Fact Sheet for Celltrion Sampinute™ COVID-19 Antigen MIA

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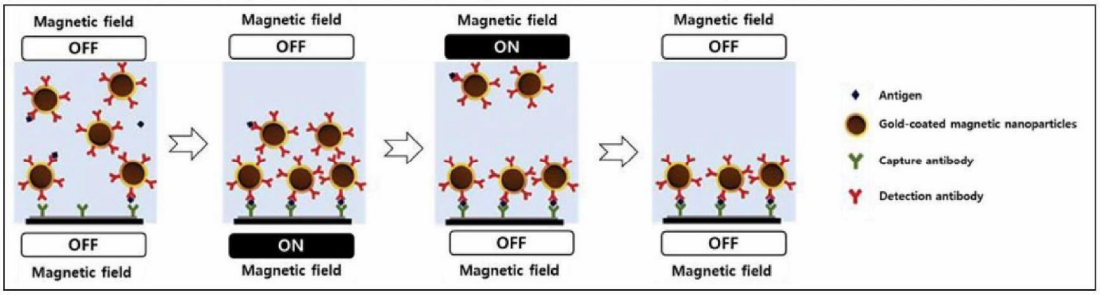
Updated: August 20, 2020

Coronavirus Disease 2019 (COVID-19)

1. What are the symptoms of COVID-19?

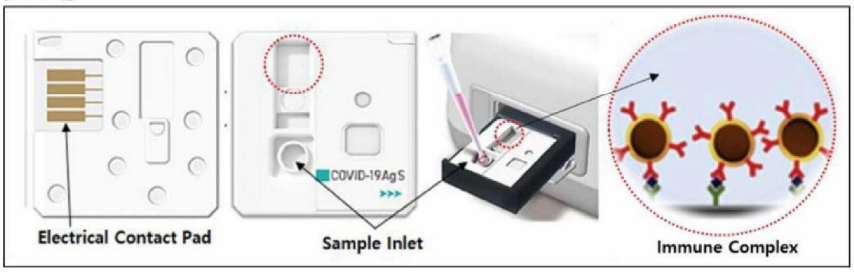
Many patients with confirmed COVID-19 have developed fever and/or symptoms of acute respiratory illness (e.g., cough, difficulty breathing). The current information available to characterize the spectrum of clinical illness associated with COVID-19 suggests that symptoms include cough, shortness of breath or dyspnea, fever, chills, myalgias, headache, sore throat or new loss of taste or smell. Based on what is known about the virus that causes COVID-19, signs and symptoms may appear any time from 2 to 14 days after exposure to the virus. Based on preliminary data, the median incubation period is approximately 5 days, but may range 2-14 days.

2. What is Celltrion Sampinute™ COVID-19 Antigen MIA Test and Principle?



Celltrion Sampinute™ COVID-19 Antigen MIA Test is a new assay format with high sensitivity and specificity using Lab-on-a-chip technology. This technology includes a device and a cartridge using magnetic-force assisted electrochemical sandwich immunoassay, where SARS-CoV-2 spike protein (S) antigen can be detected by magnetic actuation and electrochemical detection of probes for immune complex formation. The device combined with the cartridge was designed for detecting the presence of Sars-CoV2 S antigen of virus by highly specific antibodies generated based on Celltrion's antibody technologies. The analyzing device automates all process including sample filtration, antigen enrichment, antigen-antibody reaction, and detection of the SARS-CoV-2 S antigen by immunoassays.

If SARS-CoV-2 S antigens are present in the sample, they start to form a complex with anti-S antibodies conjugated to magnetic nanoparticles. The complex is then bound by antibodies coated on the working electrode. The unbound magnetic nanoparticles were removed by a wash buffer. The currents increase as the bounded SARS-CoV-2 with magnetic nanoparticle conjugates. The positive test results mean the existence of SARS-CoV-2 as the S antigens with anti-S antibodies formed immune complexes. Celltrion's high specific antibodies against Sars-CoV2 S antigens are applied in a cartridge and it can be read out on a novel platform maximizing the sensitivity of the pure signals.



3. Intended Use

The Celltrion Sampinute™ COVID-19 Antigen MIA Test is composed of a cartridge and the Sampinute analyzer. They are intended for the qualitative detection of SARS-CoV-2 spike proteins from nasopharyngeal swab (NPS) or oropharyngeal swab (OPS) specimens collected from individuals suspected of COVID-19 by their medical service provider. 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. The Celltrion Sampinute™ COVID-19 Antigen MIA Test is intended for the qualitative detection of SARS-CoV-2 spike antigens from nasopharyngeal swab (NPS), oropharyngeal swab (OPS) and sputum specimens collected from individuals suspected of COVID-19 by their medical service provider. Results are for the identification of SARS-CoV-2 spike protein antigen. Antigen is generally detectable in upper respiratory specimens during the acute phase of infection.

Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for treatment or other patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information. The Celltrion Sampinute™ COVID-19 Antigen MIA Test is intended for use by trained clinical laboratory personnel and individuals trained in point of care settings. If infection with a SARS-CoV-2 is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions for virulent SARS-CoV-2. Virus detection test should be attempted in BSL 2+ facility.

4. Instructions for Use

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

a. Put on a clean pair of gloves.

b. Touch the 'RUN TEST' button.

STEP 2. Scan operator code

a. Scan the code of the operator with a barcode scanner or type it using the keypad.

b. Touch the 'OK' button.

STEP 3. Scan patient code

a. Scan the code of the sample with a barcode scanner or type it using the keypad.

b. Touch the 'OK' button.

STEP 4. Cartridge QR code scan

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

STEP 5. Test cartridge insertion

a. Take out Celltrion Sampinute™ COVID-19 Antigen MIA Test cartridge from the aluminum pouch.

b. Insert a test cartridge to the tray following the correct position.

c. When the Celltrion Sampinute™ COVID-19 Antigen MIA Test cartridge is inserted in the correct position, the screen automatically proceeds to the sample injection step.

STEP 6. Inject sample to Celltrion Sampinute™ COVID-19 Antigen MIA Test

a. Check that the universal transport medium tube cap is closed.

b. Vortex the collection tube for at least 1 minute to sufficiently mix the specimen.

c. Set the volume on the micropipette at 50 µL and assemble the disposable tip.

d. Open the cap on the universal transport medium tube.

e. Withdraw the sample with the micropipette. Ensure that no bubbles are present in the pipette tip.

f. Insert the sample into the inlet of the Celltrion Sampinute™ COVID-19 Antigen MIA Test cartridge.

g. Touch the 'OK' button.

h. Discard the used micropipette tip.

STEP 7. Analyzing process and test results

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.

d. Touch the 'Done' button.

STEP 8. Discard the used cartridge

a. Properly remove the cartridge from tray and discard it in a safe place under relevant regulations.

5. The Clinical Performance of the Celltrion Sampinute™ COVID-19 Antigen MIA Test

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 nasopharyngeal swab (NPS) specimens, which have been previously characterized and were supplied frozen 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).

Result		RT-PCR		Total
		Positive	Negative	
Celltrion Sampinute™ COVID-19 Antigen MIA Test	Positive	34	0	34
	Negative	2	36	38
Total		36	36	72

6. Where can I go for updates and more information?

Distributor Information:

Celltrion Healthcare Co., Ltd

4F, 19, Academy-ro 51beon-gil, Yeonsu-gu, Incheon 22014, Republic of Korea

Manufacturer Information:

BBB Inc.

7F, 22, Teheran-ro 81-gil, Gangnam-gu, Seoul, Republic of Korea

Tel: +82 5.1.2e E-mail: 5.1.5

References

(1) Hwang H., Choi E., Han S., Lee Y., Choi T., Kim M., Shin H., Kim J., and Choi J. MESIA: Magnetic Force-Assisted Electrochemical Sandwich Immunoassays for Quantification of Prostate-Specific Antigen in Human Serum. Analytica Chimica Acta 1081 (2019) 92-100.

(2) Baker S., Frias L., and Bendix A. Coronavirus live updates: More than 92,000 people have been infected and at least 3,100 have died. The US has reported 6 deaths. Here's everything we know. Business Insider. March 09, 2020.

(3) How COVID-19 Spreads. *U.S. Centers for Disease Control and Prevention (CDC)*. 2 April 2020.