

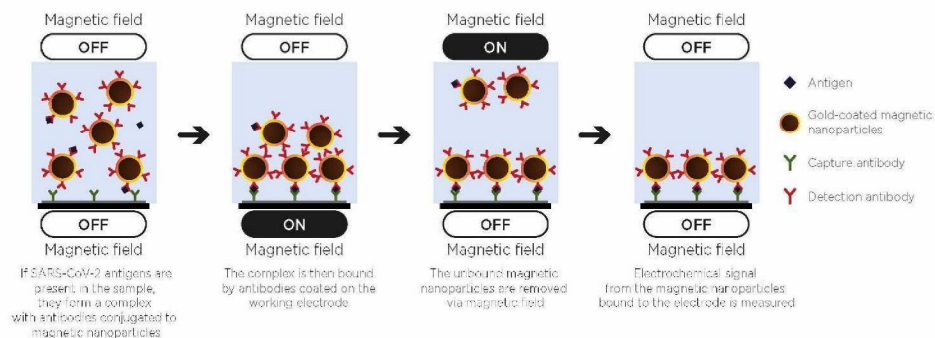
## Celltrion Sampinute™ COVID-19 Antigen MIA

- Qualitative detection of SARS-CoV-2 spike proteins
  - ✓ Quick : Rapid diagnosis within 10 mins
  - ✓ Accurate : High accuracy with sensitivity (94.4%), and specificity (100.0%)
  - ✓ Easy : Fully automated analysis with Celltrion Sampinute™ Analyzer
  - ✓ On-site diagnosis: Delivers lab-quality results at the point of care
  - ✓ Traceability: Automatically stores test and user history
- CE marked

### Principle

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.

\* MIA: Magnetic ImmunoAssay



### Product Component

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.
- Positive control solution (1) : salt solution with non-infectious SARS-CoV-2 antigen and less than 0.1% sodium azide
- Package insert (1)



Celltrion Sampinute™ COVID-19 Antigen MIA



Celltrion Sampinute™ Analyzer

### Key specification

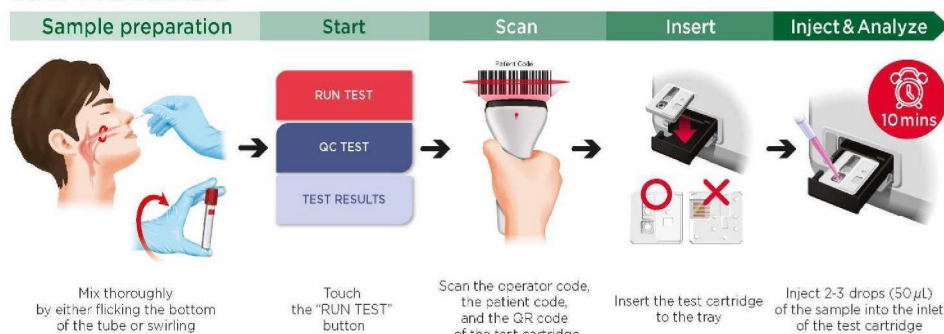
Assay method	Magnetic force-assisted electrochemical sandwich immunoassay
Shelf Life	12 months (2-8°C)
Measurement temperature range	15-30°C (59-86°F)
Kit storage and stability	Keep the product refrigerated (2-8°C, 36-46°F). Upon preparation, cartridge must be at room temperature (15-30°C, 59-86°F) at least 30 minutes before use

## Celltrion Sampinute™ COVID-19 Antigen MIA

### Sample Collection: Nasopharyngeal Swab Sample Specimen

- Insert the sterile nasal swab through the nostril parallel to the palate (not upwards).
- 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 and directly into sterile tubes containing the reagent solution.

### Test Procedure



- ✓ The barcode scanner has to be purchased separately. If you do not have a barcode scanner, you can manually enter the code using the keypad.
- ✓ The cartridge must be at room temperature (15-30°C, 59-86°F) at least 30 minutes before use.
- ✓ Before using the test cartridges, please conduct a full system check and quality control test according to the Celltrion Sampinute™ Analyzer user manual.

### Interpretation of Result

- Test results must be evaluated in conjunction with other clinical data available to the physician.

Result	Interpretation
<p><b>Positive</b> 6.22 5.0</p>	<p><b>SARS-CoV-2 spike proteins are detected.</b></p> <ul style="list-style-type: none"> <li>* The electric current detected is higher than the assay cut-off.</li> </ul>
<p><b>Negative</b> 3.86 5.0</p>	<p><b>SARS-CoV-2 spike proteins are not detected.</b></p> <ul style="list-style-type: none"> <li>* The electric current detected is lower than the assay cut-off.</li> </ul>

### Clinical Performance

- 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)					
	Positive	Negative	Total			
Celltrion Sampinute™ COVID-19 Antigen MIA	Positive	34	0	34	Sensitivity	94.4%
	Negative	2	36	38	Specificity	100.0%
	Total	36	36	72	PPV	100.0%
					NPV	94.7%

\* Sensitivity = True Positives / (True Positives + False Negatives)

\* Specificity = True Negatives / (True Negatives + False Positives)

\* PPV (Positive Predictive Value) = True Positives / (True Positives + False Positives)

\* NPV (Negative Predictive Value) = True Negatives / (False Negatives + True Negatives)

#### References

1. Hwang H., Cho E., Han S., Lee Y., Choi T., Kim M., Shin H., Kim J., and Cho J. MESA: Magnetic Force Assisted Electrochemical Sandwich Assays for Quantification of Protein-Specific Antigen in Human Serum. *Analytica Chimica Acta* 7067 (2019) 92-100.
2. Baker S., Frias L., and Bendis A. Coronavirus live updates: More than 92,000 people have been infected and at least 3,200 have died. *The US has reported 6 deaths. Here's everything we know. Business Insider*, March 03, 2020.
3. How COVID-19 Spreads. *U.S. Centers for Disease Control and Prevention (CDC)*, 2 April 2020.

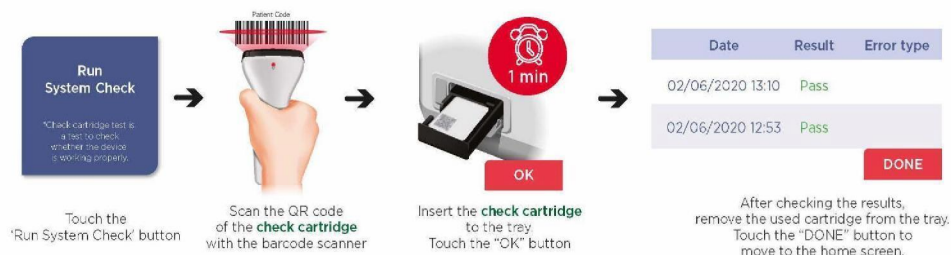
# Celltrion Sampinute™ COVID-19 Antigen MIA

## Quality Control prior to the actual test: System Check & Quality Control Test

- Before the actual sample test, the Celltrion Sampinute™ Analyzer and the Celltrion Sampinute™ COVID-19 Antigen MIA test cartridges must go through a system check, as well as an external quality control test using positive and negative sample control solutions.
- Celltrion Sampinute™ Analyzer Components: Celltrion Sampinute™ Analyzer (IEA), Check Cartridge (IEA), User manual

### System Check Procedure

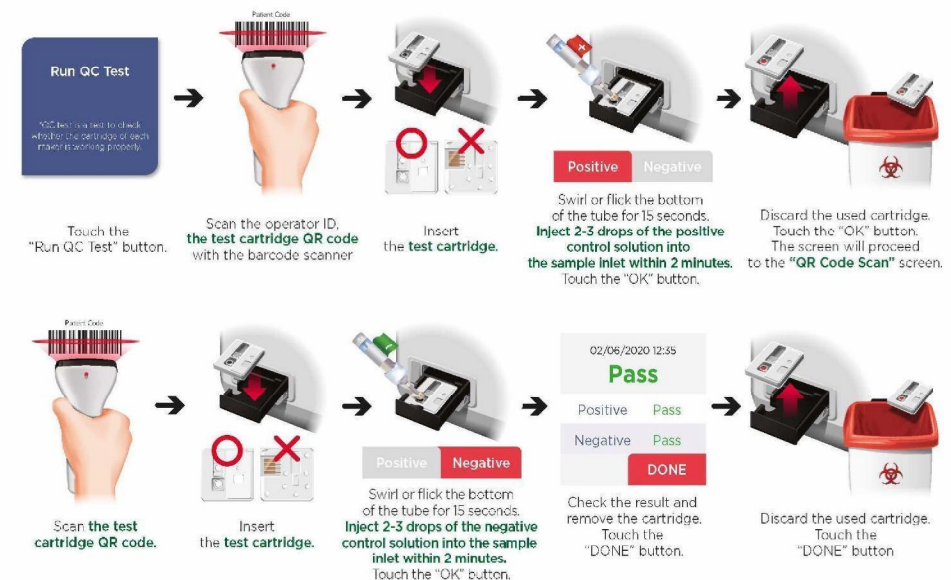
- The purpose of this test is to verify the proper operation of the Celltrion Sampinute™ Analyzer



- Note:**
- Pass: Indicates that the device is working properly and a "V" (✓) mark is displayed on the screen.
  - Fail: An error message and an "X" (✗) mark is displayed on the screen. Try out the test again or contact the administrator. If the test fails under [Settings → Lock Settings → QC fail → ON], a test cannot be run.

### Quality Control Test Procedure

- The purpose of the external quality control test is to ensure that the test kit properly differentiates the positive and negative samples before the test of the patient specimen.



- Note:**
- If you do not have a barcode scanner, touch "Input operator ID manually" to enter the code using the keypad.
  - The barcode scanner has to be purchased separately. If the QR code recognition fails, scan a new cartridge pouch. Please check if the cartridge type is correct.