

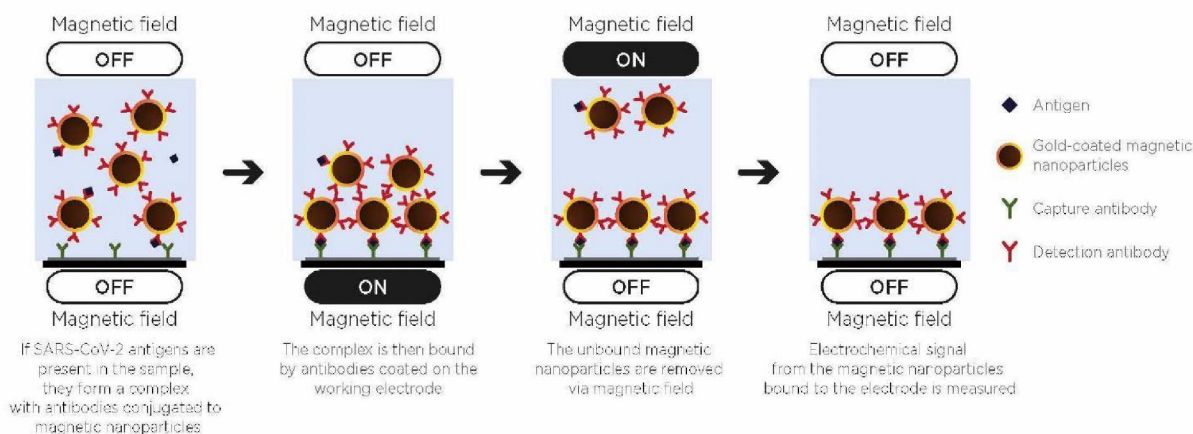
Celltrion Sampinute™ COVID-19 Antigen MIA

- 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)



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Celltrion Sampinute™ Analyzer

Key specification

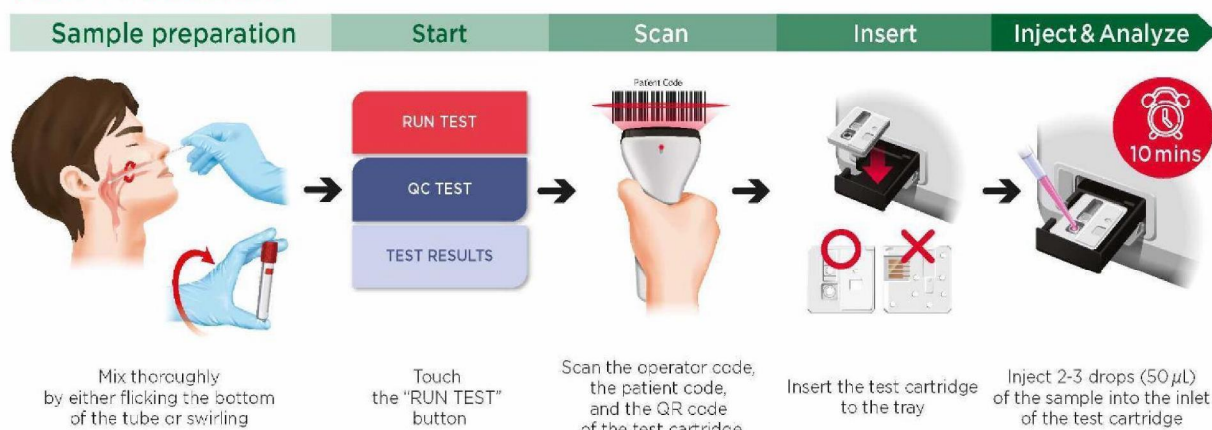
Assay method	Magnetic force-assisted electrochemical sandwich immunoassay
Shelf Life	12 months (2-8°C)
Measurement temperature range	15-30°C (59-86°F)
Kit storage and stability	Keep the product refrigerated (2-8°C, 36-46°F). Upon preparation, cartridge must be at room temperature (15-30°C, 59-86°F) at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

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

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

- Hasang H., Choi E., Han S., Lee Y., Choi T., Kim M., Shin H., Kim J., and Choi J. MESIA: Magnetic Force-Assisted Electrochemical Sandwich Immunosensors for Quantification of Prostate-Specific Antigen in Human Serum. *Analytica Chimica Acta* 1061 (2019) 92-100.
- Baker S., Elias L., and Bendix 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.
- How COVID-19 Spreads. U.S. Centers for Disease Control and Prevention (CDC). 2 April 2020.

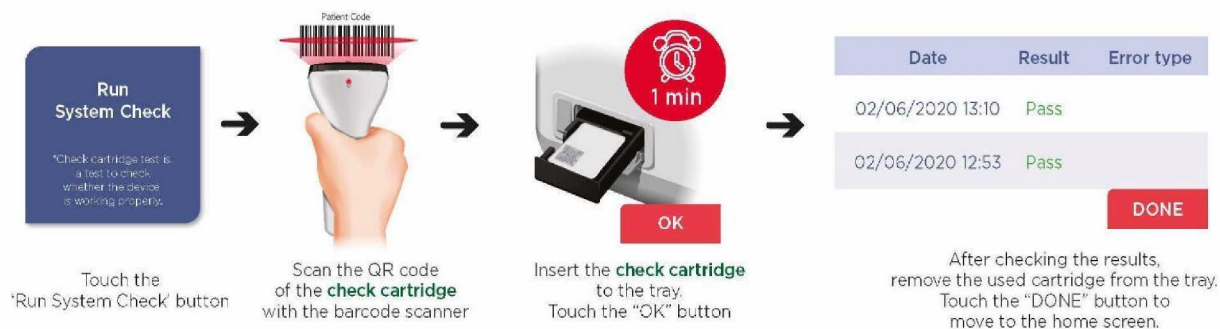
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Quality Control prior to the actual test: System Check & Quality Control Test

- 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 (1EA), Check Cartridge (1EA), User manual

System Check Procedure

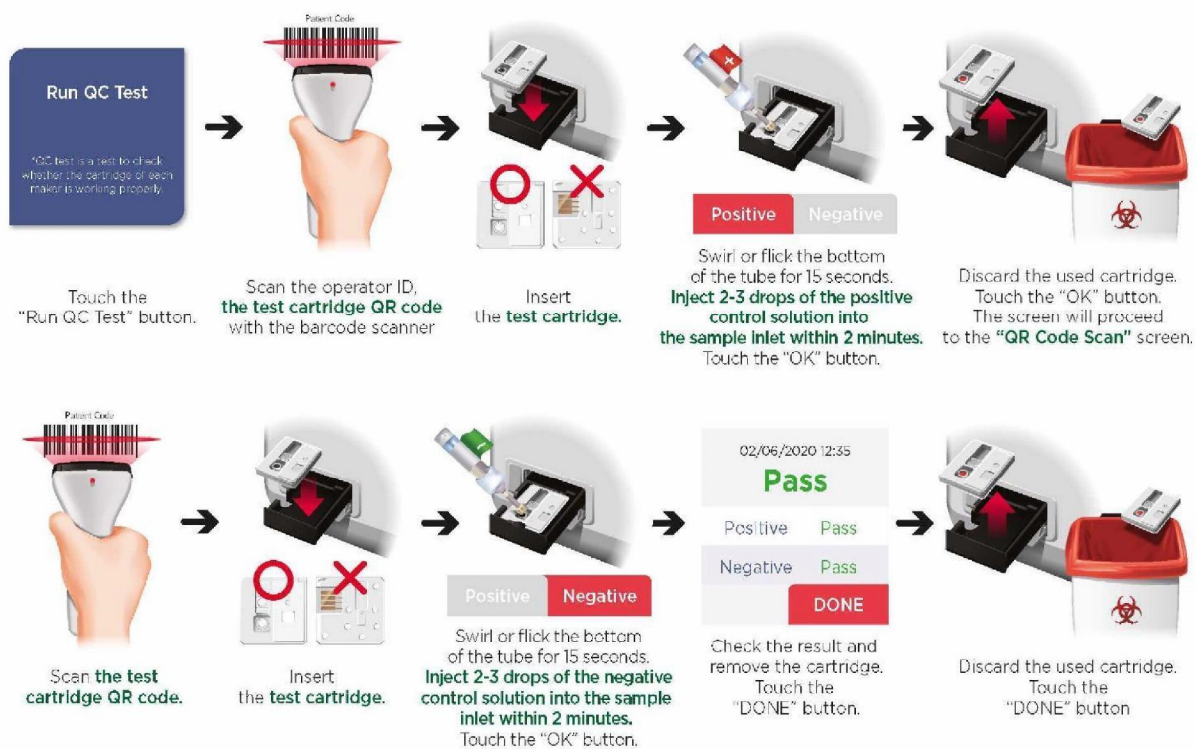
- The purpose of this test is to verify the proper operation of the Celltrion Sampinute™ Analyzer



- 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.