SIEMENS

Dimension Vista® System

SARS-CoV-2 Total Antibody assay (COV2T)

For Use Under Emergency Use Authorization Only.

For *in vitro* diagnostic use.

For Prescription Use Only.

Current Revision and Date[a]	Rev. 02, 2022-01	
Product Name	Dimension Vista SARS-CoV-2 Total antibody assay (COV2T)	REF K7414 11417414
Abbreviated Product Name	Dimension Vista COV2T	
Test Name/ID	COV2T	
Systems	Dimension Vista System	
Materials Required but Not Provided	SARS-CoV-2 Total antibody calibrator (COV2T CAL/CV2T CAL)	REF KC813 11417413
	SARS-CoV-2 Total antibody Quality Control (COV2T/CV2T) Pos/Neg	REF KC815 11417415
Specimen Types	Serum, dipotassium EDTA plasma, lithium heparin plasma	
Sample Volume	10 µL	
Measuring Interval	The assay reports results as positive or negative	

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

Intended Use

The Dimension Vista® SARS-CoV-2 Total antibody assay (COV2T) is for *in vitro* diagnostic use in the qualitative detection of total antibodies (including IgG and IgM) to SARS-CoV-2 in human serum and plasma (dipotassium EDTA and lithium heparin) using the Dimension Vista® System.

This assay is intended 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 Vista® SARS-CoV-2 Total antibody assay (COV2T) 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 antibodies. 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 Vista® SARS-CoV-2 Total antibody assay (COV2T) 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 Vista® SARS-CoV-2 Total antibody assay (COV2T) may occur due to cross-reactivity from pre-existing antibodies or other possible causes.

The Dimension Vista® SARS-CoV-2 Total antibody assay (COV2T) is only for use under the Food and Drug Administration's Emergency Use Authorization.

Summary and Explanation

The Dimension Vista COV2T assay is a chemiluminescent immunoassay used for the detection of total antibodies to SARS-CoV-2 in human serum and plasma from patients who may have been exposed to coronavirus disease (COVID-19).

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] About 20% of infections identified to date produce severe disease, principally the Acute Respiratory Distress Syndrome (ARDS) requiring intensive care unit treatment.[4,8,9] Differentiating COVID-19 from other respiratory pathogens is essential for implementing infection control measures, such as isolation and contact tracing, as well as clinical monitoring and support.

Diagnosis of current infection with SARS-CoV-2 relies primarily on molecular testing for the viral RNA using a swab collection for sputum or throat/nasal secretions.[10,11] SARS-CoV-2 RNA testing is recommended as the most sensitive diagnostic test for early infection, as viral RNA can be detected prior to antibody seroconversion.[12,13] Production of antibodies to the virus (such as IgM and IgG) occur within 15 days in most patients, and seroconversion can be coincident with the continued detection of viral RNA.[13-16]

Serology testing is essential for disease surveillance. This is particularly true for understanding viral prevalence, as most infections cause mild or no symptoms. Assessment of antibodies to SARS-CoV-2 virus in the population aids in the understanding of disease spread (both current and recovered) and may support the assessment of immunity should the presence of antibodies prove to be protective.

Principles of the Procedure

The Dimension Vista COV2T assay is a homogeneous, sandwich chemiluminescent immunoassay based on LOCI technology. The LOCI reagents include two synthetic bead reagents and a biotinylated S1 RBD antigen. 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. Sample is incubated with Chemibeads. After 1 minute the biotinylated antigen is added to form bead-CoV-2 antibody-biotinylated antigen 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 concentration in the sample.[17-19]

Reagents

Material Description	Storage	Stability[a]
Dimension Vista COV2T	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 antigen (2.0 µg/mL, recombinant S1 RBD); mouse IgG; bovine serum albumin; bovine gamma globulin; goat serum[d]		
Wells 5–6 Empty		
Wells 7–8 Liquid Sensibeads (650 µg/mL); bovine serum albumin		
Wells 9–12 Assay buffer; bovine serum albumin; bovine gamma globulin; goat serum[d]		

[a] Refer to *Storage and Stability*.
[b] *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 Use Under Emergency Use Authorization Only.

For *in vitro* diagnostic use.

For Prescription Use Only.

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

This test has not been FDA cleared or approved.

This test has been authorized by FDA under an Emergency Use Authorization (EUA) for use by authorized laboratories; laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C 263a, that meet the requirements to perform moderate or high complexity tests.

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

This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of *in vitro* 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.

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 Vista COV2T)

CAUTION

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

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

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

Storage and Stability

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

For 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, dipotassium EDTA plasma, and lithium heparin plasma 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.[20]
- Follow recommended procedures for collection of diagnostic blood specimens by venipuncture.[21]
- Follow the instructions provided with your specimen collection device for use and processing.[22]
- Specimens with high turbidity or particulates should be centrifuged before analysis.

- Allow blood specimens to clot completely before centrifugation.[23]
- Keep tubes capped at all times.[23]

Storing the Specimen

Test specimens as soon as possible after collecting. Store specimens at 2–8°C if not tested immediately within 16 hours.[24]

Separated specimens in the primary collection device are stable for up to 7 days at 2–8°C.[24]

Separated specimens may be frozen for up to 1 month at ≤ -20°C. Avoid more than 1 freeze-thaw cycle.[24] 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 10 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 system operating instructions.

Do not use samples with apparent contamination.

Remove particulates by centrifugation according to CLSI guidance and the collection device manufacturer's recommendations.[23]

For a complete list of appropriate sample containers, refer to the system operating instructions.

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
K7414 11417414	Dimension Vista COV2T Flex Reagent Cartridge	4 x 60

Materials Required but Not Provided

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

REF	Description	
	Dimension Vista System	
KC813 11417413	SARS-CoV-2 Total antibody calibrator (COV2T CAL/CV2T CAL)	3 x 1.0 mL calibrator level 1/A 3 x 1.0 mL calibrator level 2/B
KC815 11417415	SARS-CoV-2 Total antibody Quality Control (COV2T/CV2T) Pos/Neg	6 x 1 mL positive quality control 6 x 1 mL negative quality control

Assay Procedure

Note In software version 3.9.3 or higher, reagent carryover mitigations have been implemented and the next section may be skipped.

CAUTION (Software version 3.9.2)

Reagent carryover mitigations have not been determined for this assay and potential for interactions cannot be excluded.

Process the Dimension Vista COV2T assay separately from other assays.

Prior to processing the Dimension Vista COV2T assay for patient samples, QC, and calibration, allow all other tests to complete. Ensure that no other assays are submitted for processing until all Dimension Vista COV2T testing is complete and the analyzer is in Standby.

1. With the system in Standby, follow the instructions in the Manual Order Entry section of the Vista Operator's Guide to schedule a sample.

   Note Sample ID and Fluid type are required.

   Assign the Serum test panel **cleans5**, which has been added to the method panels. Select **Submit Order**.

   The **cleans5** test is used to clean and prime the sample and reagent probes and does not require that a sample is loaded.

2. Once that testing is complete, schedule the batch of Dimension Vista COV2T assays either by manual entry or via a LIS download.

   Ensure that QC is included if your laboratory procedure requires it.

3. Once the Dimension Vista COV2T testing is complete and the instrument returns to **STANDBY**, repeat Step 1 to complete the batch testing process.

4. After repeating the batch testing process, resume testing of other assays.

Note Siemens recommends that requests for Dimension Vista COV2T assay be assigned to a separate sample ID.

The system automatically performs the following steps:

1. For serum or plasma, deliver 20 µL of antigen-coated Chemibeads to the reaction vessel.
2. The system adds 10 µL of sample to the reaction vessel.
3. Dispenses 20 µL of the biotin antigen regent into the reaction vessel.
4. Briefly mix and incubate for 12 minutes at 37°C.
5. Dispenses 20 µL of the Sensibead into a reaction vessel.
6. Incubates the mixture at 37°C.

7. Dispense 100 µL of the Assay Buffer.
8. Illumination of the complex at 680 nm generates singlet oxygen from the 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 total SARS-CoV-2 antibody concentration in the sample.
9. Reports results.

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 system operating instructions.

Performing Calibration

For calibration of the Dimension Vista COV2T assay, use SARS-CoV-2 Total antibody calibrator (COV2T CAL/CV2T CAL). Use the calibrators in accordance with the calibrator instructions for use.

Calibration Procedure

The Dimension Vista COV2T assay uses a two-point qualitative calibration that is similar to the Urine Drugs of Abuse assays on the Dimension Vista System. Refer to *Urine Drugs of Abuse and Serum Toxicology Calibration* in the Vista Operators Guide.

Follow the steps in the Entering Calibrator IFU Information section described in Calibration and Quality Control in the Vista Operators Guide.

SARS-CoV-2 Total antibody calibrator (COV2T CAL/CV2T CAL)

- calibrator level 1/A = 0 QUAL Units
- calibrator level 2/B = 1000 QUAL Units

Note Perform calibration from cups for the Dimension Vista COV2T assay.

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 Vista COV2T, use the SARS CoV 2 Total antibody Quality Control (COV2T/CV2T Pos/Neg) 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 appropriate internal laboratory quality control scheme.

Individual laboratory quality control programs and procedures may require more frequent quality control testing. For information about entering quality control definitions, refer to the system operating instructions.

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 operating instructions.

Results

Calculation of Results

The system determines the result using the calculation scheme described in the system operating instructions. The system reports the results as “POS” or “NEG” relative to the assay cutoff. Refer to *Interpretation of Results*.

Interpretation of Results

The Dimension Vista COV2T assay cutoff analyte value is 1000 QUAL units and is used to distinguish between positive and negative.

- **Positive Results:** A specimen that gives an analyte value greater than or equal to 1000 QUAL units is interpreted as "positive".
- **Negative Results:** A specimen that gives analyte values less than 1000 QUAL units is interpreted as "negative". Either the specimen does not contain detectable antibodies or antibodies are present in concentrations below the cutoff value for this assay.

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 test should not be used to diagnose or exclude active infection. Results are not intended to be used as the sole basis for patient management decisions. Test results should be interpreted in conjunction with clinical observations, patient history, epidemiological information and other laboratory findings.
- The performance of the assay has not been established with cord blood, neonatal specimens, cadaver specimens, or body fluids other than serum or plasma.
- 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.
- Patient specimens may be negative 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.
- A positive result may not indicate previousSARS-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.
- The performance of this test was established based on the evaluation of a limited number of clinical specimens. Clinical performance has not been established with 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.

Conditions of Authorization for the Laboratory

The Dimension Vista COV2T 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/in-vitro-diagnostics-euas

However, to assist clinical laboratories using the Dimension Vista COV2T assay, the relevant Conditions of Authorization are listed below:

- Authorized laboratories[a] using the Dimension Vista COV2T 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 Dimension Vista COV2T 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 Dimension Vista COV2T assay are not permitted.
- Authorized laboratories that receive the Dimension Vista COV2T assay will notify the relevant public health authorities of their intent to run the assay prior to initiating testing.
- Authorized laboratories using the Dimension Vista COV2T 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 Dimension Vista COV2T assay 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 the Dimension Vista COV2T assay must be appropriately trained in automated immunoassay techniques and use appropriate laboratory and personal protective equipment when handling this kit, and use the Dimension Vista COV2T 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 Dimension Vista COV2T assay.
- Siemens Healthineers, authorized distributors, and authorized laboratories using the Dimension Vista COV2T 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, to perform moderate or high complexity tests" as "authorized laboratories".

Performance Characteristics

Measuring Interval

The Dimension Vista COV2T assay reports results as positive or negative.

Note Results indicated above assay range may be reported as positive.

Seroconversion Sensitivity

Up to 17 serial draws from 9 SARS CoV 2 PCR positive patients from the United States were collected and evaluated using the Dimension Vista COV2T assay. All samples were tested in singlicate. The following results were obtained.

Panel ID	Bleed Number	Days Post PCR Positive	QUAL Units	Result Interpretation
Panel 1	1	4	230	Negative
	2	7	9715	Positive
	3	24	> 30,000	Positive
	4	25	> 30,000	Positive
	5	26	> 30,000	Positive
	6	27	> 30,000	Positive
	7	28	> 30,000	Positive
	8	29	> 30,000	Positive
	9	30	> 30,000	Positive
	10	31	> 30,000	Positive
Panel 2	1	7	6778	Positive
	2	10	11,569	Positive
	3	22	15,431	Positive
	4	24	21,767	Positive

Panel ID	Bleed Number	Days Post PCR Positive	QUAL Units	Result Interpretation
Panel 3	1	4	14,052	Positive
	2	5	27,513	Positive
	3	6	> 30,000	Positive
	4	7	> 30,000	Positive
Panel 4	1	1	4130	Positive
	2	3	14,274	Positive
	3	4	19,256	Positive
Panel 5	1	2	21,827	Positive
	2	3	28,983	Positive
Panel 6	1	10	25,478	Positive
	2	11	27,077	Positive
	3	12	25,008	Positive
	4	13	28,925	Positive
	5	14	25,473	Positive
	6	16	26,188	Positive
	7	16	27,490	Positive
Panel 7	1	8	> 30,000	Positive
	2	9	> 30,000	Positive
	3	9	> 30,000	Positive
	4	10	> 30,000	Positive
	5	11	> 30,000	Positive
	6	12	> 30,000	Positive
	7	13	> 30,000	Positive
	8	14	> 30,000	Positive
	9	15	> 30,000	Positive
	10	16	> 30,000	Positive
	11	17	> 30,000	Positive
	12	18	> 30,000	Positive
	13	19	> 30,000	Positive
	14	20	> 30,000	Positive
	15	21	> 30,000	Positive
	16	22	> 30,000	Positive
	17	23	> 30,000	Positive

Panel ID	Bleed Number	Days Post PCR Positive	QUAL Units	Result Interpretation
Panel 8	1	22	17,706	Positive
	2	23	17,356	Positive
	3	24	14,554	Positive
	4	25	14,666	Positive
	5	26	12,566	Positive
	6	26	13,032	Positive
	7	27	13,408	Positive
Panel 9	1	7	15,028	Positive
	2	10	> 30,000	Positive
	3	11	> 30,000	Positive
	4	15	> 30,000	Positive
	5	16	> 30,000	Positive
	6	17	> 30,000	Positive
	7	18	> 30,000	Positive
	8	19	> 30,000	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.[25] The performance of the Dimension Vista COV2T assay was determined by testing a total of 1735 samples using the Dimension Vista System.

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

Positive Percent Agreement

Positive percent agreement was determined by testing 206 samples from individuals with a clinical diagnosis of COVID-19 based on a positive polymerase chain reaction (PCR) method and days post-symptom onset. The results are shown in the table below:

Days Post PCR Positive	N[a]	Positive	Negative	Positive Percent Agreement (95% CI)[b]
0–6	96	64	32	66.67% (57.32%–75.29%)
7–13	38	37	1	97.37% (94.72%–99.53%)
≥ 14	72	72	0	100.00% (95.83%–100.00%)

[a] Number of samples tested.

[b] Confidence Interval.

Days Post Symptom Onset	N[a]	Positive	Negative	Positive Percent Agreement (95% CI)[b]
0–6	81	52	29	64.20% (53.66%–73.78%)
7–13	46	42	4	91.30% (85.08%–96.57%)
≥ 14	79	79	0	100.00% (96.20%–100.00%)

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

Negative Percent Agreement

Negative percent agreement was determined by testing 1529 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]
Apparently Healthy	1462	1459	3	99.79% (99.66%–99.93%)
Apparently Healthy Pregnant Women	67	67	0	100.00% (98.80%–100.00%)
Total	**1529**	**1526**	**3**	**99.80% (99.67%–99.93%)**

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

Precision

The assay was designed to have the following precision.

Concentration Interval	Precision	
QUAL Units	Repeatability (Within-Run)	Within-Laboratory (Total Precision)
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.[26] Samples were assayed on the Dimension Vista System in duplicate in 2 runs per day for 20 days.

The following results were obtained:

Qualitative Analysis

Specimen Type	N[a]	Mean QUAL	Repeatability SD[b] QUAL	Repeatability CV[c] (%)	Within-Laboratory SD QUAL	Within-Laboratory CV (%)
Serum A	80	899	9.3	1.0	27.3	3.0
Serum B	80	2596	28.4	1.1	60.6	2.3
Control 1[d]	80	0	1.9	N/A[e]	2.3	N/A
Control 2[f]	80	1624	40.2	2.5	60.7	3.7

[a] Number of results.
[b] Standard deviation.
[c] Coefficient of variation.
[d] Negative.
[e] Not applicable.
[f] Positive.

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

Specimen Equivalency

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

Forty-five native matched samples (serum, lithium heparin, K_2EDTA) with PCR positive results from an FDA authorized device were tested n=1 on the Dimension Vista COV2T device. Specimen equivalency was determined using the Deming linear regression model using the Dimension Vista System in accordance with CLSI Document EP09-A3.[27] The following results were obtained:

Specimen (y)	N[a]	Sample Interval	Slope	r[b]
Potassium EDTA	45	1745–64,744	1.01	0.998
Lithium Heparin	45	1745–64,744	0.99	0.997

[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

Hemolysis, Icterus, and Lipemia (HIL)

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 Vista COV2T assay is designed to have ≤ 10% interference from hemoglobin, bilirubin, and intralipid. Bias > 10% is considered interference. Analyte results should not be corrected based on this bias.

Interfering testing was performed in accordance with CLSI Document EP07-ED3.[28] The following results were obtained:

Substance	Substance Concentration Conventional Units (SI Units)	Analyte Concentration QUAL Units	Bias %
Hemoglobin	1000 mg/dL (0.625 mmol/L)	39 1043	-6.2 1.1
Bilirubin, conjugated	40 mg/dL (475 µmol/L)	39 1114	-2.4 -4.8
Bilirubin, unconjugated	40 mg/dL (684 µmol/L)	39 1151	-3.5 -3.4
Lipemia (Intralipid)[a]	1500 mg/dL (16.95 mmol/L)	38 1077	1.0 -0.3

[a] SI units calculated as triolein.

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

Interfering Substances

Interference testing was performed in accordance with CLSI Document EP07-ED3.[28]

Biotin interference was measured by the paired difference approach for biotin concentrations of 1200 ng/mL and 600 ng/mL spiked into one negative patient pool and 3 positive patient samples (one low positive, one mid-range positive and one high positive). The qualitative patient results were not impacted up to 1200 ng/mL of biotin. Due to the nature of the interference, the specificity of the assay is not impacted by biotin. Negative patient results are unlikely to be misinterpreted as positive results as a consequence of biotin interference. The following results were obtained:

		Biotin Conc. ng/mL	
		600	**1200**
Negative Pool	**QUAL Units**	40	38
	% Bias	3	-1
	Result	Negative	Negative
Low Positive	**QUAL Units**	2366	1701
	% Bias	-4	-31
	Result	Positive	Positive
Mid-Range Positive	**QUAL Units**	20,162	14,791
	% Bias	-3	-29
	Result	Positive	Positive
High Positive	**QUAL Units**	43,131	31,847
	% Bias	-7	-32
	Result	Positive	Positive

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.[28] The assay was evaluated for potential cross-reactivity in specimens with other viral and microbial antibodies and other disease states. No false positive results were observed with the potential cross-reactants listed in the following table:

Clinical Category	Number Tested	Number Positive with Dimension Vista COV2T Assay
Anti-Influenza A	7	0
Anti-Influenza B	10	0
Anti-HBV	10	0
Antinuclear antibody (ANA)	10	0
Hepatitis B core antigen (anti-HBc) IgM	16	0
Hepatitis B surface antigen (HBs Ag)	10	0
Hepatitis C virus (HCV) antibody	10	0
Human immunodeficiency virus (HIV) antibody	10	0
Influenza antibody (unknown type)	10	0
Anti-Respiratory Syncytial Virus	9	0
Toxoplasma IgG	9	0
Total	**111**	**0**

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

Standardization

Values assigned to the SARS-CoV-2 Total antibody calibrator (COV2T CAL/CV2T CAL) are traceable to the established SARS-CoV-2 cutoff through the Dimension EXL and Dimension Vista 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
	CE Marking with Notified Body		Keep away from sunlight and/or heat
	Temperature Limit		Lower Limit of Temperature

Symbol	Symbol Title	Symbol	Symbol Title
	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)	UNITS C	Common Units
UNITS SI	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	**Contents**		Reconstitution volume
LEVEL	Level	SCALERS	Scalers

Legal Information

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