SAMPINUTE
COVID-19 Antigen MIA

IVD Rx only

in vitro Diagnostic Use

Sampinute™ COVID-19 Antigen MIA Quick Reference Guide

BMD013BQUS Rev0B Date 2020-10

For use under the Emergency Use Authorization (EUA) only

Test Cartridge | Reagent Tube and Tip | Collection Tube

Cleaning

Clean the analyzer periodically with a soft and dry cloth. Do not use highly corrosive cleaning solutions or chemicals, or a cleaning tissue containing chemical substances that may damage the device. Wipe the tray carefully with an alcohol-moistened swab if needed.

- ***Make sure to turn off when cleaning the device.***
- ***Avoid contact with the electrode when cleaning as it is a sensitive part.***

The Sampinute™ COVID-19 Antigen MIA is a magnetic force-assisted electrochemical sandwich immunoassay for use with the Sampinute™ Analyzer, intended for the qualitative detection of receptor binding domains (RBDs) spike proteins from SARS-CoV-2 in nasopharyngeal swab specimens directly collected or collected in either BD Universal Viral Transport Media, Copan UTM-RT or CDC's formulation of VTM from individuals who are suspected of COVID-19 by their healthcare provider within the first five days of symptom onset.

Read thoroughly the Sampinute™ Analyzer User Manual and Sampinute™ COVID-19 Antigen MIA test cartridge insert before reading the Quick Reference Guide or conducting a test, as it is not a complete comprehensive insert.

The Sampinute™ Analyzer should be operated at room temperature between 15°C and 30°C (59°F and 86°F) and 10% - 80% relative humidity. 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 for SOP-DSR-052-05, specimens can be stored at room temperature (15-30°C, 59-86°F) for up to 3 hours and at 2-8°C (36-46°F) for up to 48 hours after collection. If a delay in testing or shipping is expected, store specimens (either dry swab or VTM) at -70°C (-94°F) or below. Check the expiration date on the outer test kit package and each individual test package before using.

Preparing the sample

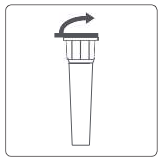
Collect a patient swab sample before Running the Test.

Specimen Collection and Handling: Proper specimen collection and handling of nasal swabs is required to ensure accurate results (refer to Sampinute™ COVID-19 Antigen MIA test cartridge insert). Additional training or guidance is recommended if operators are not experienced with specimen collection and handling procedures.

Option 1 - Swab Test Procedure in Reagent Solution Tube:

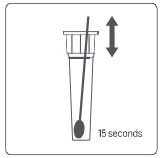
1

Aseptically take off and discard the cap from the tube.



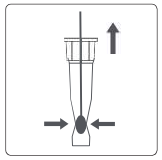
2

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.



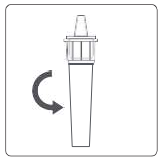
3

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.



4

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.



Option 2 - Swab Test Procedure in Viral Transport Media:

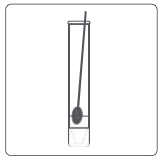
Do not use tips, tubes or caps taken from other products.
If frozen specimens were prepared, melt the frozen specimens completely before the test.

1

Open the cap of the transport media tube.

2

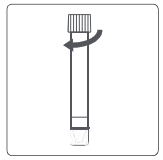
Swirl the swab in the solution for 15 seconds. Plunge the swab in vertical motion for at least another 15 seconds in the solution. Mix thorougly by either flicking the bottom of the tube or swirling. Ensure that the solution does not splash out of the tube when swirling and plunging.



This test has not been FDA cleared or approved; the test has been authorized by FDA under an Emergency Use Authorization (EUA) for use by laboratories certified under the CLIA that meet the requirements to perform moderate or high complexity tests.
This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

3

Check that the transport media tube cap is closed.



4

If a vortex mixer can be used, vortex for at least 1 minute the collection tube to ensure thorough mixing.

Warnings and Precautions

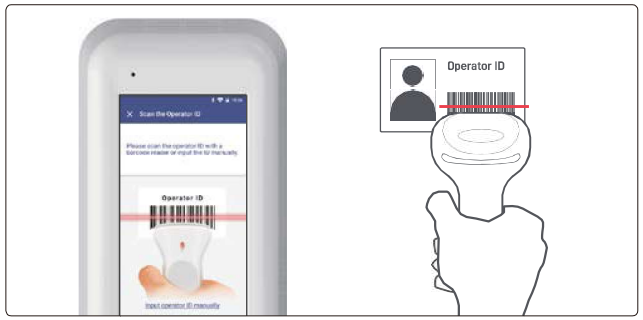
All components including the package can be disposed of as Biohazard waste. Refer to the product safety data sheet for information regarding risk, safety and disposal available at www.celltrion.com. Follow all basic precautions needed for handling chemicals and reagents within the laboratory and proper laboratory safety techniques at all times when handling SARS-CoV-2 patient specimens. Patient swabs, used test cartridges, pipette tips, transport media collection tubes and reagent solution tubes should be regarded as potentially infectious and handled cautiously. Local regulations or accreditation requirements should be followed to establish proper handling and disposal methods. Sources of the components are certified as free from infectious or contagious material. Still, the components should be treated as potentially infectious.

Refer to the CDC Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons for Coronavirus Disease 2019 (COVID-19) https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html

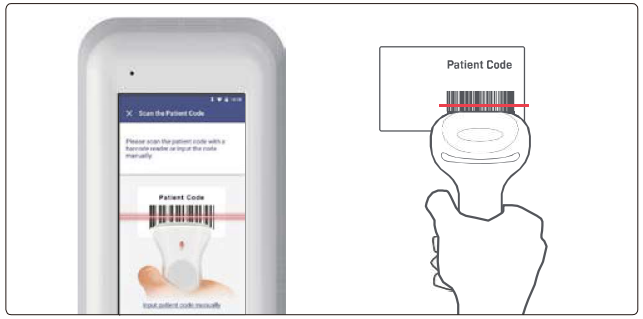
Running the Test

1. Touch 'RUN TEST' to start the test.

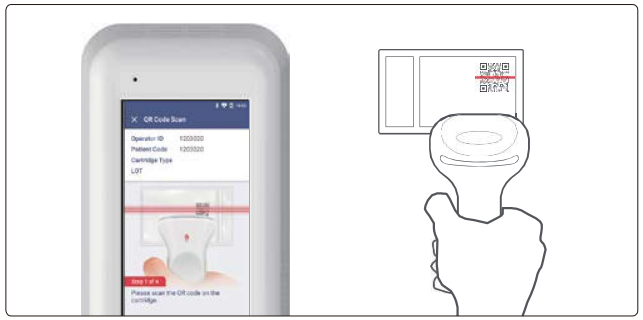
2. Scan operator ID with barcode scanner or enter *via* keypad.



3. Scan patient code with barcode scanner or enter *via* keypad.



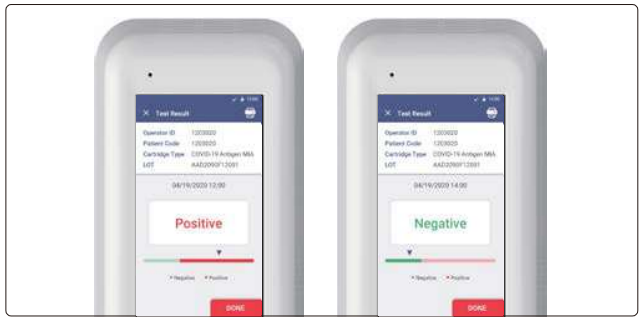
4. Scan QR code on cartridge pouch with barcode scanner. Open pouch to take out test cartridge.



5. Remove the aluminium tape attached on top of the cartridge. Insert the test cartridge onto the tray according to instructions on the screen.

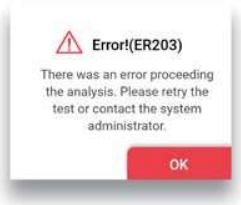
6. Prepare a test sample and inject it (either 1-2 drops with reagent tube or 50µL with pipette) according to the Sampinute™ Analyzer User Manual. Touch 'OK' to initiate analysis.

7. When the test is completed, the results are displayed on the touch-screen.



Interpretation of Results

Positive Test Results: SARS-CoV-2 proteins are present. However, it does not rule out co-infection with other pathogens.
Negative Test Results: Negative results are 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 decisions.



Invalid Results : In the event of an error, the device will display a message (as shown above). All messages the instrument status or error and an instruction to be followed. In the example above, remove the used test cartridge and retry the test. If the problem persists, contact the system administrator.

Quality Controls

Please perform the system check and the QC test prior to sample tests. You must carry out a Quality Control Test using the Sampinute™ COVID-19 Antigen MIA Control Solutions to assess the performance of the Sampinute ™ Analyzer and Sampinute™ COVID-19 Antigen MIA test cartridges. If the Control Solutions do not perform as required, re-test using a new test cartridge – if problems persist contact BBB Inc. (*via* website: www.bbbtech.com) or Celltrion USA, Inc. (*via* email: Sampinute@celltrion.com), Monday through Friday, from 9:00 a.m. to 6:00 p.m., Korea Standard Time. This test has been authorized only for the detection of proteins from SARS-CoV-2.

Customer Service

If the instrument does not perform as expected, please contact BBB Inc. (*via* website: www.bbbtech.com) or Celltrion USA, Inc. (*via* email: Sampinute@celltrion.com).

Distributor Information

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