SIEMENS

ADVIA Centaur® XP
ADVIA Centaur® XPT
Immunoassay Systems

SARS-CoV-2 IgG (COV2G)

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

Current Revision and Date[a]	Rev. 01, 2020-06	
Product Name	ADVIA Centaur SARS-CoV-2 IgG (COV2G)	REF 11206992 (100 tests)
		REF 11206993 (500 tests)
Abbreviated Product Name	ADVIA Centaur COV2G	
Test Name/ID	COV2G	
Systems	ADVIA Centaur XP system ADVIA Centaur XPT system	
Materials Required but Not Provided	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 COV2G QC	REF 11206994
	ADVIA Centaur Multi-Diluent 12	REF 04786546 (vial)
Specimen Types	Serum, potassium EDTA plasma, lithium heparin plasma	
Sample Volume	10 µL	
Measuring Interval	0.50–20.00 Index	

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

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Intended Use

The ADVIA Centaur® SARS-CoV-2 IgG (COV2G) assay is for *in vitro* diagnostic use in the qualitative and semi-quantitative detection of IgG antibodies to SARS-CoV-2 in human serum and plasma (EDTA and lithium heparin) using the ADVIA Centaur® XP and ADVIA Centaur® XPT systems.

This assay is intended as an aid in the diagnosis of patients with suspected SARS-CoV-2 infection and as an aid in identifying patients with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection.

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] Surveillance testing for SARS-CoV-2-specific antibodies is necessary to understand the scope of infection, especially in the asymptomatic population.[12]

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.[13,14] 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. Multiple vaccines in development target or include the S1 RBD, as initial data indicate antibodies to this region can be neutralizing.[15-24] The ability to identify specific antibodies associated with neutralization will be an important adjunct to the detection of an immune response to the SARS-CoV-2 virus.

Principles of the Procedure

The ADVIA Centaur COV2G assay is a fully automated 2-step sandwich immunoassay using indirect chemiluminescent technology. The patient specimen is 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 COV2G 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%) **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; sodium azide (< 0.1%) **Ancillary Well Reagent** 10.0 mL/reagent pack Buffer; surfactant; bovine serum albumin; horse serum; sodium azide (< 0.1%)	Unopened at 2–8°C Onboard	Until expiration date on product 28 days
ADVIA Centaur COV2G CAL[a, b] **COV2G 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.* **COV2G 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
ADVIA Centaur Multi-Diluent 12[a, c] 20.0 mL/vial Human serum; detergents; glycerol; anti-foam; preservatives	At 2–8°C Opened at 2–8°C	Until expiration date on product 21 weeks
ADVIA Centaur Wash 1[a, d] 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, d] 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] Refer to *Optional Materials*.
[d] Refer to *Materials Required but Not Provided*.

Warnings and Precautions

For *in vitro* diagnostic use.

For Professional Use.

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.[25-27]

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 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.

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

Specimen Collection and Handling

Serum and plasma (potassium EDTA and 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.[27]
- Follow recommended procedures for collection of diagnostic blood specimens by venipuncture.[28]
- Follow the instructions provided with your specimen collection device for use and processing.[29]
- Allow blood specimens to clot completely before centrifugation.[26]
- Keep tubes capped at all times.[26]
- Test specimens as soon as possible after collecting. Store specimens at 2–8°C if not tested immediately within 8 hours.

Storing the Specimen

- Thawed frozen specimens must be clarified by centrifugation prior to testing. Do not store in a frost-free freezer.
- 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 2 days, ship specimens frozen. Store samples capped and upright at 2–8°C upon arrival.

Preparing the Samples

This assay requires 10 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.

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.[26]

Procedure

Materials Provided

The following materials are provided:

REF	Contents	Number of Tests
11206992	1 ReadyPack primary reagent pack containing ADVIA Centaur COV2G Lite Reagent, Solid Phase, and Ancillary Well Reagent 1 vial ADVIA Centaur COV2G CAL low calibrator CAL L 1 vial ADVIA Centaur COV2G CAL high calibrator CAL H ADVIA Centaur COV2G master curve card ADVIA Centaur COV2G CAL calibrator assigned value sheets and barcode labels	100
11206993	5 ReadyPack primary reagent packs containing ADVIA Centaur COV2G Lite Reagent, Solid Phase, and Ancillary Well Reagent 2 vials ADVIA Centaur COV2G CAL low calibrator CAL L 2 vials ADVIA Centaur COV2G CAL high calibrator CAL H ADVIA Centaur COV2G master curve card ADVIA Centaur COV2G 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]	
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	
11206994	ADVIA Centaur COV2G 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 and barcode labels
04786546	ADVIA Centaur Multi-Diluent 12 (diluent)	20.0 mL/vial DIL

Assay Procedure

The system automatically performs the following steps:

1. Dispenses 10 µL of sample into a cuvette.
2. Dispenses 100 µL of Solid Phase and 100 µL of Ancillary Well Reagent, then incubates for 18 minutes at 37°C.
3. Performs a wash sequence using ADVIA Centaur Wash 1.
4. Resuspends the washed particles in 150 µL of ADVIA Centaur Wash 1.
5. Dispenses 100 µL of Lite Reagent, then incubates for 18 minutes at 37°C.
6. Performs a wash sequence using ADVIA Centaur Wash 1.
7. Dispenses 300 µL each of ADVIA Centaur Acid Reagent and ADVIA Centaur Base Reagent to initiate the chemiluminescent reaction.
8. 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

A daily cleaning procedure must be completed prior to and after your laboratory's batched testing for the ADVIA Centaur COV2G assay.

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 COV2G 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 for each assay 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 COV2G assay, use the ADVIA Centaur COV2G QC or an equivalent product at least once during each day that samples are analyzed. Additional quality control material of known analyte concentration can be used at the discretion of the laboratory. 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*.

Dilutions

Sample	Dilution	Minimum Sample Volume (µL)
Serum and plasma	1:2	100
Serum and plasma	1:4	50
Serum and plasma	1:8	25

The system does not perform onboard dilutions for the ADVIA Centaur COV2G assay.

If patient results exceed the measuring interval of the assay, or if laboratory protocol requires manual dilution, manually dilute the patient sample.

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 COV2G assay results in Index Values and as Nonreactive or Reactive:

- **Nonreactive:** < 1.0 Index. These samples are considered negative for SARS-CoV-2 IgG antibodies.
- **Reactive:** ≥ 1.0 Index. These samples are considered positive for SARS-CoV-2 IgG antibodies.

The cut-off value for the ADVIA Centaur COV2G assay was verified based on clinical agreement of results.

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:

- 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.
- 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.
- It is currently unknown how long SARS-CoV-2 antibodies persist following infection and if the presence of antibodies confers protective immunity.
- A reactive test result does not exclude past or present infection by other coronaviruses, such as SARS-CoV-1, MERS-CoV, HKU1, 229E, NL63, or OC43, or due to cross-reactivity from pre-existing antibodies or other possible causes.
- A nonreactive test result does not exclude the possibility of exposure to or infection with SARS-CoV-2. Patient specimens may be nonreactive if collected during the early (pre-seroconversion) phase of illness or due to a decline in titer over time. In addition, the immune response may be depressed in elderly, immunocompromised, or immunosuppressed patients.
- This test should not be used for donor screening.

Performance Characteristics

Measuring Interval

0.50–20.00 Index is reported as Nonreactive (< 1.0 Index) or Reactive (≥ 1.0 Index).

The lower end of the measuring interval is defined by the LoQ. Report patient results below the measuring interval as < 0.50 Index. When sample results exceed the measuring interval, refer to *Dilutions*.

Detection Capability

Detection capability was determined in accordance with CLSI Document EP17-A2.[30] The following results were obtained:

Method	Result (Index)
Limit of Blank (LoB)	0.40
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 assay is designed to have an LoB ≤ 0.40 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 assay is designed to have an LoD ≤ 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 assay is designed to have an LoQ ≤ 0.60 Index.

Report patient results below the measuring interval as < 0.50 Index.

Seroconversion Sensitivity

A total of 129 specimens were collected serially from 29 subjects with a clinical diagnosis of COVID-19 based on a positive SARS-CoV-2 polymerase chain reaction (PCR) method. Of these, seroconversion was observed in 8 panels with 3 or more blood draws. The results are shown in the table below:

			First Draw		Last Nonreactive Draw		First Reactive Draw		Last Draw	
Panel	Number of Draws	Number of Reactive Draws	Days Post PCR Positive	Index	Days Post PCR Positive	Index	Days Post PCR Positive	Index	Days Post PCR Positive	Index
A	8	6	5	0.12	6	0.19	7	1.21	12	8.89
B	7	6	6	0.12	6	0.12	9	1.65	17	4.44
C	4	3	0	0.00	0	0.00	6	7.79	8	8.04
D	4	2	5	0.02	6	0.10	9	1.66	10	4.72
E	5	2	0	0.01	4	0.30	5	1.39	12	8.66
F	3	2	0	0.46	0	0.46	2	5.56	3	4.11
G	4	2	5	0.02	6	0.05	8	1.24	10	6.14
H	7	3	2	0.15	4	0.57	5	3.20	7	6.94

Clinical Sensitivity and Specificity

Clinical sensitivity and specificity were determined in accordance with CLSI Document EP12-A2.[31] The performance of the ADVIA Centaur COV2G assay was determined by testing a total of 2020 samples using the ADVIA Centaur XP system.

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

Clinical Sensitivity

Clinical sensitivity was determined by testing 189 samples from individuals with a clinical diagnosis of COVID-19 based on a positive polymerase chain reaction (PCR) method. The results are shown in the table below:

Days Post PCR Positive	Number Tested	Reactive	Nonreactive	Positive Percent Agreement (95% CI)
0–6	86	46	40	53.49% (42.41%–64.23%)
7–13	61	57	4	93.44% (84.05%–98.18%)
≥14	42	42	0	100.00% (91.59%–100.00%)

Clinical Specificity

Clinical specificity was determined by testing 1831 samples collected 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	1734	1732	2	99.88% (99.58%–99.99%)
Apparently Healthy Pregnant Women	97	97	0	100.00% (96.27%–100.00%)
Total	**1831**	**1829**	**2**	**99.89% (99.61%–99.99%)**

Precision

Precision was determined in accordance with CLSI Document EP05-A3.[32] Samples were assayed in duplicate in 2 runs per day for 20 days.

			Repeatability		Within-Laboratory Precision	
Specimen Type	N[a]	Mean (Index)	SD[b] (Index)	CV[c] (%)	SD (Index)	CV (%)
Serum A	80	0.85	0.03	3.4	0.04	4.4
Serum B	80	1.79	0.05	3.0	0.07	4.1
Serum C	80	7.03	0.32	4.6	0.43	6.1
Plasma, Lithium Heparin	80	1.85	0.06	3.2	0.07	3.9
Plasma, EDTA	80	1.74	0.04	2.0	0.05	2.8

			Repeatability		Within-Laboratory Precision	
Specimen Type	N[a]	Mean (Index)	SD[b] (Index)	CV[c] (%)	SD (Index)	CV (%)
Control 1	80	0.00	0.00	N/A[d]	0.01	N/A
Control 2	80	2.16	0.08	3.5	0.12	5.7

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

The assay was designed to have the following precision.

Concentration Interval	Precision	
Index Value	Repeatability (Within-Run)	Within-Laboratory (Total Precision)
0.80–2.00	≤ 12.0% CV	≤ 15.0% CV
> 2.00	≤ 10.0% CV	≤ 12.0% CV

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

Specimen Equivalency

Specimen equivalency was determined using a linear regression model using the ADVIA Centaur XP system in accordance with CLSI Document EP09-A3.[33] The following results were obtained:

Tube (y) vs. Serum (x)	N[a]	Sample Interval	Slope	Intercept	r[b]
EDTA (plasma)	35	0.63–18.28	0.97	0.08	0.997
lithium heparin (plasma)	35	0.53–19.03	1.01	-0.12	0.996

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

The assay is designed to have a slope of 0.90–1.10 for alternate tube types versus serum.

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.[34] Testing demonstrated a ≤ 10% change for each substance. The following results were obtained:

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

Substance	Substance Test Concentration
Cholesterol	500 mg/dL
Protein, total	12 g/dL

Cross-Reactivity

Cross-reactivity was determined in accordance with CLSI Document EP07-ed3.[34] The assay was evaluated for potential cross-reactivity in specimens with other viral and microbial antibodies and other disease states.

Clinical Category	Number Tested	Number Reactive with ADVIA Centaur COV2G Assay
Autoimmune diseases[a]	24	0
Chlamydia trachomatis IgM	5	0
Cytomegalovirus (CMV) IgM	5	0
Epstein Barr virus (EBV) IgG	4	0
Epstein Barr virus (EBV) IgM	10	0
Hepatitis A virus (HAV) IgM	4	0
Hepatitis B core (anti-HBc) IgM	10	0
Hepatitis B core (anti-HBc) total antibody	15	0
Hepatitis C virus (HCV) antibody	25	0
Herpes simplex virus (HSV) IgM	12	0
Herpes simplex virus type 1 (HSV-1) IgG	14	0
Herpes simplex virus type 2 (HSV-2) IgG	8	0
Human anti-mouse antibody (HAMA)	15	0
Human chorionic gonadotropin (hCG)	10	0
Human immunodeficiency virus (HIV) antibody	9	0
Influenza antibody	29	0
Influenza A antibody	6	0
Influenza B antibody	30	0
Measles antibody	5	0
Mycoplasma pneumoniae IgG	9	0
Parvovirus B19 antibody	7	0
Respiratory pathogen antibodies[b]	19	0
Respiratory syncytial virus (RSV) antibody	20	0
Treponema pallidum (Syphilis) IgG	5	0
Varicella zoster virus (VZV) IgG	16	0

Clinical Category	Number Tested	Number Reactive with ADVIA Centaur COV2G Assay
Varicella zoster virus (VZV) IgM	5	0
Total	**321**	**0**

[a] This group consists of samples from 24 subjects with autoimmune disease states, including anti-nuclear antibody (ANA; N = 6), Graves' disease (N = 6), rheumatoid factor (RF; N = 7), Sjogren's syndrome (N = 3), and systemic lupus erythematosus (SLE; N = 2).

[b] This panel consists of samples from 19 subjects with antibodies to multiple respiratory pathogens, including Adenovirus antibodies (N = 6), *Bordetella pertussis* IgG (N = 17), *Chlamydia pneumoniae* IgG (N = 18), *Chlamydia psittaci* IgM (N = 1), *Haemophilus influenzae* b (Hib) IgG (N = 10), Influenza A IgG (N = 17), Influenza A IgM (N = 1), Influenza B IgG (N = 15), and *Mycoplasma pneumoniae* IgG (N = 4).

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

Dilution Recovery

Two serum samples, three lithium heparin plasma samples, and one EDTA plasma sample in the range of 12.65–32.97 Index were diluted 1:2, 1:4, and 1:8 with Multi-Diluent 12 and assayed for recovery. The recoveries ranged from 82.7%–111.6% with a mean of 97.1%.

Sample	Dilution	Observed (Index)	Expected (Index)	Recovery (%)
Serum 1	—	31.47	—	—
	1:2	16.18	15.74	102.8
	1:4	8.45	7.87	107.3
	1:8	3.88	3.93	98.6
	Mean			102.9
Serum 2	—	32.97	—	—
	1:2	13.63	16.49	82.7
	1:4	7.80	8.24	94.7
	1:8	3.95	4.12	95.9
	Mean			91.1
Lithium heparin plasma 1	—	21.40	—	—
	1:2	10.64	10.70	99.5
	1:4	5.03	5.35	94.1
	1:8	2.25	2.68	84.2
	Mean			92.6
Lithium heparin plasma 2	—	20.46	—	—
	1:2	9.27	10.23	90.6
	1:4	4.71	5.11	92.1
	1:8	2.29	2.56	89.4
	Mean			90.7

Sample	Dilution	Observed (Index)	Expected (Index)	Recovery (%)
Lithium heparin plasma 3	—	12.65	—	—
	1:2	7.02	6.33	110.9
	1:4	3.19	3.16	100.9
	1:8	1.48	1.58	93.5
	Mean			101.8
EDTA plasma 1	—	21.19	—	—
	1:2	9.67	10.60	91.2
	1:4	5.47	5.30	103.3
	1:8	2.96	2.65	111.6
	Mean			102.0
Mean				**97.1**

Results were established using the Atellica IM COV2G assay, which has the same reagent formulations as the ADVIA Centaur COV2G assay. Assay results obtained at individual laboratories may vary from the data presented.

Standardization

The assay standardization for the ADVIA Centaur COV2G assay is based on agreement with known positive and negative SARS-CoV-2 samples. Assigned values for calibrators are traceable to this standardization.

Technical Assistance

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

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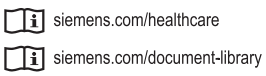
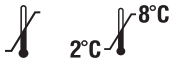
Definition of Symbols

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
Rev. REVISION	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.

Symbol	Symbol Title and Description
	Biological risks Potential biological risks are associated with the medical device.
	Corrosive
	Dangerous to environment
	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
	*In vitro* diagnostic medical device

Symbol	Symbol Title and Description
	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.
	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)
	Variable hexadecimal number that ensures the Master Curve and Calibrator definition values entered are valid.
	Master Curve Definition
	Lot Details
	Common Units

Symbol	Symbol Title and Description
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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