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CE IVD

Celltrion Sampinute™ COVID-19 Antigen MIA

User Manual

HEALTHCARE
CELLTRION™

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Product Introduction

Intended Use

The Celltrion Sampinute™ COVID-19 Antigen MIA is intended for the qualitative detection of spike proteins of SARS-CoV-2 in nasopharyngeal swab (NPS) specimens in conjunction with the Sampinute™ Analyzer. The test cartridge, with the analyzer, incorporates a technique called magnetic force-assisted electrochemical sandwich immunoassay[i]. The technique entails the use of magnetic nanoparticles (MNPs) and electrochemical sensors conjugated with monoclonal antibodies specific for the receptor binding domains (RBD) of SARS-CoV-2 spike proteins to facilitate the electrochemical sandwich immunoassay.

SARS-CoV-2 spike proteins are generally detectable in NPS specimens during the acute phase of infection. Hence, results reveal the presence or absence of SARS-CoV-2 viral antigens in the NPS specimens. Positive results indicate the presence of viral antigens, but clinical correlations with patient history and other diagnostic information are necessary to determine infection status. 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. Laboratories within the United States and its territories are required to report all positive results to the appropriate public health authorities.

Negative results should be treated as presumptive and confirmed with a molecular assay, if patient management is necessary. Negative results do not rule out the possibility of COVID-19 infection and should not be used as the sole basis for treatment or patient management decisions, including infection-control decisions. Negative results should be considered in the context of a patient's recent exposures, history and clinical signs and symptoms consistent with COVID-19.

The Celltrion Sampinute™ COVID-19 Antigen MIA is intended for use with Celltrion Sampinute™ Analyzer by medical professionals or trained operators who are proficient in the use of the device. Both the Sampinute™ Analyzer and the Sampinute™ COVID-19 Antigen MIA are only for use under the Food and Drug Administration's Emergency Use Authorization.

Principle

The Celltrion Sampinute™ COVID-19 Antigen MIA employs magnetic force-assisted electrochemical sandwich immunoassay that is used with Celltrion Sampinute™ Analyzer to detect spike proteins from SARS-CoV-2.

The recommended period of incubation until the test is equivalent to that of diagnostic PCR testing for SARS-CoV-2. (It can be found that the virus has a median incubation time of approximately 5.1 days. Symptoms usually manifest after being infected for 12 days.) The patient sample is collected using a NPS and is either directly placed into the Reagent Tube supplied in the kit or a universal viral transport System. In the case of the Reagent Tube, the sample should be processed for analysis within one hour. As for the universal viral transport System, room temperature-equilibrated samples can be directly processed for analysis. If the transport System is frozen, the sample should be fully thawed and equilibrated to room temperature.

The sample is dispensed into the sample inlet of a Celltrion Sampinute™ COVID-19 Antigen MIA test cartridge.

Product Description

The sample flows along the microfluidic channel, and if SARS-CoV-2 spike proteins are present in the sample, they form complexes with anti-SARS-CoV-2 spike protein antibodies conjugated to MNPs. These complexes eventually encounter and bind onto the working electrode of the electrochemical sensor, that is coated with anti-SARS-CoV-2 spike protein antibodies. *Via* magnetic actuation, the antigen-antibody reactions are actively controlled. This ensures that the MNPs and the antigens are thoroughly mixed to form immuno-complexes on the electrode. The unbound MNPs are removed *via* magnetic field.

Subsequently to the magnetic actuation step, the device proceeds to the introduction of a detection buffer followed by the electrochemical measurement step, wherein a voltage is applied to induce electrochemical oxidation and reduction of gold on the MNPs, resulting in the electric current.

The test results reveal the presence (positive) or absence (negative) of SARS-CoV-2 spike protein antigens.

The Celltrion Sampinute™ Analyzer will display the test results (positive, negative) on the screen.

Principal Ingredients and Amounts

Each test cartridge of the Celltrion Sampinute™ COVID-19 Antigen MIA contains the main reactants and components shown below:

- MNPs conjugated with monoclonal antibodies specific for receptor binding domain (RBD) of spike protein from SARS-CoV-2.
- Electrodes coated with monoclonal antibodies specific for RBD of spike protein from SARS-CoV-2.

Warnings & Precautions

- Only use Celltrion Sampinute™ COVID-19 Antigen MIA test cartridges with the Celltrion Sampinute™ Analyzer.
- Do not use expired Celltrion Sampinute™ COVID-19 Antigen MIA test cartridges.
- Do not use Celltrion Sampinute™ COVID-19 Antigen MIA test cartridges that are damaged or broken.
- The recommended measurement temperature range is 15-30°C (59-86°F).
- Only use the Celltrion Sampinute™ COVID-19 Antigen MIA test cartridges after a full system check according to the Celltrion Sampinute™ Analyzer user manual.
- Wear disposable protective gloves when handling the Celltrion Sampinute™ COVID-19 Antigen MIA test cartridges and human specimens.
- If transport of the samples is required, the following transport media have been tested and shown not to interfere with the performance of the test.
  - BD™ Universal Viral Transport System
  - Copan® UTM-RT® System
  - CDC VTM according to SOP#: DSR-052-02

Product Description

- Gently press the Celltrion Sampinute™ COVID-19 Antigen MIA test cartridge down onto the tray of the Celltrion Sampinute™ Analyzer gently until it will go no further.
- The product is for single use only. Do not re-use.
- Place the test cartridge on the tray with the labelled side facing up.
- Take a precise amount of sample for each test and insert it into the sample inlet at once.
- Discard the Celltrion Sampinute™ COVID-19 Antigen MIA test cartridge after use as required by internal quality control procedures and in accordance with the WEEE Directive (2002/96/EC).
- Do not swallow or damage the Celltrion Sampinute™ COVID-19 Antigen MIA test cartridge.
- The product is for *in vitro* diagnostics.
- The product is indicated for use in clinical laboratories.
- Follow safety procedures set by your institution for working with chemicals and handling biological specimens.
- This test has not been FDA-cleared or -approved. The test has been validated, but FDA's independent review of this validation is pending.
- This test has been validated only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens.

Storage and Handling Requirements of Cartridge

- Keep the cartridge packaged in the provided aluminium pouch.
- Keep the product refrigerated (2-8°C, 36-46°F).
- **Upon preparation, the test cartridge must be placed at room temperature (15-30°C, 59-86°F) at least 30 minutes before use.**
- Use the cartridge immediately after opening the aluminum pouch. Do not expose the product to direct sunlight.

Product Description

Product Component

The **Celltrion Sampinute™ COVID-19 Antigen MIA** test cartridge can test 25 specimens or quality control samples. The test cartridge box contains the following:

- Celltrion Sampinute™ COVID-19 Antigen MIA (25) : test cartridges with monoclonal anti-SARS-CoV-2 antibodies, MNPs, and electrochemical sensors.
- Reagent Tubes (25): solutions for collecting specimens.
- Sterile nasal swabs (25) : flexible swabs for collecting specimens.
- Negative control solution (1) : salt solution with less than 0.1% sodium azide. Upon measurement, the results are expected to show negative, as no spike proteins are present in the control solution. One valid result of the analysis of the negative control solution should be obtained per package.
- Positive control solution (1) : salt solution with non-infectious SARS-CoV-2 antigen and less than 0.1% sodium azide. Upon measurement, the results are expected to show positive, as SARS-CoV-2 spike proteins are present in the control solution. One valid result of the analysis of the positive control solution should be obtained per package.
- Package insert (1)

Materials required, but not provided

- Celltrion Sampinute™ Analyzer
- Adapter
- Power cord
- Barcode scanner
- Printer
- BD Universal Viral Transport (UVT), Copan Universal Transport Media (UTM), or Viral Transport Media (VTM), the preparation of which follows the CDC protocol
- A pipette and disposable tips to transfer the specimen (or a glass capillary)
- A vortex shaker (or a mixer)

Test Procedures

Sample Requirements

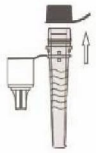
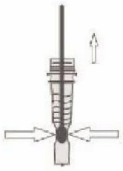
See below for the recommended requirements for sample collection, preparation and handling that will help ensure accurate test results.

Specimen Type	• The human nasopharyngeal swab (NPS) specimen is collected using a sterile cotton swab and placed in 1-3 mL of transport medium.
Minimum Sample Volume	• 1-2 drops per 1 test cartridge
Collection	Insert the sterile nasal swab through the nostril parallel to the palate (not upwards) until resistance is encountered or the distance is equivalent to that from the ear to the nostril of the patient, indicating contact with the nasopharynx. The swab should reach depth equal to the distance from nostrils to the outer opening of the ear. Gently rub and roll the swab. Leave the swab in place for several seconds to absorb secretions. Slowly remove the swab while rotating it. Place swabs immediately into sterile tubes containing the reagent solution.
Transport and Storage	The reagent solutions should be stored at room temperature (15-30°C, 59-86°F) upon testing. It is recommended that the specimens upon collection are processed and analyzed as soon as possible. The specimen would only be viable for processing for up to one hour. For UVT, UTM, VTM and transport media prepared according to the CDC protocol, store specimens at room temperature (15-30°C, 59-86°F) for up to 4 hours and at 2-8°C (36-46°F) for up to 72 hours after collection. If a delay in testing or shipping is expected, store specimens at -70°C (-94°F) or below.

Proper handling of the specimen during collection, storage, and transport is very important for the performance of the test. Inadequate handling may yield a false result.

Test Procedures

Sample Requirements

<table>
<tr>
<td rowspan="2">Swab Test Procedure</td>
<td>Reagent Solution
 
 
15 seconds
 
  </td>
<td>Place swabs immediately and directly into sterile tubes containing the reagent solution.
To collect a sample:
1. Aseptically take off and discard the cap from the tube.
1. Insert the swab into the tube. Swirl the swab in the solution for 15 seconds. Plunge the swab in vertical motion for at least another 15 seconds in the solution. Ensure that the solution does not splash out of the tube when swirling and plunging.
1. Remove and discard the swab while pressing against the sides of the tube to ensure maximum amount of liquid has been squeezed from the swab.
1. Assemble and press the tip firmly onto the reagent solution tube containing the specimen. Mix thoroughly by either flicking the bottom of the tube or swirling.</td>
</tr>
<tr>
<td>Transport Media
  </td>
<td>1. Place the swab immediately and directly into the Viral Transport System or Universal Transport Media System following their package instructions for use inserted.
1. Check that the transport media tube cap is closed.
1. If frozen specimens were prepared, melt the frozen specimens completely before the test.
1. Mix thoroughly by either flicking the bottom of the tube or swirling. If a vortex mixer can be used, Vortex for at least 1 minute the collection tube to ensure thorough mixing.</td>
</tr>
</table>

Test Procedures

Sample Preparation

STEP 1. Touch the '**RUN TEST**' button to start test

a. Put on a clean pair of gloves.
b. Touch the **'RUN TEST'** button.

- Test temperature range is 15℃~30℃.
- Run test within the test temperature range.
- If the temperature is out of the range, a test cannot be run.
- When the battery level becomes 15% or lower, you cannot start a test.
- Fully charge the battery before running a test.

STEP 2. Scan operator code

a. Scan the operator ID with a barcode scanner or manually enter using the keypad.
b. Touch the **'OK'** button only if entered manually.

STEP 3. Scan patient code

a. Scan the patient code with the barcode scanner or manually enter the code using the keypad. Touch the "OK" button only if entered manually.
b. The operator ID and the patient code are displayed on the screen. The screen subsequently proceeds to the screen for QR code scan.

Test Procedures

Sample Measurement Method

STEP 4. Cartridge QR code scan

a. Scan the QR code on the cartridge pouch with a barcode scanner.

b. After scanning the QR code, the cartridge type and LOT code will be displayed on the screen, and the predetermined "cut-off" value of the cartridge (shown in) is also recognized, which is unchangeable and varies depending on the lot. (The cut-off value for each lot is pre-determined *via* selection and analysis of a few sample cartridges of each lot. The cut-off value defines the threshold signal for distinguishing negative and positive results.)

Subsequently, the screen proceeds to cartridge insertion.

(The barcode scanner has to be purchased separately. If the QR code recognition fails, scan a new cartridge pouch. After scanning, please ensure that the cartridge type displayed on screen is Sampinute™ COVID-19 Antigen MIA.)

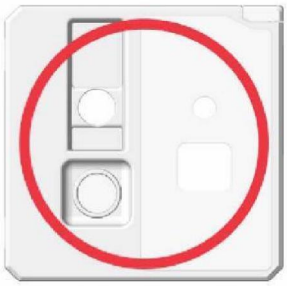
- Barcode scanner has to be purchased separately.
- If QR code recognition fails, scan a new cartridge pouch.
- After scanning, please ensure the cartridge type displayed on screen is **Celltrion Sampinute™ COVID-19 Antigen MIA**.

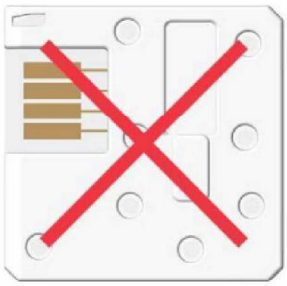
STEP 5. Test cartridge insertion

a. Take out a **Celltrion Sampinute™ COVID-19 Antigen MIA** test cartridge.

b. Insert a test cartridge in the correct position.

c. When the test cartridge is inserted in the correct position, the screen automatically proceeds to the sample injection stage.





- Ensure the correct operator ID and patient code are entered before inserting a cartridge.
- Check the QR code of the cartridge to be inserted is scanned.
- Ensure the correct test cartridge is being used for the target analyte.
- Before inserting a cartridge, ensure that you are not using an already used one.
- When the error message "**Please contact the system administrator**" is displayed after inserting a cartridge, stop the process and contact the administrator to resolve the issue.

Test Procedures

Sample Measurement Method

STEP 6. Injection of sample into test cartridge using the reagent solution included in the package

a. Prepare the sample according to "Collection" tab of the table on page 8 and "Reagent Solution" tab on page 9.
b. Ensure that the specimen is mixed thoroughly by either flicking the bottom of the tube or swirling.
c. Add 1-2 drops of the sample into the inlet of the Celltrion Sampinute™ COVID-19 Antigen MIA test cartridge by inverting the tube and holding it vertically approximately an inch above the sample inlet, squeezing the bottom of the tube gently. (Injected sample needs to fill up the inlet of the cartridge, and excess volume can be used for further testing if required.)
d. Touch the "OK" button.

STEP 7. Injection of sample into test cartridge using the Transport Media

a. Prepare the sample according to "Collection" tab of the table on page 8 and "Transport Media" tab on page 9.
b. Set the volume of the micropipette at 50μL and attach disposable tip.
c. Remove cap on the collection tube.
f. Withdraw the sample in the collection tube with the micropipette. Check that the pipette tip does not contain bubbles.
c. Draw 50 μL of the specimen and insert it into the inlet of the cartridge.
d. Touch the "OK" button.

Injected sample needs to fill up the inlet of a cartridge.

Test Procedures

Sample Measurement Method

STEP 8. Analyzing Process & Test Result

a. The progress of the analysis is shown as a percentage.
b. When the analysis is completed, the result of the measurement is displayed on the screen with the patient/sample code and the LOT number, and the tray at the bottom of the device is ejected.
c. Remove the used test cartridge from the tray following **STEP 8**.
d. Touch the **'DONE'** button.

> ⚠ Do not turn off or unplug the power adaptor while a test is in progress. (Otherwise, the test may be stopped.)

STEP 9. Discard the used cartridge.

Refer to the images below to eject the cartridge from the tray.
Discard the Celltrion Sampinute™ COVID-19 Antigen MIA test cartridge with any components used after use as required by internal quality control procedures and in accordance with the WEEE Directive (2002/96/EC).



Test Procedures

Test Result

a. Results of past tests can be viewed by touching the **"Test Results"** button on the home screen.

b. All test results are displayed in the order from the newest to oldest scan.

c. You can select specific results to view details.

d. If a printer is connected, you can print the results by clicking the print icon.

Result	Interpretation
	SARS-CoV-2 spike proteins are detected. *The electric current detected is higher than the assay cut-off.
	SARS-CoV-2 spike proteins are not detected. *The electric current detected is lower than the assay cut-off.

Clinical Performance

Clinical performance

Positive clinical specimens in viral transport media (VTM) were used for clinical validation.

The clinical performance of Celltrion Sampinute™ COVID-19 Antigen MIA was established with a study using NPS specimens, which have been previously characterized and were supplied by a biorepository in the United States.

In the clinical performance, seventy-two (72) samples were measured, resulting in a sensitivity of 94.4% (34/36) and a specificity of 100.0% (36/36).

	Results of Reference Device (RT-PCR)						95% CI	
		POS	NEG	Total	Sensitivity	94.4%	80.0%	99.0%
Celltrion Sampinute™ COVID-19 Antigen MIA	POS	34	0	34	Specificity	100.0%	88.0%	100.0%
	NEG	2	36	38	PPV	100.0%	89.9%	100.0%
	Total	36	36	72	NPV	94.7%	82.7%	98.5%
					Prevalence	50.0%		
					% agreement	97.2%		

Hypothetical Positive and Negative Predictive Values

	PPV			NPV		
Prevalence (%)	Estimates (%)	95% CI (%)		Estimates (%)	95% CI (%)	
1.0	100.0	15.0	100.0	99.9	94.8	100.0
2.0	100.0	26.2	100.0	99.9	94.6	100.0
5.0	100.0	47.0	100.0	99.7	94.2	100.0
10.0	100.0	63.9	100.0	99.4	93.3	100.0
15.0	100.0	72.6	100.0	99.0	92.4	99.9
20.0	100.0	78.0	100.0	98.6	91.5	99.8
25.0	100.0	81.6	100.0	98.2	90.4	99.7
30.0	100.0	84.2	100.0	97.7	89.2	99.5
35.0	100.0	86.1	100.0	97.1	87.9	99.4
40.0	100.0	87.6	100.0	96.4	86.4	99.1
45.0	100.0	88.9	100.0	95.7	84.7	98.9
50.0	100.0	89.9	100.0	94.7	82.7	98.5

Analytical Performance

Analytical performance

a) Limit of Detection

Materials: We conducted the testing with SARS-CoV-2 strain isolated from positive NPS specimens obtained from a biorepository (with a determined titer of 1.2×10^4 $TCID_{50}$/mL). The specimen was used as the starting point for preparing serial dilution samples.

The purpose of the LoD studies is to determine the lowest detectable concentration of SARS-CoV-2. The LoD was determined by limiting dilution studies. Dilutions were carried out with reagent solutions. For each test, 50 µL of the diluted sample was added to a sterile nasal swab before conducting the assay based on the Instruction For Use of the Celltrion Sampinute™ COVID-19 Antigen MIA test cartridge.

The test consisted of two steps for LoD determination:

1. Tentative LoD Confirmation

The cartridges were first tested in a series of 10-fold dilutions (n=3) to determine the dilution concentration that produced a 100% detection rate (3/3) with the subsequent dilution producing a detection rate of less than 100%.

Based on this testing, the concentration chosen was 1.2×10^2 $TCID_{50}$/mL.

2. LoD Confirmation

A total of forty (40) replicates were then further tested in a series of 2-fold dilutions (twenty (20) replicates with two reagent lots) to determine the minimum dilution concentration at which at least 95% of the true positive specimens were tested positive for a given target. 1.2×10^2 $TCID_{50}$/mL chosen from the "Tentative LoD Confirmation" step was used as the starting point for the dilution.

Based on this testing, the LoD was concluded to be 3.0×10^1 $TCID_{50}$/mL.

b) Cross-reactivity and c) Microbial Interference

Cross-reactivity of the cartridges was evaluated by testing various viruses (16) and microorganisms (9 including pooled human nasal wash) that potentially may cross-react with the Celltrion Sampinute™ COVID-19 Antigen MIA. The final concentration of each organism is documented in the table below. Each microorganism and virus was prepared in the absence and presence of SARS-CoV-2 at 3xLoD concentration. Both the cross-reactivity and microbial interference studies were conducted in triplicate. Each microorganism was diluted in BD™ Universal Viral Transport System.

The results show neither observed cross-reactivity nor microbial interference with the organisms at the concentrations tested (see the table in the next page).

Of all the tests recommended for cross-reactivity, the remaining five that were not included in the wet testing were analyzed *in silico via* Basic Local Alignment Search Tool managed by National Center for Biotechnology Information to determine the likelihood of leading to cross-reactivity.

- *Bordetella pertussis*: One area of sequence showed 17% homology with 8.89 % of the sequence. Thus, a very low likelihood of cross-reactivity exists between the pathogens.
- *Pneumocystis jirovecii*: 45.4% homology was found for one particular segment of sequence across 9 % of the sequence. Thus, a very low likelihood of cross-reactivity exists between the pathogens.
- *Mycobacterium tuberculosis*: No sequence homology was found between SARS-CoV-2 and *M. tuberculosis*. Thus, no cross-reactivity exists between SARS-CoV-2.

Analytical Performance

Analytical Performance

Cross-Reactivity & Microbial Interference: Celltrion Sampinute™ COVID-19 Antigen MIA - Wet Testing

Organism	Final Concentration Tested	Cross-Reactivity Results (Count)	Interference Result (Count)
Coronavirus 229E	5.44×10^5 $TCID_{50}$/mL	0/3	3/3
Coronavirus OC43	2.91×10^5 $TCID_{50}$/mL	0/3	3/3
Coronavirus NL63	7.05×10^5 $TCID_{50}$/mL	0/3	3/3
Coronavirus HKU1	4.07×10^5 PFU/mL	0/3	3/3
SARS-CoV-1	1.00×10^5 PFU/mL	0/3	3/3
MERS	1.02×10^5 PFU/mL	0/3	3/3
Adenovirus type 1	1.10×10^6 $TCID_{50}$/mL	0/3	3/3
Parainfluenza virus 1	1.13×10^6 PFU/mL	0/3	3/3
Parainfluenza virus 2	1.18×10^6 PFU/mL	0/3	3/3
Parainfluenza virus 3	1.51×10^6 PFU/mL	0/3	3/3
Parainfluenza virus 4	5.42×10^5 PFU/mL	0/3	3/3
Enterovirus	5.80×10^5 PFU/mL	0/3	3/3
Rhinovirus	3.19×10^5 PFU/mL	0/3	3/3
Respiratory Syncytial virus A	6.10×10^5 PFU/mL	0/3	3/3
Human metapneumovirus	1.71×10^5 PFU/mL	0/3	3/3
Influenza A	1.09×10^6 $TCID_{50}$/mL	0/3	3/3
Influenza B	1.09×10^6 $TCID_{50}$/mL	0/3	3/3
Candida albicans	3.23×10^6 CFU/mL	0/3	3/3
Chlamydia pneumoniae	1.61×10^6 IFU/mL	0/3	3/3
Haemophilus influenzae	2.07×10^6 CFU/mL	0/3	3/3
Pooled human nasal wash	100%	0/3	3/3
Mycoplasma pneumoniae	1.05×10^6 CFU/mL	0/3	3/3
Streptococcus pneumoniae	1.05×10^8 CFU/mL	0/3	3/3
Legionella pneumophila	3×10^6 CFU/mL	0/3	3/3
Streptococcus pyogenes	2×10^6 CFU/mL	0/3	3/3

Analytical Performance

Analytical performance

d) Endogenous interference study

A total of 16 potentially interfering substances, either naturally present in respiratory specimens or artificially introduced into the nasal cavity or nasopharynx, were tested in this study to evaluate the susceptibility of the Celltrion Sampinute™ COVID-19 Antigen MIA test cartridges to potentially interfering substances when elevated levels of these substances were added to SARS-CoV-2 positive or negative samples.

The potentially interfering substances were spiked into the SARS-CoV-2 positive or negative samples at elevated levels. For each test, a sterile nasal swab was swirled in the diluted samples before conducting the assay based on the Instruction For Use of the Celltrion Sampinute™ COVID-19 Antigen MIA test cartridge. Concentrations of potentially interfering substances were tested and the study results are summarized in the table below.

Substance	Concentration	SARS-CoV-2 Positive Sample	SARS-CoV-2 Negative Sample
Whole Blood	4%	3/3	0/3
Mucin (Bovine submaxillary gland)	0.5%	3/3	0/3
Tamiflu (Oseltamivir)	5 mg/mL	3/3	0/3
Mupirocin	10 mg/mL	3/3	0/3
Tobramycin	4 µg/mL	3/3	0/3
Sore Throat Phenol Spray	15% v/v	3/3	0/3
Homeopathic Nasal Spray (Alkalol)	1:10 dilution	3/3	0/3
Ricola (Menthol)	1.5 mg/mL	3/3	0/3
Sucrets (Dyclonine/Menthol)	1.5 mg/mL	3/3	0/3
Chloraseptic (Menthol/Benzocaine)	1.5 mg/mL	3/3	0/3
CVS Nasal Drops (Phenylephrine)	15% v/v	3/3	0/3
Afrin (Oxymetazoline)	15% v/v	3/3	0/3
CVS Nasal Spray (Cromolyn)	15% v/v	3/3	0/3
Naso GEL (NeilMed)	5% v/v	3/3	0/3
Zicam	5% v/v	3/3	0/3
Fluticasone Propionate	5% v/v	3/3	0/3

The study results show no interference with the Celltrion Sampinute™ Analyzer and the Celltrion Sampinute™ COVID-19 Antigen MIA test cartridges observed in the presence of potentially interfering substances at the concentrations tested in this study.

Analytical Performance

Analytical performance

e) High-dose hook effect

No high-dose hook effect was observed up to 3×10^5 $TCID_{50}$/mL of SARS-CoV-2 when measured with the Celltrion Sampinute™ Analyzer and Celltrion Sampinute™ COVID-19 Antigen MIA.

f) Matrix equivalency

SARS-CoV-2 strain was formulated in four (4) negative matrices: BD universal viral transport system (UVT), COPAN universal transport System (UTM), Centers for Disease Control and Prevention VTM (DSR-052-02), and the reagent solution with less than 0.1% sodium azide (contained in Reagent Tube) at a final concentration of 1 x LoD.

The transport media systems containing the contrived samples were stored at 2 - 8°C (36 - 46°F). Each transport media was tested in three (3) replicates and 3 Lots.

All four (4) matrices (BD UVT, COPAN UTM, VTM made according to the CDC SOP (DSR-052-02), and the reagent solution with less than 0.1% sodium azide) show the same results with %CV of less than 10%.

References

Symbol Guide

Please refer to the following symbols that can be found on the external package, package descriptions, enclosed papers, etc.

 Manufacturer	 Authorized Representative in European community
 Date of Manufacture	 Use by/Expiry date (for test cartridge)
 Batch code (for test cartridge)	 Catalogue number (for test cartridge)
 Serial number (for analyzer)	 To indicate the temperature limitation in which the transport package has to be kept and handled
 To indicate the humidity limitation in which the transport package has to be kept and handled	 Biological risks
 Do not reuse. (for test cartridge)	 Please refer to user manual.
 Caution, please refer to accompanying documents	 In Vitro Diagnostic Medical Device/In Vitro diagnostic use
 Control	 Contains sufficient for <n> tests.
 Waste electrical and electronic equipment (WEEE)	 Important
 Research Use Only	

References

Product Warranty

BBB Inc. offers product warranty in accordance with "Regulations on Consumer Dispute Resolution" as follows.
Within the warranty period, if the product fails due to manufacturing defect(s) or spontaneous failure, it will be replaced without any charges.

Warranty Period : One year from the purchase date.

Distributor Information

Celltrion Healthcare Co., Ltd.
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