SIEMENS

Dimension® EXL™ integrated chemistry system

SARS-CoV-2 IgG (CV2G)

For Use Under Emergency Use Authorization Only.

For *in vitro* diagnostic use.

For Prescription Use Only.

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

Current Revision and Date[a]	Rev. 01, 2021-04	
Product Name	Dimension EXL SARS-CoV-2 IgG (CV2G)	REF RF870 11417770
Abbreviated Product Name	Dimension EXL CV2G	
Test Name/ID	CV2G	
Systems	Dimension EXL with LOCI Module or Dimension EXL 200 using software version 10.4.3 or higher	
Materials Required but Not Provided	SARS-CoV-2 IgG calibrator (COV2G CAL/CV2G CAL)	REF KC872 11417772
	SARS-CoV-2 IgG Quality Control (COV2G QC/CV2G QC)	REF KC873 11417773
	Dimension Heterogeneous Immunoassay Module Reaction Vessels	REF RXV1A 10445044
Specimen Types	Serum, dipotassium EDTA plasma, lithium heparin plasma	
Sample Volume	2 µL	
Measuring Interval	610–140,000 Ind	

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

For USA

- **Use of this test is limited to laboratories certified under Clinical Laboratory Improvement Amendments of 1988 (CLIA) that meet requirements to perform moderate- or high-complexity testing.**
- **Negative results do not preclude acute SARS-CoV-2 infection. If acute infection is suspected, direct testing for SARS-CoV-2 is necessary.**
- **Results from antibody testing should not be used to diagnose or exclude acute SARS-CoV-2 infection.**
- **Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E.**

Intended Use

The Dimension® EXL™ SARS-CoV-2 IgG (CV2G) assay is a chemiluminescent immunoassay intended for qualitative and semiquantitative detection of IgG antibodies to SARS-CoV-2 in human serum and plasma (dipotassium EDTA and lithium heparin) using the Dimension® EXL™ integrated chemistry system with LOCI® Module. The Dimension® EXL™ SARS-CoV-2 IgG (CV2G) 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 Dimension® EXL™ SARS-CoV-2 IgG (CV2G) 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 (CLIA) of 1988, 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 Dimension® EXL™ SARS-CoV-2 IgG (CV2G) 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 Dimension® EXL™ SARS-CoV-2 IgG (CV2G) assay may occur due to cross-reactivity from pre-existing antibodies or other possible causes.

The Dimension® EXL™ SARS-CoV-2 IgG (CV2G) 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 Angiotensin-converting enzyme 2 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.[14-23]

Principles of the Procedure

The Dimension EXL CV2G assay is a homogeneous, sandwich chemiluminescent immunoassay based on Luminescent Oxygen Channeling Immunoassay (LOCI) technology. The LOCI reagents include two synthetic bead reagents and a biotinylated anti-Human IgG antibody. The first bead reagent (Sensibeads) is coated with streptavidin and contains photosensitizer dye. The second bead reagent (Chemibeads) is coated with anti-FITC (Fluorescein isothiocyanate) antibody and contains chemiluminescent dye. For this assay the anti-FITC antibody coated-Chemibeads are predecorated with fluoresceinated S1 RBD antigen. The patient sample is incubated with Chemibeads. After 1 minute the biotinylated antibody is added to form bead-SARS-CoV-2 antigen-biotinylated antibody sandwiches. After incubation, Sensibeads are added and bind to the biotin to form bead-pair immunocomplexes. Illumination of the complex at 680 nm generates singlet oxygen from Sensibeads which diffuses into the Chemibeads, triggering a chemiluminescent reaction. The resulting signal is measured at 612 nm and is a direct function of the amount of SARS-CoV-2 IgG antibody present in the sample.[24-26]

Reagents

Material Description	Storage	Stability[a]
Dimension EXL CV2G	Unopened at 2–8°C	Until expiration date on product
Wells 1–2[c] Liquid Chemibeads (200 µg/mL, recombinant S1 RBD antigen); bovine serum albumin; mouse IgG	Onboard[b] Open well	30 days 3 days
Wells 3–4 Liquid biotinylated antibody (40 µg/mL, monoclonal mouse anti-human IgG); mouse IgG; bovine serum albumin; bovine gamma globulin; goat serum[d]		
Wells 5–6 Liquid Sensibeads (1500 µg/mL); bovine serum albumin; human gamma globulin		
Wells 7–8 Assay buffer; bovine serum albumin		

[a] Refer to *Storage and Stability*.
[b] Refer to *Onboard Stability*.
[c] Wells are numbered consecutively from the wide end of the cartridge.
[d] Goat serum contains sodium azide (0.00062%).

Warnings and Precautions

For *in vitro* diagnostic use.

For Prescription Use Only.

For Use Under Emergency Use Authorization Only.

This test has not been FDA cleared or approved, but has been authorized for emergency use 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.

The emergency use of 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 declaration is terminated or authorization is revoked sooner.

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

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

Warning!
May cause an allergic skin reaction. Harmful to aquatic life with long lasting effects.
Wear protective gloves/protective clothing/eye protection/face protection. Avoid release to the environment. 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); (Dimension EXL CV2G)

Warning! Potential Biohazard

Contains human source material.

Caution: All products containing human source material should be treated as potentially infectious. Source material from human blood from which this product was derived was found negative when tested in accordance with current FDA required tests described in 21 CFR 610.40(a) and (b). No known test methods can offer assurance that products derived from human sources will not transmit infectious agents; this material should be handled using good laboratory practices and universal precautions.

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 unopened product at 2–8°C. Do not use products beyond the expiration date printed on the product labeling.

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

Onboard Stability

Discard products at the end of the onboard stability interval.

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

Do not use products beyond the expiration date printed on the product labeling.

Specimen Collection and Handling

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

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.

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]
- Specimens with high turbidity or particulates should be centrifuged before analysis.

- Allow blood specimens to clot completely before centrifugation.[30]
- Keep tubes capped at all times.[30]

Storing the Specimen

Test specimens as soon as possible after collecting. Store specimens at 2–8°C if not tested immediately within 16 hours.[31]

Separated specimens in the primary collection device are stable for up to 7 days at 2–8°C.[31]

Separated specimens may be frozen for up to 1 month at ≤ -20°C. The samples may be frozen once. Do not store in a frost-free freezer. Thoroughly mix thawed specimens and centrifuge before using.

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.

Store samples capped and upright at 2–8°C upon arrival. If shipment is expected to exceed 7 days, ship specimens frozen.

Preparing the Samples

This assay requires 2 µL of serum or plasma 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 information about determining the minimum required volume, refer to the Dimension EXL Operator's Guide and Online Help.

Do not use samples with apparent contamination.

Remove particulates by centrifugation according to CLSI guidance and the collection device manufacturer's recommendations.[30]

For a complete list of appropriate sample containers, refer to the Dimension EXL Operator's Guide and Online Help.

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

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

Procedure

Materials Provided

The following materials are provided:

REF	Contents	Number of Tests
RF870 11417770	Dimension EXL CV2G Flex Reagent Cartridge	8 x 60

Materials Required but Not Provided

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

REF	Description	
	Dimension EXL with LOCI Module Dimension EXL 200	
KC872 11417772	SARS-CoV-2 IgG calibrator (COV2G CAL/CV2G CAL)	2 x 1.0 mL calibrator level 1/A 2 x 1.0 mL calibrator level 2/B 2 x 1.0 mL calibrator level 3/C 2 x 1.0 mL calibrator level 4/D 2 x 1.0 mL calibrator level 5/E
KC873 11417773	SARS-CoV-2 IgG Quality Control (COV2G QC/CV2G QC)	6 x 1.0 mL positive quality control 6 x 1.0 mL negative quality control
RXV1A 10445044	Dimension Heterogeneous Immunoassay Module Reaction Vessels	

Assay Procedure

For information about loading samples and ordering tests, refer to the Dimension EXL Operator's Guide and Online Help.

Semiquantitative Mode

The system automatically defaults to semiquantitative mode.

Qualitative Mode

For information about running in qualitative mode, refer to the Dimension EXL Operator's Guide and Online Help.

Note Use the following settings in the configuration screen.

1. Set units to **QUAL**.
2. Change calculation type to **Linear**.
3. Select **suppress numerical values**.
4. Store changes.

The system automatically performs the following steps:

1. For serum or plasma, delivers 20 µL of antigen-coated Chemibeads into the reaction vessel.
2. Adds 2 µL of sample into the reaction vessel.
3. Dispenses 20 µL of the biotinylated antibody reagent into the reaction vessel.
4. Briefly mixes and incubates for 12 minutes at 37°C.
5. Dispenses 20 µL of the Sensibeads into the reaction vessel.
6. Incubates the mixture at 37°C.
7. Dispenses 100 µL of the Assay Buffer into the reaction vessel.
8. Illuminates the complex at 680 nm. This generates singlet oxygen from the Sensibeads which diffuses into the Chemibeads, triggering a chemiluminescent reaction.

9. Measures emission at 612 nm and is a direct function of the total SARS-CoV-2 antibody concentration in the sample.
10. Reports “POS”, “NEG” results (qualitative and semiquantitative mode) and Ind values (semiquantitative mode) for “POS” results within the acceptable measuring interval.

Test Duration: approximately 16 minutes

Preparing the Reagents

All reagents are liquid and ready to use.

Preparing the System

For information about loading reagents, refer to the Dimension EXL Operator's Guide and Online Help.

Performing Calibration

For calibration of the Dimension EXL CV2G assay, use SARS-CoV-2 IgG calibrator (COV2G CAL/CV2G CAL). Use the calibrators in accordance with the calibrator instructions for use.

Calibration Procedure

Semiquantitative Mode

Refer to the Dimension EXL Operator's Guide and Online Help to set up and run a 5 level LOGIT calibration for semiquantitative calibration.

Qualitative Mode

Refer to the steps below for qualitative calibration.

1. Configure the assay to use QUAL units. Refer to the Dimension EXL Operator's Guide and Online Help.
2. Enter the following calibrator information in the fields on the **Enter Data** screen:
   - **Position:** Segment letter and position number of CAL 2/B
   - **Patient Name:** Enter Calibrator name
   - **Sample No.:** Enter Calibrator Lot No.
   - **Location:** Leave blank
   - **Tests:** Request three tests for the Dimension EXL CV2G assay
   - **Mode:** Select **F7: Next Mode**, change field to **Sample Cup**
   - **Priority:** Select **F4: Next Priority**, change field to **QC**
   - **Fluid:** Select **F8: Next Fluid**, change field to **Serum QC3**

   WARNING

   When processing Dimension EXL CV2G, **Serum QC3** is reserved for the calibrator. An erroneous calibration of the assay could occur if any other fluid designation or material is used.
3. Add a minimum of 0.1 mL of the SARS-CoV-2 IgG calibrator (COV2G CAL/CV2G CAL) level 2 to a 1.5 mL sample cup.
4. Place the sample cup into the segment position entered on the **Enter Sample Data** screen.

5. Select **F2: Process Single**.

   The following message will appear:

   This fluid (Serum QC 3) will calibrate a CV2G method. Continue? (y/n)

6. Select **y** to begin the calibration.
7. When calibration is completed, run the SARS-CoV-2 IgG Quality Control (COV2G QC/CV2G QC).

Calibration Frequency

Calibrate the assay every 14 days.

In addition, perform a calibration:

- At the end of the calibration interval.
- When changing lot numbers of reagents.
- When indicated by quality control results.
- After major maintenance or service.

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

Performing Quality Control

For quality control of the Dimension EXL CV2G, use the SARS-CoV-2 IgG Quality Control (COV2G QC/CV2G QC) or an equivalent product at least once during each day that samples are analyzed. Additional quality control material can be used at the discretion of the laboratory. Use the quality control material in accordance with the quality control instructions for use.

In addition, perform quality control:

- Following a valid calibration.
- With use of a new lot of reagent.
- When troubleshooting test results that do not match clinical conditions or symptoms.

Follow government regulations or accreditation requirements for quality control frequency.

Acceptable performance is achieved when the analyte values obtained are within the expected control interval for the system, as indicated by the manufacturer of the control material or within the interval determined by an internal laboratory quality control procedure.

Individual laboratory quality control programs and procedures may require more frequent quality control testing. For information about entering quality control definitions, refer to the Dimension EXL Operator's Guide and Online Help.

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 Dimension EXL Operator's Guide and Online Help.

Results

Calculation of Results

The system determines the result using the calculation scheme described in the Dimension EXL Operator's Guide and Online Help. If using this assay in qualitative mode, the system reports the results as "POS" or "NEG" relative to the assay cutoff. The Dimension EXL CV2G assay cutoff analyte value is 1000 QUAL units and is used to distinguish between positive and negative. If using this assay in semiquantitative mode, the system reports the results as "POS" or "NEG" relative to the assay cutoff and a numeric value in Ind units for "POS" results within the acceptable measuring interval. The Dimension EXL CV2G assay cutoff analyte value is 1000 Ind units and is used to distinguish between positive and negative. If using this assay as semiquantitative use Ind units. Refer to *Interpretation of Results*.

Interpretation of Results

Note Refer to *Calculation of Results* for differences between semiquantitative and qualitative results.

Interpretation of Results in Qualitative Mode

Analyte Value	Result	Test Result Interpretation
< 1000 QUAL	NEG	IgG antibodies to SARS-CoV-2 are not detected
≥ 1000 QUAL	POS	IgG antibodies to SARS-CoV-2 are detected

Interpretation of Results in Semiquantitative Mode

Analyte Value	Interpretation	Description
< 1000 Ind	NEG	IgG antibodies to SARS-CoV-2 are not detected
≥ 1000 Ind to 140,000 Ind	POS; Numerical value is reported to the end user	IgG antibodies to SARS-CoV-2 are detected
> 140,000 Ind	POS; Value above ULMI is not reported[a]	IgG antibodies to SARS-CoV-2 are detected

[a] ULMI- upper limit of 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:

- The clinical applicability of a quantitative or semiquantitative result is currently unknown and cannot be interpreted as an indication or degree of immunity nor protection from infection, 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 manufacturer's assays for specific SARS-CoV-2 serological markers.
- Performance of the assay has not been established with cord blood, neonatal specimens, cadaver specimens, or body fluids other than serum or plasma.

- 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 obtained with the assay may not be used interchangeably with values obtained with different manufacturer's 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 positive test 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 positive 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.
- Due to the risk of false positive results, confirmation of positive results should be considered using a second, different IgG assay.
- A negative test 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.
- A negative test result does not exclude the possibility of exposure to or infection with SARS-CoV-2. 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 negative if collected during the early (preseroconversion) 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.
- The test may have lower sensitivity for IgG detection in symptomatic individuals prior to 8 days since symptom onset.
- 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.
- The performance of this test was established based on the evaluation of a limited number of clinical specimens collected from the United States prior to mid November 2019 and between April 2020 to June 2020. 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.
- 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.

Conditions of Authorization for the Laboratory

The Dimension EXL CV2G 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 Dimension EXL CV2G assay ("your product" in the conditions below) must adhere to the Conditions of Authorization indicated in the Letter of Authorization as listed below:

- Authorized laboratories[a] using your product 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 your product must 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 Dimension EXL CV2G assay are not permitted.
- Authorized laboratories that receive your product must notify the relevant public health authorities of their intent to run the assay prior to initiating testing.
- Authorized laboratories using your product 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 your product and report to DMD/OHT7-OIR/OPEQ/ CDRH (via email: CDRH EUA Reporting@fda.hhs.gov) and Siemens Healthineers Technical Support (tel: +1 (800) 441-9250) any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of the assay of which they become aware.
- All laboratory personnel using your product must be appropriately trained in automated immunoassay techniques and use appropriate laboratory and personal protective equipment when handling this kit, and use your product 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 your product.
- Siemens Healthineers, authorized distributors, and authorized laboratories using the Dimension EXL CV2G 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

Measuring Interval

Note Refer to *Calculation of Results* for differences between semiquantitative and qualitative results.

The measuring interval for the Dimension EXL CV2G assay is 610–140,000 Ind. Results are reported as positive (≥ 1000 Ind) or negative (< 1000 Ind). Positive results are reported in semiquantitative numeric mode with a value in Ind units within the measuring interval.

Note Positive results indicated above the upper limit of the assay measuring interval should be reported as qualitatively positive and the numeric value should be reported as "> 140,000 Ind". Do not report numeric values above 140,000 Ind with the assay range flag.

Detection Capability

Note This section does not apply when running the assay in qualitative mode.

Detection capability was determined in accordance with CLSI Document EP17-A2.[32]

Assay 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 LoB is 550 Ind.

The LoD corresponds to the lowest concentration of IgG antibodies to SARS-CoV-2 that can be detected with a probability of 95%. The LoD is 610 Ind.

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 is 610 Ind.

The lower limit of the measuring interval is defined by the LoQ (610 Ind), however, report negative patient results as < 1000 Ind.

Seroconversion Sensitivity

Up to 17 serial draws from 12 SARS-CoV-2 PCR positive patients from the United States were collected and evaluated using the Dimension EXL CV2G assay. All samples were tested in singlicate. The seroconversion study demonstrates the change in CV2G results over time. At this time, it is unknown for how long antibodies persist following infection and if the presence of antibodies confers protective immunity. The following results were obtained.

Panel ID	Bleed Number	Days Post PCR Positive	Ind	Result Interpretation
Panel 1	1	4	802	Negative
	2	7	16,438	Positive
	3	24	138,587	Positive
	4	25	>140,000	Positive
	5	26	>140,000	Positive
	6	27	>140,000	Positive
	7	28	>140,000	Positive
	8	29	>140,000	Positive
	9	30	138,654	Positive
	10	31	135,692	Positive
Panel 2	1	7	2557	Positive
	2	10	8639	Positive
	3	22	23,782	Positive
	4	24	37,343	Positive

Panel ID	Bleed Number	Days Post PCR Positive	Ind	Result Interpretation
Panel 3	1	4	2167	Positive
	2	5	5551	Positive
	3	6	12,051	Positive
	4	7	18,099	Positive
Panel 4	1	1	1574	Positive
	2	3	12,262	Positive
	3	4	19,836	Positive
Panel 5	1	2	11,791	Positive
	2	3	30,757	Positive
Panel 6	1	9	44,381	Positive
	2	10	50,412	Positive
	3	11	52,248	Positive
	4	12	51,545	Positive
	5	13	53,331	Positive
	6	14	55,908	Positive
	7	15	59,657	Positive
Panel 7	1	8	>140,000	Positive
	2	9	>140,000	Positive
	3	9	>140,000	Positive
	4	10	>140,000	Positive
	5	11	>140,000	Positive
	6	12	>140,000	Positive
	7	13	129,883	Positive
	8	14	126,433	Positive
	9	15	118,496	Positive
	10	16	111,321	Positive
	11	17	104,512	Positive
	12	18	100,978	Positive
	13	19	80,972	Positive
	14	20	75,044	Positive
	15	21	75,621	Positive
	16	22	74,493	Positive
	17	23	80,278	Positive

Panel ID	Bleed Number	Days Post PCR Positive	Ind	Result Interpretation
Panel 8	1	22	60,041	Positive
	2	23	57,570	Positive
	3	24	56,516	Positive
	4	25	56,497	Positive
	5	26	55,860	Positive
	6	26	28,690	Positive
	7	27	32,661	Positive
Panel 9	1	7	14,992	Positive
	2	10	61,925	Positive
	3	11	73,330	Positive
	4	15	100,261	Positive
	5	16	106,057	Positive
	6	17	105,521	Positive
	7	18	109,147	Positive
	8	19	105,037	Positive
Panel 10	1	0	1536	Positive
	2	1	1795	Positive
Panel 11	1	5	632	Negative
	2	6	677	Negative
	3	7	864	Negative
	4	8	1226	Positive
	5	11	2280	Positive
	6	12	2937	Positive
	7	13	4068	Positive
Panel 12	1	0	10,773	Positive
	2	1	15,516	Positive

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

Clinical Agreement

Positive percent agreement and negative percent agreement were determined in accordance with CLSI Document EP12-A2.[33] The performance of the Dimension EXL CV2G assay was determined by testing a total of 1754 samples using the Dimension EXL system.

Positive Percent Agreement

Positive percent agreement was determined by testing 245 samples from individuals with a clinical diagnosis of COVID-19 based on a positive polymerase chain reaction (PCR) method and presented by days post-symptom onset. The results are shown in the table below:

Days Post Symptom Onset	N[a]	Positive	Negative	Positive Percent Agreement (95% CI)[b]
≤ 7	113	70	43	61.9% (52.7%–70.4%)
8–14	42	39	3	92.9% (81.0%–97.5%)
≥ 15	90	90	0	100.0% (95.9%–100.0%)

[a] Number of samples tested.
[b] Confidence Interval.

Negative Percent Agreement

Negative percent agreement was determined by testing 1509 samples collected prior to the COVID-19 outbreak (before mid-December 2019) from apparently healthy individuals and apparently healthy pregnant women in the United States. The results are shown in the table below:

Group	N[a]	Negative	Positive	Negative Percent Agreement (95% CI)[b]
Healthy Individuals	1442	1442	0	100.0% (99.7%–100%)
Healthy, Pregnant Women	67	67	0	100.0% (94.6%–100.0%)
Total	**1509**	**1509**	**0**	**100.0% (99.7%–100.0%)**

[a] Number of samples tested.
[b] Confidence Interval.

Single Site Precision Study

The assay was designed to have the following precision.

Concentration Interval	Precision	
(Ind)	Repeatability (% CV)	Within-Laboratory (% CV)
800–2000	≤ 10.0% CV	≤ 12.0% CV
> 2000	≤ 12.0% CV	≤ 15.0% CV

Precision was determined in accordance with CLSI Document EP05-A3.[34] Samples were assayed on the Dimension EXL in duplicate in 2 runs per day for 20 days.

The following results were obtained:

Semiquantitative Analysis

			Repeatability (Within-Run)		Within-Laboratory (Total Precision)	
Specimen Type	**N[a]**	**Mean (Ind)**	**SD[b] (Ind)**	**CV[c] (%)**	**SD (Ind)**	**CV (%)**
Serum A	80	805	10.3	1.28	25.2	3.13
Serum C	80	926	8.9	0.97	26.5	2.86
Serum D	80	1405	14.2	1.01	44.3	3.15
Serum B	80	2854	40.3	1.41	101.7	3.56
Serum E	80	106,957	2295.4	2.15	3902.2	3.65
Control 1[d]	80	571	19.0	3.34	28.2	4.93
Control 2[e]	80	2239	49.9	2.23	137.6	6.15

[a] Number of results.
[b] Standard deviation.
[c] Coefficient of variation.
[d] Negative.
[e] Positive.

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

Precision Study for Evaluation of Instrument-to-Instrument and Lot-to-Lot Variability (Reproducibility)

Instrument and lot variability of the Dimension EXL CV2G assay was evaluated on 2 Dimension EXL 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 of the Dimension EXL CV2G assay are presented in the following table:

The following results were obtained:

			Repeatability		Between–Run		Between–Day		Between–Lot		Between Instrument/Site		Total Precision	
Specimen Type	N[a]	Mean (Ind)	SD[b] (Ind)	CV[c] (%)	SD (Ind)	CV (%)	SD (Ind)	CV (%)	SD (Ind)	CV (%)	SD (Ind)	CV (%)	SD (Ind)	CV (%)
Serum A	48	791	9.7	1.2	7.8	1.0	0.0	0.0	15.4	1.9	0.0	0.0	19.8	2.5
Serum C	48	920	17.4	1.9	0.0	0.0	7.9	0.9	7.1	0.8	10.7	1.2	23.0	2.5
Serum D	48	1409	24.9	1.8	0.0	0.0	6.8	0.5	30.5	2.2	0.0	0.0	40.0	2.8
Serum B	48	2894	42.3	1.5	26.3	0.9	24.4	0.8	154.7	5.3	114.9	4.0	200.5	6.9
Serum E	48	105,215	2802.9	2.7	0.0	0.0	2289.8	2.2	0.0	0.0	3535.7	3.4	5059.7	4.8
Control 1[d]	48	545	14.1	2.6	11.2	2.0	0.0	0.0	35.4	6.5	0.0	0.0	39.7	7.3
Control 2[e]	48	2394	48.4	2.0	27.5	1.1	0.0	0.0	226.3	9.4	0.0	0.0	233.0	9.7

[a] Number of results.
[b] Standard deviation.
[c] Coefficient of variation.
[d] Negative.
[e] Positive.

Specimen Equivalency

Specimen equivalency was determined using the weighted Deming linear regression model of matched sample sets (serum, dipotassium EDTA plasma, and lithium heparin plasma) from the same donors on the Dimension EXL 200 in accordance with CLSI Document EP35.[35] Slope, intercept and correlation coefficient were calculated. Results from plasma samples were compared to serum results. The following results were obtained:

Specimen (y)	N[a]	Sample Interval (Ind)	y-intercept	Slope	r[b]
Dipotassium EDTA plasma	45	1323–119,342	1.18	1.00	0.999
Lithium Heparin plasma	45	1323–119,342	-18.03	1.01	0.999

[a] Number of samples tested.

[b] Correlation coefficient.

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

Interferences

Interfering testing was performed on endogenous and potentially interfering substances commonly found in serum and plasma specimens in accordance with CLSI Document EP07-ED3.[36] Bias is the difference in the results between the control sample (does not contain the interferent) and the test sample (contains the interferent) expressed in percent. The Dimension EXL CV2G assay has ≤ 10% interference from hemoglobin, bilirubin, intralipid, biotin at 1200 ng/mL, and total protein. The Dimension EXL CV2G assay showed > 10% interference from biotin at 3500 ng/mL.

Hemolysis, Icterus, and Lipemia (HIL)

The following results were obtained:

Substance	Substance Concentration Conventional Units (SI Units)	Analyte Concentration (Ind)	Bias %
Hemoglobin	1000 mg/dL (0.625 mmol/L)	531 1189	2.0 -1.1
Bilirubin, conjugated	40 mg/dL (475 mmol/L)	541 1181	-1.4 -2.9
Bilirubin, unconjugated	40 mg/dL (684 mmol/L)	524 1165	1.9 0.2
Lipemia (Intralipid®)[a]	1500 mg/dL (16.95 mmol/L)	538 1192	-0.7 -2.0

[a] SI units calculated as triolein.

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

Interfering Substances

The following results were obtained:

Substance	Substance Concentration Conventional Units (SI Units)	Analyte Concentration (Ind)	Bias %
Biotin	1200 ng/mL	531 1187	-1.1 -5.1
Total Protein	18 g/dL	492 846 116,261	-4.3 -0.1 -1.7

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

Cross-Reactivity

Cross-reactivity was determined in accordance with CLSI Document EP07-ED3.[36] The assay was evaluated for potential cross-reactivity in specimens with other viral and microbial antibodies and other disease states. No false positives were observed with the potential cross-reactants tested below.

Clinical Category	Number Tested	Number Positive with Dimension EXL CV2G Assay
Adenovirus	5	0
Anti-Influenza A virus IgG and IgM	7	0
Anti-Influenza B virus IgG and IgM	10	0
Anti-hepatitis B virus IgG and IgM	10	0
Anti-Respiratory Syncytial Virus IgG	9	0
Antinuclear antibody (ANA)	10	0
Bordetella pertussis IgG	10	0
Cytomegalovirus IgG	5	0
Epstein Barr Virus	10	0
Hepatitis B core antigen (anti-HBc) IgM	16	0
Hepatitis B surface antigen (HBs Ag)	10	0
Hepatitis C virus (HCV) IgG and IgM	10	0
Human immunodeficiency virus (HIV) total antibody	10	0
Haemophilus influenzae IgG	10	0
Multiple myeloma	10	0
Streptococcus pneumoniae IgG	8	0
Treponema pallidum	10	0
Toxoplasma gondii IgG	9	0
Total	**169**	**0**

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

Linearity

Linearity testing was performed in accordance with CLSI Document EP06-A.[37] Patient pools containing high levels of SARS-CoV-2 IgG (1 serum, 1 dipotassium EDTA plasma, and 1 lithium heparin plasma) were diluted with negative basepool to prepare a dilution series comprised of nine test levels. Each level was tested in 3 replicates using 2 reagent lots in each specimen matrix using the Dimension EXL System. Linearity was evaluated for each type of specimen using 2 lots. Linearity was demonstrated for the analytical measuring interval of 610–140,000 Ind with deviations from linearity within 15%. Taking into consideration the estimates of LoB, LoD, LoQ, precision, and linearity, the analytical measuring interval of the Dimension EXL CV2G assay is 610–140,000 Ind.

Standardization

Values assigned to the SARS-CoV-2 IgG calibrator (COV2G CAL/CV2G CAL) are traceable to the established SARS-CoV-2 cutoff through the Dimension EXL system patient sample concordance testing.

Currently no reference standard is available for this assay.

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	Symbol	Symbol Title
	Legal Manufacturer		Authorized Representative in the European Community
	Use-by Date		Batch Code
	Catalog Number		Contains sufficient for <n> tests
	Consult Instruction for Use		Version of Instruction for Use
	Internet URL address to access the electronic instructions for use		Revision
	*In vitro* diagnostic medical device		Unique Device Identification (UDI) barcode
RxOnly	Prescription device (US only)		CE Marking

Symbol	Symbol Title	Symbol	Symbol Title
	CE Marking with Notified Body		Keep away from sunlight and/or heat
	Temperature Limit		Lower Limit of Temperature
	Upper Limit of Temperature		Do not freeze
	Do not re-use		This way up
	Recycle		Caution / Warning
	Biological Risk		Explosive (GHS)
	Flammable (GHS)		Oxidizing (GHS)
	Corrosive (GHS)		Toxic (GHS)
	Irritant (GHS)		Respiratory / Internal Health (GHS)
	Environmental (GHS)		Common Units
	International System of Units	**YYYY-MM-DD**	Date format (year-month-day)
YYYY-MM	Date format (year-month)		Printed with soy ink
	Mixing of substances		Non-sterile
	**Contents**		Reconstitution volume
	Level		Scalers

Legal Information

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SIEMENS

Dimension Vista® System
Dimension® EXL™ integrated chemistry system
LOCI® Module

SARS-CoV-2 IgG Quality Control (COV2G QC/ CV2G QC)

Current Revision and Date[a]	Rev. 01, 2021-01	
Product Name	Dimension Vista/Dimension EXL SARS-CoV-2 IgG Quality Control (COV2G QC/CV2G QC)	REF KC873 11417773
Abbreviated Product Name	Dimension Vista COV2G QC Dimension EXL CV2G QC	
	6 x 1.0 mL positive quality control 6 x 1.0 mL negative quality control	
Systems	Dimension Vista System Dimension EXL with LOCI Module Dimension EXL 200	

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

CE

For USA

For Use Under Emergency Use Authorization Only.

For *in vitro* diagnostic use.

For Prescription Use Only.

Intended Use

The SARS-CoV-2 IgG Quality Control (COV2G QC/CV2G QC) material is an *in vitro* diagnostic product to monitor the accuracy of the SARS-CoV-2 IgG antibody assay (COV2G QC/CV2G QC) on the Dimension Vista® System and the Dimension® EXL™ integrated chemistry system with LOCI® module.

Material Description

Material Description	Storage	Stability[a]
Dimension Vista/Dimension EXL SARS-CoV-2 IgG Quality Control (COV2G QC/CV2G QC) 1.0 mL/vial Neg (-): human plasma base; Pos (+): bovine serum albumin containing SARS-CoV-2 Spike S1 Antibody	Unopened at -25 – -15°C	Until expiration date on product
	Opened at 2–8°C	10 days after opening product
	Punctured at 2–8°C[b]	10 days after puncturing product
	Unopened at 2–8°C	10 days after thaw

[a] Refer to *Storage and Stability*.

[b] Dimension Vista System.

Note Once the cap is removed, assigned values are stable for 10 days when re-capped immediately after use and stored at 2–8°C. Do not use re-capped vials on board the instrument.

Warnings and Precautions

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 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 product has been 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* 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. § 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.

H317, H412	**Warning!**
P280, P273,	May cause an allergic skin reaction. Harmful to aquatic life with long
P302+P352,	lasting effects.
P333+P313,	Wear protective gloves/protective clothing/eye protection/face protection.
P362+P364, P501	Avoid release to the environment. 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); (Dimension Vista/Dimension EXL COV2G QC/CV2G QC Pos and Neg)

Caution Potential Biohazard

Contains human source material.

Caution: 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.

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.

Note For information about quality control material preparation, refer to *Preparing the Quality Control Materials*.

Storage and Stability

Store unopened product at -25 to -15°C. Do not use products beyond the expiration date printed on the product labeling.

Do not refreeze.

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

Performing Quality Control

For quality control of the Dimension Vista COV2G and Dimension EXL CV2G assays, use the Dimension Vista/Dimension EXL COV2G QC/CV2G QC at least once during each day that samples are analyzed.

In addition, perform quality control:

- Following a valid calibration.
- With use of a new lot of reagent.
- When troubleshooting test results that do not match clinical conditions or symptoms.

Additional quality control material can be used at the discretion of the laboratory.

Qualitative

The Dimension Vista/Dimension EXL COV2G QC/CV2G QC should be used in accordance with the Dimension Vista/Dimension EXL COV2G QC/CV2G QC IFU. The Dimension Vista/Dimension EXL COV2G QC/CV2G QC is a separate qualitative (POS/NEG) quality control material. The system reports quality control results as "POS" or "NEG" relative to the assay cutoff.

Semiquantitative

The negative quality control will generate an "Assay Range" flag due to the assigned value being below the LoQ of 610 Ind units. This flag generation is expected. Troubleshooting is recommended when quality control recovery is outside the lot-specific range listed in the lot-specific value sheet or laboratory generated quality control ranges. Dilution studies are not necessary with a known standard or quality control with the Dimension EXL CV2G assay when this flag is generated for the negative quality control.

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

- For the assigned values and quality control definitions, refer to the quality control lot-specific value sheet CONTROL LOT VAL provided. The assigned values are traceable to the standardization of the assay.

For instructions about how to perform the quality control procedure, refer to the Dimension EXL Operator's Guide and Online Help or Dimension Vista Operator's Guide and Online Help.

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 Dimension EXL Operator's Guide and Online Help or Dimension Vista Operator's Guide and 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.

Preparing the Quality Control Materials

Quality controls are frozen. Allow to equilibrate to room temperature (18–30°C) for one hour (no more than two hours), then gently mix and invert the vials to ensure homogeneity of the material. The required volume for testing depends on the number of replicates. For information about sample volume requirements, refer to the Dimension EXL Operator's Guide and Online Help or Dimension Vista Operator's Guide and Online Help.

Note Use quality control material within the stability limits specified in *Storage and Stability* and discard any remaining material.

Quality Control Procedure

The required volume for testing depends on the number of replicates. For information about sample volume requirements, refer to the Dimension EXL Operator's Guide and Online Help or Dimension Vista Operator's Guide and Online Help.

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

- For the assigned values and quality control definitions, refer to the quality control lot-specific value sheet CONTROL LOT VAL provided. The assigned values are traceable to the standardization of the assay.
- 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 Dimension EXL Operator's Guide and Online Help or Dimension Vista Operator's Guide and Online Help.

Taking Corrective Action

Acceptable performance is achieved when the analyte values obtained are within the expected control interval for the system, as indicated by the manufacturer of the control material or within the interval determined by an appropriate internal laboratory quality control scheme.

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. If the results continue to fall outside your laboratory's protocol, recalibrate the assay and run the controls again.

If necessary, contact your local technical support provided or distributor for assistance.

Limitations

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

The Dimension Vista/Dimension EXL SARS-CoV-2 IgG Quality Control (COV2G QC/CV2G QC) is only for use with the Dimension Vista/Dimension EXL SARS-CoV-2 IgG antibody assay (COV2G/CV2G). Assay values have not been established for assays other than SARS-CoV-2 IgG Quality Control (COV2G QC/CV2G QC).

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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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. *Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline—Fourth Edition*. Wayne, PA: Clinical and Laboratory Standards Institute; 2014. CLSI Document M29-A4.
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Definition of Symbols

The following symbols may appear on the product labeling:

Symbol	Symbol Title	Symbol	Symbol Title
	Legal Manufacturer		Authorized Representative in the European Community
	Use-by Date		Batch Code
	Catalog Number		Contains sufficient for <n> tests

Symbol	Symbol Title	Symbol	Symbol Title
	Consult Instruction for Use		Version of Instruction for Use
	Internet URL address to access the electronic instructions for use		Revision
	*In vitro* diagnostic medical device		Unique Device Identification (UDI) barcode
RxOnly	Prescription device (US only)		CE Marking
	CE Marking with Notified Body		Keep away from sunlight and/or heat
	Temperature Limit		Lower Limit of Temperature
	Upper Limit of Temperature		Do not freeze
	Do not re-use		This way up
	Recycle		Caution / Warning
	Biological Risk		Explosive (GHS)
	Flammable (GHS)		Oxidizing (GHS)
	Corrosive (GHS)		Toxic (GHS)
	Irritant (GHS)		Respiratory / Internal Health (GHS)
	Environmental (GHS)		Common Units
	International System of Units	**YYYY-MM-DD**	Date format (year-month-day)
YYYY-MM	Date format (year-month)		Printed with soy ink
	Mixing of substances		Non-sterile

Symbol	Symbol Title	Symbol	Symbol Title
CONTENTS	Contents	→	Reconstitution volume
LEVEL	Level	SCALERS	Scalers

Legal Information

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SIEMENS

Dimension Vista® System
Dimension® EXL™ integrated chemistry system
LOCI® Module

SARS-CoV-2 IgG calibrator (COV2G CAL/ CV2G CAL)

Current Revision and Date[a]	Rev. 01, 2021-01	
Product Name	Dimension Vista/Dimension EXL SARS-CoV-2 IgG calibrator (COV2G CAL/ CV2G CAL)	REF KC872 11417772
Abbreviated Product Name	Dimension Vista COV2G CAL Dimension EXL CV2G CAL	
	2 x 1.0 mL calibrator level 1/A 2 x 1.0 mL calibrator level 2/B 2 x 1.0 mL calibrator level 3/C 2 x 1.0 mL calibrator level 4/D 2 x 1.0 mL calibrator level 5/E	
Systems	Dimension Vista System Dimension EXL with LOCI Module Dimension EXL 200	

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

CE

For USA

For Use Under Emergency Use Authorization Only.

For *in vitro* diagnostic use.

For Prescription Use Only.

Intended Use

The SARS-CoV-2 IgG calibrator (COV2G CAL/CV2G CAL) is an *in vitro* diagnostic product for calibration of the SARS-CoV-2 IgG antibody assays (COV2G/CV2G) on the Dimension Vista® System and the Dimension® EXL™ integrated chemistry system with LOCI® module.

Material Description

Material Description	Storage	Stability[a]
Dimension Vista/Dimension EXL SARS-CoV-2 IgG calibrator (COV2G CAL/CV2G CAL) 1.0 mL/vial Level 1/A: human plasma base; Level 2/B: human plasma base containing SARS-CoV-2 Spike S1 Antibody; Levels 3/C, 4/D, and 5/E: bovine serum albumin containing SARS-CoV-2 Spike S1 Antibody	Unopened at -25 – -15°C	Until expiration date on product
	Opened at 2–8°C	10 days after opening product
	Punctured at 2–8°C[b]	10 days after puncturing product
	Unopened at 2–8°C	10 days after thaw

[a] Refer to *Storage and Stability*.

[b] Dimension Vista System.

Note Once the cap is removed, assigned values are stable for 10 days when re-capped immediately after use and stored at 2–8°C. Do not use re-capped vials on board the instrument.

Warnings and Precautions

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 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 product has been 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* 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. § 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.

H317, H412	**Warning!**
P280, P273,	May cause an allergic skin reaction. Harmful to aquatic life with long
P302+P352,	lasting effects.
P333+P313,	Wear protective gloves/protective clothing/eye protection/face protection.
P362+P364, P501	Avoid release to the environment. 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); (Dimension Vista/Dimension EXL COV2G CAL/CV2G CAL Levels 1/A, 2/B, 3/C, 4/D, and 5/E)

Caution Potential Biohazard

Contains human source material.

Caution: 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.

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.

Note For information about calibrator preparation, refer to *Preparing the Calibrators*.

Storage and Stability

Store unopened product at -25 to -15°C. Do not use products beyond the expiration date printed on the product labeling.

Do not refreeze.

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

Performing Calibration

For calibration of the Dimension Vista/Dimension EXL SARS-CoV-2 IgG antibody assay (COV2G/CV2G), use SARS-CoV-2 IgG calibrator (COV2G CAL/CV2G CAL).

Use the following lot-specific materials to perform calibration:

- For the assigned values and calibrator definitions, refer to the calibrator lot-specific value sheet CAL LOT VAL provided. The assigned values are traceable to the standardization of the assay.

Perform a calibration:

- At the end of the calibration interval.
- When changing lot numbers of reagents.

- When indicated by quality control results.
- After major maintenance or service.

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

For instructions about how to perform the calibration procedure, refer to the Dimension EXL Operator's Guide and Online Help or Dimension Vista Operator's Guide and Online Help.

For information about calibration, refer to the assay instructions for use.

Preparing the Calibrators

Calibrators are frozen. Allow to equilibrate to room temperature (18-30°C) for one hour (no more than two hours), then gently mix and invert the vials to ensure homogeneity of the material.

Calibration Procedure

Use the following lot-specific materials to perform calibration:

- For the assigned values and calibrator definitions, refer to the calibrator lot-specific value sheet CAL LOT VAL provided. The assigned values are traceable to the standardization of the assay.
- Generate lot-specific barcode labels to use with the calibrator samples, if necessary.

For instructions about how to perform the calibration procedure, refer to the Dimension EXL Operator's Guide and Online Help or Dimension Vista Operator's Guide and Online Help.

Technical Assistance

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

siemens-healthineers.com

References

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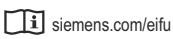	Internet URL address to access the electronic instructions for use		Revision
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	Irritant (GHS)		Respiratory / Internal Health (GHS)
	Environmental (GHS)		Common Units

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YYYY-MM	Date format (year-month)	PRINTED WITH SOY INK	Printed with soy ink
	Mixing of substances		Non-sterile
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