SIEMENS Healthineers

SARS-CoV-2 Total (COV2T)

For Use Under Emergency Use Authorization Only

For *in vitro* diagnostic use.

For prescription use only.

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

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

Current Revision and Date[a]	Rev. 03, 2021-05	
Product Name	Atellica IM SARS-CoV-2 Total (COV2T)	REF 11206711 (100 tests) REF 11206923 (500 tests)
Abbreviated Product Name	Atellica IM COV2T	
Test Name/ID	COV2T	
Systems	Atellica IM Analyzer	
Materials Required but Not Provided	Atellica IM COV2T QC	REF 11206712
Optional Materials	Atellica IM Multi-Diluent 2	REF 10995644
	Atellica IM COV2T MCM	REF 11207584
Specimen Types	Serum, potassium EDTA plasma, lithium heparin plasma	
Sample Volume	50 µL	
Measuring Interval	0.60–75.00 Index	

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

Intended Use

The Atellica® IM SARS-CoV-2 Total (COV2T) assay is a chemiluminescent immunoassay intended for the qualitative and semi-quantitative detection of total antibodies (including IgG and IgM) to SARS-CoV-2 in human serum and plasma (potassium EDTA and lithium heparin) using the Atellica® IM Analyzer. The Atellica IM SARS-CoV-2 Total (COV2T) 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 Atellica IM SARS-CoV-2 Total (COV2T) assay should not be used to diagnose or exclude acute SARS-CoV-2 infection. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C 263a, that meet requirements to perform moderate or high complexity tests.

Results are for the detection of SARS CoV-2 total 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 Atellica IM SARS-CoV-2 Total (COV2T) assay early after infection is unknown. Negative results do not preclude acute SARS-CoV-2 infection. If acute infection is suspected, direct testing for SARS-CoV-2 is necessary.

False positive results for the Atellica IM SARS-CoV-2 Total (COV2T) assay may occur due to cross-reactivity from pre-existing antibodies or other possible causes.

The Atellica IM SARS-CoV-2 Total (COV2T) 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] About 20% of infections identified to date produce severe disease, principally 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. Production of antibodies to the virus (such as IgM and IgG) occurs within 15 days in most individuals, and seroconversion can be coincident with the continued detection of viral RNA.[12-15]

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).

Principles of the Procedure

The Atellica IM COV2T assay is a fully automated 1-step antigen sandwich immunoassay using acridinium ester chemiluminescent technology, in which antigens are bridged by antibodies present in the sample. The Solid Phase contains a preformed complex of streptavidin-coated microparticles and biotinylated SARS-CoV-2 spike 1 receptor binding domain (S1 RBD) recombinant antigens. This reagent is used to capture anti-SARS-CoV-2 antibodies in the sample. The Lite Reagent contains acridinium-ester-labeled SARS-CoV-2 recombinant S1 RBD antigens used to detect anti-SARS-CoV-2 antibodies bound to the Solid Phase.

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

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

Reagents

Material Description	Storage	Stability
Atellica IM COV2T ReadyPack® primary reagent pack[a, b] **Lite Reagent** 10.0 mL/reagent pack Recombinant SARS-CoV-2 S1 RBD antigen (~0.3 µg/mL) labeled with acridinium ester in buffer; bovine serum albumin; goat serum; surfactant; sodium azide (< 0.1%) **Solid Phase** 10.0 mL/reagent pack Streptavidin-coated paramagnetic microparticles preformed with biotinylated SARS-CoV-2 S1 RBD antigen (~1.0 µg/mL) in buffer; bovine serum albumin; goat serum; surfactant; sodium azide (< 0.1%)	Unopened at 2–8°C Onboard	Until expiration date on product 28 days
Atellica IM COV2T CAL[a, b] 1.0 mL/vial Processed* human plasma nonreactive for antibodies to SARS-CoV-2 and processed* human plasma spiked with antibodies to SARS-CoV-2; sodium azide (< 0.1%) **Processed plasma is defibrinated and filtered plasma.*	Unopened at 2–8°C Opened at 2–8°C At room temperature	Until expiration date on product 60 days 8 hours
Atellica IM Multi-Diluent 2 ReadyPack ancillary reagent pack[a, b, c] 10.0 mL/pack Goat serum; sodium azide (0.1%); preservatives	Unopened at 2–8°C Onboard	Until expiration date on product 28 days

[a] Store in an upright position.

[b] Prevent exposure to sunlight and heat.

[c] Refer to *Optional Materials*.

Warnings and Precautions

For Use Under Emergency Use Authorization Only

For *in vitro* diagnostic use only.

For prescription use only.

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

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

The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of *in vitro* diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

CAUTION

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

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

CAUTION POTENTIAL BIOHAZARD

Contains human source material. Each donation of human blood or blood component was tested by FDA-approved methods for the presence of antibodies to human immunodeficiency virus type 1 (HIV-1) and type 2 (HIV-2), as well as for hepatitis B surface antigen (HBsAg) and antibody to hepatitis C virus (HCV). The test results were negative (not repeatedly reactive). No test offers complete assurance that these or other infectious agents are absent; this material should be handled using good laboratory practices and universal precautions.[16-18]

CAUTION

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

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

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

Storage and Stability

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

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

Onboard Stability

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

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

Specimen Collection and Handling

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

Collecting the Specimen

- Observe universal precautions when collecting specimens. Handle all specimens as if they are capable of transmitting disease.[18]
- Follow recommended procedures for collection of diagnostic blood specimens by venipuncture.[19]
- Follow the instructions provided with your specimen collection device for use and processing.[20]
- Allow blood specimens to clot completely before centrifugation.[17]
- Keep tubes capped at all times.[17]

Storing the Specimen

- Samples are stable for up to 24 hours onboard the system.
- Separated samples are stable for up to 3 days at room temperature, and for up to 5 days at 2–8°C.
- Thawed frozen specimens must be clarified by centrifugation prior to testing. Do not store in a frost-free freezer. Avoid more than 3 freeze-thaw cycles.
- Freeze samples, devoid of red blood cells, at ≤ -20°C for longer storage.

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

Transporting the Specimen

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

Store samples capped and upright at 2–8°C upon arrival. If shipment is expected to exceed 5 days, ship specimens frozen.

Preparing the Samples

This assay requires 50 µL of sample for a single determination. This volume does not include the unusable volume in the sample container or the additional volume required when performing duplicates or other tests on the same sample. For a complete list of appropriate sample containers and information about determining the minimum required volume, refer to the system online help.

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

Do not use samples with apparent contamination.

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

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

Remove particulates by centrifugation according to CLSI guidance and the collection device manufacturer's recommendations.[17]

Procedure

Materials Provided

The following materials are provided:

REF	Contents	Number of Tests
11206711	1 ReadyPack primary reagent pack containing Atellica IM COV2T Lite Reagent and Solid Phase Atellica IM COV2T master curve and test definition MC TDEF 1 vial Atellica IM COV2T CAL low calibrator CAL L 1 vial Atellica IM COV2T CAL high calibrator CAL H Atellica IM COV2T CAL calibrator assigned value sheet CAL LOT VAL	100
11206923	5 ReadyPack primary reagent packs containing Atellica IM COV2T Lite Reagent and Solid Phase Atellica IM COV2T master curve and test definition MC TDEF 2 vials Atellica IM COV2T CAL low calibrator CAL L 2 vials Atellica IM COV2T CAL high calibrator CAL H Atellica IM COV2T CAL calibrator assigned value sheet CAL LOT VAL	500

Materials Required but Not Provided

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

REF	Description	
	Atellica IM Analyzer[a]	
11206712	Atellica IM COV2T QC (quality control material)	2 x 2.0 mL negative quality control, level 1 CONTROL – 1 2 x 2.0 mL positive quality control, level 2 CONTROL + 2 Quality control assigned value sheet CONTROL LOT VAL

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

Optional Materials

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

REF	Description	
10995644	Atellica IM Multi-Diluent 2 (diluent)	2 ReadyPack ancillary reagent packs containing 10.0 mL/pack DIL
11207584	Atellica IM COV2T MCM (master curve material)	4 x 1.0 mL levels of master curve material MCM

Assay Procedure

The system automatically performs the following steps:

1. Dispenses 50 µL of sample into a cuvette.
2. Dispenses 100 µL of Solid Phase, then incubates for 3 minutes at 37°C.
3. Dispenses 100 µL of Lite Reagent, then incubates for 5 minutes at 37°C.

4. Separates, aspirates, then washes the cuvette with Atellica IM Wash.
5. Dispenses 300 µL each of Atellica IM Acid and Atellica IM Base to initiate the chemiluminescent reaction.
6. Reports results.

Preparing the Reagents

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

Preparing the System

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

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

Master Curve Definition

Before initiating calibration on each new lot of reagent, enter the assay master curve and test definition by scanning the MC TDEF 2D barcodes. For information about entering the master curve and test definition, refer to the system online help.

Performing Calibration

For calibration of the Atellica IM COV2T assay, use the calibrators provided with each kit.

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

Calibration Frequency

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

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

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

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

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

Preparing the Calibrators

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

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

Calibration Procedure

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

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

Use the following lot-specific materials to perform calibration:

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

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

Performing Quality Control

For quality control of the Atellica IM COV2T assay, use the Atellica IM COV2T QC at least once during each day that samples are analyzed. Use the quality control material in accordance with the quality control instructions for use. For the assigned values, refer to the quality control value sheet CONTROL LOT VAL provided.

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

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

Test quality control samples after a successful calibration.

Taking Corrective Action

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

Results

Calculation of Results

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

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

Dilutions

The measuring interval is 0.60–75.00 Index. For information about dilution options, refer to the system online help.

Dilute and retest samples with values > 75.00 Index to obtain accurate results.

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

For automated dilutions, perform the following activities.

- Load Atellica IM Multi-Diluent 2.
- Ensure that sufficient sample volume is available. Refer to the table below.
- Select the appropriate dilution factor.

For automatic dilutions, enter a dilution setpoint ≤ 75 Index.

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

Sample	Dilution	Sample Volume (µL)
Serum and plasma	1:5	50

Interpretation of Results

The system reports Atellica IM COV2T assay results in Index Values and as Nonreactive or Reactive:

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

Numeric results are reported for samples with values between 1.00 and 75.00 Index. Numeric results below 1.00 Index should not be reported outside of the laboratory. Results above 75.00 Index are reported as > 75.00 Index.

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

Limitations

The following information pertains to limitations of the assay:

- Use of the Atellica IM COV2T assay is limited to laboratory personnel who have been trained. Not for home use.
- False positive results may occur due to cross-reactivity from pre-existing antibodies or other possible causes.
- This assay has not been evaluated with fingerstick specimens. This test is not authorized for use with fingerstick whole blood.
- The clinical applicability of a semi-quantitative result is currently unknown and cannot be interpreted as an indication or degree of immunity nor protection from infection, nor can the results from this assay be compared to results from other SARS-CoV-2 antibody assays.
- This device should not be used to diagnose or exclude acute SARS-CoV-2 infection. Direct testing for SARS-CoV-2 with a molecular assay should be performed to evaluate acute infection in symptomatic individuals.

- Performance characteristics have not been established for the assay used in conjunction with other manufacturers' assays for specific SARS-CoV-2 serological markers. Laboratories are responsible for establishing their own performance characteristics.
- The performance of the assay has not been established with cord blood, neonatal specimens, cadaver specimens, or body fluids other than serum or plasma.
- Results obtained with the assay may not be used interchangeably with values obtained with different manufacturers' test methods.
- A positive result may not indicate previous SARS-CoV-2 infection. Consider other information, including clinical history and local disease prevalence, in assessing the need for a second, but different, serology test to confirm an immune response.
- A negative result for an individual subject indicates absence of detectable anti-SARS-CoV-2 antibodies. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. A negative result can occur if the quantity of the anti-SARS-CoV-2 antibodies present in the specimen is below the detection limits of the assay, or the antibodies that are detected are not present during the stage of disease in which a sample is collected.
- Performance has only been established with the specimen types listed in the Intended Use. Other specimen types have not been evaluated and should not be used with this assay.
- Results are not intended to be used as the sole basis for patient management decisions. Test results should be interpreted in conjunction with clinical observations, patient history, epidemiological information, and other laboratory findings.
- SARS-CoV-2 antibodies may not be detectable in individuals with recent infections (7–10 days or less) or in samples collected from individuals less than 7 days from a positive polymerase chain reaction (PCR) result. Specimens may be nonreactive if collected during the early (pre-seroconversion) phase of illness or due to a decline in titer over time. In addition, the immune response may be depressed in elderly, immunocompromised, or immunosuppressed patients.
- It is not known at this time if the presence of antibodies to SARS-CoV-2 confers immunity to re-infection.
- This test should not be used for donor screening to prevent SARS-CoV-2 transmission during blood, tissue, or organ donations.
- The performance of this test has not been established in individuals that have received a COVID-19 vaccine. The clinical significance of a positive or negative antibody result following COVID-19 vaccination has not been established, and the result from this test should not be interpreted as an indication or degree of protection from infection after vaccination.
- The performance of this test was established based on the evaluation of a limited number of clinical specimens. The samples for the negative percent agreement study were all collected prior to November 2019 from the US. The samples for the positive percent agreement study were collected between March and July 2020 from US-based vendors. 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.

Conditions of Authorization for the Laboratory

The Atellica IM SARS-CoV-2 Total (COV2T) assay Letter of Authorization, along with the authorized Fact Sheet for Healthcare Providers, the authorized Fact Sheet for Recipients, and authorized labeling are available on the FDA website:

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

However, to assist clinical laboratories using the Atellica IM SARS-CoV-2 Total (COV2T) assay, the relevant Conditions of Authorization are listed below:

- Authorized laboratories[a] using the Atellica IM SARS-CoV-2 Total (COV2T) assay must include, with test result reports, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.
- Authorized laboratories using the Atellica IM SARS-CoV-2 Total (COV2T) assay must use the product as outlined in the authorized labeling. Deviations from the authorized procedures, including the authorized instruments, authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to use the Atellica IM SARS-CoV-2 Total (COV2T) assay are not permitted.
- Authorized laboratories that receive the Atellica IM SARS-CoV-2 Total (COV2T) assay must notify the relevant public health authorities of their intent to run the assay prior to initiating testing.
- Authorized laboratories using the Atellica IM SARS-CoV-2 Total (COV2T) assay must have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.
- Authorized laboratories must collect information on the performance of the Atellica IM SARS-CoV-2 Total (COV2T) assay and report to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) and Siemens Healthineers Technical Support (https://www.siemens-healthineers.com/en-us/; tel: 1-877-229-3711) any suspected occurrence of false reactive or false nonreactive results and significant deviations from the established performance characteristics of the assay of which they become aware.
- All laboratory personnel using the Atellica IM SARS-CoV-2 Total (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 Atellica IM SARS-CoV-2 Total (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 the Atellica IM SARS-CoV-2 Total (COV2T) assay.
- Siemens Healthineers, authorized distributors, and authorized laboratories using the Atellica IM SARS-CoV-2 Total (COV2T) 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, to perform moderate or high complexity tests” as “authorized laboratories".

Performance Characteristics

Analytical Measuring Interval

0.60–75.00 Index is reported as Nonreactive (< 1.00 Index) or Reactive (≥ 1.00 Index).

The lower limit of the analytical measuring interval is defined by the LoQ (0.60 Index). However, report nonreactive results as < 1.00 Index. When sample results exceed the upper limit of the analytical measuring interval, refer to *Dilutions*.

Detection Capability

Detection capability was determined in accordance with CLSI Document EP17-A2.[21] The following results were obtained:

Method	Result (Index)
Limit of Blank (LoB)	0.30
Limit of Detection (LoD)	0.50
Limit of Quantitation (LoQ)	0.60

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

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

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

The LoQ corresponds to the lowest concentration of total antibodies to SARS-CoV-2 in a sample at which the within laboratory CV is ≤ 20%. The LoQ of the assay based on 2 reagent lots is 0.60 Index.

The lower limit of the analytical measuring interval is defined by the LoQ (0.60 Index). However, report nonreactive results as < 1.00 Index.

Seroconversion Sensitivity

A total of 406 specimens were collected serially from 85 subjects with a clinical diagnosis of COVID-19 based on a positive SARS-CoV-2 polymerase chain reaction (PCR) result. Of these, seroconversion was observed in 13 panels with 2 or more nonreactive blood draws and 2 or more reactive blood draws. The results are shown in the table below:

			First Draw		Last Nonreactive Draw		First Reactive Draw		Last Draw	
Panel	Number of Draws	Number of Reactive Draws	Days Post PCR Positive	Index	Days Post PCR Positive	Index	Days Post PCR Positive	Index	Days Post PCR Positive	Index
A	8	6	5	0.30	6	0.70	7	3.45	12	65.82
B	8	6	3	0.21	4	0.41	5	1.92	12	58.52
C	5	2	0	0.14	4	0.90	8	>75.00	10	>75.00
D	7	5	3	0.27	4	0.61	5	1.56	12	35.71
E	7	5	0	0.25	3	0.53	4	1.34	11	63.78
F	5	3	5	0.19	6	0.70	7	2.27	10	29.99
G	7	5	0	0.20	2	0.65	3	3.27	7	>75.00
H	5	2	0	0.12	3	0.20	14	43.54	17	48.06
I	4	2	0	0.23	6	0.21	13	18.03	17	17.49

			First Draw		Last Nonreactive Draw		First Reactive Draw		Last Draw	
Panel	Number of Draws	Number of Reactive Draws	Days Post PCR Positive	Index	Days Post PCR Positive	Index	Days Post PCR Positive	Index	Days Post PCR Positive	Index
J	4	2	2	0.22	4	0.87	6	23.13	22	>75.00
K	9	4	0	0.15	12	0.26	16	22.00	26	43.12
L	5	2	1	0.22	7	0.27	9	1.04	12	11.37
M	4	2	0	0.10	2	0.04	10	>75.00	12	49.28

Clinical Agreement

Positive percent agreement and negative percent agreement were determined in accordance with CLSI Document EP12-A2.[22] A retrospective study was conducted in order to evaluate the clinical performance of the Atellica IM COV2T assay. The performance of the Atellica IM COV2T assay was determined by testing a total of 1390 samples using the Atellica IM Analyzer.

Positive Percent Agreement

Positive percent agreement was determined by testing 299 samples collected from 229 unique donor subjects with a clinical diagnosis of COVID-19 based on a positive polymerase chain reaction (PCR) result using the first bleed from each subject in each stratified time category. The following table describes positive percent agreement by time of sampling following a positive PCR result:

Days Post PCR Positive	Number Tested	Reactive	Nonreactive	Positive Percent Agreement (95% CI)
0–7	163	99	64	60.74% (53.07%–67.90%)
8–14	69	62	7	89.86% (80.51% –95.00%)
≥ 15	67	66	1	98.51% (92.02% –99.74%)

Negative Percent Agreement

Negative percent agreement was determined by testing 1091 samples collected prior to the COVID-19 outbreak (before November 2019) from apparently healthy individuals and apparently healthy pregnant women in the United States. The results are shown in the table below:

Group	Number Tested	Nonreactive	Reactive	Negative Percent Agreement (95% CI)
Apparently Healthy	993	991	2	99.80% (99.27%–99.98%)
Apparently Healthy Pregnant Women	98	98	0	100.00% (96.31%–100.00%)
Total	**1091**	**1089**	**2**	**99.82% (99.34%–99.98%)**

Supplemental Clinical Agreement Study

A modified Solid Phase buffer formulation was introduced to the Atellica IM COV2T assay subsequent to the collection of the clinical agreement data presented above. A supplemental clinical agreement study was performed using the modified buffer formulation.

Positive Percent Agreement

Positive percent agreement was determined by testing 49 PCR positive clinical specimens on the Atellica IM COV2T assay using the modified buffer formulation. The following table describes positive percent agreement by time of sampling following a positive PCR result:

Days Post PCR Positive	Number Tested	Reactive	Nonreactive	Positive Percent Agreement (95% CI)
0–7	2	2	0	100% (34.24%–100%)
8–14	3	3	0	100% (43.85% –100%)
≥ 15	44	44	0	100% (91.97% –100%)

Negative Percent Agreement

Negative percent agreement was determined by testing 1001 samples collected prior to the COVID-19 pandemic (before November 2019) from apparently healthy individuals (including apparently healthy pregnant women). Testing was performed on the Atellica IM COV2T assay using the modified buffer formulation. The results are shown in the table below:

Group	Number Tested	Nonreactive	Reactive	Negative Percent Agreement (95% CI)
Apparently Healthy	1001	999	2	99.80% (99.27%–99.95%)

Precision

Single-Site Precision

Precision was determined in accordance with CLSI Document EP05-A3.[23] A single-site precision study for the Atellica IM COV2T assay was conducted. Samples and assay controls (a Negative Control and a Positive Control) were assayed in duplicate in 2 runs per day for 20 days using the Atellica IM Analyzer. Results for the precision of the Atellica IM COV2T assay are presented in the following table:

			Repeatability		Within-Laboratory Precision	
Specimen Type	**N[a]**	**Mean (Index)**	**SD[b] (Index)**	**CV[c] (%)**	**SD (Index)**	**CV (%)**
Plasma A	80	1.19	0.033	2.8	0.087	7.3
Plasma B	80	1.77	0.032	1.8	0.107	6.0
Plasma C	80	2.43	0.064	2.6	0.171	7.0
Plasma D	80	5.57	0.088	1.6	0.338	6.1
Plasma E	80	21.72	0.409	1.9	1.976	9.1
Serum A	80	18.95	0.455	2.4	1.531	8.1
Serum B	80	37.61	0.905	2.4	3.408	9.1
Control 1	80	0.02	0.010	N/A[d]	0.023	N/A
Control 2	80	2.80	0.060	2.2	0.172	6.1

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

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

Instrument and Lot Reproducibility

Reproducibility of the Atellica IM COV2T assay was evaluated on 2 Atellica IM instruments using 2 reagent lots. Samples and assay controls (a Negative Control and a Positive Control) were assayed in duplicate in 2 runs per day for 3 days. The data were analyzed to calculate the following components of precision: repeatability, between-run, between-day, between-lot, between-instrument, and reproducibility (total). Results for the reproducibility of the Atellica IM COV2T assay are presented in the following tables:

			Repeatability		Between-Run		Between-Day		Between-Lot		Between-Instrument		Reproducibility	
Sample	**N[a]**	**Mean (Index)**	**SD[b] (Index)**	**CV[c] (%)**	**SD (Index)**	**CV (%)**	**SD (Index)**	**CV (%)**	**SD (Index)**	**CV (%)**	**SD (Index)**	**CV (%)**	**SD (Index)**	**CV (%)**
Plasma A	48	5.56	0.162	2.9	0.051	0.9	0.331	6.0	0.000	0.0	0.142	2.6	0.398	7.2
Plasma B	48	11.73	0.189	1.6	0.181	1.5	0.482	4.1	0.601	5.1	0.000	0.0	0.814	6.9
Plasma C	48	35.41	0.965	2.7	0.000	0.0	2.010	5.7	2.323	6.6	0.000	0.0	3.220	9.1
Plasma D	48	71.64	2.277	3.2	0.959	1.3	6.377	8.9	1.431	2.0	0.000	0.0	6.987	9.8

			Repeatability		Between-Run		Between-Day		Between-Lot		Between-Instrument		Reproducibility	
Sample	N[a]	Mean (Index)	SD[b] (Index)	CV[c] (%)	SD (Index)	CV (%)	SD (Index)	CV (%)	SD (Index)	CV (%)	SD (Index)	CV (%)	SD (Index)	CV (%)
Control 1	48	0.06	0.030	N/A[d]	0.000	N/A	0.015	N/A	0.031	N/A	0.000	N/A	0.046	N/A
Control 2	48	2.89	0.078	2.7	0.104	3.6	0.084	2.9	0.055	1.9	0.055	1.9	0.173	6.0

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

Specimen Equivalency

Matched sample sets (serum, EDTA plasma, and lithium heparin plasma) from the same donors were used for the matrix comparison studies. Samples contained SARS-CoV-2 total antibody levels distributed across the measuring interval. Specimen equivalency was determined by testing the samples with the Atellica IM COV2T assay using the Atellica IM Analyzer in accordance with CLSI Document EP35-Ed1.[24]

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

Tube (y) vs. Serum (x)	N[a]	Sample Interval	Slope	Intercept	r[b]
EDTA (plasma)	40	0.60–65.43	0.92	0.18	0.997
Lithium heparin (plasma)	40	0.63–72.00	1.01	-0.02	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

Interference testing was performed in accordance with CLSI Document EP07-ed3.[25] The impact of potentially interfering substances on the detection of SARS-CoV-2 antibodies with the Atellica IM COV2T assay was evaluated with endogenous substances commonly found in serum and plasma specimens, including biotin, conjugated bilirubin, unconjugated bilirubin, hemoglobin, triglycerides, and protein. Serum samples were spiked with SARS-CoV-2 antibody at the following levels: unspiked, high negative (~0.6 Index), low positive (~1.0 Index), and mid-positive (~4.0 Index; for protein only). Testing demonstrated a ≤ 10% change for each substance at the indicated concentration.

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

Cross-Reactivity

Cross-reactivity was determined in accordance with CLSI Document EP07-ed3.[25] The assay was evaluated for potential cross-reactivity using specimens containing antibodies to other pathogens and other disease states using the Atellica IM COV2T assay with the Atellica IM Analyzer.

Clinical Category	Number Tested	Number Reactive with Atellica IM COV2T Assay
Autoimmune diseases[a]	14	0
Candida albicans total antibody	10	1
Chlamydia pneumoniae IgG	10	0
Chlamydia trachomatis IgM	5	0
Cytomegalovirus (CMV) IgG	15	0
Cytomegalovirus (CMV) IgM	5	0
Epstein Barr virus (EBV) IgG	5	0
Epstein Barr virus (EBV) IgM	5	0
Haemophilus influenzae b (Hib) IgG	20	0
Hepatitis A virus (HAV) IgM	5	0
Hepatitis B core (anti-HBc) IgM	5	0
Hepatitis C virus (HCV) total antibody	5	0
Herpes simplex virus (HSV) IgM	3	0
Human anti-mouse antibody (HAMA)	4	0
Human coronavirus antibodies[b]	29	0
Human immunodeficiency virus (HIV) total antibody	10	0
Human metapneumovirus (HMPV) IgG	5	0
Influenza total antibody	29	0
Influenza A total antibody	6	0
Influenza B total antibody	10	0
Measles total antibody	5	0
Middle East respiratory syndrome coronavirus (MERS-CoV) IgG	5	0
Mycoplasma pneumoniae IgG	19	0
Parvovirus B19 total antibody	5	0
Respiratory pathogen antibodies[c]	23	0
Respiratory syncytial virus (RSV) total antibody	20	0
Severe acute respiratory syndrome coronavirus (SARS-CoV-1) IgG	5	0
Streptococcus pneumoniae anti-PCP IgG	10	0

Clinical Category	Number Tested	Number Reactive with Atellica IM COV2T Assay
Toxoplasma gondii total antibody	10	0
Toxoplasma gondii IgG	20	0
Varicella zoster virus (VZV) total antibody	5	0
Total	**327**	**1**

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

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

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

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

Linearity

Linearity testing was performed in accordance with CLSI Document EP06-A.[26]

Sample pools containing high levels of SARS-CoV-2 total antibodies (1 serum, 1 EDTA plasma, and 1 lithium heparin plasma) were diluted with the respective negative pool to prepare a dilution series comprised of thirteen (13) levels. Each level was tested in 3 replicates using the Atellica IM Analyzer.

Linearity was demonstrated for the analytical measuring interval of 0.60–75.00 Index using the Atellica IM Analyzer with deviations from linearity within 15%.

Extended Measuring Interval (Dilutions)

Samples including serum, lithium heparin plasma, and EDTA plasma in the range of 96.71–247.41 Index were diluted 1:5 with Atellica IM Multi-Diluent 2 and assayed for recovery. The recoveries ranged from 86.9%–105.8%.

The extended measuring interval of the Atellica IM COV2T assay by dilution of 1:5 with Atellica IM Multi-Diluent 2 is 75.00–375 Index.

Sample	Dilution	Observed (Index)	Expected (Index)	Recovery (%)
Serum 1	—	124.29	—	—
	1:5	24.69	24.86	99.3%
Serum 2	—	96.71	—	—
	1:5	19.12	19.34	98.9%
Serum 3	—	119.22	—	—
	1:5	24.33	23.84	102.0%
Serum 4	—	247.41	—	—
	1:5	43.00	49.48	86.9%
Lithium heparin plasma 1	—	99.24	—	—

Sample	Dilution	Observed (Index)	Expected (Index)	Recovery (%)
	1:5	19.18	19.85	96.6%
Lithium heparin plasma 2	—	61.79	—	—
	1:5	11.54	12.36	93.4%
EDTA Plasma 1	—	96.83	—	—
	1:5	19.40	19.37	100.2%
EDTA Plasma 2	—	111.51	—	—
	1:5	23.60	22.30	105.8%
Mean				**97.9%**

Traceability

The Atellica IM COV2T assay is traceable to an internal standard based on agreement with known positive and negative SARS-CoV-2 samples.

Technical Assistance

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

siemens-healthineers.com

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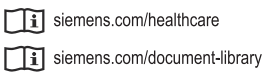
Definition of Symbols

The following symbols may appear on the product labeling:

Symbol	Symbol Title and Description
	Consult instructions for use
	Version of instructions for use
	Internet URL address to access the electronic instructions for use
Rev. REVISION	Revision
	Caution Consult instructions for use or accompanying documents for cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device.
	Biological risks Potential biological risks are associated with the medical device.
	Corrosive
	Dangerous to environment
	Irritant Oral, dermal, or inhalation hazard
	Inhalation hazard Respiratory or internal health
	Flammable Flammable to extremely flammable
	Oxidizing
	Explosive

Symbol	Symbol Title and Description
	Toxic
	Compressed gas
	Keep away from sunlight Prevent exposure to sunlight and heat.
	Up Store in an upright position.
	Do not freeze
	Temperature limit Upper and lower limits of temperature indicators are adjacent to the upper and lower horizontal lines.
	Handheld barcode scanner
	*In vitro* diagnostic medical device
	Contains sufficient for <n> tests Total number of IVD tests the system can perform with the IVD kit reagents appears adjacent to the symbol.
RxOnly	Prescription device (US only) Applies only to United States-registered IVD assays. CAUTION: Federal (USA) law restricts this device to sale by or on the order of a licensed healthcare professional.
	Mixing of substances Mix product before use.
	Reconstitute and mix lyophilized product before use.
	Target
	Interval
	Legal Manufacturer
	Authorized Representative in the European Community
	Use-by date Use by the designated date.
	Batch code

Symbol	Symbol Title and Description
REF	Catalog number
	Recycle
	Printed with soy ink
CE	CE Mark
CE XXXX	CE Mark with notified body ID number Notified body ID number can vary.
YYYY-MM-DD	Date format (year-month-day)
CHECKSUM	Variable hexadecimal number that ensures the Master Curve and Calibrator definition values entered are valid.
MC DEF	Master Curve Definition
LOT DTL	Lot Details
UNITS C	Common Units
UNITS SI	International System of Units
MATERIAL	Material
MATERIAL ID	Unique material identification number
CONTROL NAME	Name of control
CONTROL TYPE	Type of control

Legal Information

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SIEMENS Healthineers

SARS-CoV-2 Total Quality Control (COV2T QC)

Current Revision and Date[a]	Rev. 02, 2021-05
Product Name	Atellica IM SARS-CoV-2 Total Quality Control (COV2T QC)
Abbreviated Product Name	Atellica IM COV2T QC
	2 x 2.0 mL negative quality control level 1 CONTROL – 1 REF 11206712 2 x 2.0 mL positive quality control level 2 CONTROL + 2 Quality control assigned value sheet CONTROL LOT VAL
Systems	Atellica IM Analyzer

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

FOR USA:

For Use Under Emergency Use Authorization Only

For *in vitro* diagnostic use.

For Professional Use.

CE

Intended Use

The Atellica® IM SARS-CoV-2 Total Quality Control (COV2T QC) is for *in vitro* diagnostic use in monitoring the precision and accuracy of the Atellica® IM SARS-CoV-2 Total (COV2T) assay using the Atellica® IM Analyzer.

Material Description

Material Description	Storage	Stability
Atellica IM COV2T QC 2.0 mL/vial Processed human plasma nonreactive and reactive for SARS-CoV-2 antibodies; sodium azide (< 0.1%)	At 2–8°C	Until expiration date on product
	Opened at 2–8°C	60 days
	At room temperature	8 hours
	Atellica® Sample Handler[a]	

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

Warnings and Precautions

FOR USA:

For Use Under Emergency Use Authorization Only

For *in vitro* diagnostic use.

For Prescription Use Only.

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

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

The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of *in vitro* diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

CAUTION

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

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

CAUTION POTENTIAL BIOHAZARD

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

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

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

Storage and Stability

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

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

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

Performing Quality Control

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

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

Treat all quality control samples the same as patient samples.

Preparing the Quality Control Materials

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

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

Quality Control Procedure

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

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

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

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

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

Taking Corrective Action

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

Expected Values

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

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

Limitations

The Atellica IM COV2T QC is for use only with the Atellica IM COV2T assay. Assay values have not been established for assays other than the Atellica IM COV2T assay.

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

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

Technical Assistance

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

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References

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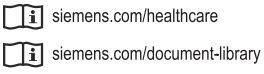
2. Clinical and Laboratory Standards Institute. *Procedures for the Handling and Processing of Blood Specimens for Common Laboratory Tests; Approved Guideline—Fourth Edition*. Wayne, PA: Clinical and Laboratory Standards Institute; 2010. CLSI Document GP44-A4.
3. Clinical and Laboratory Standards Institute. *Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline—Fourth Edition*. Wayne, PA: Clinical and Laboratory Standards Institute; 2014. CLSI Document M29-A4.

Definition of Symbols

The following symbols may appear on the product labeling:

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

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

Symbol	Symbol Title and Description
	Legal Manufacturer
	Authorized Representative in the European Community
	Use-by date Use by the designated date.
	Batch code
	Catalog number
	Recycle
	Printed with soy ink
	CE Mark
	CE Mark with notified body ID number Notified body ID number can vary.
YYYY-MM-DD	Date format (year-month-day)
	Variable hexadecimal number that ensures the Master Curve and Calibrator definition values entered are valid.
	Common Units
	International System of Units
	Material
	Unique material identification number
	Name of control
	Type of control

Legal Information

Atellica is a trademark of Siemens Healthcare Diagnostics.

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SIEMENS Healthineers

SARS-CoV-2 Total Master Curve Material (COV2T MCM)

Current Revision and Date[a]	Rev. 01, 2021-05
Product Name	Atellica IM SARS-CoV-2 Total Master Curve Material (COV2T MCM)
Abbreviated Product Name	Atellica IM COV2T MCM
	4 x 1.0 mL levels of master curve material MCM 1–4 REF 11207584 Master curve material assigned value sheet MCM LOT VAL
Systems	Atellica IM Analyzer

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

FOR USA:

For Use Under Emergency Use Authorization Only

For *in vitro* diagnostic use only.

For Prescription use only.

For Professional Use.

Intended Use

The Atellica® IM SARS-CoV-2 Total Master Curve Material (COV2T MCM) is for *in vitro* diagnostic use in the verification of calibration and measuring interval of the Atellica® IM SARS-CoV-2 Total (COV2T) assay.

Material Description

Material Description	Storage	Stability
Atellica IM COV2T MCM[a, b] **MCM 1:** 1.0 mL/vial Processed* human plasma nonreactive for SARS-CoV-2 antibodies; sodium azide (< 0.1%) **Processed plasma is defibrinated and filtered plasma.*	Unopened at 2–8°C	Until expiration date on product
	Opened at 2–8°C	60 days
	At room temperature	8 hours
Atellica IM COV2T MCM[a, b] **MCM 2–4:** 1.0 mL/vial Processed* human plasma reactive for SARS-CoV-2 antibodies; sodium azide (< 0.1%) **Processed plasma is defibrinated and filtered plasma.*	Unopened at 2–8°C	Until expiration date on product
	Opened at 2–8°C	60 days
	At room temperature	8 hours

[a] Store in an upright position.

[b] Prevent exposure to sunlight and heat.

Warnings and Precautions

FOR USA:

For Use Under Emergency Use Authorization Only

For *in vitro* diagnostic use.

For Prescription Use Only.

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

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

The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of *in vitro* diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

CAUTION

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

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

CAUTION POTENTIAL BIOHAZARD

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

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

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

Storage and Stability

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

Preparing the Master Curve Material

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

Master curve materials greater than the assay's measuring interval may be diluted with Atellica IM COV2T MCM level 1 to within the measuring interval of the assay.

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

Scheduling the Master Curve Material

For instructions about how to perform measuring interval verification, refer to the system online help.

- Allow the master curve material to come to room temperature.
- Gently mix each vial and dispense a sufficient volume of each level into the appropriate sample cup.

  Note The required sample volume for testing depends on several factors. For information about sample volume requirements, refer to the system online help.
- Do not pour the material back into the vials after testing because evaporation can occur, which may affect performance.
- Dispose of material remaining in the sample cups after 8 hours.
- Do not refill sample cups when the contents are depleted. If required, dispense fresh material into a new sample cup.

Evaluating the Results

Refer to the Atellica IM COV2T MCM value sheet MCM LOT VAL for the assigned values. The assigned values represent the acceptable results for master curve material tested in triplicate as unknown samples. Each level is expected to be within its assigned interval. When evaluating results that are outside of the acceptable interval, use the same criteria used when evaluating patient and quality control results.

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

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

Technical Assistance

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

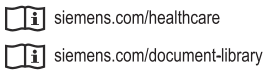
siemens-healthineers.com

References

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

Definition of Symbols

The following symbols may appear on the product labeling:

Symbol	Symbol Title and Description
	Consult instructions for use
	Version of instructions for use
	Internet URL address to access the electronic instructions for use
	Revision
	Caution Consult instructions for use or accompanying documents for cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device.
	Biological risks Potential biological risks are associated with the medical device.
	Corrosive
	Dangerous to environment
	Irritant Oral, dermal, or inhalation hazard
	Inhalation hazard Respiratory or internal health
	Flammable Flammable to extremely flammable
	Oxidizing
	Explosive
	Toxic
	Compressed gas
	Keep away from sunlight Prevent exposure to sunlight and heat.

Symbol	Symbol Title and Description
	Up Store in an upright position.
	Do not freeze
	Temperature limit Upper and lower limits of temperature indicators are adjacent to the upper and lower horizontal lines.
	Handheld barcode scanner
	*In vitro* diagnostic medical device
	Contains sufficient for <n> tests Total number of IVD tests the system can perform with the IVD kit reagents appears adjacent to the symbol.
RxOnly	Prescription device (US only) Applies only to United States-registered IVD assays. CAUTION: Federal (USA) law restricts this device to sale by or on the order of a licensed healthcare professional.
	Mixing of substances Mix product before use.
	Reconstitute and mix lyophilized product before use.
	Target
	Interval
	Legal Manufacturer
	Authorized Representative in the European Community
	Use-by date Use by the designated date.
	Batch code
	Catalog number
	Recycle
	Printed with soy ink
	CE Mark

Symbol	Symbol Title and Description
CE 0088	CE Mark with notified body ID number Notified body ID number can vary.
YYYY-MM-DD	Date format (year-month-day)
CHECKSUM	Variable hexadecimal number that ensures the Master Curve and Calibrator definition values entered are valid.
UNITS C	Common Units
UNITS SI	International System of Units
MATERIAL	Material
MATERIAL ID	Unique material identification number
CONTROL NAME	Name of control
CONTROL TYPE	Type of control

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Atellica® IM SARS-CoV-2 Total (COV2T)	REF 11206711 (100T) REF 11206923 (500T)

IVD

FOR US

RxOnly

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- This product has been authorized only for detecting the presence of total antibodies to SARS-CoV-2, not for any other viruses or pathogens.
- The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of *in vitro* diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3 (b)(1), unless the declaration is terminated or authorization is revoked sooner.
- This card is not the full instructions for use (IFU). The full IFU can be downloaded from the Siemens Healthineers website at siemens.com/eifu; a printed copy of the IFU can be obtained free of charge by contacting Siemens Healthineers Customer Support at 1-888-588-3916.

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Atellica® IM SARS-CoV-2 Total (COV2T) Quality Control (QC)	REF 11206712
Atellica® IM SARS-CoV-2 Total (COV2T) Master Curve Material (MCM)	REF 11207584

IVD

FOR US

RxOnly

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