.
6. Load the samples according to the system online help.

Note Dispose of any QC material that remains in the sample container after 8 hours. Do not refill or reuse sample containers. Do not return any QC material back into the original container.

Taking Corrective Action

If the quality control results do not fall within the assigned values, do not report results. Perform corrective actions in accordance with established laboratory protocol. For suggested protocol, refer to the system online help.

Expected Values

For the assigned values, refer to the quality control assigned value sheet provided. A satisfactory level of performance is achieved when the analyte values obtained are within the expected control interval for the system or within your interval, as determined by an appropriate internal laboratory quality control scheme. Follow your laboratory's quality control procedures if the results obtained do not fall within the acceptable limits. For information about entering QC definitions, refer to the system online help.

The assigned values are traceable to the standardization of the assay. For additional information, refer to the assay instructions for use.

Limitations

The ADVIA Centaur sCOVG QC is for use only with the ADVIA Centaur sCOVG assay. Assay values have not been established for assays other than the ADVIA Centaur sCOVG assay.

The results obtained using quality control material depend on several factors. Erroneous results can occur from causes such as improper storage, inadequate mixing, reconstitution errors, or sample handling errors associated with system or assay procedures.

The assigned control values should be used as a guide in evaluating performance. The control targets and intervals should be adapted to each laboratory's individual requirements. Values obtained should fall within the established interval. Each laboratory should establish corrective measures if individual values fall outside the interval. Follow the applicable government regulations and local guidelines for quality control.

Technical Assistance

For customer support, contact your local technical support provider or distributor. siemens-healthineers.com

References

1. Centers for Disease Control. Perspectives in disease prevention and health promotion update: Universal precautions for prevention of transmission of human immunodeficiency virus, hepatitis B virus and other bloodborne pathogens in healthcare settings. *MMWR*. 1988;37(24):377–382, 387–388.
2. Clinical and Laboratory Standards Institute. *Procedures for the Handling and Processing of Blood Specimens for Common Laboratory Tests; Approved Guideline—Fourth Edition*. Wayne, PA: Clinical and Laboratory Standards Institute; 2010. CLSI Document GP44-A4.
3. Clinical and Laboratory Standards Institute. *Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline—Fourth Edition*. Wayne, PA: Clinical and Laboratory Standards Institute; 2014. CLSI Document M29-A4.

Definition of Symbols

The following symbols may appear on the product labeling:

Symbol	Definition	Symbol	Definition
IVD	*In vitro* diagnostic medical device	REF	Catalog number
	Legal Manufacturer	EC REP	Authorized Representative in the European Community
CE	CE Mark	CE XXXX	CE Mark with notified body ID number Notified body ID number can vary.
	Consult instructions for use		Biological risks Potential biological risks are associated with the medical device.
	Do not freeze		Temperature limit

Symbol	Definition	Symbol	Definition
	Lower limit of temperature		Upper limit of temperature
	Keep away from sunlight Prevent exposure to sunlight and heat.		Up Store in an upright position.
	Use-by date Use by the designated date.		Contains sufficient for <n> tests Total number of IVD tests the system can perform with the IVD kit reagents appears adjacent to the symbol.
 YYYY-MM-DD	Batch code		Shake the reagent pack vigorously. Refer to *Preparing Reagents* in the assay-specific ADVIA Centaur product instructions for detailed information.
	Date format (year-month-day)	Rev.	Revision
	Master Curve Definition		Variable hexadecimal number that ensures the Master Curve and Calibrator definition values entered are valid.
	Lot Details		Printed with soy ink
	Recycle	RxOnly	Prescription device (US only)

Legal Information

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SIEMENS

ADVIA Centaur®
Immunoassay Systems

SARS-CoV-2 IgG Master Curve Material (sCOVG MCM)

Current Revision and Date[a]	Rev. 01, 2021-06
Product Name	ADVIA Centaur SARS-CoV-2 IgG Master Curve Material (sCOVG MCM)
Abbreviated Product Name	ADVIA Centaur sCOVG MCM
	4 x 1.0 mL levels of master curve material MCM 1–4 REF 11207586 Master curve material assigned value sheet
Systems	ADVIA Centaur systems

[a] A vertical bar in the page margin indicates technical content that differs from the previous version.

FOR USA:

For Use Under Emergency Use Authorization Only

For *in vitro* diagnostic use only.

For Prescription Use Only.

Intended Use

The ADVIA Centaur® SARS-CoV-2 IgG Master Curve Material (sCOVG MCM) is for *in vitro* diagnostic use in the verification of calibration and measuring interval of the ADVIA Centaur SARS-CoV-2 IgG (sCOVG) assay.

Material Description

Material Description	Storage	Stability
ADVIA Centaur sCOVG MCM[a, b] **MCM: 1:** 1.0 mL/vial Processed* human plasma nonreactive for SARS-CoV-2 antibodies; sodium azide (< 0.1%) **Processed plasma is defibrinated and filtered plasma.*	Unopened at 2–8°C Opened at 2–8°C At room temperature	Until expiration date on product 60 days 8 hours
ADVIA Centaur sCOVG MCM[a, b] **MCM 2–4:** 1.0 mL/vial Horse serum spiked with human monoclonal IgG antibodies to SARS-CoV-2; sodium azide (< 0.1%)	Unopened at 2–8°C Opened at 2–8°C At room temperature	Until expiration date on product 60 days 8 hours

[a] Store in an upright position.

[b] Prevent exposure to sunlight and heat.

Warnings and Precautions

FOR USA:

For Use Under Emergency Use Authorization Only

For *in vitro* diagnostic use.

For Prescription Use Only.

This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories.

This product is for use with a test authorized only for detecting the presence of IgG antibodies against SARS-CoV-2, not for any other viruses or pathogens.

The emergency use of this product 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 Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

CAUTION

Federal (USA) law restricts this device to sale by or on the order of a licensed healthcare professional.

Safety data sheets (SDS) available on siemens-healthineers.com.

CAUTION POTENTIAL BIOHAZARD

Contains human source material. Each donation of human blood or blood component was tested by FDA-approved methods for the presence of antibodies to human immunodeficiency virus type 1 (HIV-1) and type 2 (HIV-2), as well as for hepatitis B surface antigen (HBsAg) and antibody to hepatitis C virus (HCV). The test results were negative (not repeatedly reactive). No test offers complete assurance that these or other infectious agents are absent; this material should be handled using good laboratory practices and universal precautions.[1-3]

CAUTION

This device contains material of animal origin and should be handled as a potential carrier and transmitter of disease.

Contains sodium azide as a preservative. Sodium azide can react with copper or lead plumbing to form explosive metal azides. On disposal, flush reagents with a large volume of water to prevent buildup of azides. Disposal into drain systems must be in compliance with prevailing regulatory requirements.

Dispose of hazardous or biologically contaminated materials according to the practices of your institution. Discard all materials in a safe and acceptable manner and in compliance with prevailing regulatory requirements.

Storage and Stability

Do not use products beyond the expiration date printed on the product labeling. For information about product storage and stability, refer to *Material Description*.

Preparing the Master Curve Material

Master curve materials are liquid and ready to use. Allow the master curve material to come to room temperature. Gently mix and invert the vials to ensure homogeneity of the material.

Master curve materials greater than the assay's measuring interval may be diluted with Atellica IM sCOVG MCM level 1 to within the measuring interval of the assay.

Note Use master curve materials within the stability limits specified in *Material Description* and discard any remaining material.

Scheduling the Master Curve Material

Schedule the master curve material using the following steps:

1. Ensure that a valid calibration is available for the assay on the system.
2. Schedule the master curve material for three replicates, in order of increasing concentration:
   - Add Level 1 to the work list.
   - Add Level 2 to the work list.
   - Continue until all levels are scheduled.
3. Label sample containers to identify each MCM level.
4. Gently mix each vial of master curve material and dispense an adequate volume into each sample container.
5. Place the master curve material on the system from the lowest concentration to the highest concentration.
6. Start the system, if required.

Note Dispose of any master curve material that remains in the sample container after 8 hours. Do not refill or reuse sample containers. Do not return any master curve material back into the original container.

Evaluating the Results

Refer to the ADVIA Centaur sCOVG MCM assigned value sheet for the assigned values. The assigned values represent the acceptable results for master curve material tested in triplicate as unknown samples. Each level is expected to be within its assigned interval. When evaluating results that are outside of the acceptable interval, use the same criteria used when evaluating patient and quality control results.

Master curve material is not intended for use as routine quality control material or as calibration material.

The results obtained depend on several factors. Erroneous results can occur from causes such as improper storage, inadequate mixing, reconstitution errors, or sample handling errors.

Technical Assistance

For customer support, contact your local technical support provider or distributor.

siemens-healthineers.com

References

1. Centers for Disease Control. Perspectives in disease prevention and health promotion update: Universal precautions for prevention of transmission of human immunodeficiency virus, hepatitis B virus and other bloodborne pathogens in healthcare settings. *MMWR*. 1988;37(24):377–382, 387–388.
2. Clinical and Laboratory Standards Institute. *Procedures for the Handling and Processing of Blood Specimens for Common Laboratory Tests; Approved Guideline—Fourth Edition*. Wayne, PA: Clinical and Laboratory Standards Institute; 2010. CLSI Document GP44-A4.
3. Clinical and Laboratory Standards Institute. *Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline—Fourth Edition*. Wayne, PA: Clinical and Laboratory Standards Institute; 2014. CLSI Document M29-A4.

Definition of Symbols

The following symbols may appear on the product labeling:

Symbol	Definition	Symbol	Definition
IVD	*In vitro* diagnostic medical device	REF	Catalog number
	Legal Manufacturer	EC REP	Authorized Representative in the European Community
CE	CE Mark	CE XXXX	CE Mark with notified body ID number Notified body ID number can vary.
	Consult instructions for use		Biological risks Potential biological risks are associated with the medical device.
	Do not freeze		Temperature limit
	Lower limit of temperature		Upper limit of temperature
	Keep away from sunlight Prevent exposure to sunlight and heat.		Up Store in an upright position.
	Use-by date Use by the designated date.	Σ (n)	Contains sufficient for <n> tests Total number of IVD tests the system can perform with the IVD kit reagents appears adjacent to the symbol.
LOT	Batch code		Shake the reagent pack vigorously. Refer to *Preparing Reagents* in the assay-specific ADVIA Centaur product instructions for detailed information.
YYYY-MM-DD	Date format (year-month-day)	Rev.	Revision
MC DEF	Master Curve Definition	CHECKSUM	Variable hexadecimal number that ensures the Master Curve and Calibrator definition values entered are valid.
LOT DTL	Lot Details	PRINTED WITH SOY INK	Printed with soy ink
	Recycle	RxOnly	Prescription device (US only)

Legal Information

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ADVIA Centaur® SARS-CoV-2 IgG (sCOVG)	REF 11207376 (100T) REF 11207377 (500T)

IVD

FOR US

RxOnly

For Emergency Use Authorization Only

- This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories.
- This product has been authorized only for detecting the presence of IgG antibodies to SARS-CoV-2, not for any other viruses or pathogens.
- The emergency use of this product 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 Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3 (b)(1), unless the declaration is terminated or authorization is revoked sooner.
- This card is not the full instructions for use (IFU). The full IFU can be downloaded from the Siemens Healthineers website at siemens.com/eifu; a printed copy of the IFU can be obtained free of charge by contacting Siemens Healthineers Customer Support at 1-888-588-3916.

ADVIA Centaur® SARS-CoV-2 IgG (sCOVG) Quality Control (QC)	REF	11207378
ADVIA Centaur® SARS-CoV-2 IgG (sCOVG) Master Curve Material (MCM)	REF	11207586

IVD

FOR US

RxOnly

For Emergency Use Authorization Only

- This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories.
- This product is for use with a test authorized only for detecting the presence of IgG antibodies to SARS-CoV-2, not for any other viruses or pathogens.
- The emergency use of this product 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 Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3 (b)(1), unless the declaration is terminated or authorization is revoked sooner.
- This product is not the full instructions for use (IFU). The full IFU can be downloaded from the Siemens Healthineers website at siemens.com/eifu; a printed copy of the IFU can be obtained free of charge by contacting Siemens Healthineers Customer Support at 1-888-588-3916.