SIEMENS Healthineers

SARS-CoV-2 Antigen (CoV2Ag)

For Use Under Emergency Use Authorization Only

For *in vitro* diagnostic use.

For prescription use only.

Assay for the Detection of SARS-CoV-2 Antigen

Current Revision and Date[a]	Rev. 05, 2023-05	
Product Name	Atellica IM SARS-CoV-2 Antigen (CoV2Ag)	REF 11207861 (100 tests)
		REF 11207862 (500 tests)
Abbreviated Product Name	Atellica IM CoV2Ag	
Test Name/ID	CoV2Ag	
Systems	Atellica IM Analyzer	
Materials Required but Not Provided	Atellica IM CoV2Ag Calibrator (CoV2Ag CAL)	REF 11208048
	Atellica IM CoV2Ag Quality Control (CoV2Ag QC)	REF 11207863
	Sample Inactivation Media	REF 11208651
	Atellica IM Probe Wash 3 (PW3)	REF 10995666
Specimen Types	Anterior nasal swab	
Sample Volume	100 µL	
Measuring Interval	0.10–1000 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 Antigen (CoV2Ag) assay is a chemiluminescent immunoassay intended for the qualitative detection of SARS-CoV-2 nucleocapsid protein antigen in anterior nasal (AN) swab specimens collected in Siemens Healthineers Sample Inactivation Media, from individuals who are suspected of COVID-19 by their healthcare provider within the first 7 days of symptom onset when tested at least twice over three days, with at least 48 hours between tests, using the Atellica® IM Analyzer. Testing is limited to 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.

The Atellica IM SARS-CoV-2 Antigen (CoV2Ag) assay does not differentiate between SARS-CoV and SARS-CoV-2.

Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen, which is generally detectable in anterior nasal (nares) swab samples during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with past medical history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses and the agent detected may not be the definitive cause of disease. Laboratories within the United States and its territories are required to report all results to the appropriate public health authorities.

All negative results should be treated as presumptive and confirmation with a molecular assay, if necessary, for patient management may be performed. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control measures, such as isolating from others and wearing masks. Negative results should be considered in the context of a patient's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19.

The Atellica IM SARS-CoV-2 Antigen (CoV2Ag) assay is intended for use by trained clinical laboratory personnel specifically instructed and trained in *in vitro* diagnostic procedures and proper infection control procedures.

In the United States, the Atellica IM SARS-CoV-2 Antigen (CoV2Ag) assay is only for *in vitro* diagnostic use under the Food and Drug Administration's Emergency Use Authorization. This product has not been FDA cleared or approved.

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 primarily through infected secretions, such as saliva and respiratory droplets or aerosols.[6] Evidence supports spread by both symptomatic and asymptomatic individuals.[7] The virus incubation period ranges from 2–14 days following exposure, with most cases showing symptoms within approximately 5 days after exposure.[8]

SARS-CoV-2 nucleic acid amplification testing, such as reverse transcription polymerase chain reaction (RT-PCR), is considered the gold standard for diagnostic testing for current infection, typically using an upper respiratory tract specimen. RT-PCR detects the genetic material of the virus, while antigen tests detect a viral protein (e.g. nucleocapsid). Immunoassays that detect the SARS-CoV-2 nucleocapsid antigen are also used for the diagnosis of current infection.[9] Due to the highly contagious nature of this virus and the mode of transmission, the need for additional, less complex testing solutions has been recognized. Antigen testing, as part of a SARS-CoV-2 testing strategy, can be used to identify symptomatic and asymptomatic individuals currently infected with SARS-CoV-2.[9]

Principles of the Procedure

The Atellica IM CoV2Ag assay is a fully automated 1-step sandwich immunoassay using acridinium ester chemiluminescent technology. The Solid Phase reagent containing streptavidin magnetic latex particles coated with biotinylated anti-SARS-CoV-2 mouse monoclonal capture antibodies and the Lite Reagent containing acridinium-ester-labeled anti-SARS-CoV-2 mouse monoclonal antibodies are added to the sample. The SARS-CoV-2 antigen in the sample complexes with the antibodies. Antibody-antigen complexes will form if SARS-CoV-2 antigen is present in the sample.

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

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

Reagents

Material Description	Storage	Stability
Atellica IM CoV2Ag ReadyPack® primary reagent pack[a, b] **Lite Reagent** 4.0 mL/reagent pack Mouse monoclonal anti-SARS-CoV-2 antibodies labeled with acridinium ester (~0.60 µg/mL); buffer; surfactant; bovine serum albumin (BSA); goat serum; mouse IgG; bovine gamma globulin; goat gamma globulin; sodium azide (< 0.1%) **Solid Phase** 10.5 mL/reagent pack Streptavidin-coated paramagnetic microparticles preformed with biotinylated SARS-CoV-2 monoclonal antibodies (~0.016 mg/mL); buffer; BSA; goat serum; bovine gamma globulin; surfactant; sodium azide (< 0.1%)	Unopened at 2–8°C Onboard	Until expiration date on product 21 days
Atellica IM CoV2Ag Readypack ancillary reagent pack **Ancillary Reagent**[a, b] 10.0 mL/reagent pack Buffer; BSA; preservatives	Unopened at 2–8°C Onboard	Until expiration date on product 21 days
Atellica IM PW3[a, c] 50.0 mL/pack Sodium hypochlorite (0.5%), sodium hydroxide (< 0.5%), pH 11.0	Unopened at 2–8°C Onboard	Until expiration date on product 100 days

[a] Store in an upright position.

[b] Prevent exposure to sunlight and heat.

[c] Reagent is required, but not provided in the assay kit. Refer to *Materials Required but Not Provided*.

Warnings, Precautions, and Safety Information

For Use Under Emergency Use Authorization Only

For *in vitro* diagnostic use only.

For prescription use only.

In the U.S., this product has not been FDA cleared or approved, but has been authorized by FDA under an Emergency Use Authorization (EUA) for use by authorized laboratories; use by 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 product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens.

In the U.S., 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 the authorization is revoked sooner.

For more information on EUAs please visit: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization

For the most up to date information on COVID-19, please visit: www.cdc.gov/COVID19

Laboratories within the U.S and its territories are required to report all results to the appropriate public health laboratories

Do not use this kit beyond the use by date printed on the product label.

Do not use if any of the test kit contents or packaging is damaged.

Test components are single-use. Do not re-use.

Do not touch the swab tip.

Do not pool the contents of different vials of the same reagent (even if the reagents are from the same lot). Calibrators are also lot-specific and cannot be shared between kits.

Treat all specimens as potentially infectious. Follow universal precautions when handling samples, this kit, and its contents.

Proper laboratory safety techniques should be followed at all times when working with SARS-CoV-2 patient samples.

All results must be interpreted together with other clinical information available.

Read all instructions carefully before performing the test. Failure to follow the instructions may result in inaccurate test results.

In order to obtain accurate results, the test must follow this package insert.

Serial testing should be performed in individuals with negative results at least twice over three days (with 48 hours between tests) for symptomatic individuals. You may need to purchase additional tests to perform this serial (repeat) testing.

Inadequate or inappropriate sample collection, storage, and transport can result in incorrect results.

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.

H412	Harmful to aquatic life with long lasting effects.
P273, P501	Avoid release to the environment. Dispose of contents and container in accordance with all local, regional, and national regulations. **Contains:** Sodium hypochlorite (Atellica IM PW3)

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.

Do not eat, drink, or smoke in the area where the specimens and kit contents are handled. Use appropriate precautions in the collection, handling, storage, and disposal of patient samples and used kit contents.

Dispose of hazardous or biologically contaminated materials in accordance with federal, state, and local requirements. 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. Do not use if the test device package is damaged.

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

Anterior nasal (AN) swab specimens stored in Sample Inactivation Media (REF 11208651) is the recommended sample type for this assay. This assay has not been authorized for use with transport media other than Sample Inactivation Media.

Inadequate or inappropriate sample collection, storage, and transport can result in incorrect results.

Do not use heat-inactivated specimens.

Use appropriate precautions when collecting, handling, storing, and transporting swab specimens. Refer to the CDC's "Interim Guidelines for Collection, Handling and Transportation of clinical specimens from persons with Coronavirus Disease 2019 (COVID-19)"[10] and to the WHO's interim guidance document, "Laboratory testing for coronavirus disease (COVID-19) in suspected human cases"[11], for proper procedures.

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

- Handle all specimens as if they are capable of transmitting disease.[12]
- When collecting any type of sample, follow universal collection precautions and guidelines according to your organization. Users should be trained in appropriate sample collection and handling procedures.
- For the collection of AN swab specimens, follow the Centers for Disease Control and Prevention (CDC) Swab Collection Guidelines[10] and the swab manufacturers' recommendations.
- Keep tubes capped at all times.

Storing the Specimen

- Inactivated samples are stable for up to 4 hours onboard the system.
- Inactivated samples can be stored at 2–8°C for up to 3 days.
- Freeze inactivated samples at ≤ -20°C for longer storage. Do not store in a frost-free freezer. Avoid more than 2 freeze-thaw cycles. Thoroughly mix thawed inactivated samples and centrifuge them 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.

Ship specimens frozen if specimen storage exceeds sample stability specified in *Storing the Specimen*.

Preparing the Samples

This assay requires 100 µL of sample for a single determination. This volume does not include the unusable volume in the sample container or the additional volume required when performing duplicates or other tests on the same sample. For a complete list of appropriate sample containers and information about determining the minimum required volume, refer to the system online help.

Do not use samples with apparent contamination.

Sample Preparation of Swab Specimens Prior to Testing

Perform the following steps to prepare specimens received in Sample Inactivation Media (REF 11208651) prior to loading the sample on the system.

WARNING

Use appropriate precautions for handling potentially infectious specimens when performing the procedures described below. Refer to *Specimen Collection and Handling*.

1. Allow the sample to thaw, if necessary.
2. Carefully remove the cap from the sample tube. Roll the swab at least 5 times against the side of the tube and remove the swab. Dispose of the used swab into a biohazardous waste collection container.
3. The inactivated sample should be tested as soon as possible. If the sample cannot be tested immediately, store the sample according to the storage guidance in *Storing the Specimen*.

   Note Transferring the inactivated sample received in Sample Inactivation Media (REF 11208651) to another cup is not required, as it can be placed directly on the Atellica IM Analyzer.
4. Before placing samples on the system, ensure that samples are free of bubbles, foam, or particulate matter. Remove particulates by centrifugation, if necessary.
5. Place the sample cup containing the inactivated sample on the system for testing.

Procedure

Materials Provided

The following materials are provided:

REF	Contents	Number of Tests
11207861	1 ReadyPack primary reagent pack containing Atellica IM CoV2Ag Lite Reagent and Solid Phase 1 ReadyPack ancillary reagent pack containing Atellica IM CoV2Ag Ancillary Reagent ANC Atellica IM CoV2Ag master curve and test definition MC TDEF	100
11207862	5 ReadyPack primary reagent packs containing Atellica IM CoV2Ag Lite Reagent and Solid Phase 5 ReadyPack ancillary reagent packs containing Atellica IM CoV2Ag Ancillary Reagent ANC Atellica IM CoV2Ag master curve and test definition MC TDEF	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]	
11208048	Atellica IM CoV2Ag CAL (calibrator)	2 x 1.0 mL low calibrator CAL | L 2 x 1.0 mL high calibrator CAL | H calibrator assigned value sheet CAL | LOT | VAL
11207863	Atellica IM CoV2Ag QC (quality control material)	2 x 1.6 mL negative quality control, level 1 CONTROL | – | 1 2 x 1.6 mL positive quality control, level 2 CONTROL | + | 2 quality control assigned value sheet CONTROL | LOT | VAL
11208651	Sample Inactivation Media (inactivation reagent)	50 x 1.0 mL
10995666	Atellica IM PW3 (probe wash)	50.0 mL/pack WASH

[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.

Assay Procedure

The system automatically performs the following steps:

1. Dispenses 100 µL of sample into a cuvette.
2. Dispenses 60 µL of Ancillary Reagent, then incubates for 6 minutes at 37°C.
3. Dispenses 105 µL of Solid Phase and 40 µL of Lite Reagent, then incubates for 18 minutes at 37°C.
4. Separates the Solid Phase from the mixture and aspirates the unbound reagent.
5. Performs a wash sequence using Atellica IM Wash.
6. Dispenses 300 µL each of Atellica IM Acid and Atellica IM Base to initiate the chemiluminescent reaction.
7. 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.

Note The Ancillary Reagent provided in this kit is matched to the Solid Phase and Lite Reagent. Do not mix Ancillary Reagent lots with different lots of Solid Phase and Lite Reagent.

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 CoV2Ag assay, use the Atellica IM CoV2Ag CAL. Use the calibrators in accordance with the calibrator instructions for use.

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	48
Pack Calibration	21
Reagent Onboard Stability	21

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 Atellica IM CoV2Ag assay, use the Atellica IM CoV2Ag QC or an equivalent product 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.

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. Individual laboratory quality control programs and procedures may require more frequent quality control testing.

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

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.

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. The system reports results in Index Values. Refer to *Interpretation of Results*.

Interpretation of Results

The system reports Atellica IM CoV2Ag assay results in Index Values and as Nonreactive or Reactive:

- **Nonreactive:** < 1.00 Index. These samples are considered presumptive negative for SARS-CoV-2 nucleocapsid antigen.
- **Reactive:** ≥ 1.00 Index. These samples are considered positive for SARS-CoV-2 nucleocapsid antigen.

The cut-off value for the Atellica IM CoV2Ag assay was verified based on clinical agreement of results.

Repeat testing is needed to improve test accuracy. Please follow the table below when interpreting test results.

Test Interpretation

Status on First Day of Testing	First Result Day 1	Second Result Day 3	Third Result Day 5	Interpretation
With Symptoms	Positive	N/A[a]	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	N/A	Negative for COVID-19

[a] Not applicable

Results should be considered in the context of an individual's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19.

COVID-19 Positive (+)

Repeat testing does not need to be performed if patients have a positive result at any time.

A positive test result means that the virus that causes COVID-19 was detected in the sample, and it is very likely the individual has COVID-19 and is contagious. Please contact the patient's doctor/primary care physician (if applicable) and the local health authority immediately and instruct your patient to adhere to the local guidelines regarding self isolation. There is a very small chance that this test can give a positive result that is incorrect (a false positive).

Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Individuals who test positive with the Atellica IM CoV2Ag assay should self-isolate and seek follow up care with their physician or healthcare provider as additional confirmatory testing with a molecular test for positive results may also be necessary, if there is a low likelihood of COVID-19, such as in individuals without known exposures to COVID-19 or residing in communities with low prevalence of infection.

COVID-19 Negative (-)

To increase the chance that the negative result for COVID-19 is accurate, you should:

Test again in 48 hours if the individual has symptoms on the first day of testing.

A negative test result indicates that the virus that causes COVID-19 was not detected in the sample. A negative result does not rule out COVID-19. There is a higher chance of false negative results with antigen tests compared to laboratory-based tests such as PCR tests. If the test is negative but COVID-19-like symptoms, e.g., fever, cough, and/or shortness of breath continue, follow up testing for SARS-CoV-2 with a molecular test or testing for other respiratory disease should be considered. If applicable, seek follow up care with the primary health care provider.

All negative results should be treated as presumptive and confirmation with a molecular assay may be necessary if there is a high likelihood of SARS-CoV-2 infection, such as in an individual with a close contact with COVID-19 or with suspected exposure to COVID-19 or in communities with high prevalence of infection. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions.

Limitations

The following information pertains to limitations of the assay:

- This device has been evaluated for use with human specimen material only.
- The performance of the assay has not been established with specimen types other than those defined in the *Intended Use*.
- The performance of this test was evaluated using Sample Inactivation Media only. The use of other viral transport media should not be used in conjunction with this test.
- The performance of this test has not yet been clinically validated for use in patients without signs and symptoms of respiratory infection.
- Failure to follow the instructions for use may adversely affect test performance and/or invalidate the test result.
- Results should be considered in the context of a patient's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19, and confirmed with a molecular assay, if necessary, for patient management.
- A false negative result may occur due to inadequate sample collection, storage, and/or handling.
- A false negative result may occur if the concentration of the target antigen in the clinical specimen is below the detection limits of the device.
- Positive test results do not rule out co-infections with other pathogens.
- Negative results should be treated as presumptive and confirmation with a molecular assay, if necessary for patient management, may be performed.
- Percent interference > 15% was observed in contrived samples of 100% pooled human nasal wash, which may result in a false negative.
- Percent interference > 15% was observed in contrived samples containing 15% Afrin, which may result in a false negative.
- The performance of this test is dependent upon proper specimen collection, handling, storage, and preparation. Failure to observe proper procedures in any one of these steps can lead to incorrect results.
- Results from antigen testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to determine infection status.

- This test does not differentiate between SARS-CoV and SARS-CoV-2.
- If the differentiation of specific SARS viruses and strains is needed, additional testing, in consultation with state or local public health departments, is required.
- This test cannot rule out diseases caused by other bacterial or viral pathogens.
- This test will indicate the presence of SARS-CoV-2 nucleocapsid protein antigen in the specimen from both viable and non-viable SARS-CoV-2 virus. Test performance depends on the amount of virus (antigen) in the sample and may or may not correlate with viral culture results performed on the same sample.
- This device is a qualitative test and does not provide information on the viral concentration present in the specimen.
- The performance of this test was established based on the evaluation of a limited number of clinical specimens collected between January 25, 2022 and February 10, 2022. 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.
- Positive and negative predictive values are highly dependent on prevalence. False-negative test results are more likely during peak activity when the prevalence of the disease is high. False-positive test results are more likely during the periods of low SARS-CoV-2 activity when prevalence is moderate to low.
- There is a higher chance of false negative results with antigen tests than with laboratory-based molecular tests due to the sensitivity of the test technology. This means that there is a higher chance this test will give a false negative result in an individual with COVID-19 as compared to a molecular test, especially in samples with low viral load.
- If the patient continues to have symptoms of COVID-19, and both the patient's first and second tests are negative, the patient may not have COVID-19, however additional follow-up may be needed.
- If the test is positive, then proteins from the virus that causes COVID-19 have been found in the sample and the individual likely has COVID-19.

Conditions of Authorization for the Laboratory

The Atellica IM SARS-CoV-2 Antigen (CoV2Ag) 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

Authorized laboratories using the Atellica IM CoV2Ag assay must adhere to the Conditions of Authorization indicated in the Letter of Authorization as listed below:

- Authorized laboratories[a] using this product must include with test result reports, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.
- Authorized laboratories using this product 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 CoV2Ag assay are not permitted.
- Authorized laboratories that receive this product must notify the relevant public health authorities of their intent to run the assay prior to initiating testing.

- Authorized laboratories using this product must have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.
- Authorized laboratories must collect information on the performance of this product 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 this product must be appropriately trained in automated immunoassay techniques and use appropriate laboratory and personal protective equipment when handling this kit, and use this product in accordance with the authorized labeling. All laboratory personnel using the assay must also be trained in and be familiar with the interpretation of results of this product.
- Siemens Healthineers, authorized distributors, and authorized laboratories using this product must ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

[a] The letter of authorization refers to, "Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform moderate or high complexity tests" as "authorized laboratories".

Performance Characteristics

Measuring Interval

0.10–1000 Index is reported as Nonreactive (< 1.00 Index) or Reactive (≥ 1.00 Index).

Detection Capability

Limit of Detection (LoD) = 624 $TCID_{50}$/mL

LOD was determined by evaluating different dilutions of gamma irradiated viral lysate SARS-CoV-2 (USA WA1/2020) in Sample Inactivation Media (REF 11208651). The study was performed by adding 50µL of viral solution to dry swabs and eluting the swabs in Sample Inactivation Media (REF 11208651). LoD is defined as the lowest virus concentration at which a minimum of 19 out of 20 generate a Reactive result. Testing was performed with the Atellica IM CoV2Ag assay using the Atellica IM Analyzer.

Based upon the testing procedure for this study, the LoD of 624 $TCID_{50}$/mL equates to 31.2 $TCID_{50}$/swab.

The LoD corresponds to the lowest concentration of SARS-CoV-2 antigen that can be detected with a probability of 95%.

NIH/RADx Variant Testing (Omicron Testing)

The performance of this test device in the detection of the Omicron variant of SARS-CoV-2 was evaluated in a dilution series of live clinical specimens which were positive for the Omicron variant. This testing was conducted by the National Institutes of Health (NIH) as a component of the Rapid Acceleration of Diagnostics (RADx®) initiative. Compared to an EUA authorized RT-PCR method, the Atellica IM CoV2Ag assay detected 100% of live virus Omicron samples at a Ct-value of 24.5 (n=5). Testing was also compared to two additional EUA-authorized antigen tests (Assay #1 and Assay #2). Omicron dilutions at lower viral concentrations (Ct-values greater than 25.6 for live virus) were not detected by the Atellica IM CoV2Ag assay in this study.

Omicron Live Pool 1	Average Ct	Assay #1	Assay #2	Atellica IM CoV2Ag Assay Percent Positive (n=5)
Dilution 1	19.4	100	100	100
Dilution 2	20.6	100	100	100
Dilution 3	21.6	100	100	100
Dilution 4	22.4	100	100	100
Dilution 5	23.3	100	100	100
Dilution 6	24.5	0	100	100
Dilution 7	25.6	0	100	0
Dilution 8	26.5	0	0	0
Dilution 9	27.7	0	0	0
Dilution 10	28.5	0	0	0
Dilution 11	29.4	0	0	0
Dilution 12	30.3	0	0	0

Clinical Agreement

Positive percent agreement and negative percent agreement were determined by testing a total of 166 anterior nasal (AN) swab samples in accordance with CLSI Document EP12-A2.[13] Samples were collected from 68 male and 98 female symptomatic individuals suspected of COVID-19 and enrolled sequentially (all-comers), with one or more confirmed symptoms based on CDC guidelines and within 7 days of symptom onset. All samples were collected between January and February 2022 from 2 vendors at 5 sites in the U.S. Of the 47 RT-PCR positive samples, 44 were confirmed as the Omicron variant using next-generation sequencing and 3 samples failed sequencing due to an insufficient quantity of viral material.

The samples were collected in Sample Inactivation Media (REF 11208651), refrigerated from the time of collection, and tested with the Atellica IM CoV2Ag assay using the Atellica IM Analyzer. The results were compared to FDA EUA-authorized RT-PCR comparator results.

Subject Demographics by Age

	Anterior Nasal Swab Samples (N=166)		
Age (Years)	Number Tested	Atellica IM CoV2Ag Assay - Reactive	Prevalence
< 22	29	9	31%
22–59	117	29	25%
≥ 60	20	2	10%

Performance in Anterior Nasal Swab Samples Collected from RT-PCR Positive Symptomatic and RT-PCR Negative Individuals

		Comparative PCR Method		
		Positive	**Negative**	**Total**
Atellica IM CoV2Ag Assay	**Reactive**	40	0	40
	Nonreactive	7	119	126
	Total	**47**	**119**	**166**
Positive Percent Agreement: 85.11% (95% Confidence Interval: 72.31%–92.59%) Negative Percent Agreement: 100% (95% Confidence Interval: 96.78%–100%)				

Performance in RT-PCR Positive Anterior Nasal Swab Samples Collected from Symptomatic Individuals from Date of Symptom Onset

Days Since Symptom Onset	Comparative PCR Method - Positive (Cumulative)	Atellica IM CoV2Ag Assay - Reactive (Cumulative)	Positive Percent Agreement (%)	95% Confidence Interval
1	11	8	72.73%	43.44%–90.25%
2	22	18	81.82%	61.48%–92.69%
3	30	24	80.00%	62.69%–90.49%
4	35	28	80.00%	64.11%–89.96%
5	40	33	82.50%	68.05%–91.25%
6	44	37	84.09%	70.63%–92.07%
7	47	40	85.11%	72.31%–92.59%

Performance of SARS-CoV-2 Antigen Test with Serial Testing

A prospective clinical study was conducted between January 2021 and May 2022 as a component of the Rapid Acceleration of Diagnostics (RADx) initiative from the National Institutes of Health (NIH). A total of 7,361 individuals were enrolled via a decentralized clinical study design, with a broad geographical representation of the United States. Per inclusion criteria, all individuals were asymptomatic upon enrollment in the study and at least 14 days prior to it and did not have a SARS-CoV-2 infection in the three months prior to enrollment. Participants were assigned to one of three EUA authorized SARS-CoV-2 OTC rapid antigen tests to conduct serial testing (every 48 hours) for 48 days. If an antigen test was positive, the serial-antigen testing result is considered positive.

At each rapid antigen testing time point, study subjects also collected a nasal swab for comparator testing using a home collection kit (using a 15-minute normalization window between swabs). SARS-CoV-2 infection status was determined by a composite comparator method on the day of the first antigen test, using at least two highly sensitive EUA RT-PCRs. If results of the first two molecular test were discordant, a third highly sensitive EUA RT-PCR test was performed, and the final test result was based upon the majority rule.

Study participants reported symptom status throughout the study using the MyDataHelps app. Two-day serial antigen testing is defined as performing two antigen tests 36–48 hours apart. Three-day serial antigen testing is defined as performing three antigen tests over five days with at least 48 hours between each test.

Out of the 7,361 participants enrolled in the study, 5,609 were eligible for analysis. Among eligible participants, 57 (39%) reported symptoms on the first day of infection. Performance of the antigen test with serial testing in symptomatic individuals is described in the table below.

Data establishing PPA of COVID-19 antigen serial testing compared to the molecular comparator single day testing throughout the course of infection with serial testing. Data is from only symptomatic patients antigen tests in the study.

Days After First PCR Positive Test Result	Symptomatic on First Day of Testing		
	Ag Positive / PCR Positive (Antigen Test Performance % PPA)		
	1 Test[a]	2 Tests[b]	3 Tests[c]
0	34/57 (59.6%)	47/51 (92.2%)	44/47 (93.6%)
4	55/58 (94.8%)	53/54 (98.1%)	39/40 (97.5%)
8	12/17 (70.6%)	12/17 (70.6%)	7/11 (63.6%)
10	4/9 (44.4%)	3/7 (42.9%)	

[a] One (1) test performed on the noted days after first PCR positive test result. Day 0 is the first day of documented infection with SARS-CoV-2.

[b] Two (2) tests performed an average of 48 hours apart. The first test performed on the indicated day and the second test performed 48 hours later.

[c] Three (3) tests performance an average of 48 hours apart. The first test performed on the indicated day, the second test performed 48 hours later, and a final test performed 48 hours after the second test.

Interferences

Interference testing was performed using the Atellica IM Analyzer. Percent interference > 15% was observed for Afrin (oxymetazoline) and pooled human nasal wash; this did not result in a false negative result. None of the other substances tested were found to interfere with the clinical interpretation of the test in nonreactive and weakly reactive samples at the substance test concentrations indicated below. The following results are representative of the performance of the assay:

Substance	Substance Test Concentration	Nonreactive Sample	Spiked Reactive Sample
Afrin (oxymetazoline)	15% v/v	Negative	Positive
Alkalol homeopathic nasal wash	1:10 dilution	Negative	Positive
Biotin	3500 ng/mL	Negative	Positive
Chloraseptic (benzocaine/menthol)	1.5 mg/mL	Negative	Positive
CVS Nasal Drops (phenylephrine)	15% v/v	Negative	Positive
CVS Nasal Spray (cromolyn)	15% v/v	Negative	Positive
Fluticasone propionate	5% v/v	Negative	Positive

Substance	Substance Test Concentration	Nonreactive Sample	Spiked Reactive Sample
Hemoglobin	75 mg/dL	Negative	Positive
Mucin	0.5%	Negative	Positive
Mupirocin	10 mg/mL	Negative	Positive
Naso GEL (NeilMed)	5% v/v	Negative	Positive
Pooled human nasal wash	100% v/v	Negative	Positive
Sore throat phenol spray	15% v/v	Negative	Positive
Tamiflu (oseltamivir phosphate)	5 mg/mL	Negative	Positive
Tobramycin	4 µg/mL	Negative	Positive
Whole blood	4% v/v	Negative	Positive
Zicam Nasal Spray	5% v/v	Negative	Positive

Cross-Reactivity

The assay was evaluated for potential cross-reactivity in specimens with various microorganisms and viruses using the Atellica IM Analyzer. The following results are representative of the performance of the assay:

Microorganism/Virus	Concentration Tested	Nonreactive Sample	Spiked Reactive Sample
Adenovirus 7a	10^5 PFU/mL[a]	Negative	Positive
Bordetella pertussis	10^6 CFU/mL[b]	Negative	Positive
Candida albicans	10^6 CFU/mL	Negative	Positive
Chlamydia pneumoniae	10^6 IFU/mL[c]	Negative	Positive
Enterovirus 68	10^5 PFU/mL	Negative	Positive
Haemophilus influenzae	10^6 CFU/mL	Negative	Positive
Human coronavirus 229E	10^5 PFU/mL	Negative	Positive
Human coronavirus NL63	10^5 PFU/mL	Negative	Positive
Human coronavirus OC43	10^5 PFU/mL	Negative	Positive
Human Metapneumovirus (hMPV)	10^5 PFU/mL	Negative	Positive
Human parainfluenza virus 1 (HPIV-1)	10^5 PFU/mL	Negative	Positive
Human parainfluenza virus 2 (HPIV-2)	10^5 PFU/mL	Negative	Positive
Human parainfluenza virus 3 (HPIV-3)	10^5 PFU/mL	Negative	Positive
Human parainfluenza virus 4 (HPIV-4)	10^5 PFU/mL	Negative	Positive
Influenza A (H1N1)	10^5 PFU/mL	Negative	Positive
Influenza B	10^5 PFU/mL	Negative	Positive
Legionella pneumophila	10^6 CFU/mL	Negative	Positive

Microorganism/Virus	Concentration Tested	Nonreactive Sample	Spiked Reactive Sample
Middle East respiratory syndrome coronavirus (MERS-CoV)	10^5 PFU/mL	Negative	Positive
Mycobacterium tuberculosis	10^6 CFU/mL	Negative	Positive
Mycoplasma pneumoniae	10^6 CCU/mL[d]	Negative	Positive
Pneumocystis jirovecii (PJP)	10^6 CFU/mL	Negative	Positive
Respiratory syncytial virus (RSV)	10^5 PFU/mL	Negative	Positive
Rhinovirus	10^5 PFU/mL	Negative	Positive
Staphylococcus aureus	10^6 CFU/mL	Negative	Positive
Staphylococcus epidermidis	10^6 CFU/mL	Negative	Positive
Streptococcus pneumoniae	10^6 CFU/mL	Negative	Positive
Streptococcus pyogenes	10^6 CFU/mL	Negative	Positive
Streptococcus salivarius	10^6 CFU/mL	Negative	Positive

[a] PFU = plaque-forming unit
[b] CFU = colony-forming unit
[c] IFU = inclusion forming unit
[d] CCU = color changing unit

In Silico analysis using the Basic Local Alignment Search Tool (BLAST) managed by the National Center for Biotechnology Information (NCBI) was used to assess the degree of protein sequence homology to estimate the cross-reactivity with SARS-CoV-2 virus in the presence of organisms that were not available for wet testing. There was 36.74% homology between SARS-CoV-2 nucleocapsid and human coronavirus HKU1 nucleocapsid, suggesting a low likelihood of cross-reactivity; however, cross-reactivity cannot be ruled out. The comparison between SARS-CoV-2 nucleocapsid protein and SARS-CoV-1 shows homology of 90.52% and suggests that there may be significant cross-reactivity in this assay.

High-Dose Hook Effect

No false negative results due to a high-dose hook effect were found with the Atellica IM CoV2Ag assay up to 2.6 x 10^5 $TCID_{50}$/mL.

Standardization

The assay standardization for the Atellica IM CoV2Ag assay is based on agreement with known positive and negative SARS-CoV-2 samples. Assigned values for calibrators are traceable to this standardization.

Technical Assistance

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

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Definition of Symbols

The following symbols may appear on the product labeling:

Symbol	Symbol Title	Symbol	Symbol Title
	Manufacturer		Authorized representative in the European Community
	Use-by date		Batch code

Symbol	Symbol Title	Symbol	Symbol Title
REF	Catalog number	Σ	Contains sufficient for <n> tests
	Consult Instructions for Use	Rev. XX	Version of Instructions for Use
siemens.com/eifu	Internet URL address to access the electronic instructions for use	Rev. REVISION	Revision
IVD	*In vitro* diagnostic medical device	UDI	Unique Device Identifier
RxOnly	Prescription device (US only)	CE	CE Marking
CE XXXX	CE Marking with Notified Body		Keep away from sunlight
	Temperature limit		Lower limit of temperature
	Upper limit of temperature		Do not freeze
	Do not re-use		This way up
	Recycle		Caution
	Biological risks		Document face up[a]
UNITS C	Common Units	UNITS SI	International System of Units
YYYY-MM-DD	Date format (year-month-day)	YYYY-MM	Date format (year-month)
	Handheld barcode scanner		Mixing of substances
	Target		Interval
CHECKSUM	Variable hexadecimal number that ensures the Master Curve and Calibrator definition values entered are valid.	MATERIAL	Material
MATERIAL ID	Unique material identification number	CONTROL NAME	Name of control
CONTROL TYPE	Type of control	CAL LOT VAL	Calibrator lot value
CONTROL LOT VAL	Quality control lot value		

[a] Indicates Assay-eNote

Legal Information

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SIEMENS Healthineers

Sample Inactivation Media

For Use Under an Emergency Use Authorization Only

For *in vitro* diagnostic use.

For prescription use only.

Current Revision and Date[a]	Rev. 02, 2023-05	
Product Name	Sample Inactivation Media (50 x 1.0 mL)	REF 11208651
Systems	Atellica IM Analyzer ADVIA Centaur XP system ADVIA Centaur XPT system	

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

Intended Use

Sample Inactivation Media is used for the processing of anterior nasal swab specimens prior to testing samples with the Atellica® IM SARS-CoV-2 Antigen (CoV2Ag) assay or ADVIA Centaur® SARS-CoV-2 Antigen (CoV2Ag) assay.

Material Description

Material Description	Storage	Stability
Sample Inactivation Media[a] 1.0 mL/tube Buffer; surfactant; fetal bovine serum; preservatives	Unopened at 2–30°C	Until expiration date on product

[a] Prevent exposure to sunlight and heat.

Warnings and Precautions

For Use Under an Emergency Use Authorization Only

For *in vitro* diagnostic use only.

For prescription use only.

In the USA, this product has not been FDA cleared or approved, but has been authorized by FDA under an EUA for use by authorized laboratories; use by laboratories certified under CLIA that meet requirements to perform moderate or high complexity tests.

This product is for use with a test that has been authorized only for the presence of SARS-CoV-2 Antigen, not for any other viruses or pathogens.

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

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

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

Storage and Stability

Store Sample Inactivation Media at 2–30°C, away from light and heat.

Avoid bacterial contamination.

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

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

Sample Inactivation Procedure

For information about using the Sample Inactivation Media to process samples prior to testing, refer to the assay instructions for use.

Limitations

- The performance of the Sample Inactivation Media has not been established with any assays or specimen types other than those defined in the *Intended Use*.
- Do not use to inactivate any viruses other than SARS-CoV-2.
- All samples (including inactivated samples) and reagents containing biological materials used for the assay must be considered as potentially able to transmit infectious agents. All samples, reagents, and associated waste must be handled with extreme care and disposed of in compliance with the laboratory guidelines and the statutory provisions in force in each country.

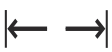
Technical Assistance

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

siemens-healthineers.com

Definition of Symbols

The following symbols may appear on the product labeling:

Symbol	Symbol Title	Symbol	Symbol Title
	Manufacturer		Authorized representative in the European Community
	Use-by date		Batch code
	Catalog number		Contains sufficient for <n> tests
	Consult Instructions for Use		Version of Instructions for Use
	Internet URL address to access the electronic instructions for use		Revision
	*In vitro* diagnostic medical device		Unique Device Identifier
RxOnly	Prescription device (US only)		CE Marking
	CE Marking with Notified Body		Keep away from sunlight
	Temperature limit		Lower limit of temperature
	Upper limit of temperature		Do not freeze
	Do not re-use		This way up
	Recycle		Caution
	Biological risks		Document face up[a]
	Common Units		International System of Units
YYYY-MM-DD	Date format (year-month-day)	**YYYY-MM**	Date format (year-month)
	Handheld barcode scanner		Mixing of substances
	Target		Interval
	Variable hexadecimal number that ensures the Master Curve and Calibrator definition values entered are valid.		Material
	Unique material identification number		Name of control

Symbol	Symbol Title	Symbol	Symbol Title
CONTROL TYPE	Type of control	CAL LOT VAL	Calibrator lot value
CONTROL LOT VAL	Quality control lot value		

[a] Indicates Assay-*e*Note

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SIEMENS Healthineers

SARS-CoV-2 Antigen Calibrator (CoV2Ag CAL)

Current Revision and Date[a]	Rev. 03, 2023-05	
Product Name	Atellica IM SARS-CoV-2 Antigen Calibrator (CoV2Ag CAL)	
	Atellica IM CoV2Ag CAL	
	2 x 1.0 mL low calibrator CAL L 2 x 1.0 mL high calibrator CAL H Calibrator lot-specific value sheet CAL LOT VAL	11208048
	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 an Emergency Use Authorization Only

For *in vitro* diagnostic use.

For Prescription Use Only.

For Professional Use.

Intended Use

The Atellica® IM SARS-CoV-2 Antigen Calibrator (CoV2Ag CAL) is for *in vitro* diagnostic use in calibrating the Atellica IM CoV2Ag assay using an Atellica® immunoassay analyzer.

Material Description

Material Description	Storage	Stability
Atellica IM CoV2Ag CAL[a, b] **CoV2Ag CAL L**: 1.0 mL/vial; frozen Buffer; bovine serum albumin; preservatives **CoV2Ag CAL H**: 1.0 mL/vial; frozen Recombinant SARS-CoV-2 nucleocapsid antigen; buffer; bovine serum albumin; preservatives	Frozen at ≤ -20°C Thawed at 2–8°C At room temperature	Until expiration date on product 5 days[c] 4 hours

[a] Store in an upright position.

[b] Prevent exposure to sunlight and heat.

[c] Product may be refrozen 1 time within 5 days for future use. Once re-thawed, use within the same day and discard any remaining material.

Warnings and Precautions

FOR USA:

For Use Under an Emergency Use Authorization Only

For *in vitro* diagnostic use.

For Prescription Use Only.

For Professional Use.

In the USA, this product has not been FDA cleared or approved, but has been authorized by FDA under an EUA for use by authorized laboratories; use by laboratories certified under CLIA that meet requirements to perform moderate or high complexity tests.

This product is for use with a test that has been authorized only for the presence of SARS-CoV-2 Antigen, not for any other viruses or pathogens.

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

Read all instructions carefully before performing the test. Failure to follow the instructions may result in inaccurate test results.

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

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

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

Storage and Stability

Store all calibrators 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 *Material Description*.

Performing Calibration

Calibration Frequency

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

Preparing the Calibrators

Allow the calibrators to thaw. Gently mix and invert the vials to ensure homogeneity of the material.

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

Calibration Procedure

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

Use the following lot-specific materials to perform calibration:

- For the calibrator definitions, refer to the lot-specific 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.

Technical Assistance

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

siemens-healthineers.com

Definition of Symbols

The following symbols may appear on the product labeling:

Symbol	Symbol Title	Symbol	Symbol Title
	Manufacturer	EC REP	Authorized representative in the European Community
	Use-by date	LOT	Batch code
REF	Catalog number		Contains sufficient for <n> tests
	Consult Instructions for Use		Version of Instructions for Use
	Internet URL address to access the electronic instructions for use	Rev. REVISION	Revision
IVD	*In vitro* diagnostic medical device	UDI	Unique Device Identifier
RxOnly	Prescription device (US only)	CE	CE Marking
CE XXXX	CE Marking with Notified Body		Keep away from sunlight
	Temperature limit		Lower limit of temperature
	Upper limit of temperature		Do not freeze
	Do not re-use		This way up
	Recycle		Caution

Symbol	Symbol Title	Symbol	Symbol Title
	Biological risks		Document face up[a]
UNITS C	Common Units	UNITS SI	International System of Units
YYYY-MM-DD	Date format (year-month-day)	YYYY-MM	Date format (year-month)
	Handheld barcode scanner		Mixing of substances
	Target		Interval
CHECKSUM	Variable hexadecimal number that ensures the Master Curve and Calibrator definition values entered are valid.	MATERIAL	Material
MATERIAL ID	Unique material identification number	CONTROL NAME	Name of control
CONTROL TYPE	Type of control	CAL LOT VAL	Calibrator lot value
CONTROL LOT VAL	Quality control lot value		

[a] Indicates Assay-eNote

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SARS-CoV-2 Antigen Quality Control (CoV2Ag QC)

Current Revision and Date[a]	Rev. 04, 2023-05
Product Name	Atellica IM SARS-CoV-2 Antigen Quality Control (CoV2Ag QC)
Abbreviated Product Name	Atellica IM CoV2Ag QC
	2 x 1.6 mL negative quality control, level 1 CONTROL – 1 REF 11207863 2 x 1.6 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 an Emergency Use Authorization Only

For *in vitro* diagnostic use.

For Prescription Use Only.

For Professional Use.

Intended Use

The Atellica® IM SARS-CoV-2 Antigen Quality Control (CoV2Ag QC) is for *in vitro* diagnostic use in monitoring the performance of the Atellica IM CoV2Ag assay using an Atellica® immunoassay analyzer for the qualitative detection of SARS-CoV-2 nucleocapsid antigen.

This test has not been FDA cleared or approved; but has been authorized by FDA under an Emergency Use Authorization (EUA) for use by authorized laboratories; use by laboratories certified under CLIA that meet the requirements to perform moderate or high complexity tests.

This test has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens. The emergency use of this test is 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 Act, 21 U.S.C. § 360bbb3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

Material Description

Material Description	Storage	Stability
Atellica IM CoV2Ag QC[a, b] **CoV2Ag Control 1**: 1.6 mL/vial; frozen Buffer; bovine serum albumin; preservatives **CoV2Ag Control 2**: 1.6 mL/vial; frozen Recombinant SARS-CoV-2 nucleocapsid antigen; buffer; bovine serum albumin; preservatives	Frozen at ≤ -20°C	Until expiration date on product
	Thawed at 2–8°C	7 days[c]
	At room temperature	4 hours
	Atellica® Sample Handler[d]	

[a] Store in an upright position.

[b] Prevent exposure to sunlight and heat.

[c] Product may be refrozen 1 time within 7 days for future use. Once re-thawed, use within the same day and discard any remaining material.

[d] 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 an Emergency Use Authorization Only

For *in vitro* diagnostic use.

For Prescription Use Only.

For Professional Use.

In the USA, this product has not been FDA cleared or approved, but has been authorized by FDA under an EUA for use by authorized laboratories; use by laboratories certified under CLIA that meet requirements to perform moderate or high complexity tests.

This product is for use with a test that has been authorized only for the presence of SARS-CoV-2 Antigen, not for any other viruses or pathogens.

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

Read all instructions carefully before performing the test. Failure to follow the instructions may result in inaccurate test results.

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

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

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

Storage and Stability

Store quality control materials in an upright position, away from light and heat. Do not use products beyond the expiration date printed on the product labeling.

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.

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

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

Allow quality control materials to thaw. 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 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 CoV2Ag QC is for use only with the Atellica IM CoV2Ag assay. Assay values have not been established for assays other than the Atellica IM CoV2Ag 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.

siemens-healthineers.com

Definition of Symbols

The following symbols may appear on the product labeling:

Symbol	Symbol Title	Symbol	Symbol Title
	Manufacturer		Authorized representative in the European Community
	Use-by date		Batch code
	Catalog number		Contains sufficient for <n> tests
	Consult Instructions for Use		Version of Instructions for Use
	Internet URL address to access the electronic instructions for use		Revision
	*In vitro* diagnostic medical device		Unique Device Identifier
	Prescription device (US only)		CE Marking
	CE Marking with Notified Body		Keep away from sunlight
	Temperature limit		Lower limit of temperature
	Upper limit of temperature		Do not freeze
	Do not re-use		This way up

Symbol	Symbol Title	Symbol	Symbol Title
	Recycle		Caution
	Biological risks		Document face up[a]
UNITS C	Common Units	UNITS SI	International System of Units
YYYY-MM-DD	Date format (year-month-day)	YYYY-MM	Date format (year-month)
	Handheld barcode scanner		Mixing of substances
	Target		Interval
CHECKSUM	Variable hexadecimal number that ensures the Master Curve and Calibrator definition values entered are valid.	MATERIAL	Material
MATERIAL ID	Unique material identification number	CONTROL NAME	Name of control
CONTROL TYPE	Type of control	CAL LOT VAL	Calibrator lot value
CONTROL LOT VAL	Quality control lot value		

[a] Indicates Assay-eNote

Legal Information

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Atellica® IM SARS-CoV-2 Antigen (CoV2Ag)	REF 11207861 (100T) REF 11207862 (500T)

IVD

FOR US

RxOnly

For Emergency Use Authorization 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 the detection of proteins from 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.

Atellica® IM SARS-CoV-2 Antigen (CoV2Ag) Calibrator (CAL)	REF 11208048
Atellica® IM SARS-CoV-2 Antigen (CoV2Ag) Quality Control (QC)	REF 11207863
Sample Inactivation Media	REF 11208651

IVD

FOR US

RxOnly

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- This product is for use with a test authorized only for the detection of proteins from 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.
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