SIEMENS Healthineers

SARS-CoV-2 IgG (COV2G)

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 reinfection.

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

Current Revision and Date[a]	Rev. 01, 2020-07	
Product Name	Atellica IM SARS-CoV-2 IgG (COV2G)	REF 11206997 (100 tests) REF 11206998 (500 tests)
Abbreviated Product Name	Atellica IM COV2G	
Test Name/ID	COV2G	
Systems	Atellica IM Analyzer	
Materials Required but Not Provided	Atellica IM COV2G QC	REF 11206999
Optional Materials	Atellica IM Multi-Diluent 12	REF 10995550 (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.

Intended Use

The Atellica® IM SARS-CoV-2 IgG (COV2G) assay is a chemiluminescent immunoassay intended for qualitative and semi-quantitative detection of IgG antibodies to SARS-CoV-2 in human serum and plasma (potassium EDTA and lithium heparin) using the Atellica® IM Analyzer. The Atellica IM SARS-CoV-2 IgG (COV2G) 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 Atellica IM SARS-CoV-2 IgG (COV2G) assay should not be used to diagnose 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 positive results to the appropriate public health authorities.

The sensitivity of the Atellica IM SARS-CoV-2 IgG (COV2G) 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 Atellica IM SARS-CoV-2 IgG (COV2G) assay may occur due to cross-reactivity from pre-existing antibodies or other possible causes.

The Atellica IM SARS-CoV-2 IgG (COV2G) 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. Multiple vaccines in development target or include the S1 RBD, as initial data indicate antibodies to this region can be neutralizing.[14-23] 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 Atellica IM 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
Atellica IM 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
Atellica IM 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
Atellica IM 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

[a] Store in an upright position.
[b] Prevent exposure to sunlight and heat.
[c] Refer to *Optional Materials*.

Warnings and Precautions

For Use Under Emergency Use Authorization Only

For *in vitro* diagnostic use only.

For prescription use only.

This test has not been FDA cleared or approved; the test has been authorized by FDA under an Emergency Use Authorization (EUA) for use by 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.

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

This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of *in vitro* diagnostic tests 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 authorization is terminated or 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.[24-26]

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.

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.[26]
- Follow recommended procedures for collection of diagnostic blood specimens by venipuncture.[27]
- Follow the instructions provided with your specimen collection device for use and processing.[28]
- Allow blood specimens to clot completely before centrifugation.[25]

- Keep tubes capped at all times.[25]
- 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.[25]

Procedure

Materials Provided

The following materials are provided:

REF	Contents	Number of Tests
11206997	1 ReadyPack primary reagent pack containing Atellica IM COV2G Lite Reagent, Solid Phase, and Ancillary Well Reagent Atellica IM COV2G master curve and test definition MC TDEF 1 vial Atellica IM COV2G CAL low calibrator CAL L 1 vial Atellica IM COV2G CAL high calibrator CAL H Atellica IM COV2G CAL calibrator assigned value sheet CAL LOT VAL	100
11206998	5 ReadyPack primary reagent packs containing Atellica IM COV2G Lite Reagent, Solid Phase, and Ancillary Well Reagent Atellica IM COV2G master curve and test definition MC TDEF 2 vials Atellica IM COV2G CAL low calibrator CAL L 2 vials Atellica IM COV2G CAL high calibrator CAL H Atellica IM COV2G CAL calibrator assigned value sheet CAL LOT VAL	500

Materials Required but Not Provided

The following materials are required to perform this assay, but are not provided:

REF	Description	
	Atellica IM Analyzer[a]	
11206999	Atellica IM 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 CONTROL LOT VAL

[a] Additional system fluids are required to operate the system: Atellica IM Wash, Atellica IM Acid, Atellica IM Base, and Atellica IM Cleaner. For system fluid instructions for use, refer to the Document Library.

Optional Materials

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

REF	Description	
10995550	Atellica IM 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 12 minutes at 37°C.
3. Performs a wash sequence using Atellica IM Wash.
4. Resuspends the washed particles in 150 µL of Atellica IM Wash.
5. Dispenses 100 µL of Lite Reagent, then incubates for 8 minutes at 37°C.

6. Performs a wash sequence using Atellica IM Wash.
7. Dispenses 300 µL each of Atellica IM Acid and Atellica IM Base 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 Atellica IM 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 and test definition by scanning the MC TDEF 2D barcodes. For information about entering the master curve and test definition, refer to the system online help.

Performing Calibration

For calibration of the Atellica IM 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:

- When changing lot numbers of primary reagent packs.
- At the end of the lot calibration interval, for a specified lot of calibrated reagent on the system.
- At the end of the pack calibration interval, for calibrated reagent packs on the system.
- When indicated by quality control results.
- After major maintenance or service, if indicated by quality control results.

Note When loading a new primary reagent pack, a calibration is not required if there is a valid lot calibration. For information about lot calibration and pack calibration, refer to the system online help.

Stability Interval	Days
Lot Calibration	28
Pack Calibration	14
Reagent Onboard Stability	28

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.

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

Use the following lot-specific materials to perform calibration:

- For the master curve and assay test definitions, refer to the lot-specific master curve and test definition sheet MC TDEF provided with the assay reagents.
- Calibrators provided in an assay kit must only be used with reagents from that assay kit lot. Do not use calibrators from one assay kit lot with reagents from a different assay kit lot.
- For the calibrator definitions, refer to the calibrator assigned value sheet CAL LOT VAL provided with the calibrator materials.
- Generate lot-specific barcode labels to use with the calibrator samples.

For instructions about how to perform the calibration procedure, refer to the system online help.

Performing Quality Control

For quality control of the Atellica IM COV2G assay, use the Atellica IM COV2G 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 value sheet CONTROL LOT VAL 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 Atellica IM COV2G 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.

For manual dilutions, perform the following actions:

- Use Atellica IM 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 Atellica IM COV2G assay results in Index Values and as Nonreactive or Reactive:

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

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:

- The clinical applicability of a quantitative or semi-quantitative result is currently unknown and cannot be interpreted as an indication or degree of immunity nor protection from reinfection, nor compared to 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. 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.
- 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.
- SARS-CoV-2 antibodies may not be detectable in patients with recent infections (7–10 days or less) or in samples collected from patients less than 7 days from a positive polymerase chain reaction (PCR) result. 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.
- It is not known at this time if the presence of antibodies to SARS-CoV-2 confers immunity to re-infection.
- This test should not be used for donor screening.

Conditions of Authorization for the Laboratory

The Atellica IM SARS-CoV-2 IgG (COV2G) assay Letter of Authorization, along with the authorized Fact Sheet for Healthcare Providers, the authorized Fact Sheet for Patients, 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/vitro-diagnostics-euas

Authorized laboratories using the Atellica IM SARS-CoV-2 IgG (COV2G) assay must adhere to the Conditions of Authorization indicated in the Letter of Authorization as listed below:

- Authorized laboratories[a] using the Atellica IM SARS-CoV-2 IgG (COV2G) assay will 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 Atellica IM SARS-CoV-2 IgG (COV2G) assay will use the product as outlined in the Instructions for Use. 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 Atellica IM SARS-CoV-2 IgG (COV2G) assay are not permitted.
- Authorized laboratories that receive the Atellica IM SARS-CoV-2 IgG (COV2G) assay will notify the relevant public health authorities of their intent to run the assay prior to initiating testing.
- Authorized laboratories using the Atellica IM SARS-CoV-2 IgG (COV2G) assay will have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.

- Authorized laboratories will collect information on the performance of the Atellica IM SARS-CoV-2 IgG (COV2G) 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 or false nonreactive results and significant deviations from the established performance characteristics of the assay of which they become aware.
- All laboratory personnel using the Atellica IM SARS-CoV-2 IgG (COV2G) assay must be appropriately trained in automated immunoassay techniques and use appropriate laboratory and personal protective equipment when handling this kit, and use the Atellica IM SARS-CoV-2 IgG (COV2G) 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 Atellica IM SARS-CoV-2 IgG (COV2G) assay.
- Siemens Healthineers, authorized distributors, and authorized laboratories using the Atellica IM SARS-CoV-2 IgG (COV2G) assay will 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

Analytical Measuring Interval

0.50–20.00 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.[29] 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 estimate of the LoB based on 2 reagent lots is 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 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 131 specimens were collected serially from 28 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	5	5	0.10	7	0.99	8	3.18	12	7.05
B	7	6	6	0.08	6	0.08	9	1.50	17	3.81
C	4	3	0	0.00	0	0.00	6	5.85	8	6.13
D	4	2	5	0.02	6	0.08	9	1.52	10	3.56
E	5	2	0	0.01	4	0.24	5	1.12	12	6.93
F	3	2	0	0.88	0	0.88	2	6.60	3	4.44
G	5	3	5	0.02	6	0.04	8	1.25	10	5.52
H	8	4	2	0.10	4	0.45	5	1.44	7	5.64

Clinical Agreement

Positive percent agreement and negative percent agreement were determined in accordance with CLSI Document EP12-A2.[30] The performance of the Atellica IM COV2G assay was determined by testing a total of 2038 samples using the Atellica IM Analyzer.

Positive Percent Agreement

Positive percent agreement was determined by testing 197 retrospective samples collected over the course of time from 94 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)
0–6	91	51	40	56.04% (45.25%–66.44%)
7–13	64	59	5	92.19% (82.70%–97.41%)
≥14	42	42	0	100.00% (91.59%–100.00%)

Negative Percent Agreement

Negative percent agreement was determined by testing 1841 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	1744	1743	1	99.94% (99.68%–100.00%)
Apparently Healthy Pregnant Women	97	97	0	100.00% (96.27%–100.00%)
Total	**1841**	**1840**	**1**	**99.95% (99.70%–100.00%)**

Precision

Single-Site Precision

A single-site precision study for the Atellica IM COV2G assay was conducted in accordance with CLSI Document EP05-A3.[31] 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 Atellica IM Analyzer. Results for the precision of the Atellica IM COV2G assay 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	0.81	0.02	2.7	0.03	3.8
Serum B	80	1.72	0.04	2.0	0.05	2.8
Serum C	80	7.23	0.33	4.5	0.58	8.0
Plasma, Lithium Heparin	80	1.82	0.04	2.0	0.07	4.0
Plasma, EDTA	80	1.76	0.04	2.3	0.08	4.5
Control 1	80	0.01	0.01	N/A[d]	0.01	N/A
Control 2	80	1.83	0.07	3.9	0.11	6.2

[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 Atellica IM COV2G assay was evaluated on 2 Atellica IM 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 3 days. The data were analyzed to calculate the following components of precision: repeatability, between-run, between-day, between-lot, between-instrument, and reproducibility (total). Results for the reproducibility of the Atellica IM COV2G assay 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	48	0.89	0.02	2.6	0.02	2.2	0.02	2.0	0.05	6.1	0.00	0.0	0.07	7.3
Serum B	48	2.00	0.04	2.0	0.02	1.2	0.07	3.3	0.17	8.5	0.00	0.0	0.19	9.4
Serum C	48	8.99	0.37	4.1	0.28	3.1	0.00	0.0	0.26	2.9	0.17	1.9	0.56	6.2
Serum D	48	19.51	1.31	6.7	0.91	4.6	0.74	3.8	0.00	0.0	0.89	4.5	1.97	10.1
Plasma, Lithium Heparin	48	1.97	0.04	2.2	0.02	0.9	0.04	2.2	0.09	4.6	0.03	1.3	0.11	5.7
Plasma, EDTA	48	2.00	0.04	2.1	0.02	1.1	0.04	2.2	0.14	6.9	0.00	0.0	0.15	7.6
Control 1	48	0.01	0.00	N/A[d]	0.00	N/A	0.00	N/A	0.00	N/A	0.01	N/A	0.01	N/A
Control 2	48	2.03	0.07	3.4	0.00	0.0	0.01	0.2	0.09	4.5	0.05	2.3	0.12	6.1

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

Specimen Equivalency

Matched sample sets (serum, EDTA plasma, 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 COV2G assay using the Atellica IM Analyzer. Using a linear regression model, results from plasma samples were compared to serum results in accordance with CLSI Document EP35-Ed1.[32] The following results were obtained:

Tube (y) vs. Serum (x)	N[a]	Sample Interval	Slope (95% CI)	Intercept (95% CI)	r[b]
EDTA (plasma)	36	0.61–17.06	1.05 (1.02–1.07)	-0.09 (-0.27–0.10)	0.997
lithium heparin (plasma)	36	0.55–16.15	1.02 (0.99–1.06)	-0.06 (-0.30–0.18)	0.995

[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.[33] The impact of potentially interfering substances on the detection of SARS-CoV-2 IgG antibodies with the Atellica IM COV2G 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 (~2.5 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.[33] The assay was evaluated for potential cross-reactivity using specimens containing antibodies to other pathogens and other disease states using the Atellica IM COV2G assay with the Atellica IM Analyzer. No false positive results were observed with the potential cross-reactants listed in the following table:

Clinical Category	Number Tested	Number Reactive with Atellica IM 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	14	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

Clinical Category	Number Tested	Number Reactive with Atellica IM COV2G Assay
Human chorionic gonadotropin (hCG)	10	0
Human immunodeficiency virus (HIV) antibody	10	0
Influenza antibody	29	0
Influenza A antibody	6	0
Influenza B antibody	29	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	7	0
Varicella zoster virus (VZV) IgG	16	0
Varicella zoster virus (VZV) IgM	5	0
Total	**322**	**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.

Linearity

Linearity testing was performed in accordance with CLSI Document EP06-A.[34]

Patient pools containing high levels of SARS-CoV-2 IgG (1 serum, 1 EDTA plasma, 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 an Atellica IM Analyzer. Linearity was demonstrated for the analytical measuring interval of 0.50–20.00 Index with deviations from linearity within 15%.

Taking into consideration the estimates of LoB, LoD, LoQ, precision, and linearity, the analytical measuring interval of the Atellica IM COV2G assay is 0.50–20.00 Index.

Extended Measuring Interval (Dilutions)

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

The extended measuring interval of the Atellica IM COV2G assay by manual dilution of 1:2, 1;4, and 1:8 with Atellica IM Multi-Diluent 12 is 20.00–160.00 Index.

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
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**

Assay results obtained at individual laboratories may vary from the data presented.

Standardization

The Atellica IM COV2G assay standardization is traceable to an internal standard based on agreement with known positive and negative SARS-CoV-2 samples.

Currently no reference standard is available for this assay.

Technical Assistance

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

siemens-healthineers.com

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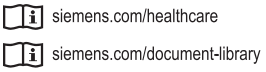
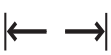
Definition of Symbols

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.
	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

Symbol	Symbol Title and Description
	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
	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.

Symbol	Symbol Title and Description
LOT	Batch code
REF	Catalog number
	Recycle
	Printed with soy ink
CE	CE Mark
CE XXXX	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

Siemens Healthcare Diagnostics Inc.
511 Benedict Avenue
Tarrytown, NY 10591
USA
siemens-healthineers.com

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

SIEMENS Healthineers

SARS-CoV-2 IgG Quality Control (COV2G QC)

Current Revision and Date[a]	Rev. 01, 2020-07
Product Name	Atellica IM SARS-CoV-2 IgG Quality Control (COV2G QC)
Abbreviated Product Name	Atellica IM COV2G QC
	2 x 2.0 mL negative quality control, level 1 CONTROL – 1 REF 11206999 2 x 2.0 mL positive quality control, level 2 CONTROL + 2 Quality control assigned value sheet CONTROL LOT VAL
Systems	Atellica IM Analyzer

[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.

For Professional Use.

Intended Use

The Atellica® IM SARS-CoV-2 IgG Quality Control (COV2G QC) is for *in vitro* diagnostic use in monitoring the precision and accuracy of the Atellica® IM SARS-CoV-2 IgG (COV2G) assay using the Atellica® IM Analyzer.

Material Description

Material Description	Storage	Stability
Atellica IM COV2G QC **COV2G Control 1**: 2.0 mL/vial Processed* human plasma nonreactive for SARS-CoV-2 antibodies; sodium azide (< 0.1%) **Processed plasma is defibrinated and filtered plasma.* **COV2G Control 2**: 2.0 mL/vial Horse serum spiked with human monoclonal IgG antibodies to SARS-CoV-2; sodium azide (< 0.1%)	At 2–8°C Opened at 2–8°C At room temperature Atellica® Sample Handler[a]	Until expiration date on product 60 days 8 hours

[a] Refer to the supplementary document "Atellica Sample Handler Calibrator and QC Storage and Stability" for information about storage and stability of materials in the Cal-QC tube storage area.

Warnings and Precautions

FOR USA:

For Use Under Emergency Use Authorization Only

For *in vitro* diagnostic use.

For Professional Use.

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]

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*.

Note Refer to the supplementary document "Atellica Sample Handler Calibrator and QC Storage and Stability" for information about storage and stability of materials in the Cal-QC tube storage area.

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 product 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.

Use the following lot-specific materials to perform quality control:

- For the quality control (QC) definitions, refer to the lot-specific value sheet CONTROL | LOT | VAL provided with the quality control materials.
- Generate lot-specific barcode labels to use with the quality control samples.

For instructions about how to perform the quality control procedure, refer to the system online help.

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 value sheet CONTROL | LOT | VAL 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 Atellica IM COV2G QC is for use only with the Atellica IM COV2G assay. Assay values have not been established for assays other than the Atellica IM COV2G 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.

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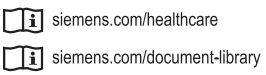
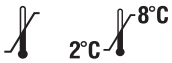
2. Clinical and Laboratory Standards Institute. *Procedures for the Handling and Processing of Blood Specimens for Common Laboratory Tests; Approved Guideline—Fourth Edition*. Wayne, PA: Clinical and Laboratory Standards Institute; 2010. CLSI Document GP44-A4.
3. Clinical and Laboratory Standards Institute. *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	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
	Irritant Oral, dermal, or inhalation hazard
	Inhalation hazard Respiratory or internal health
	Flammable Flammable to extremely flammable

Symbol	Symbol Title and Description
	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
	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

Symbol	Symbol Title and Description
EC REP	Authorized Representative in the European Community
	Use-by date Use by the designated date.
LOT	Batch code
REF	Catalog number
	Recycle
PRINTED WITH SOY INK	Printed with soy ink
CE	CE Mark
CE 0088	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.
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

Atellica is a trademark of Siemens Healthcare Diagnostics.

All other trademarks and brands are the property of their respective owners.

Siemens Healthcare Diagnostics Inc.
511 Benedict Avenue
Tarrytown, NY 10591
USA
siemens-healthineers.com

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