Sampinute™ COVID-19 Antigen MIA

For use under the Emergency Use Authorization (EUA) only

For in vitro diagnostic use

For Prescription Use only

INTENDED USE

Sampinute™ COVID-19 Antigen MIA is a magnetic force-assisted electrochemical sandwich immunoassay (MESIA) 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. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988(CLIA), 42 U.S.C. §263a, the meet requirements to perform high or moderate complexity tests.

Results are for the identification of the RBDs of SARS-CoV-2 spike protein antigens. Antigen is generally detectable in nasopharyngeal swab 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. 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 results to the appropriate public health authorities.

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. Negative results should be considered in the context of a patient's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19.

The Sampinute™ COVID-19 Antigen MIA is intended for use by trained clinical laboratory personnel specifically instructed on *in vitro* diagnostic procedures. The Sampinute™ COVID-19 Antigen MIA is only for use under the Food and Drug Administration's Emergency Use Authorization.

SUMMARY AND EXPLANATION

SARS-CoV-2, which causes the disease COVID-19, was first discovered in Wuhan, Hubei Province, China in December 2019, where it was first thought to have spread from bats. However, the coronavirus is also thought to have infected other animals as intermediary hosts.[ii] The virus spreads primarily through small droplets produced from coughing, sneezing, and talking.[iii] The median incubation time is estimated to be 5.1 days with symptoms expected to be present within 12 days of infection.[iv]

PRINCIPLE OF THE TEST

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

The patient sample is collected using a nasopharyngeal swab (NPS) and is either directly placed into the Reagent Solution Tube supplied in the kit or a validated viral transport media (VTM). In the case of the Reagent Solution, the sample should be processed for analysis within one hour. For validated VTM, room temperature-equilibrated samples can be directly processed for analysis. If the patient specimen is frozen, the sample should be fully thawed and equilibrated to room temperature.

The sample is dispensed via reagent tube or pipette into the sample inlet of a Sampinute™ COVID-19 Antigen MIA test cartridge.

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 by measuring the quantity of electric current compared to a lot-specific cut-off value. The Sampinute™ Analyzer will display the test results (positive, negative) on the screen.

REAGENTS AND MATERIALS SUPPLIED

Principal Ingredients

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

■ MNPs conjugated with monoclonal antibodies specific for RBD of spike protein from SARS-CoV-2.

■ Electrodes coated with monoclonal antibodies specific for RBD of spike protein from SARS-CoV-2.

Product Package Components

25 test cartridges of Sampinute™ COVID-19 Antigen MIA are provided in the package, which can be used to analyze up to 25 samples, including the control solutions provided in the package.

The package contains the following:

■ Sampinute™ COVID-19 Antigen MIA (25): test cartridges with monoclonal anti-SARS-CoV-2 antibodies, MNPs, and electrochemical sensors.

■ Reagent Tubes (25): containing reagent solution 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

■ 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 for SOP DSR-052-05 (https://www.cdc.gov/coronavirus/2019-ncov/downloads/Viral-Transport-Medium.pdf).

■ A pipette and disposable tips to transfer the specimen

■ A vortex shaker (or a mixer)

WARNINGS AND PRECAUTIONS

■ For in vitro diagnostic use only

■ For prescription use only.

■ 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.

■ Federal Law restricts this device to sale by or on the order of a licensed practitioner (US only).

■ Laboratories within the United States and its territories are required to report all results to the appropriate public health laboratories.

■ This test has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens.

■ Only use Sampinute™ COVID-19 Antigen MIA test cartridges with the Sampinute™ Analyzer.

■ Do not use expired Sampinute™ COVID-19 Antigen MIA test cartridges.

■ Do not use Sampinute™ COVID-19 Antigen MIA test cartridges that are damaged or broken.

■ The recommended measurement temperature range for the analyzer is 15-30°C (59-86°F).

■ Only use the Sampinute™ COVID-19 Antigen MIA test cartridges after a full system check according to the Sampinute™ Analyzer user manual.

■ Wear disposable protective gloves when handling the Sampinute™ COVID-19 Antigen MIA test cartridges and human specimens. Treat all specimens as potentially infectious and follow universal precautions when handling specimens.

■ All components of this kit should be discarded as Biohazard waste according to Federal, State and local regulatory requirements.

■ Three lots of BD UTM, Copan UTM and the CDC formulation of VTM (SOP# DSR-052-05) were validated for use with the test. Other brands of transport media should be validated prior to use.

■ Gently press the Sampinute™ COVID-19 Antigen MIA test cartridge down onto the tray of the 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 (in the case of using the reagent solution tube, insert 1-2 drops, whereas using the micropipette, draw 50 μL) for each test and insert it into the

sample inlet at once.

■ Discard the Sampinute™ COVID-19 Antigen MIA test cartridge after use as required by internal quality control procedures and in accordance with local, state and federal regulations or accreditation requirements.

■ Do not swallow or damage the Sampinute™ COVID-19 Antigen MIA test cartridge.

■ Follow safety procedures set by your institution for working with chemicals and handling biological specimens.

KIT STORAGE AND STABILITY

Keep the cartridge packaged in the provided aluminum 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.

QUALITY CONTROL

Before the actual sample test, the Sampinute™ Analyzer and the 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.

Sampinute™ Analyzer Test Internal Controls

The screen on the device will show whether the sample analyzed is either negative, positive or associated with any error(s).

All test procedures (e.g. sample injection, antigen enrichment, buffer insertion) are monitored *via* internal sensors, where errors or improper executions are communicated through   automated error messages.

The following two tables describe the errors that can occur with the Sampinute Analyzer. Table 1 describes the Error Notifications which are messages that appear on the lower side of the user interface and disappear after three seconds. Table 2 describes Error Popups which appear immediately when an error occurs during the test procedure.

Table 1:   Error notifications, their descriptions and solutions

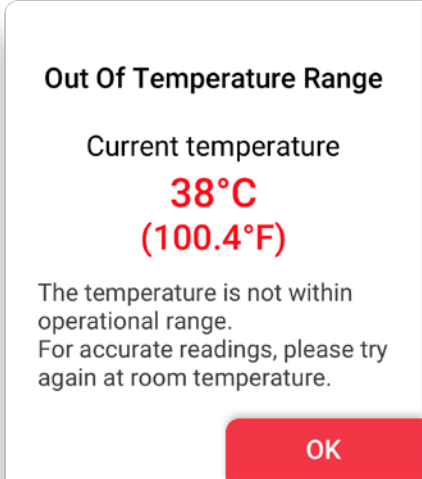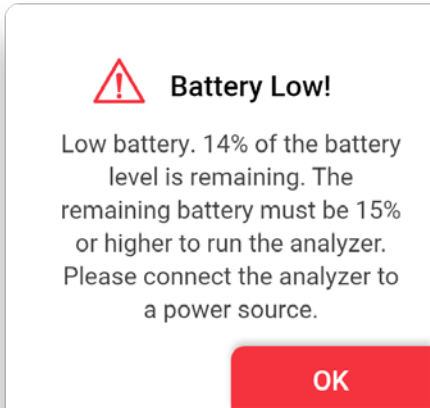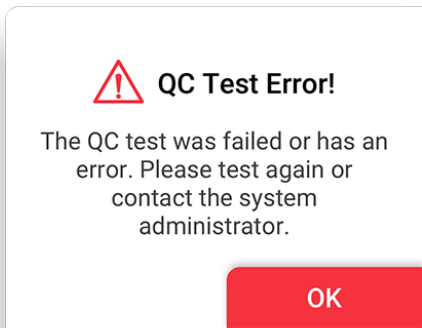| No.	Error Notifications	Descriptions and Solutions
1	Please input the admin password	Admin password is not inputted.
		Displayed when touching the '**OK**' button without having entered the admin password.
		Solution: Input the admin password and then touch the

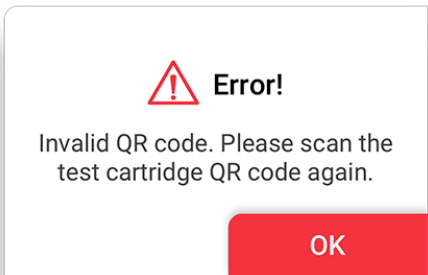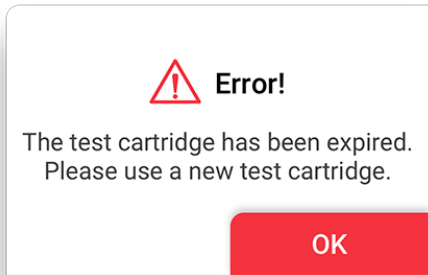| No.	Error Notifications	Descriptions and Solutions
		'**OK**' button.
2	Please input the hospital code.	Hospital code is not inputted. Displayed when touching the '**DONE**' button without having entered the hospital code. Solution: If a hospital code is required, contact the administrator. Input the hospital code and then touch the '**DONE**' button.
3	Unregistered hospital code. Please contact administrator.	Unregistered hospital code Displayed when unregistered hospital code is entered. Solution: If a hospital code is required, contact the administrator. Input registered hospital code. If the issue persists, contact the administrator.
4	Failed to connect to network. Please try again.	No response from server Displayed when device registration fails due to lost network connection or other errors which make server communication unavailable. Solution: Either try to connect again at a later time or connect to another network.
5	Unknown error. Please try again.	Wi-Fi communication error The alert pop up when Wi-Fi communication is failed. Solution: Try again. If the issue persists, then contact the administrator.
6	Please try again after connecting to a network.	No Wi-Fi Connection Displayed when device requests server communication for Wi-Fi connection. Solution: Connect to Wi-Fi.
7	Low battery. 14% of the battery level is remaining. The remaining battery must be 15% or higher to	Low battery
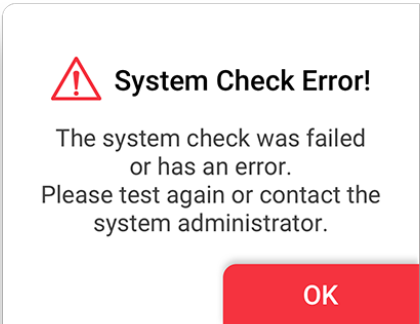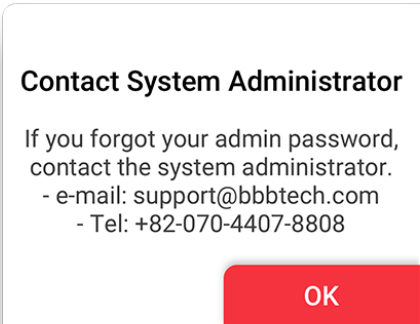
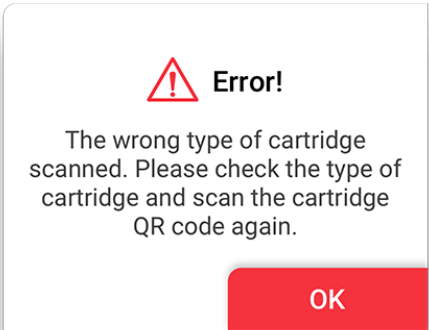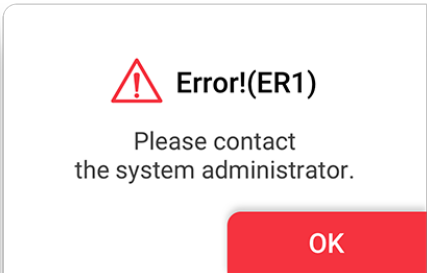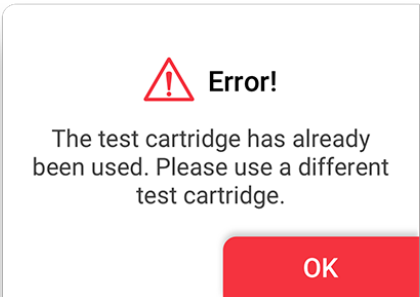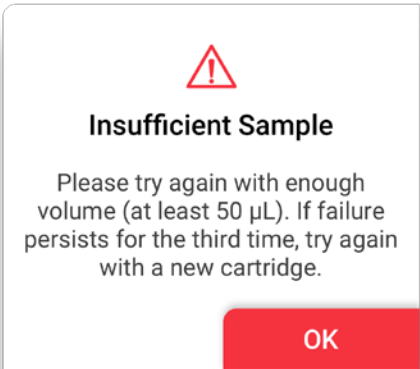| No.	Error Notifications	Descriptions and Solutions
	run the analyzer. Please connect the analyzer to a power source.	Displayed when touching the low-battery icon on the home screen. Solution: Connect to a power adapter.
8	Please perform the system check and the QC test prior to sample tests as instructed in the manual.	System check and QC test not performed Displayed when touching '**RUN TEST**' without having performed system check and QC test. Solution: Perform system check and QC test if required.
9	The system check was failed. Please check the results again. Contact the system administrator.	Displayed when touching the system check warning icon [icon 43] on the home screen under the condition that the system check was failed. Solution: Perform system check. [Settings screen → System Check → Run System Check]
10	Either the QC test was failed or no tests have been performed within the set QC interval. Please check the results again.	Displayed when touching QC! icon on the home screen under the condition that either the QC test was failed or no analyses have been run within the set QC interval. Solution: Perform the QC test.
11	The temperature is not within operational range. (Current temperature: 38°C/100.4°F)	Inappropriate temperature Displayed when touching the temperature icon on the home screen which pops up when temperature is out of range for testing. Solution: Re-locate device in an environment of operational range (15-30°C / 59-86°F).
12	The admin account automatically logged out.	Administrator account logout Displayed when administrator account logs out before power off or reboot.
13	Please input the master password.	Master password has not been entered. Displayed when the '**OK**' button is touched without master password input. Solution: Enter the master password.
14	Incorrect password. Please input the master password again.	Password input error Displayed when the correct password has not been entered.

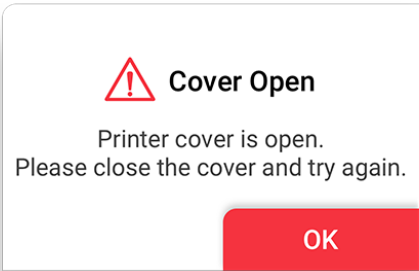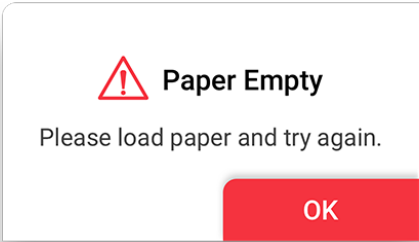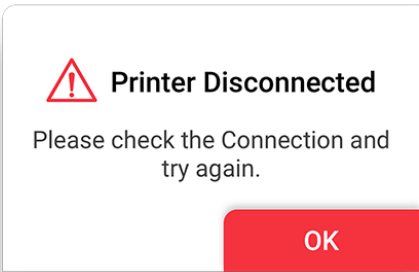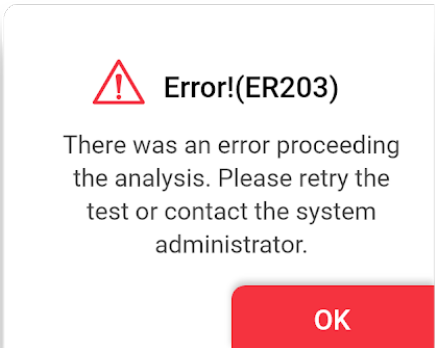| No.	Error Notifications	Descriptions and Solutions
		Solution: Enter the correct password.
15	The fan is activated due to increased internal temperature of the analyzer.	Fan activated Displayed when the fan is activated by the Celltrion Sampinute™ Analyzer's temperature sensor operation.
16	Invalid ID. Please check the ID again.	Wrong operator ID Displayed when wrong operator ID is entered. Solution: Enter the correct ID.
17	Please input the operator ID.	Operator ID has not been entered. Displayed when touching '**OK**' without entering the operator ID. Solution: Enter the operator ID.
18	Please input the patient code.	Patient code has not been entered. Displayed when touching '**OK**' without entering the patient code. Solution: Enter the patient code.
19	Please insert test cartridge in the tray.	Tray ejection failure Displayed when a cartridge is not inserted in the tray within the specified time period. Solution: Insert the cartridge immediately upon request.
20	Please remove the cartridge.	Cartridge is not removed. Displayed when cartridge is not removed upon request. Solution: Remove the cartridge.
21	Incorrect password. Please input the password correctly.	Current password mismatch. Displayed when you do not enter currently set password.

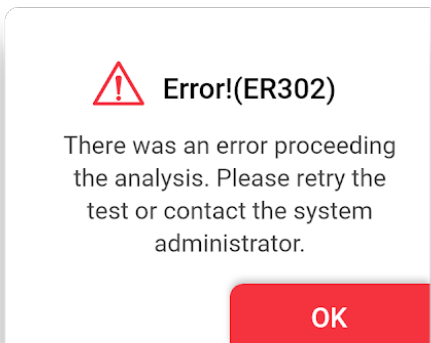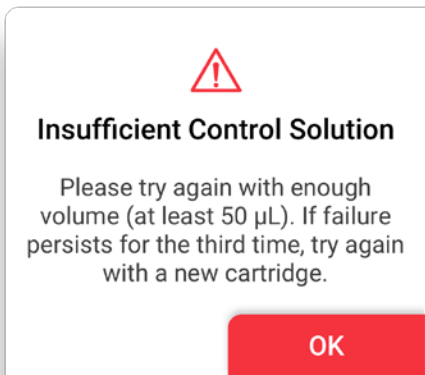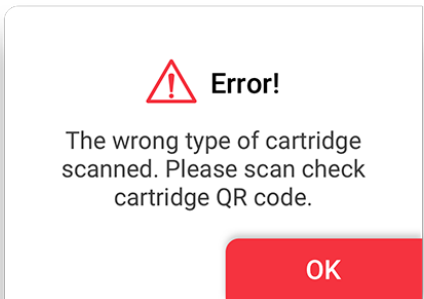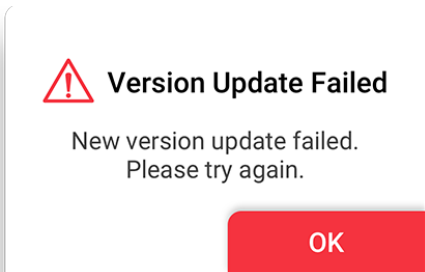| No.	Error Notifications	Descriptions and Solutions
		Solution: Enter the currently set password.
22	The new password and re-entered password do not match. Please input the passwords again.	New password mismatch Displayed on the **Change Administrator Password** screen when newly entered password does not match with the one typed in the new password confirm box. Solution: Ensure both passwords entered are the same.
23	Please input the new admin password.	New administrator password has not been entered. Displayed when a new administrator password has not been entered in the password setting screen. Solution: Enter new administrator password.
24	Please disconnect the device first and then try connecting the device.	Bluetooth disconnection Displayed when a new Bluetooth printer connection is requested while the analyzer is connected to a Bluetooth printer. Solution: Connect to the appropriate Bluetooth printer.
25	Please remove the USB port first and then try connecting the device.	USB disconnection Displayed when a Bluetooth printer connection is requested while the analyzer is connected to a USB mobile printer. Solution: Either disconnect the Bluetooth or the USB printer.

Table 2:   Error pop-ups, their descriptions and solutions

Error pop-ups	Descriptions and Solutions
Out Of Temperature Range Current temperature **38°C** **(100.4°F)** The temperature is not within operational range. For accurate readings, please try again at room temperature. OK	Inappropriate temperature Case1. Pops up when the '**RUN TEST**' button is touched on the home screen, or the '**RUN QC TEST**' button is touched. Case2. Pops up when the temperature is out of test range after the 'RUN TEST' or "RUN QC TEST" button has been touched. Solution: Move the device to the recommended operating temperature (15-30°C, 59-86°F) and wait until device temperature decreases to below 30°C (86°F).
⚠ **Battery Low!** Low battery. 14% of the battery level is remaining. The remaining battery must be 15% or higher to run the analyzer. Please connect the analyzer to a power source. OK	Low battery Case1. Pops up when the '**RUN TEST**' button is touched on the home screen, or the '**RUN QC TEST**' button is touched at 14% battery level. Case2. Pops up when the battery level is 14% and the user touched Next to proceed to the next level of the QC test. Solution: Connect the analyzer to a power source.
⚠ **QC Test Error!** The QC test was failed or has an error. Please test again or contact the system administrator. OK	QC Test error Pops up when the '**RUN TES**T' button is touched on the home screen under the condition that QC lock settings are turned '**ON**', and/or the QC TEST result is '**Fail**'. Solution: Conduct the test again. If the QC test is a fail, then contact the system administrator.

Error pop-ups	Descriptions and Solutions
⚠ **System Check Error!** The system check was failed or has an error. Please test again or contact the system administrator. **OK**	System Check Error Pops up when the '**RUN TEST**' button is touched on the home screen under the condition that the system check result is '**Fail**'. Solution: Conduct system check again. If the system check is a fail, then contact the system administrator.
Contact System Administrator If you forgot your admin password, contact the system administrator. - e-mail: support@bbbtech.com - Tel: +82-070-4407-8808 **OK**	Contact the system administrator. Pops up upon selecting '**Forgot password?**' Solution: Contact the system administrator.
⚠ **Error!** Invalid QR code. Please scan the test cartridge QR code again. **OK**	Invalid cartridge QR code Pops up when an invalid QR code is scanned. Solution: Scan a valid QR code.
⚠ **Error!** The test cartridge has been expired. Please use a new test cartridge. **OK**	Expired cartridge QR code Pops up when expired cartridge QR code is scanned. Solution: Scan a new cartridge of valid expiry date.

Error pop-ups	Descriptions and Solutions
⚠ **Error!** The wrong type of cartridge scanned. Please check the type of cartridge and scan the cartridge QR code again. **OK**	The QR code of the check cartridge is scanned. Pops up when the check cartridge's QR code is scanned instead of the test cartridge. Solution: Scan the QR code of a test cartridge.
⚠ **Error!(ER1)** Please contact the system administrator. **OK**	Tray ejection failure Pops up within 10 seconds after tray ejection fails. Solution: Contact the system administrator.
⚠ **Error!** The test cartridge has already been used. Please use a different test cartridge. **OK**	Pops up when a used cartridge is inserted. Solution: Remove used cartridge and insert a new cartridge.
⚠ **Insufficient Sample** Please try again with enough volume (at least 50 μL). If failure persists for the third time, try again with a new cartridge. **OK**	Insufficient sample Pops up when a sample test fails due to errors associated with timeout, insufficient test sample injection, etc. Solution: Insert at least 50 μL of the sample again into the inlet. If failure persists for the third time, insert a new cartridge.

Error pop-ups	Descriptions and Solutions
Cover Open Printer cover is open. Please close the cover and try again. OK	Pops up when the printer cover is open. Solution: Close the printer cover.
Paper Empty Please load paper and try again. OK	Pops up when there is no paper left in the printer. Solution: Re-fill printer with paper.
Printer Disconnected Please check the Connection and try again. OK	Printer disconnection Pops up when the printer is not connected and the user touches the '**Print**' button. Solution: Ensure that the printer is connected.
Error!(ER203) There was an error proceeding the analysis. Please retry the test or contact the system administrator. OK	Analysis failure Pops up when analysis is failed. Solution: Either try the analysis again or contact the administrator.

Error pop-ups	Descriptions and Solutions
Error!(ER302) There was an error proceeding the analysis. Please retry the test or contact the system administrator. **OK**	Analysis failure Pops up when analysis is failed. Solution: Either try the analysis again or contact the administrator.
Insufficient Control Solution Please try again with enough volume (at least 50 µL). If failure persists for the third time, try again with a new cartridge. **OK**	Insufficient solution Pops up when a solution test fails due to either timeout, insufficient solution injection, or solution reading failure. Solution: Insert at least 50 µL of the control solution again into the inlet. If failure persists for the third time, insert a new cartridge.
Error! The wrong type of cartridge scanned. Please scan check cartridge QR code. **OK**	The QR code of the test cartridge is scanned. Pops up when the QR code of the test cartridge is scanned during the System Check process. Solution: Scan the QR code of a check cartridge.
Version Update Failed New version update failed. Please try again. **OK**	New version installation failure Pops up upon new version installation failure during software update. Solution: Re-try version update.

Error pop-ups	Descriptions and Solutions
⚠ **USB Device Recognition Error** Connect a USB device and try again in 5 seconds. **OK**	USB Device Connection Error

The alert pops up when USB is removed or disconnected during software update.

Solution: Connect the USB device and try again in 5 seconds. |
| ⚠ **Update Failed** Firmware update failed. Would you like to try again? **TRY AGAIN** | Pops up when the firmware update fails.

Solution: Try updating the firmware again. |
| ⚠ **Update Failed** Firmware update failed. Please contact system administrator. **OK** | Repetitive update failure

Pops up when the firmware update fails more than 3 times.

Solution: Contact the system administrator. |
| ⚠ **Battery Low!** Battery too low to allow update. Please connect the charger and update when battery level is more than 15%. **OK** | Low battery during software update

Pops up upon touching '**Update**' when battery level is 14 % or lower.

Solution: Connect the device to a charger. |

Sampinute™ Analyzer System Check Procedure

System Check: The purpose of this test is to verify the proper operation of the Sampinute™ Analyzer.

1. Touch the '**Run System Check**' button

2. Scan the QR code of the check cartridge

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

   b. After scanning the QR code, the screen will display "Insert Check Cartridge."
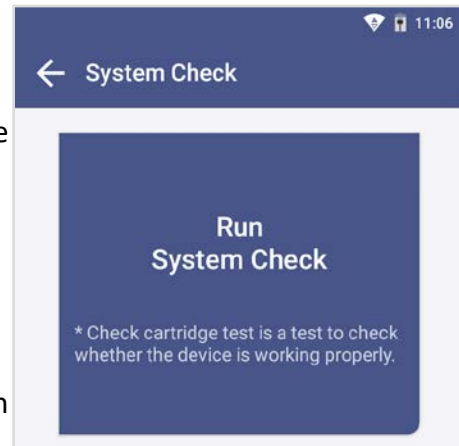
Note:

- The barcode scanner has to be purchased separately.

- If you do not scan the QR code of the test cartridge, the test will not proceed.

- If the QR code recognition continues to fail, please contact the administrator.

3. Insertion of the check cartridge tray

   a. Insert the check cartridge to the tray according to instructions on the screen.

   b. Insert the check cartridge in the correct position.

   c. Touch the **"OK"** button.
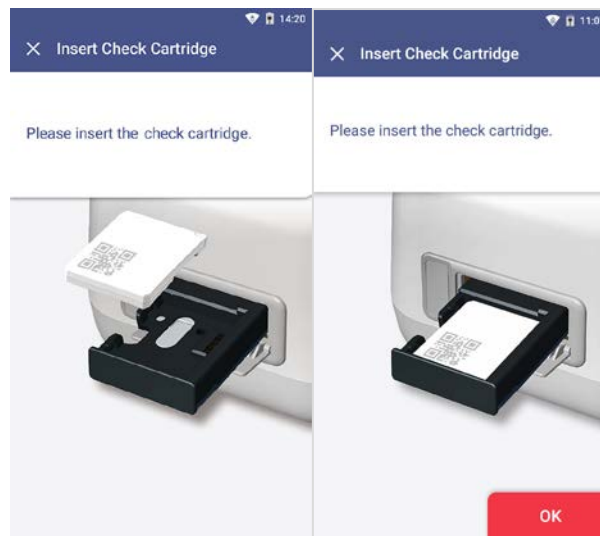
4. Start system check

    a. The system check takes about 1 minute.

5. Confirm the system check results

    a. The test results are displayed upon completion.

    b. After checking the results, remove the used cartridge from the tray.

    c. Touch the **"DONE" (** DONE **)** button to move to the home screen.

Note:

Pass: Indicates that the device is working properly and a **"V" (** ✓ **)** mark is displayed on the screen.
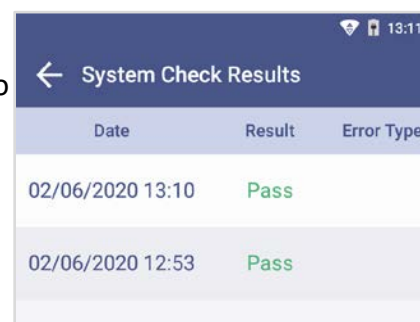
Fail: An error message and an **"X" (** ✗ **)** mark is displayed on the screen.

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.

System Check → System Check Results

The System Check Results are displayed in order from oldest to newest.

Sampinute™ Analyzer Test External Quality Control Test

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.

It is recommended that controls are run once:

- for each different test cartridge lot,

- for each new operator,

- as considered by internal quality control procedures and in accordance with local, state and federal regulations or accreditation requirements.

If either additional quality control solutions are needed or the procedure does not perform as expected, contact Celltrion Customer Services or BBB Customer Services.

- BBB Inc. (*via* website: www.bbbtech.com,or *via* phone: +82-70-4407-8808 or +82-2-565-9653)

- Celltrion USA, Inc. (*via* email: Sampinute@celltrion.com, or *via* phone: (201) 988-4615)

1. Touch the **"Run QC Test"** button.

2. Scan the operator ID.

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

Note: If you do not have a barcode scanner, touch **"Input operator ID manually"** to enter the code using the keypad.
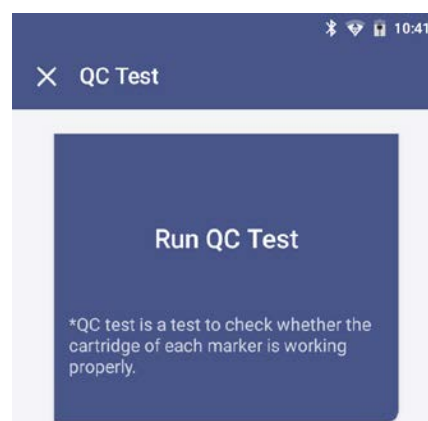
3. Scan the test cartridge QR code

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

    b. Upon scanning the QR code, the test level, cartridge type and LOT will display on the screen.

Note: 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.
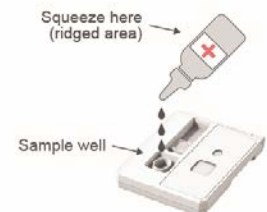
4. Insert the test cartridge

    a. Ensure the correct operator ID is entered.

    b. Check that you scanned the QR code of the cartridge to be inserted.

    c. Double check whether you are using the test cartridge for the correct target analyte.

    d. Before inserting the cartridge, ensure that you are not using a used one.

    e. When the error message, **"Please contact the system administrator"** is displayed after inserting the cartridge, stop the process and contact the administrator to resolve the issue.

5. Inject the positive control solution

    a. Swirl or flick the bottom of the tube for 15 seconds to ensure thorough mixing.

    b. Add 2-3 drops of the positive control solution into the sample inlet of the test cartridge within two minutes.

    c. Touch the **"OK" (** **)** button.

6. Discard the used cartridge in the appropriate biohazard container.

    a. Refer to the images below to eject the cartridge from the tray. Discard the Sampinute™ COVID-19 Antigen MIA test cartridge after use as required by internal quality control procedures and in accordance with local, state and federal regulations or accreditation requirements.

b. Touch the **"OK"** ( ) button.

c. When touching the **"OK"** ( ) button, the screen will proceed to the **"QR Code Scan"** screen.

7. Test cartridge QR code scan

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

b. After scanning the QR code, the test level, cartridge type and LOT will display on the screen.

Note: The barcode scanner has to be purchased separately. If the QR code recognition fails, scan a new cartridge pouch. Please check if the test marker is correct.

8. Insert the test cartridge

a. Ensure that the correct operator ID is entered before inserting the cartridge.

b. Check that you scanned the QR code of the cartridge to be inserted.

c. Double check whether you are using the test cartridge for the correct target analyte.

d. Before inserting the cartridge, ensure that you are not using a used one.

e. When the error message, **"Please contact the system administrator"** is displayed on the screen after inserting the cartridge, stop the process and contact the administrator to   resolve the issue

Warning: Cartridges should not be re-used. Cartridges should be immediately used after specimen has been added and then discarded into an appropriate biohazard container.

9. Negative control solution injection

    a. Swirl or flick the bottom of the tube for 15 seconds to ensure thorough mixing.

    b. Add 2-3 drops of the negative control solution into the sample inlet within two minutes.

    c. Touch the **"OK" (** **) button.**
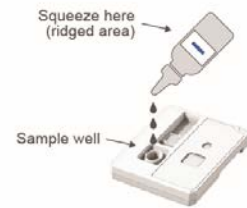
10. Check the result of the QC Test

    a. When the test is completed, the result of the QC test is displayed on the screen.

    b. Check the result and remove the cartridge from the tray.

    c. Touch the **"DONE" (** **) button → Return to the home screen.**

Note: If the test results show "Pass", then successful operation of the test cartridge is indicated. If test results show "Fail", then the accuracy of the test cannot be verified, and the test needs to be conducted again or the administrator should be contacted.
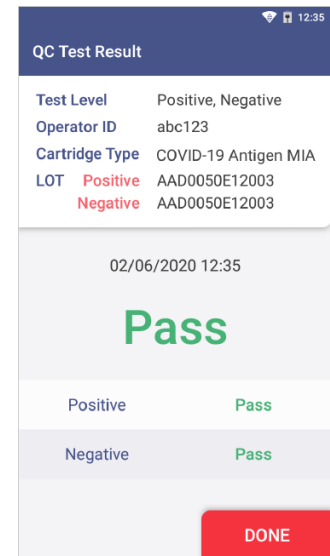
11. Discard the used cartridge.

    a. Refer to the images below to eject the cartridge from the tray.

    b. Discard the Sampinute™ COVID-19 Antigen MIA test cartridge after use as required by internal quality control procedures and in accordance with local, state and federal regulations or accreditation requirements for biohazard waste.

    c. Touch the **"DONE" (** **) button.**

SAMPLE COLLECTION AND HANDLING SAMPLE COLLECTION

Nasopharyngeal Swab Specimen

Use only synthetic fiber swabs with plastic or wire shafts. Do not use calcium alginate swabs or swabs with wooden shafts, as they may contain substances that inactivate some viruses.

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.

Specimens can be collected from both sides using the same swab, but it is not necessary to collect specimens from both sides if the minitip is saturated with fluid from the first collection. If a deviated septum or blockage creates difficulty in obtaining the specimen from one nostril, use the same swab to obtain the specimen from the other nostril.

A	Swab Test Procedure in Reagent Solution Tube

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.

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.
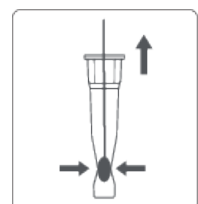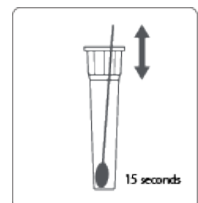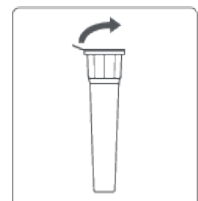
4. Assemble and press the tip firmly onto the reagent solution tube containing the specimen. Mix thoroughly by either flicking the bottom of the tube or swirling.
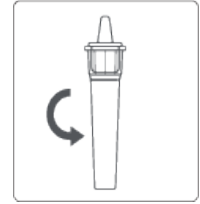
B   Swab Test Procedure in Viral Transport Media

Place the swab immediately and directly into a tube of media in the Viral Transport System or Universal Transport Media System following their package instructions for use from their packaging inserted.

1. 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 thoroughly 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.

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

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

SAMPLE 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 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.

TEST PROCEDURE

Run the test using the Sampinute™ Analyzer at a temperature range of 15-30°C (59-86°F). If the temperature is out of the   range, a test cannot be run. When the battery level is 15% or lower, you cannot start the test. Fully charge the battery before running the test.

Expiration date: Check the expiration date on each individual test package or outer box before using. ***Do not use any tests past the expiration date on the label.***

1. Wear protective gloves and then touch the "**RUN TEST**" button to start the test

    a. Put on a clean pair of gloves first.

    b. Touch the **"RUN TEST"** button.

2. Scan the operator ID

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

3. Scan the patient code

    a. Scan the patient code with the barcode scanner or manually enter the code using the keypad. Touch the **"OK"** (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.

4. Scan the QR code of the test cartridge

    a. Scan the QR code on the cartridge pouch with the 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 page 28) 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.)

5. Test cartridge insertion

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

b. Insert the test cartridge to the tray following instructions on the screen.

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

Note:

- Make sure to check whether the correct operator ID and patient codes are entered before scanning the QR code.

- Ensure that the correct test cartridge being used is the Sampinute™ COVID-19 Antigen MIA

- Before inserting the cartridge, ensure that you are not using an already used one.

- When the error message, "**Please contact the system administrator"** is displayed after inserting the cartridge, stop the process and contact the administrator to resolve the issue.

Warning: Cartridges should not be re-used. Cartridges should be immediately used after specimen has been added and then discarded into an appropriate biohazard container

6. Inject sample to the test cartridge using the reagent solution included in the package

a. Prepare the sample according to "Sample Collection – *Nasopharyngeal Swab Specimen".*
(If a vortex mixer can be used, vortex for at least 1 minute the collection tube to ensure thorough mixing.)

b. Ensure that the specimen is mixed thoroughly by either flicking the bottom of the tube

or swirling.

c. Add 2-3 drops of the sample into the inlet of the 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.) Add the sample within 5 minutes after inserting a cartridge.

d. Touch the **"OK"** (OK) button.

7. If using validated transport media, inject sample to the test cartridge.

a. Prepare the sample according to "Sample Collection – Nasopharyngeal Swab Specimen".

b. Set the volume of the micropipette at 50μL and attach disposable tip.

c. Remove cap on the collection tube.

d. Withdraw the sample in the collection tube with the micropipette. Check that the pipette tip does not contain bubbles.

e. Draw 50 μL of the specimen and insert it into the inlet of the cartridge.

f. Touch the "OK" (OK) button.

8. Process Analysis and Test Results

a. The progress of the analysis is shown as a percentage.

1) The first screen on the left displays the image below instructing to inject the reagent solution using the reagent tube. The next two screens display the analyzer`s progress in processing the specimen using the reagent solution.
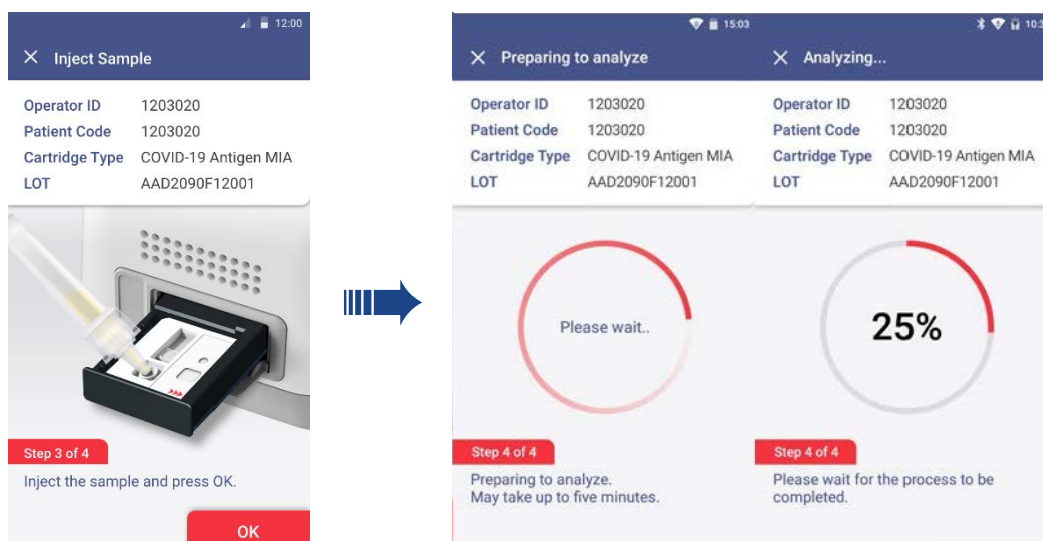
2) The first screen displays the image below instructing to inject sample with pipette using transport media. The next two screens display the analyzer's progress in processing the specimen using reagent solution.
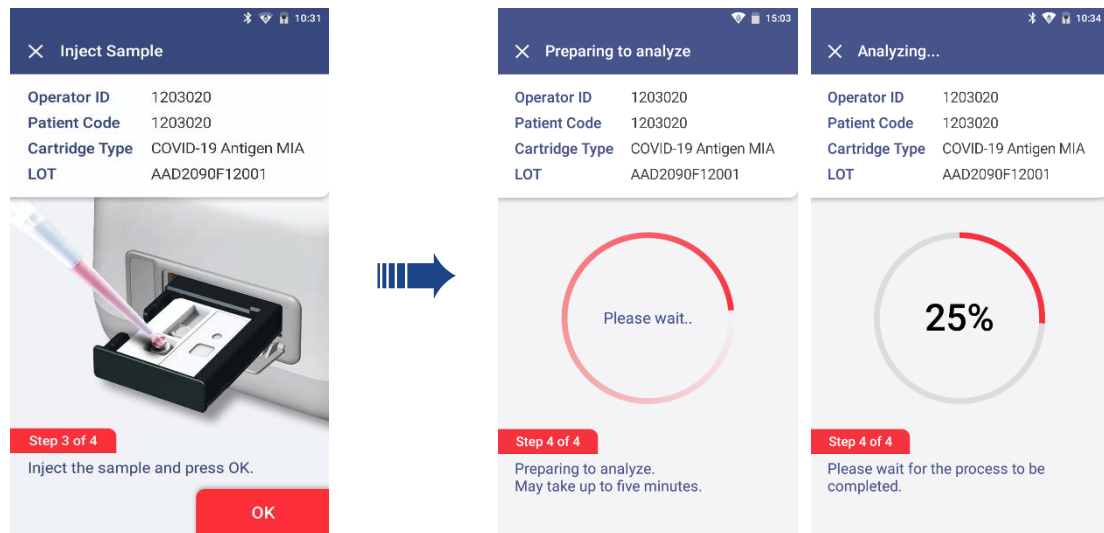
3) The screen displays images showing both the reagent tube and the pipetted VTM.

b.   When the analysis is completed, the result of the measurement is displayed on the screen with the patient code, operator ID, cartridge type and the LOT, 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.

Note:

- Do not turn off or unplug the power adaptor while a test is in progress.
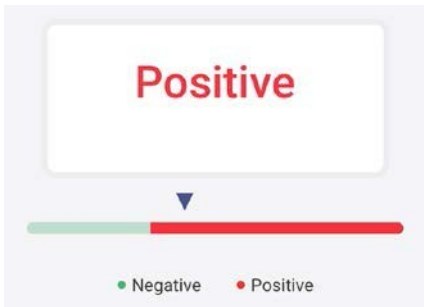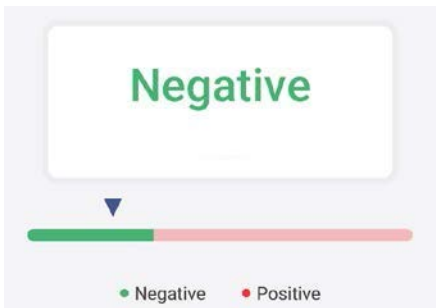
9. Discard the used cartridge in the appropriate biohazard container.

- Refer to the images below to eject the cartridge from the tray.
- Discard the Sampinute™ COVID-19 Antigen MIA test cartridge with any components used after use as required by internal quality control procedures and in accordance with local, state and federal regulations or accreditation requirements.

10. Test Results

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.
	SARS-CoV-2 spike proteins are not detected.

Warning: If refrigerated cartridges are used, ensure that they (including the pouch intact) are at room temperature (15-30°C, 59-86°F) for at least 30 minutes before using them for analysis on the Sampinute™ Analyzer. Analyzing the cartridge before the 30-minute point of room temperature incubation period, may yield false results. The user should never open the aluminum pouch, exposing the test cartridge to the ambient environment until ready for immediate use.

LIMITATIONS

- The contents of this kit are to be used for the qualitative detection of SARS-CoV-2 spike proteins from nasopharyngeal swabs. Other specimen types, such as nasal swabs, have not been validated.

- This test detects both viable (live) and non-viable SARS-CoV-2. Test performance depends on the amount of virus (antigens) in the sample and may or may not correlate with viral culture results performed on the same sample.

- A negative test result may occur if the level of antigens in a sample is below the detection limit of the test or if the sample was collected or transported improperly.

- Failure to follow the Test Procedure may adversely affect test performance and/or invalidate the test result.

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

- Positive test results do not rule out co-infections with other pathogens.

- Negative test results are not intended to rule in other non-SARS-CoV-2 viral or bacterial infections.

- Negative results should be treated as presumptive and confirmed with an FDA-authorized molecular assay, if necessary, for clinical management.

- Clinical performance was evaluated with frozen samples, and test performance may be different with fresh samples.

- If the differentiation of specific coronaviruses and strains is needed, additional testing, in consultation with state or local public health departments, is required.

- The amount of antigen in a sample may decrease as the duration of illness increases. Specimens collected after 5 days are more likely to be negative compared to RT-PCR.

CONDITIONS OF AUTHORIZATION FOR THE LABORATORY

The Sampinute™ COVID-19 Antigen MIA Letter of Authorization, along with the authorized Fact Sheet for Healthcare Providers, the authorized Fact Sheet for Patients, and authorized labeling are available on the FDA website: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas.

To assist clinical laboratories using the Sampinute™ COVID-19 Antigen MIA ("your product" in the conditions below), the relevant Conditions of Authorization are listed below:

- Authorized laboratories[1] using your product will include, with test result reports, all Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.

- Authorized laboratories using your product will use your product as outlined in the

"Sampinute™ COVID-19 Antigen MIA" Instructions for Use. Deviations from the authorized procedures, including the authorized instruments, authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to use your product are not permitted.

■ Authorized laboratories that receive your product will notify the relevant public health authorities of their intent to run your product prior to initiating tests.

■ Authorized laboratories using your product will have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.

■ Authorized laboratories will collect information on the performance of your product and report to DMD/OHT7-OIR/OPEQ/CDRH (*via* email: CDRH-EUA-Reporting@fda.hhs.gov), BBB Inc. (*via* website: www.bbbtech.com) and Celltrion USA, Inc. (*via* email: Sampinute@celltrion.com or *via* phone: (201) 988-4615) any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of your product of which they become aware.

■ All operators using your product must be appropriately trained in performing and interpreting the results of your product. Use appropriate personal protective equipment when handling this kit, and use your product in accordance with the labeling.

■ Celltrion USA, Inc., BBB Inc., and authorized laboratories using your product will ensure that any records associated with this EUA are maintained until otherwise notified by the FDA. Such records will be made available to the FDA for inspection upon request.

[1] The letter of authorization refers to, "Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high or moderate complexity tests" as "authorized laboratories."

CLINICAL PERFORMANCE

[Study 1]

Positive clinical specimens in 3mL of Becton Dickinson Universal Viral Transport System were used for clinical validation. The clinical performance of Sampinute™ COVID-19 Antigen MIA was established with a study using NPS specimens, which have been previously characterized and were supplied frozen by a biorepository in the United States. All specimens were evaluated with an EUA RT-PCR assay and confirmed to be positive. Specimens were tested by a CAP accredited laboratory by trained laboratory professionals.

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).

								95% CI	
	Results of Reference Device (RT-PCR)								
		POS	NEG	Total	Sensitivity	94.4%	80.0%	99.0%	
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%		
					%	97.2%		

[Study 2]

Positive clinical specimens with reagent solution were also used for clinical validation. The clinical performance of Sampinute™ COVID-19 Antigen MIA was established with a study using dry NPS specimens. These specimens were prospectively collected from subjects in the United States as part of a biorepository enrolling positive and negative SARS-CoV-2 specimens within five days of symptom onset. All specimens were evaluated with an EUA RT-PCR assay and confirmed to be positive. The specimens are delivered from the biorepository and stored below -70°C. 5 positive and 5 negative specimens were tested by a CAP accredited laboratory by trained laboratory professionals, and 95 negative specimens were tested at a BL2-certified laboratory by trained operators.

In the clinical performance, 105 samples were measured, resulting in a sensitivity of 100.0% (5/5) and a specificity of 100.0% (100/100).

	Results of Reference Device (RT-PCR)						95% CI	
		POS	NEG	Total	Sensitivity	100.0%	56.6%	100.0%
Sampinute™ COVID-19 Antigen MIA	POS	5	0	5	Specificity	100.0%	96.3%	100.0%
	NEG	0	100	100	PPV	100.0%	56.6%	100.0%
	Total	5	100	105	NPV	100.0%	96.3%	100.0%

ANALYTICAL PERFORMANCE

a) Limit of Detection

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

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 negative clinical matrix. 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 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 for each dilution) 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 (17) and microorganisms (11 including pooled human nasal wash) that potentially may cross-react with the Sampinute™ COVID-19 Antigen MIA using the reagent solutions. 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.

Cross-Reactivity: Sampinute™ COVID-19 Antigen MIA - Wet Testing

Organism	Final Concentration Tested	Cross-Reactivity Results (Count)	Interference Result (Count)
Coronavirus 229E	4.0×10^5 PFU/mL	0/3	3/3
Coronavirus OC43	9.8×10^5 PFU/mL	0/3	3/3
Coronavirus NL63	1.0×10^5 PFU/mL	0/3	3/3
SARS-CoV-1	2.94×10^6 U/mL	0/3	3/3
MERS	3.20×10^5 $TCID_{50}$/mL	0/3	3/3
Adenovirus type 1	1.4×10^5 PFU/mL	0/3	3/3

Parainfluenza virus 1	1.13×10^5 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
Coronavirus HKU1	1.0×10^6 U/mL	0/3	3/3
Influenza A	4.0×10^5 PFU/mL	0/3	3/3
Influenza B	4.9×10^5 PFU/mL	0/3	3/3
Candida albicans	3.23×10^6 CFU/mL	0/3	3/3
Chlamydia pneumoniae	2.0×10^7 TCID$_{50}$/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	1.05×10^6 CFU/mL	0/3	3/3

Bordetella pertussis	2.55 × 10^6 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
Streptococcus aureus	2 × 10^6 CFU/mL	0/3	3/3
Streptococcus epidermidis	2 × 10^6 CFU/mL	0/3	3/3

* Testing was performed in triplicate.
** Each microorganism was diluted in BD^{TM} Universal Viral Transport System.

The results show neither observed cross-reactivity nor microbial interference with the organisms at the concentrations tested.

Of all the tests recommended for cross-reactivity, the remaining two 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.

● *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.

● Human coronavirus HKU1: The protein sequences analyzed between the spike glycoproteins of SARS-CoV-2 and HKU1 show 29% homology. Hence, cross-reactivity is highly unlikely to occur between SARS-CoV-2 and HKU1.

d) Endogenous interference study

A total of 17 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 Sampinute™ COVID-19 Antigen MIA test cartridges to potentially interfering substances when elevated levels of these substances were added to SARS-CoV-2 positive specimens at 3xLoD or negative samples in BD™ Universal Viral Transport System.

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 Sampinute™ COVID-19 Antigen MIA test cartridge.

Concentrations of potentially interfering substances were tested, and the study results are summarized in the table below.

Potentially Interfering Substances Study: Sampinute™ COVID-19 Antigen MIA

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

Substance	Concentration	SARS-CoV-2 Positive Sample	SARS-CoV-2 Negative Sample
Fisherman's Friend	1.5 mg/mL	3/3	0/3
Fluticasone Propionate	5% v/v	3/3	0/3

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

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 Sampinute™ Analyzer and 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 medium (UTM), Centers for Disease Control and Prevention VTM (DSR-052-05), and the reagent solution with less than 0.1% sodium azide (contained in Reagent Tube) at a final concentration of 1 x LoD, 2 x LoD, 3 x LoD. In addition, negative samples were also prepared and tested.

The transport media systems containing the contrived samples were stored at 2 - 8°C (36 - 46°F) and permitted to equilibrate to room temperature 30 minutes before testing. Each transport media was tested in three (3) replicates and 3 Lots.

Matrix Equivalency Study: Sampinute™ COVID-19 Antigen MIA

Sample	BD (All Lots)			COPAN (All Lots)			CDC (All Lots)			Reagent solution (All lots)		
	Agreement (Count)	Mean (µA)	%CV	Agreement (Count)	Mean (µA)	%CV	Agreement (Count)	Mean (µA)	%CV	Agreement (Count)	Mean (µA)	%CV
3.0x LoD	100% (15/15)	11.78	5.01	100% (15/15)	10.93	6.47	100% (15/15)	10.30	5.32	100% (15/15)	11.65	6.28
2.0x LoD	100% (15/15)	8.76	5.26	100% (15/15)	9.65	6.30	100% (15/15)	8.84	4.57	100% (15/15)	9.73	6.30
1.0x LoD	100% (15/15)	5.67	7.12	100% (15/15)	6.17	6.50	100% (15/15)	5.98	6.06	100% (15/15)	5.71	6.60
Negative	100% (15/15)	3.49	8.55	100% (15/15)	3.62	9.60	100% (15/15)	3.75	9.57	100% (15/15)	3.58	8.89

All four (4) matrices (BD UVT, COPAN UTM, VTM made according to the CDC SOP (DSR-052-05), and the reagent solution with less than 0.1% sodium azide) show the same results with %CV of less than 10%.

ASSISTANCE

If you have any questions regarding the use of this product or if you want to report a test system problem, please contact BBB Inc. (*via* website: www.bbbtech.com, or *via* phone: +82-70-4407-8808 or +82-2-565-9653) or Celltrion USA, Inc. (*via* email: Sampinute@celltrion.com, or *via* phone: (201) 988-4615). Test system problems may also be reported to the FDA through the MedWatch medical products reporting program (phone: 800.FDA.1088; fax: 800.FDA.0178; http://www.fda.gov/medwatch).

SYMBOLS

[Manufacturer symbol]	Manufacturer	R only	Prescription Use Only
[Date of Manufacture symbol]	Date of Manufacture	[Hourglass symbol]	Use by/Expiry date (for test cartridge)
LOT	Batch code (for test cartridge)	REF	Catalogue number (for test cartridge)
SN	Serial number (for analyzer)	[Thermometer symbol]	To indicate the temperature limitation in which the transport package has to be kept and handled
[Humidity % symbol]	To indicate the humidity limitation in which the transport package has to be kept and handled	[Biohazard symbol]	Biological risks
[Do not reuse symbol]	Do not reuse. (for test cartridge)	[Book symbol]	Please refer to user manual.
[Caution symbol]	Caution, please refer to accompanying documents	IVD	In Vitro Diagnostic Medical Device/In Vitro diagnostic use
CONTROL	Control	[Σ symbol]	Contains sufficient for <n> tests.
[WEEE symbol]	Waste electrical and electronic equipment (WEEE)	[Checkmark symbol]	Important

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REFERENCES

[i] 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 1061 (2019) 92-100.

[ii] 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 03, 2020.

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

[iv] Clinical and Laboratory Standards Institute. Viral Culture; Approved Guidelines. CLSI document M41-A [ISBN1562386239] Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898, USA 2006.

SAMPINUTE
COVID-19 Antigen MIA

[IVD] [Rx only]
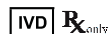
in vitro **Diagnostic Use**
Sampinute™ COVID-19 Antigen MIA
Quick Reference Guide
BMD013BQUS Rev0B Date 2020-10

For use under the Emergency Use Authorization (EUA) only

Test Cartridge	Reagent Tube and Tip	Collection Tube
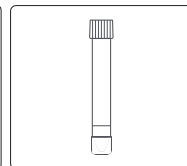
Cleaning

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.
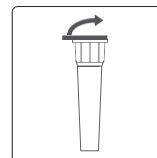
2

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.

15 seconds

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
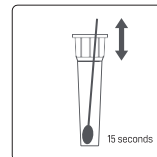
Assemble and press the tip firmly onto the reagent solution tube containing the specimen. Mix thoroughly by either flicking the bottom of the tube or swirling.
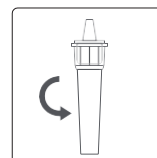
Option 2 - Swab Test Procedure in Viral Transport Media:
Do not use tips, tubes or caps taken from other products.
If frozen specimens were prepared, melt the frozen specimens completely before the test.

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 thoroughly 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.

3

Check that the transport media tube cap is closed.
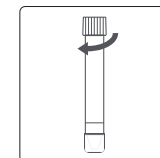
4

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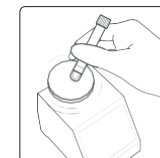
*Warnings and Precautions

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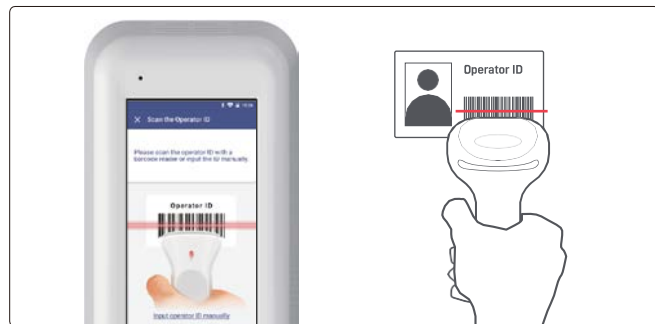Refer to the CDC Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons for Coronavirus Disease 2019 (COVID-19)
https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html
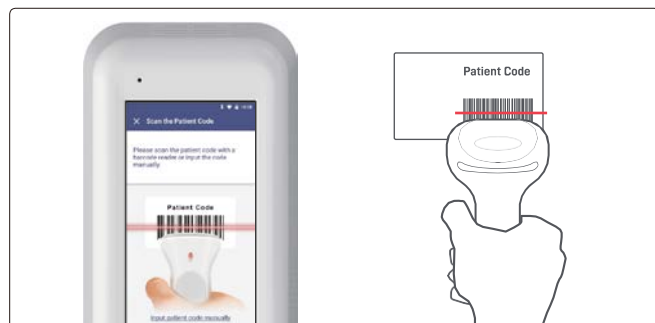
Running the Test

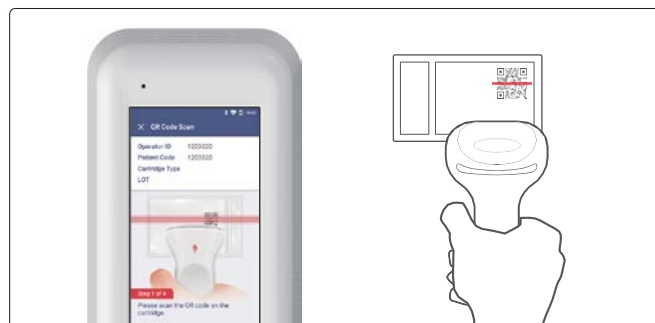1. Touch 'RUN TEST' to start the test.
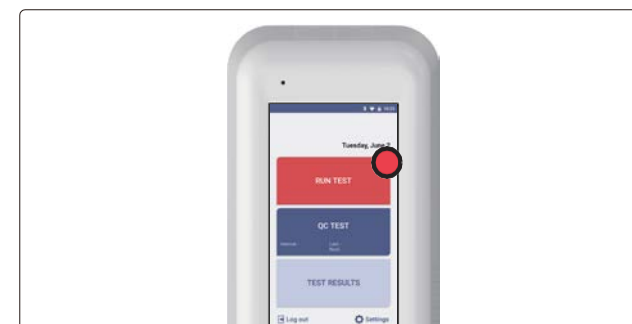
2. Scan operator ID with barcode scanner or enter *via* keypad.

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.
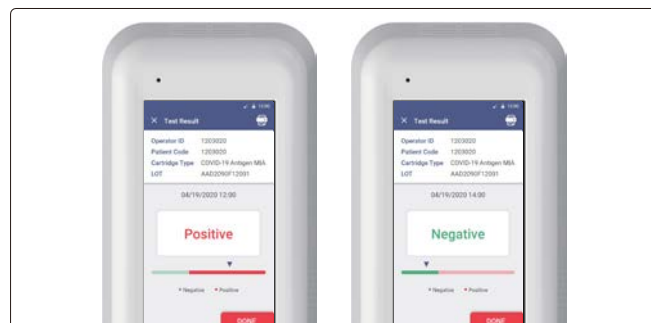
Interpretation of Results

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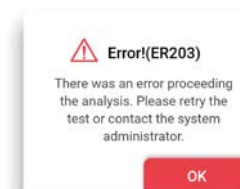
Invalid Results : In the event of an error, the device will display a message (as shown above). All messages the instrument status or error and an instruction to be followed. In the example above, remove the used test cartridge and retry the test. If the problem persists, contact the system administrator.

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.bb-btech.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

 Celltrion USA, Inc

One Evertrust Plaza Suite 1207, Jersey City, New Jersey, 07302 USA
Phone : 201-499-1844 | E-mail: Sampinute@celltrion.com
www.celltrion.com

Manufacturer Information

 BBB Inc.

Manufacturing site (Samseong Center)
7F, 22, Teheran-ro 81-gil, Gangnam-gu, Seoul, Republic of Korea
Tel .: +82-70-4407-8808| e-mail: CS@bbbtech.com

IVD R$_x$ only

SAMPINUTE™ Analyzer
User Manual

Sampinute™ Analyzer (Immunoassay analyzer)

Sampinute™ Analyzer detects specific biomarker *via* immunoassay (MESIA; Magnetic Electro-chemical Sandwich ImmunoAssay) from a small amount of test sample. Sampinute™ Analyzer is intended to be used as an *in vitro* diagnostic medical device. Please read this user manual thoroughly for correct use and keep it for future reference. For use under an Emergency Use Authorization (EUA) only.

CELLTRION USA
CELLTRION

SAMPINUTE

Table of Contents

1. Product Introduction

1-1. Intended Use

The Sampinute™ Analyzer is an instrument that performs immunoassay on test cartridges. It reads specific biomarkers within the test sample.

1-2. Principle

Sampinute™ Analyzer is an instrument based on an immunoassay technique called MESIA (Magnetic Electrochemical Sandwich Immunoassay). Sampinute™ Analyzer can be used to analyze a single or multiple analyte(s) by detecting electrochemical signals on the test cartridge, which is for a one-time *in vitro* diagnostic (IVD). The magnets within the device form magnetic fields, which facilitate the interaction of nanoprobes in the test cartridge to induce antibody-antigen reactions and remove unbound magnetic nanoprobes. The Sampinute™ Analyzer measures the concentration of any antigens or antibodies by detecting electrochemical signals from the reaction-completed magnetic nanoprobes. Sampinute™ Analyzer transmits the test data to the designated server *via* Wi-Fi.

1-3. Precautions & Warnings

Please read this user manual thoroughly for appropriate use.
Sampinute™ Analyzer is for use in IVDs.
Sampinute™ Analyzer and test cartridges are indicated for use in clinical laboratories.
Check that all components are present in the package.
Read this user manual before operating the analyzer.
The analyzer needs AC power connection to operate for an extended period of time and charge.
Please ensure your power supply is compatible with the analyzer's power specifications.
Increasing the inner temperature activates the cooling fan inside the air vent.
Establish a free distance of at least 10cm (4 inches) from the face of the air vent when installing the device.
Keep the air vent free from inflow of foreign substances.
Accidental entry of metals into the analyzer may cause breakdown or electric shock.
Please refer to product-specific package inserts included in each test kit for more information.
Turn off the power and remove the adapter if you do not expect to use the analyzer for an extended period of time.
Do not use or store the product in a location exposed to open flames.
Do not expose or store the product in a location subject to high temperature and high humidity.
Prevent water and dust from entering the device.
Do not apply excessive force, drop or step on the product.
Aluminium tapes have been attached on the top of cartridges to help sustain the quality of the cartridges. Only remove these tapes upon usage.
Avoid dropping the device while moving it.
Do not assemble or modify the analyzer.
The analyzer is not water-resistant. Do not wash it with water or touch it with wet hands.
Do not use the product to diagnose specific illnesses and conduct screening tests, such as neonatal screening.
Use the analyzer only to assist medical decision-making.
Keep this product out of the reach of children.

When discarding the analyzer, discard in a safe place in accordance with local, state and federal regulations or accreditation requirements.

For use under the Emergency Use Authorization (EUA) only

When used with the Sampinute™ COVID-19 Antigen MIA:

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.

1-4. Components

The following are the components you should check upon opening the package of Sampinute™ Analyzer.
Please check that all components are included in the box.
Please contact the purchase location if any of the following components are not included or damaged.

Sampinute™ Analyzer, 1EA
Check Cartridge, 1EA
User manual
Quick Reference Guide

1-5. Symbol Guide

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

	Manufacturer	R_{only}	Prescription Use Only
	Date of Manufacture		Use by/Expiry date (for test cartridge)
LOT	Batch code (for test cartridge)	REF	Catalogue number (for test cartridge)
SN	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	IVD	*In Vitro* Diagnostic Medical Device/*In Vitro* diagnostic use
CONTROL	Control	Σ	Contains sufficient for <n> tests.
	Waste electrical and electronic equipment (WEEE)	✓	Important

2. Product Description

2-1. Sampinute™ Analyzer

(1) Screen
Interface that the user can touch to operate the analyzer and check the results.

(2) Power Button
Button to turn the device on or off.

(3) Tray (closed)
A component to insert the test catridge.
Opening and closing of the tray are controlled by the software.

(4) Air vent
A component to control temperature inside the analyzer.

(5) Power supply connector
An adapter connection port to supply power to the device.

(6) USB port
A USB-A port for barcode scanner and mobile printer.

(7) Electrode connector for test cartridge
A connector for cartridge reading.

(8) Cartridge recognition switch
A switch to check cartridge insertion.

(9) Tray (open)
The tray is open with the cartridge inserted.
(Component as closed status shown in (3))

2-2. Check Cartridge

The check cartridge is used to evaluate instrumental and electronic operations of the analyzer. An alignment sensor is embedded in the check cartridge to check the alignment of magnets at the top and bottom of the analyzer.
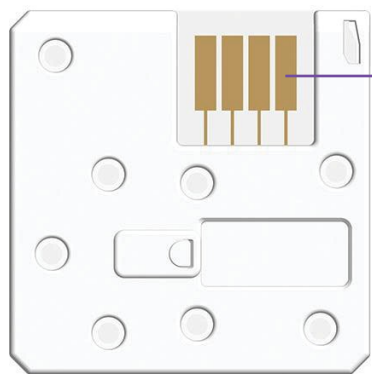
Cartridge contact pad

Contact pad for the operation check of Sampinute™ Analyzer

3. Screen Description

3-1. Home Screen
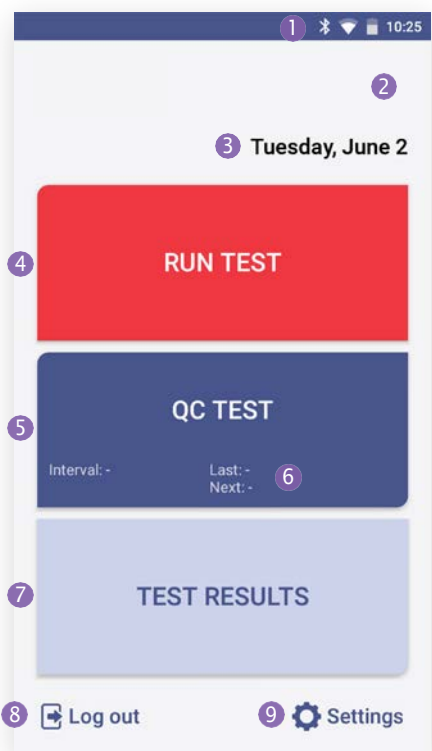
(1) Status bar
Indicates Sampinute™ Analyzer's network connection, battery level and time.

(2) Status indicating icon

QC!   is displayed when QC test result shows "fail" or the QC test is not carried out.

15↓   is displayed when battery level is 15% or lower.

is displayed when temperature is either 15˚C (59˚F) or lower, or at least 30˚C (86˚F).

Check Cartridge   is displayed when the first System Check is not performed, or System Check result is Fail.

(3) Time
Displays day, date and month.

(4) Run test
Touch the button to start the test.

(5) QC Test
Touch the button to run the QC test.

(6) QC Test interval and test information
Check QC Test intervals and recent/next test schedule of the QC test

(7) Test results
Check all test results.

(8) Admin login / logout
Login to / logout of the admin account.

(9) Settings
Change settings. Check device information and update it.

4. Initial Setup

STEP 1
Connect the power adapter.

STEP 2
Touch the '**power**' button to start.

STEP 3 Time Zone setting
Touch the '**Select Time Zone**' → Select the time zone where the user is located.
 ✲ When setting is completed, touch the '**DONE**' button.
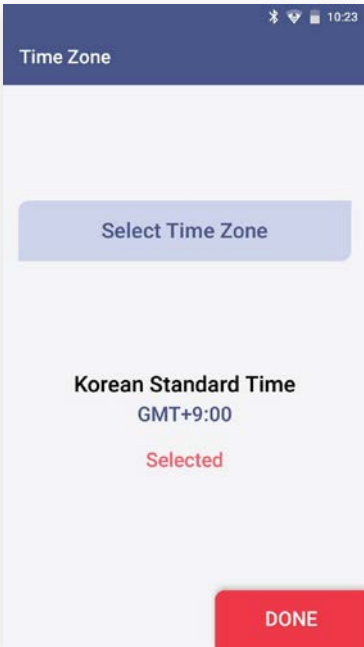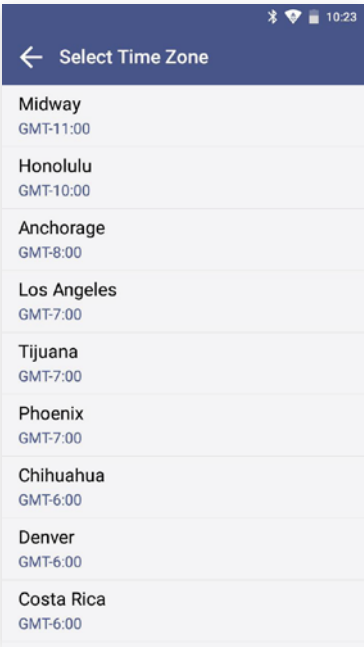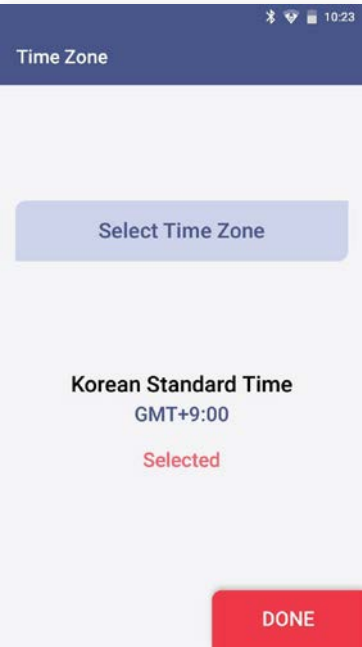
STEP 4 **Wireless network (Wi-Fi) setting**

Connect Wi-Fi ⟶ Select the Wi-Fi to connect to. ⟶ When connected, the '**DONE**' button is activated. ⟶ Touch the '**DONE**' button.
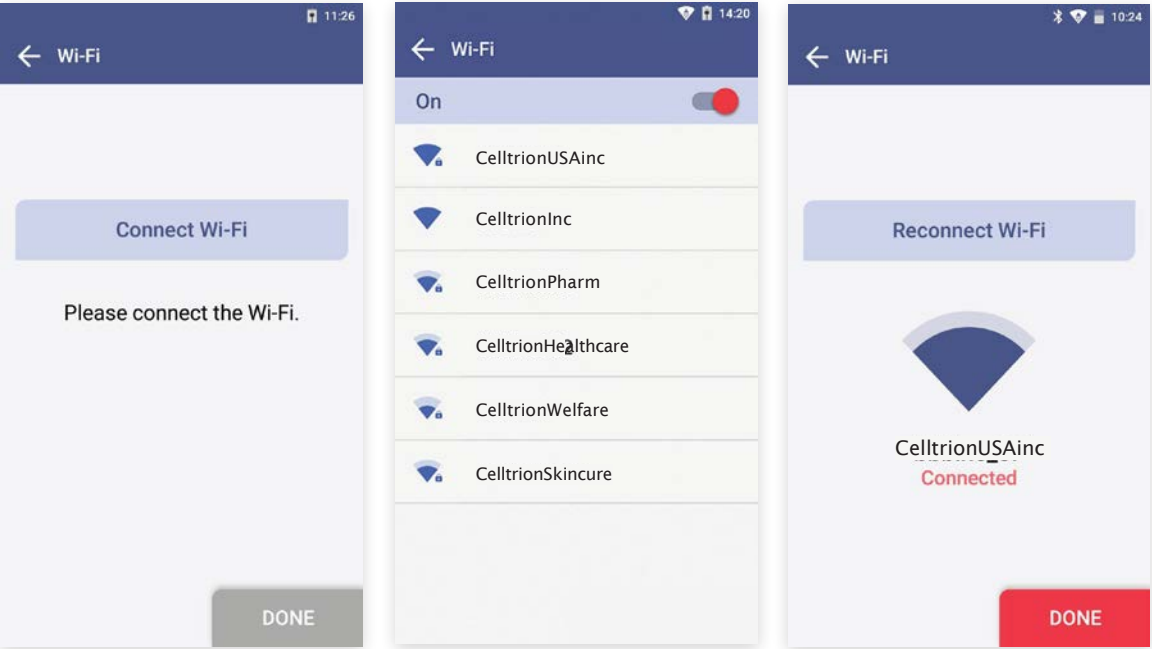
| Icon	Connection Status	Description
	Connected	Wi-Fi is connected and active.
•••	Requesting Connection	Please wait as the Wi-Fi signal is being acquired. In the case of no response, touch '**Reconnect Wi-Fi**' to try again
	Connection failure	Wi-Fi connection has failed. Check wireless connection status or select other Wi-Fi.
!	Network not connected	The icon indicates that Wi-Fi is not connected. Select the '**Reconnect Wi-Fi**' to connect in-range accessible Wi-Fi.

STEP 5 Create Admin Password
Enter admin password $\longrightarrow$ Touch the '**OK**' button
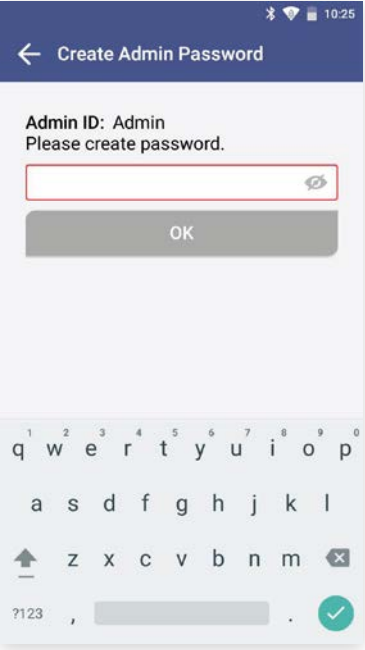
· Administrator ID is automatically set as 'Admin'.

· Please set your own admin password.

· Password is case-sensitive and must be a combination of letters and numbers.

· Your password cannot contain spaces and must be less than 45 characters long.

· Touch the eye-shaped icon ⊙ to check entered password.

STEP 6 Lock Setting
Establish QC Test settings according to each item $\longrightarrow$ Touch the '**OK**' button
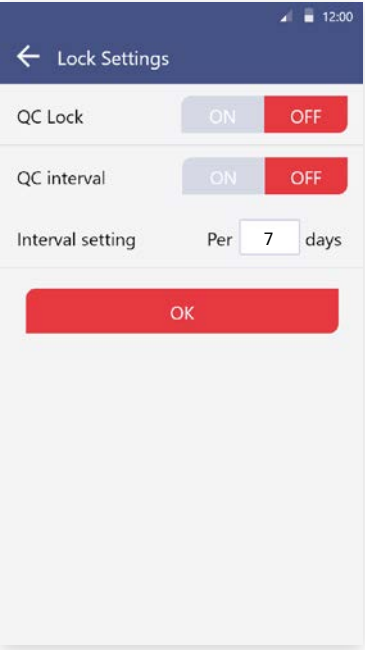
QC Lock On

· In the case of when QC Test result shows '**FAIL**', the test is unavailable until the result shows '**PASS**'.

· Conduct QC test regularly as scheduled, otherwise test cannot be run.

QC Lock Off

· A test can be run regardless of QC Test results.

QC Interval

· On: A test can only be run upon completion and passing of the QC Test on the designated QC Test date

· Off: Disables QC Test interval

· Interval setting: Set up QC Test interval within 1 to 365 days

STEP 7 Device Registration

a. Enter hospital code in the window.

b. After entering hospital code, touch the '**DONE**' button to connect to hospital server.

c. Once connected to server, initial setup is completed and the home screen will be displayed.
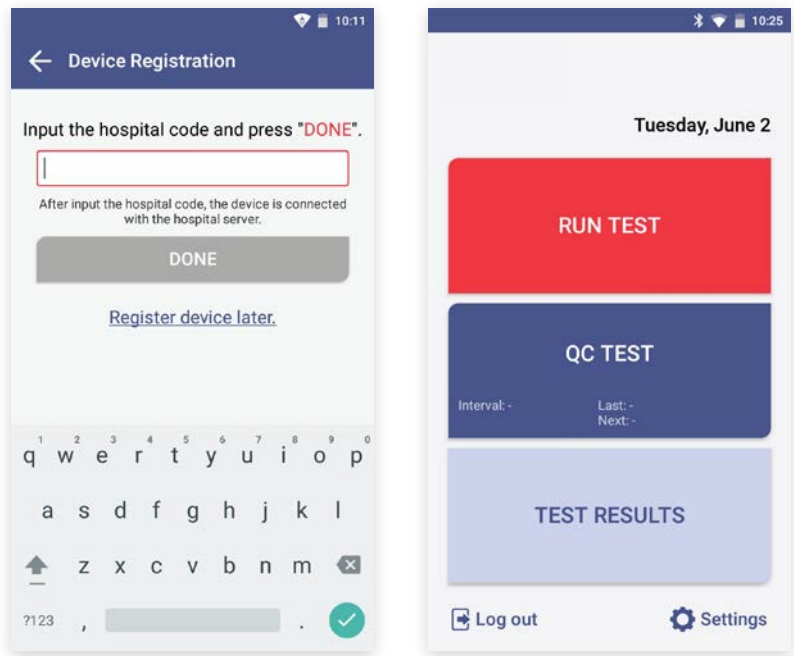
· If there is no hospital code for device registration, touch the '**Register device later'** button.

· Device registration is available later in **['Settings' → 'Device Registration'] (see Page 43).**
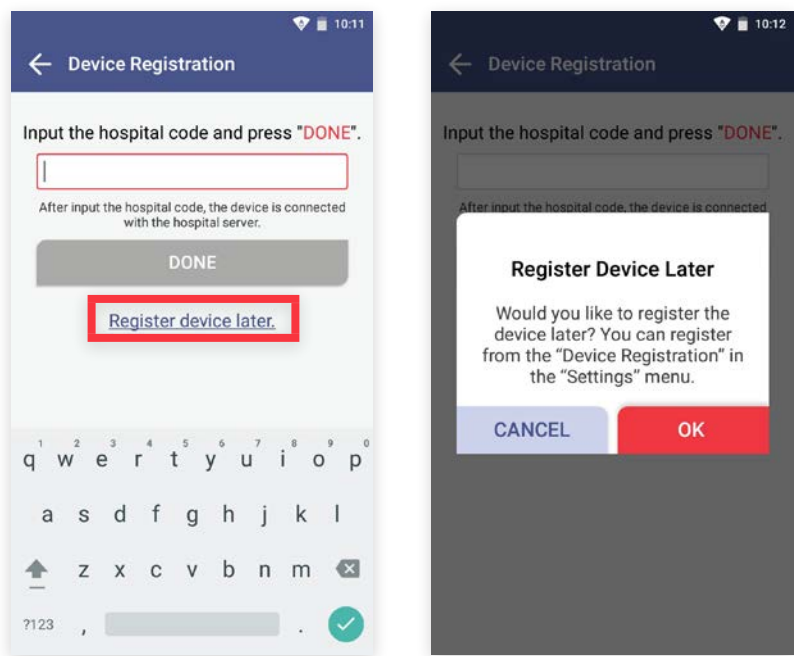
Barcode Scanner Connection
a. Connect the barcode scanner to the USB Port on the back of Sampinute™ Analyzer.
b. Barcode scanner automatically starts operation when connected to the USB port.

*Barcode scanner has to be purchased separately.

Printer Connection
a. Turn the printer on.
b. USB Connection: The printer is automatically recognized once USB cable is connected.
c. Bluetooth Connection: Please refer to **[Function settings ⟶ Printer settings] (see Page 31)**.
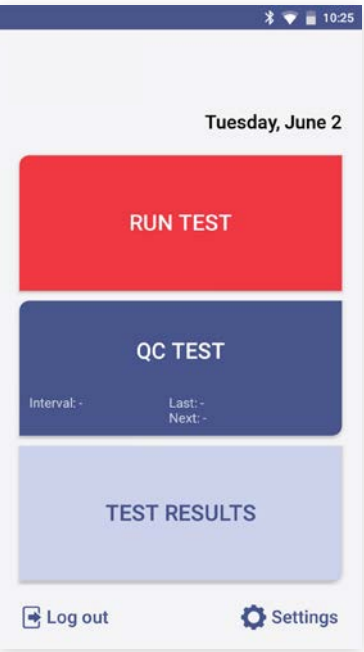
*Printer is sold separately.

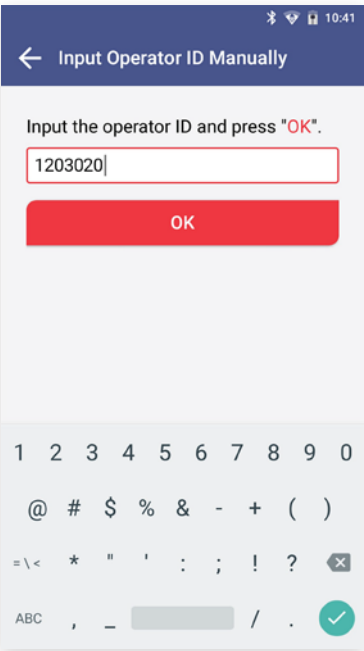# 5. Running a Test

5-1. How to Perform RUN TEST

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

· Run the test at a temperature range of 15-30°C (59-86°F).

· If the temperature is out of range, the test cannot be run.

· When the battery level is 15% or lower, you cannot start the test.

· Fully charge the battery before running a test.

STEP 2 **Scan the operator ID**

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

If you do not have a barcode scanner, touch the '**Input operator ID manually**' to enter the code using the keypad.

STEP 3 Scan the patient code

a. Scan the patient code with a barcode scanner or manually enter the patient 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 resumes to cartridge QR code scan.
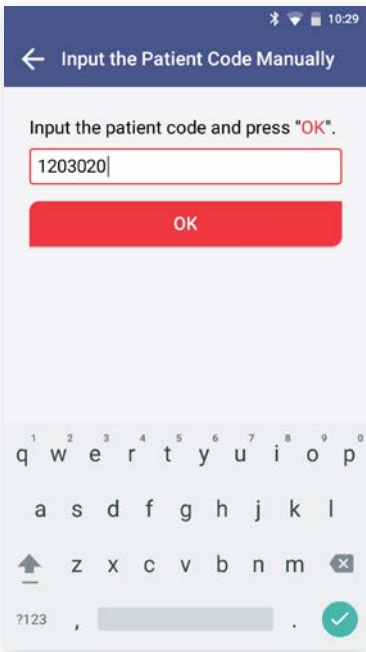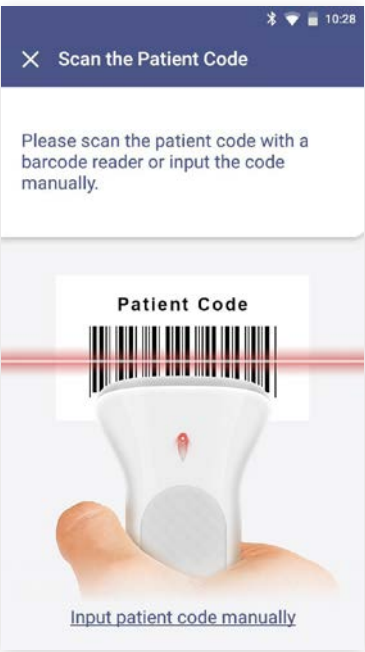
If you do not have a barcode scanner, touch the '**Input patient code manually'** to enter the code using the keypad.

STEP 4 Scan the QR code of the test cartridge

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

b. After scanning the QR code, the cartridge type and LOT will be displayed on the screen.

· The barcode scanner has to be purchased separately.

· If QR code recognition fails, scan a new cartridge pouch.

· Please check if the cartridge type of the cartridge is correct.

STEP 5 **Test cartridge insertion**

a. Remove the aluminium tape attached on top of the cartridge.

b. Insert the test cartridge to the tray according to the instructions on the screen.

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

Operator ID	1203020
Patient Code	1203020
Cartridge Type	COVID-19 Antigen MIA
LOT	AAD2090F12001

Step 2 of 4

Insert the test cartridge.

· Make sure to check whether the correct operator and patient codes are entered before scanning the QR code.

· Ensure that the correct test cartridge is being used for the target analyte.

· Before inserting the cartridge, ensure that you are not using an already used one.

· When the error message, "**Please contact the system administrator**" is displayed after inserting the cartridge, stop the process and contact the administrator to resolve the issue.

STEP 6 **Test sample injection and starting test**

a. Prepare a test sample.

b. Before injecting the sample, check injection location of the test sample and whether a sufficient amount of test sample is prepared.

c. Inject the test sample within 2 minutes after inserting a cartridge.

d. Touch the 'OK' button.
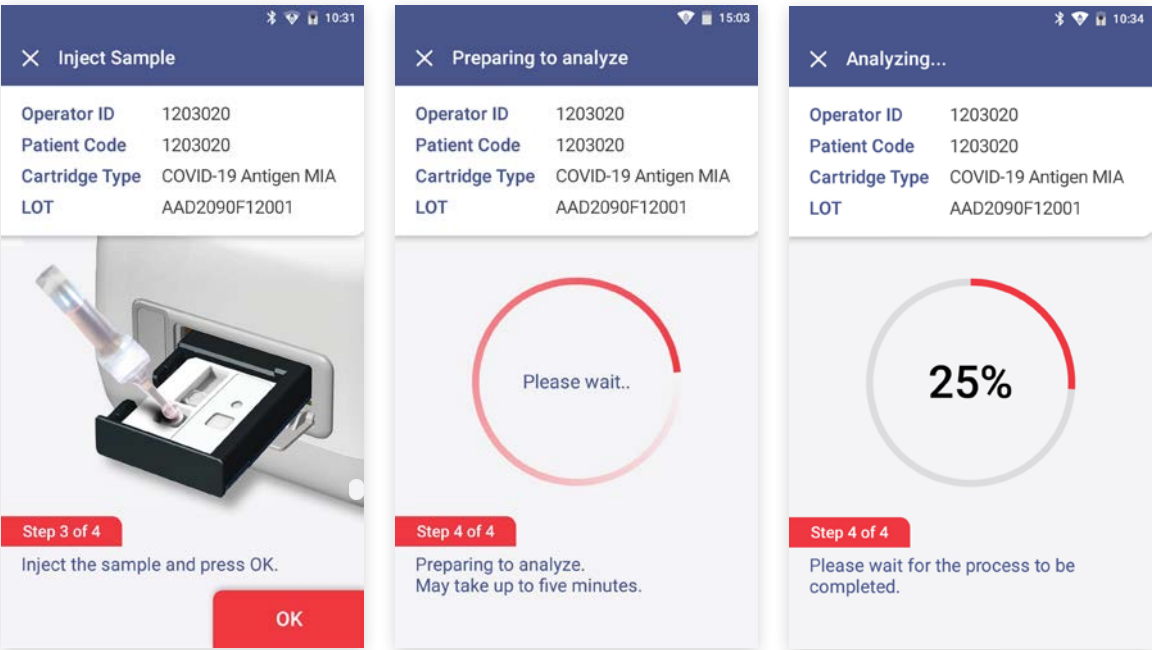
· When the analysis starts, please wait until analysis reaches '100%'.

· If the tray is not inserted into analyzer within 2 minutes after injected sample, start over with a new cartridge.

· If an error occurs in waiting mode, inject more of the sample into the cartridge inserted.

· When an error occurs in analyzing mode, start over with a new cartridge.

· Refer to the test cartridge package insert for details on how to draw test samples.

STEP 7 Check the result of the test

a. When test is completed, the result of the test is displayed on the screen.

b. Check the result and remove the cartridge from the tray.

c. Touch the 'DONE' button ⟶ Return to the home screen.
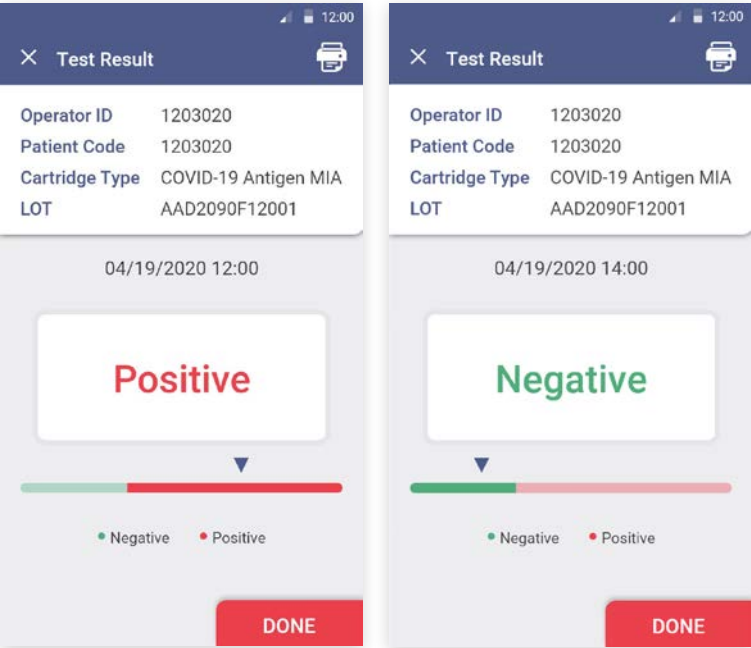
TEST RESULT: Positive or Negative - Normal operation of test cartridge

If the warning sign is displayed as shown: ***warning: unexpected signal detected.**, a retest is recommended.

STEP 8 Discard the used cartridge.

a. Refer to the images below to eject the cartridge from the tray.

b. Discard the Sampinute™ COVID-19 Antigen MIA test cartridge after use as required by internal quality control procedures and in accordance with local, state and federal regulations or accreditation requirements.
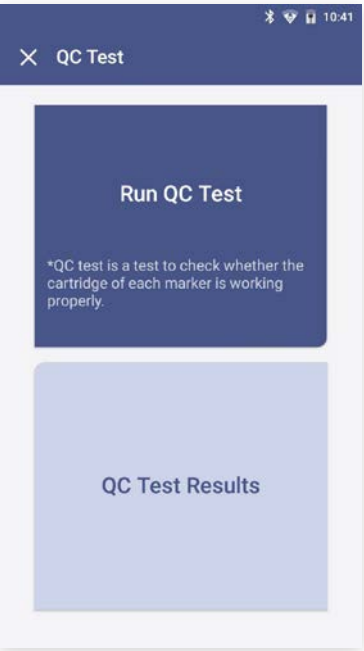
5-2. Result Management

Check the results of the test.
The results can be checked by touching the '**TEST RESULTS**' button on the home screen.
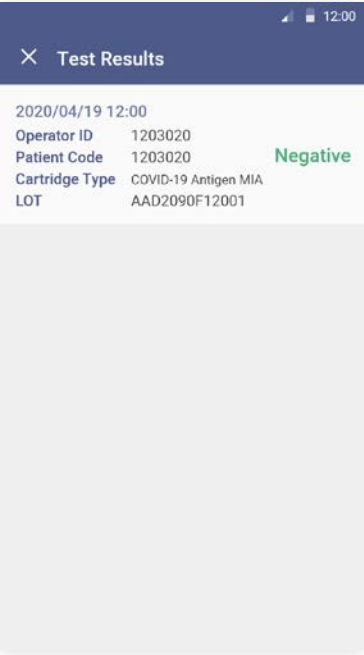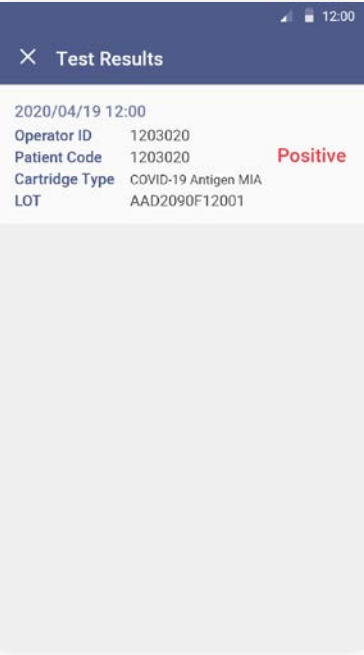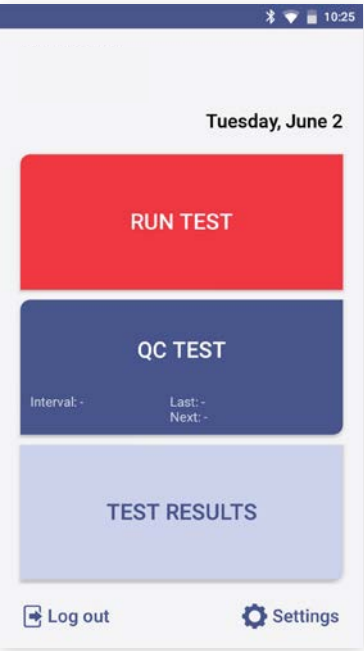
6. Running a QC Test (Control Solution Test)

STEP 1 **Touch the 'Run QC Test' button.**

· Run the test at a temperature range of 15-30°C (59-86°F).

· If the temperature is out of range, the test cannot be run.

· When the battery level is 15% or lower, you cannot start the test.

· Fully charge the battery before running a test.

STEP 2 **Scan the operator ID**

Scan the operator ID with a barcode scanner or manually enter the operator ID using the keypad. Touch the '**OK**' button only if entered manually.
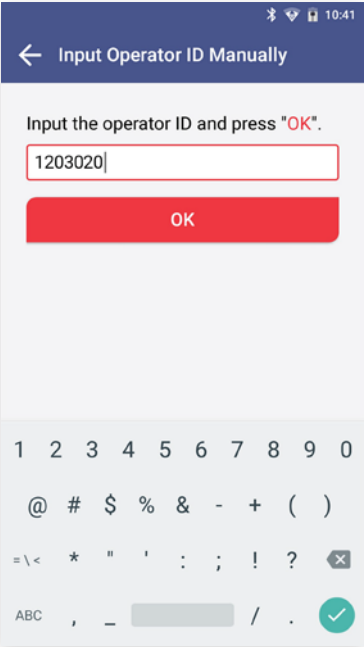
If you do not have a barcode scanner, touch the '**Input operator ID manually**' to enter the code using the keypad.

STEP 3 Scan the test cartridge QR code

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

b. Upon scanning the QR code, test level, the cartridge type and LOT will be displayed on the screen.

Please scan the QR code on the cartridge.

· The barcode scanner has to be purchased separately.

· If QR code recognition fails, scan a new cartridge pouch.

· Please check if the cartridge type is correct.

STEP 4 Insert the test cartridge

Insert the test cartridge after scan the QR code.

· Ensure the correct operator ID is entered.

· Check that you scanned the QR code of the cartridge to be inserted.

· Double check whether you are using the test cartridge for the correct target analyte.

· Before inserting a cartridge, ensure that you are not using a used one.

· Remove the aluminium tape attached on top of the cartridge.

· When the error message, **"Please contact the system administrator"** is displayed after inserting the cartridge, stop the process and contact the administrator to resolve the issue.

STEP 5 Inject the positive control solution

a. Prepare positive control solution of the same cartridge type as the inserted test cartridge.

b. Add 2-3 drops of the positive control solution into the sample inlet of the test cartridge within 2 minutes.

c. Touch the '**OK**' button.

STEP 6 Discard the used cartridge

a. Refer to the images below to eject the cartridge from the tray.

b. Discard the Sampinute™ COVID-19 Antigen MIA test cartridge after use as required by internal quality control procedures and in accordance with local, state and federal regulations or accreditation requirements.

STEP 7 Discard the used cartridge (continued)

When touching the 'OK' button, the screen will proceed to the 'QR Code Scan' screen.

STEP 8 Test cartridge QR code scan

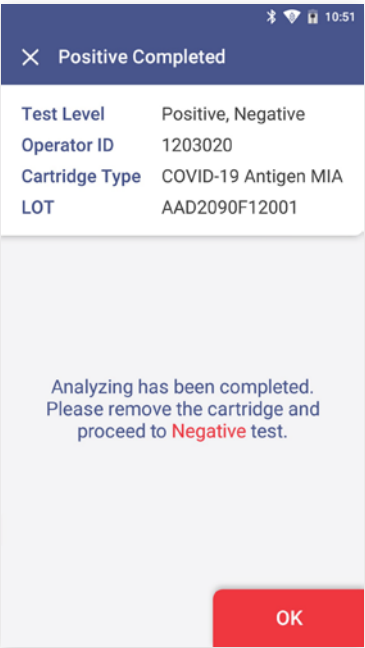a. Scan the QR code on the cartridge pouch with the barcode scanner.
b. After scanning the QR code, test level, the cartridge type and LOT will be displayed on the screen.

· Barcode scanner has to be purchased separately.

· If QR code recognition fails, scan a new cartridge pouch.

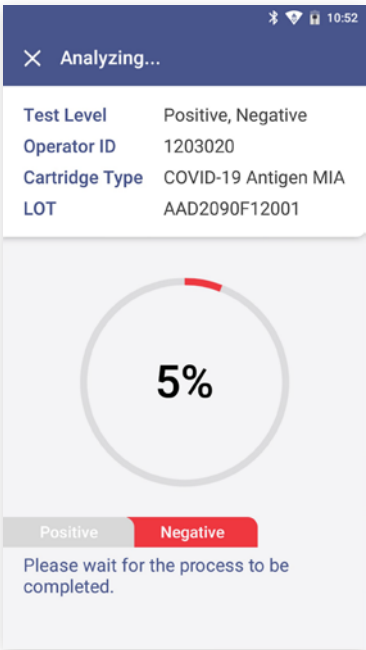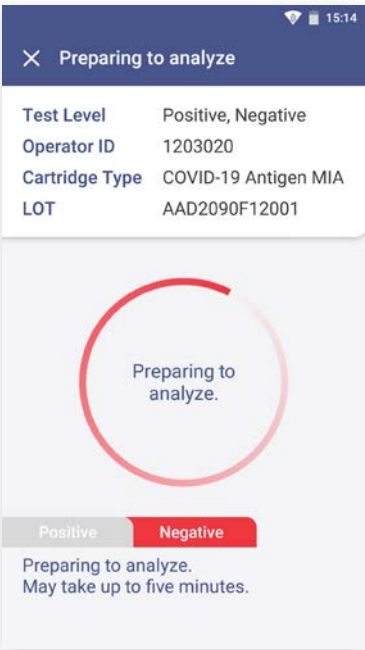· Please check if the cartridge type is correct.

STEP 9 Insert the test cartridge

Test Level Positive, Negative
Operator ID 1203020
Cartridge Type COVID-19 Antigen MIA
LOT AAD2090F12001

Please insert the test cartridge of the selected type.

· Ensure that the correct operator ID is entered before inserting the cartridge.

· Check that you scanned the QR code of the cartridge to be inserted.

· Double check whether you are using the test cartridge for the correct target analyte.

· Before inserting a cartridge, ensure that you are not using a used one.

· Remove the aluminium tape attached on top of the cartridge.

· When the error message, **"Please contact the system administrator"** is displayed after inserting the cartridge, stop the process and contact the administrator to resolve the issue.

STEP 10 Negative control solution injection

a. Prepare negative control solution of the cartridge type as the inserted test cartridge.
b. Add 2-3 drops of the negative control solution into the sample inlet within 2 minutes.
c. Touch the '**OK**' button.

Inject Control Solution

Test Level Positive, Negative
Operator ID 1203020
Cartridge Type COVID-19 Antigen MIA
LOT AAD2090F12001

Inject the Negative control solution and press OK.

OK

Preparing to analyze

Test Level Positive, Negative
Operator ID 1203020
Cartridge Type COVID-19 Antigen MIA
LOT AAD2090F12001

Preparing to analyze.

Preparing to analyze.
May take up to five minutes.

Analyzing...

Test Level Positive, Negative
Operator ID 1203020
Cartridge Type COVID-19 Antigen MIA
LOT AAD2090F12001

5%

Please wait for the process to be completed.

STEP 11 Check the result of QC test

a. When test is completed, the result of QC test is displayed on the screen.

b. Check the result and remove the cartridge from the tray.

c. Touch the '**DONE**' button ⟶ Return to the home screen.
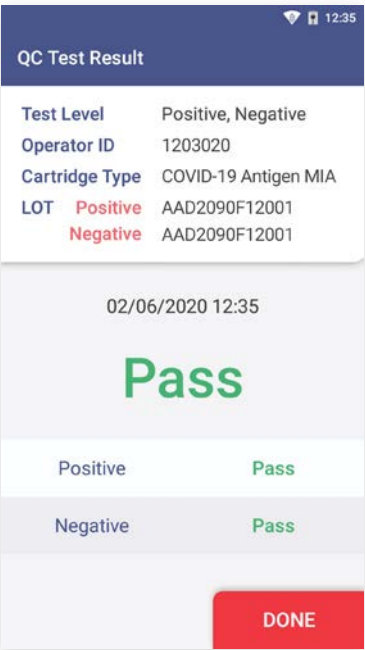
TEST RESULT: Pass - Successful operation of the test cartridge

TEST RESULT: Fail - Accuracy of the test cannot be verified, and the test needs to be conducted again or the administrator should be contacted.

STEP 12 Discard the used cartridge.
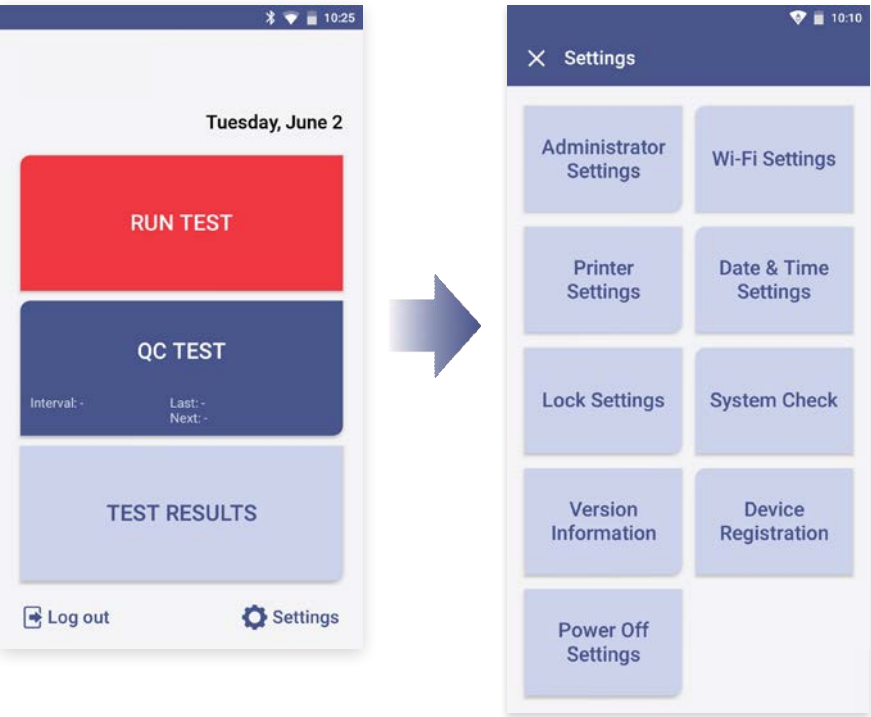
a. Refer to the images below to eject the cartridge from the tray.

b. Discard the Sampinute™ COVID-19 Antigen MIA test cartridge after use as required by internal quality control procedures and in accordance with local, state and federal regulations or accreditation requirements.

7. Function Settings

7-1. Setup Screen

Settings ⟶ Settings Menu

Settings menu

· Administrator Settings

· Wi-Fi Settings

· Printer Settings

· Date & Time Settings

· Lock Settings

· System Check

· Version Information

· Device Registration

· Power Off Settings

7-2. Administrator Settings

Administrator Information

a. Enter admin password to proceed to administrator settings.

b. Touch the '**Administrator Information**' button to check the administrator information.
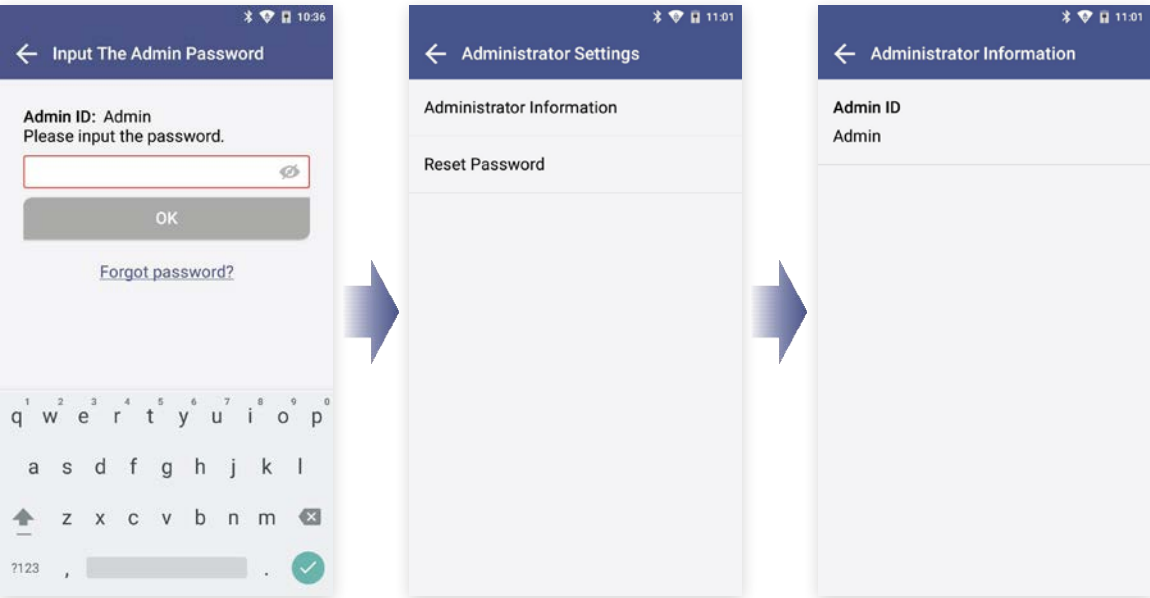
Change Administrator Password

a. Touch the '**Reset Password**' button. ⟶ Enter the current password.

b. Enter a new password in '**New password**' and '**Re-enter password**'. ⟶ Touch the '**OK**' button.
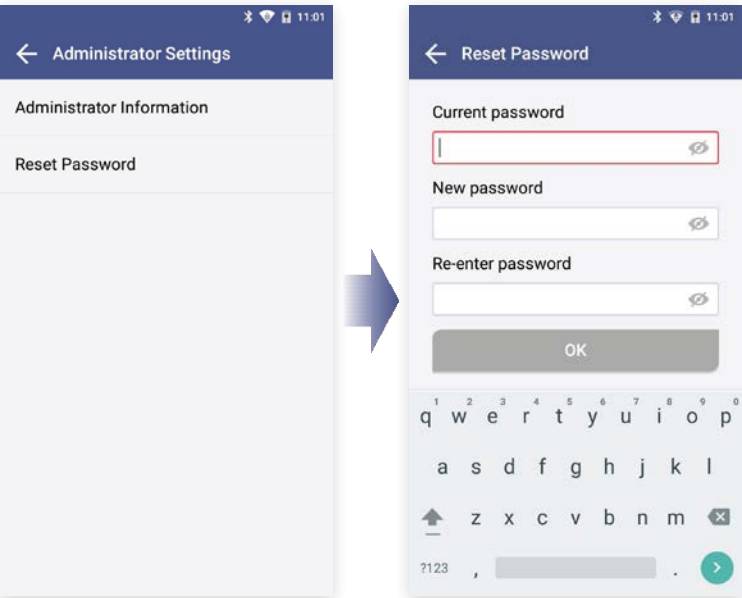
· Password is case-sensitive and must be a combination of letters and numbers.

· Your password cannot contain spaces and must be less than 45 characters long.

· Touch the eye-shaped icon 👁 to check entered password.

Forgot Password

a. If you forgot admin password, touch '**Forgot password?**'.

b. Master password input screen will be displayed.
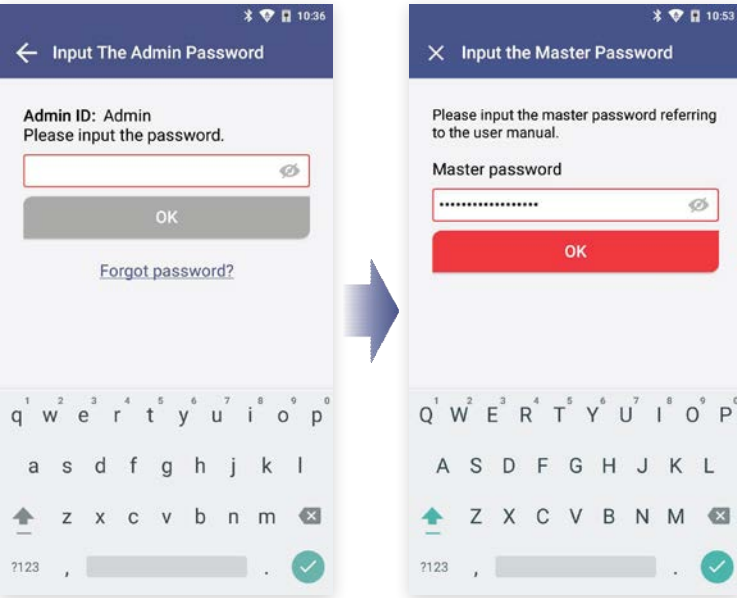
Input the Master Password

Type the master password. ⟶ Enter the new admin password. ⟶ Touch the '**OK**' button.

· Master password is the '**serial number of the device**' + '**0001**'.

· Serial number is written in the label on the bottom of the device.
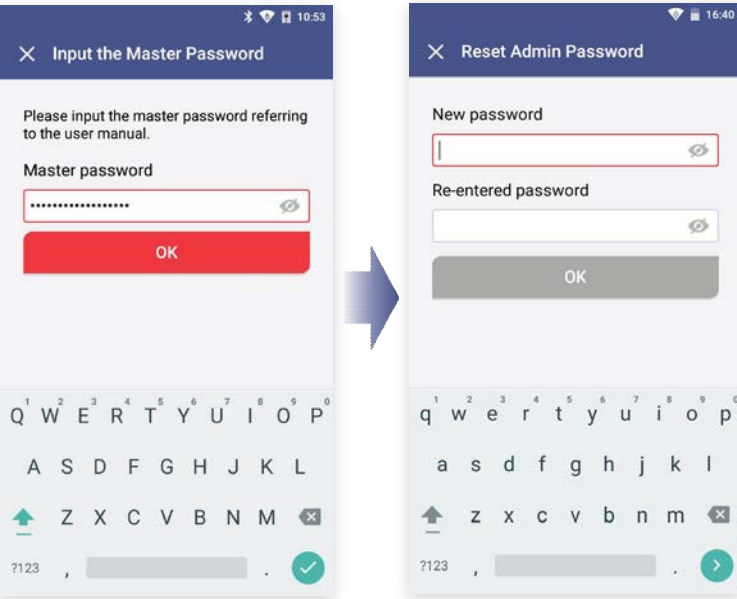
7-3. Wi-Fi Settings

Turn Wi-Fi On or Off & Connect to a Wi-Fi.
[Wi-Fi Settings ⟶ On/Off]: Turn Wi-Fi network on or off
Select '**On**': Select Wi-Fi to connect to.

7-4. Printer Settings

Print Setting

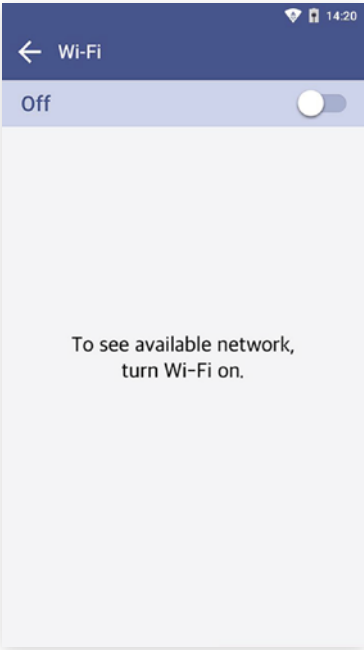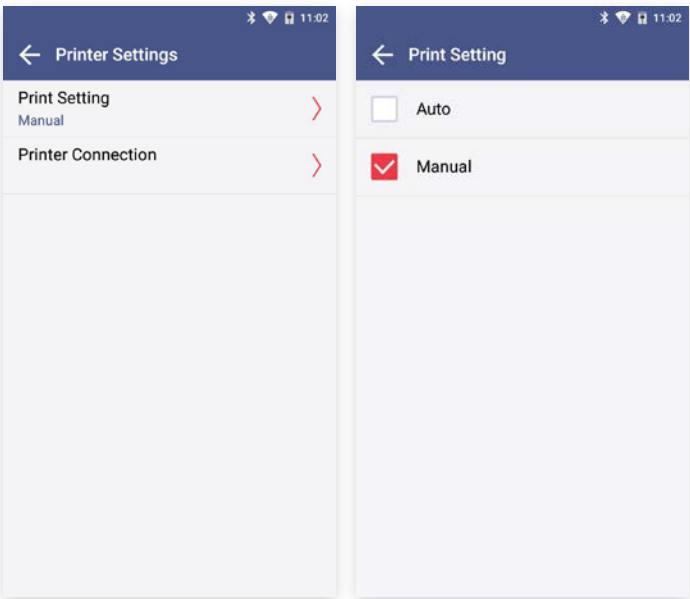Select 'Auto' or 'Manual' button in Print Setting.

Printer Connection

a. Find a printer model to link from the 'Connectable Devices' list.
b. Select the model.
c. The printer is connected and displayed in Connected Device.
d. To disconnect, touch the 'Disconnect' button.

· Printer is automatically linked when you connect USB port.
· To find a printer's model number, remove the battery of printer. Then, check the product label.
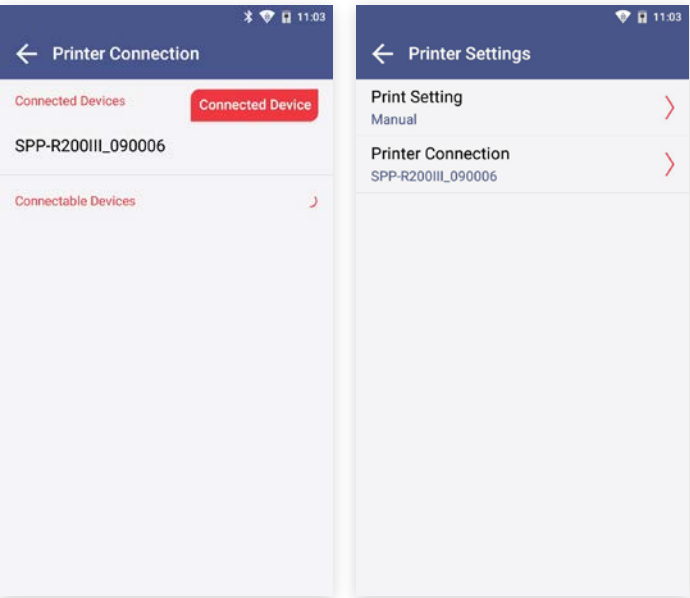
· If you try to connect with another printer *via* USB while Bluetooth has been connected prior, the Bluetooth will be unpaired and the device will be connected to the USB printer.

· Printing may be unavailable if you use a mobile printer incompatible with Sampinute™ Analyzer.

· Changing printer connection mode may cause a delay for two seconds. Please wait until the message 'Please wait' disappears.

7-5. Date & Time Settings

Date & Time Settings
Enter the admin password to access 'Date & Time Settings'.
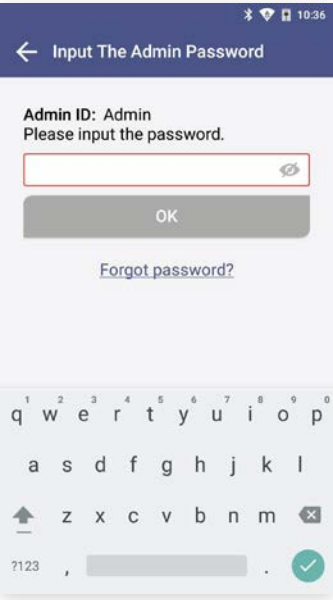
Touch 'Date & Time Settings'. ⟶ Touch 'Select Time Zone'. ⟶ Select the location.
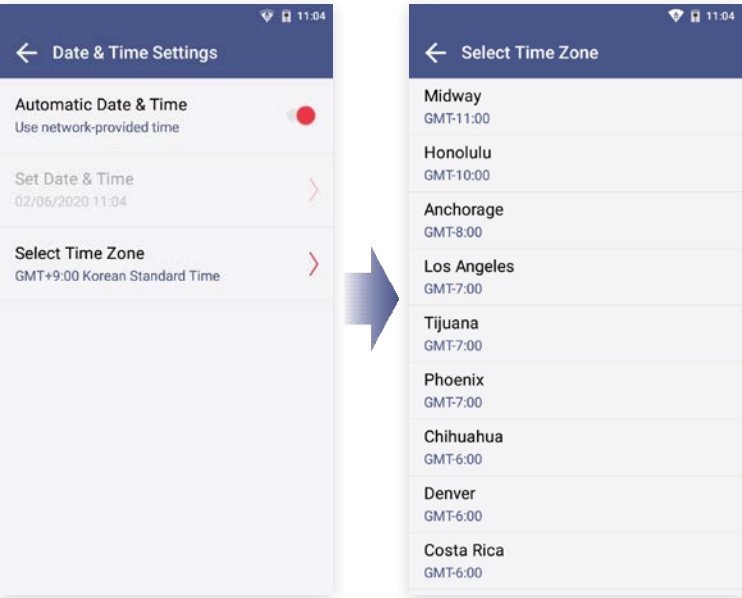
Adjust 'Set Date & Time'. ⟶ Touch the **'OK'** button.
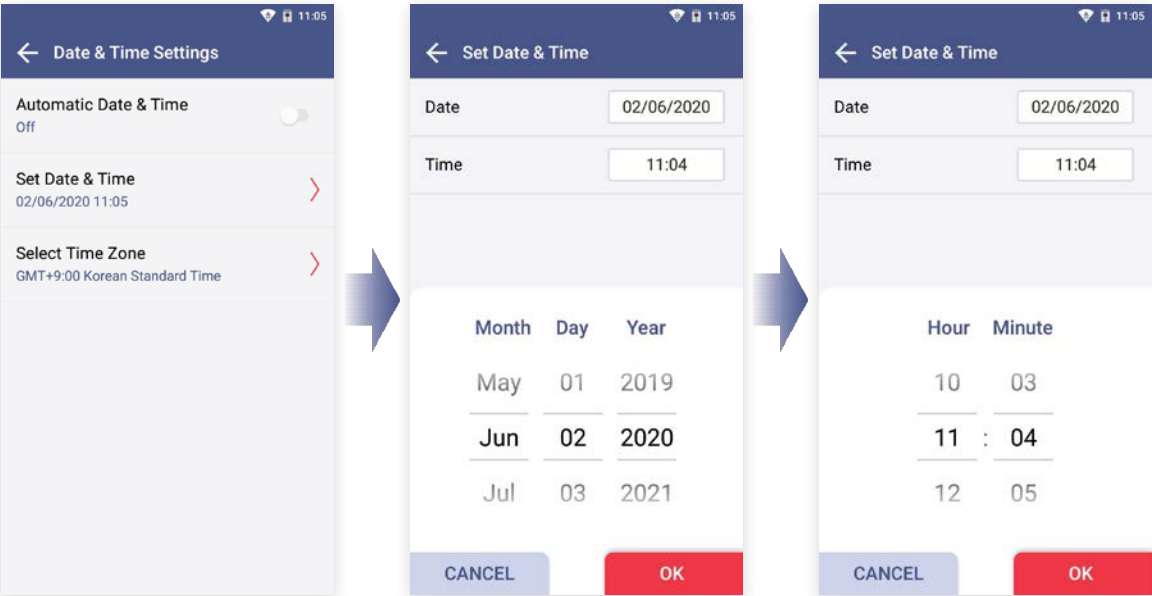
7-6. Lock Settings

STEP 1 Lock Settings

Enter the admin password to access Lock Settings.
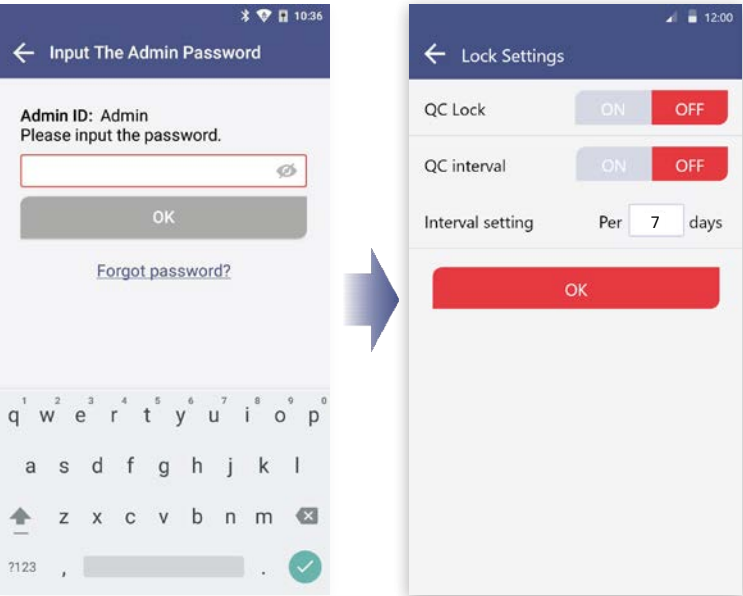
STEP 2 Lock Settings QC Test

[ON] The QC Test result must be a 'PASS' to be able to run a test.

[OFF] A test can be run regardless of QC Test result.
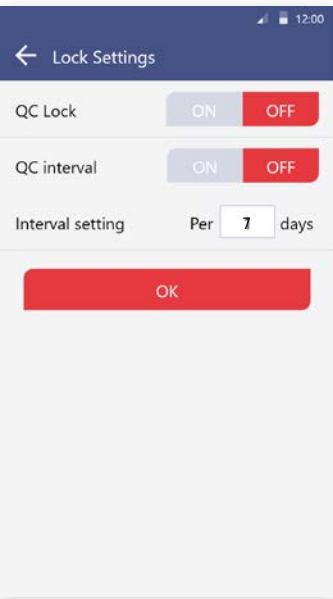
· When all settings of QC Lock are turned OFF, a test can be run even if QC Test result is 'fail'.

· The manufacturer is not responsible for the test results run under settings with all QC Lock Settings turned OFF.

STEP 3 **QC Test interval setting**

[ON] A sample test is available after conducting QC test at the intervals you set up.
[OFF] You can continue QC test without setting up intervals.
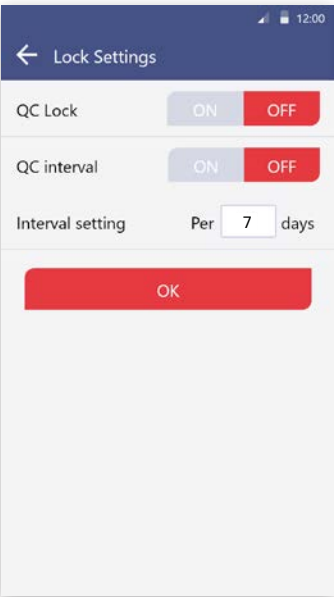
· You can set the intervals for QC test.

· When the interval is set up, it will be shown under Run QC Test

  on the home screen.

STEP 4 **Date interval setting**

a. Touch the input box and then select using the numeric keypad shown on the screen.
b. Enter a number between 1 and 365 to set up QC Test intervals.
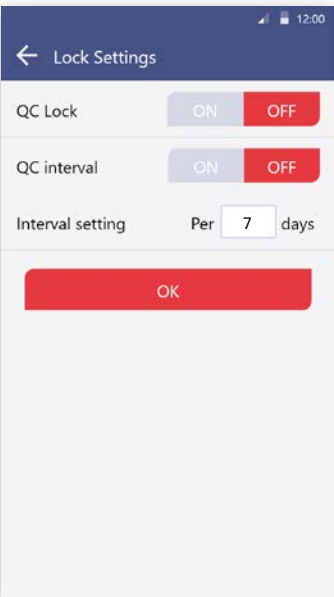
· Please input only numbers for the date interval setting.

8. Maintenance

8-1. System Check

STEP 1 Touch the 'Run System Check' button
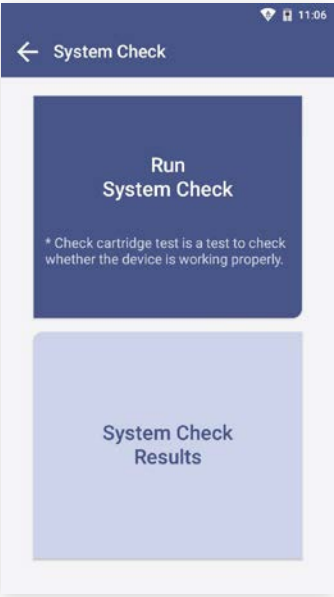
· Run the test at a temperature range of 15-30°C (59-86°F)

· If the temperature is out of range, the test cannot be run.

· When the battery level is 15% or lower, you cannot start the test.

· Fully charge the battery before running a test.

STEP 2 Scan the QR code of the check cartridge
a. Scan QR code on a check cartridge with the barcode scanner.
b. After scanning the QR code, the screen will display "Insert Check Cartridge."

· Barcode scanner has to be purchased separately.

· If you do not scan QR code of the test cartridge, the test will not proceed.

· If QR code recognition continues to fail, please contact the administrator.

STEP 3 **Insertion of check cartridge tray**

a. Insert a check cartridge to the tray according to instructions on the screen.

b. Insert the check cartridge in the correct position.

c. Touch the '**OK**' button.

STEP 4 **Start 'System Check'**
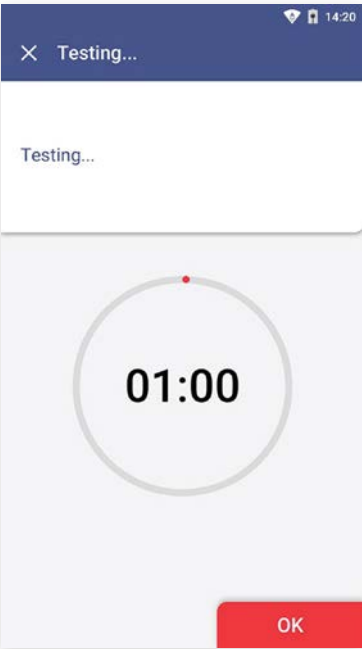
· The system check takes about 1 minute.

STEP 5 Confirm the system check results

a. The test results are displayed upon completion.
b. After checking the results, remove the used cartridge from the tray.
c. Touch the 'DONE' button to move to the home screen.
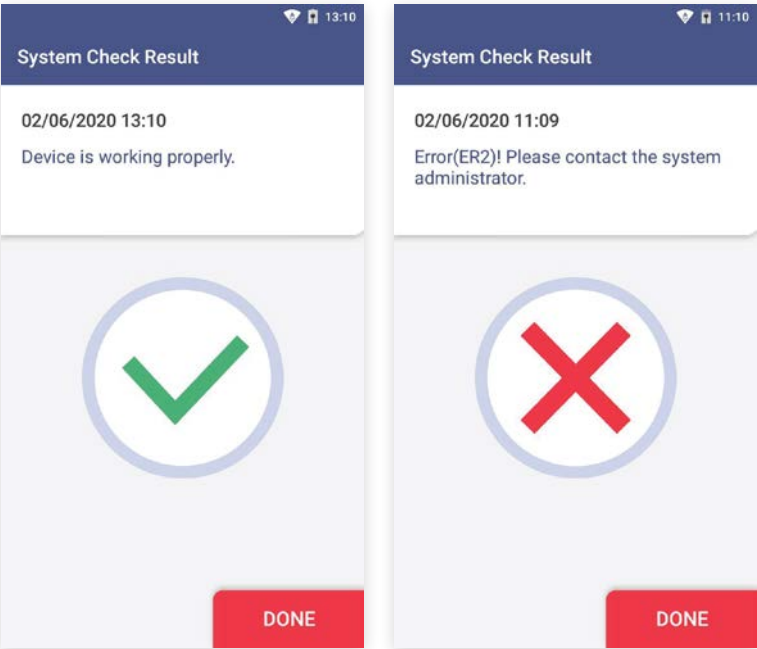
· Pass: Indicates that the device is working properly and a V mark is displayed on the screen.

· Fail: An error message and an X mark is displayed on the screen.
   Try out the test again or contact the administrator.

System Check ⟶ **System Check Result**
The System Check Results are displayed in order from the oldest to the newest.
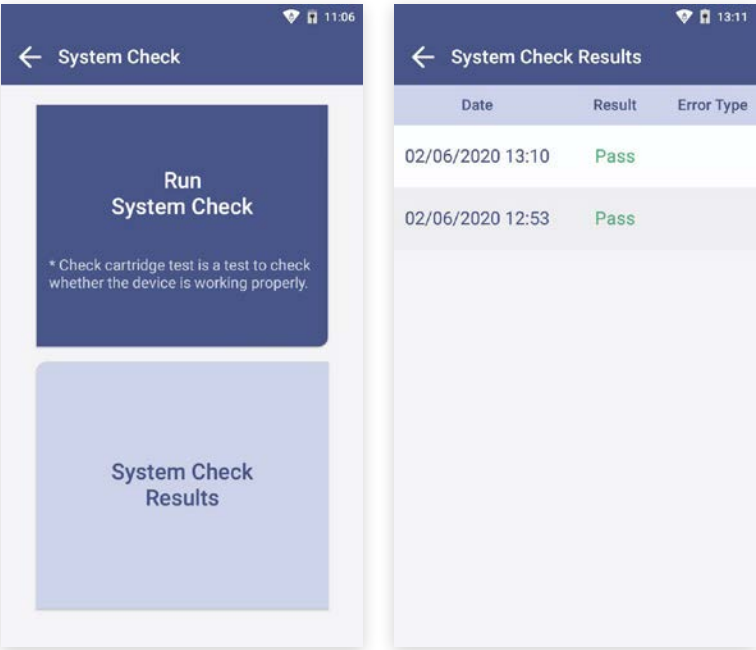
8-2. Version Information and Update

STEP 1 **Check the Version Information**

a. Type the admin password and access device registration menu.

b. Confirm the latest version
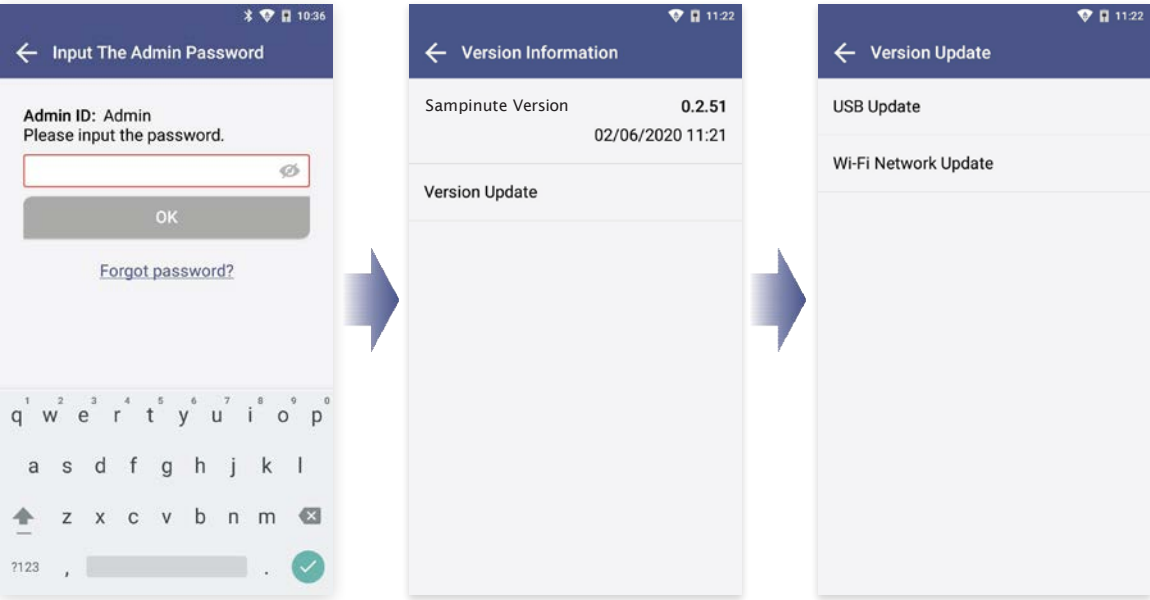
STEP 2 Update new version

Option 1. Software update by USB connection

a. Connect the USB containing the updated version to the USB port on the back of the analyzer.

b. Select '**USB Update**'. (A message to update to new version will be displayed if the software needs to be updated.)

c. Touch the '**OK**' button to update to the latest software.
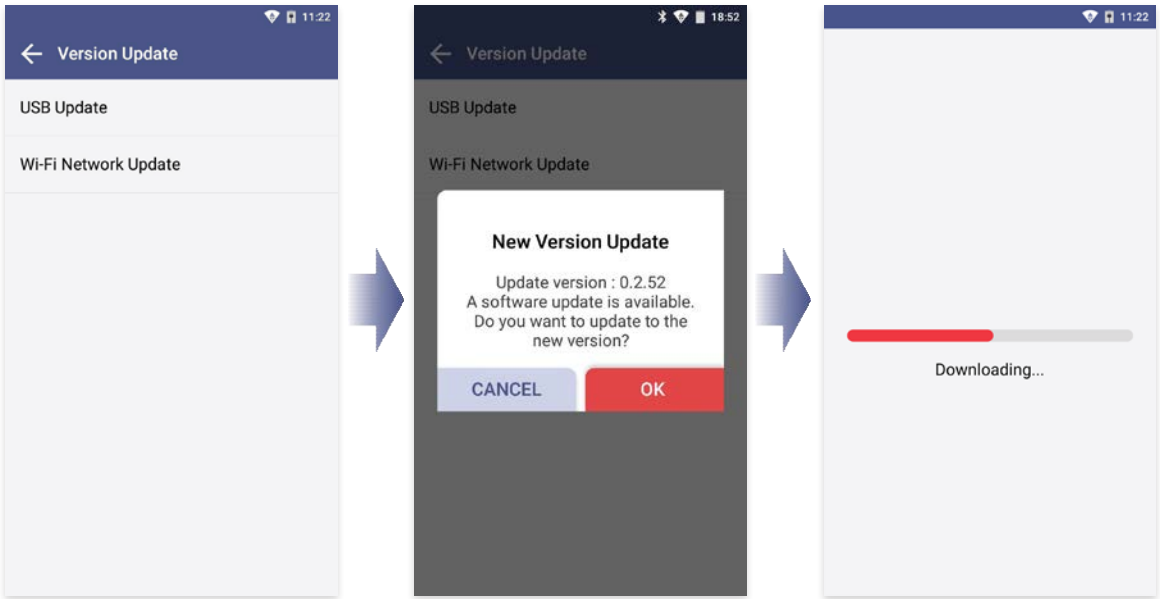
· USB connection ⟶ The above message pops up. ⟶ Check the pop-up box. ⟶ Touch OK.

· Allow USB drive connection for successful update.

· The update starts when the analyzer's battery level is 15% or higher.

· Removing the USB before finishing the update may cancel the update.

· If the update continuously fails, please contact the system administrator.

Option 2. Wireless update of software

a. Select '**WI-FI Network update**'. (A message to update to new version will be displayed if the software needs to be updated.)

b. Touch the '**OK**' button to update to the latest software.
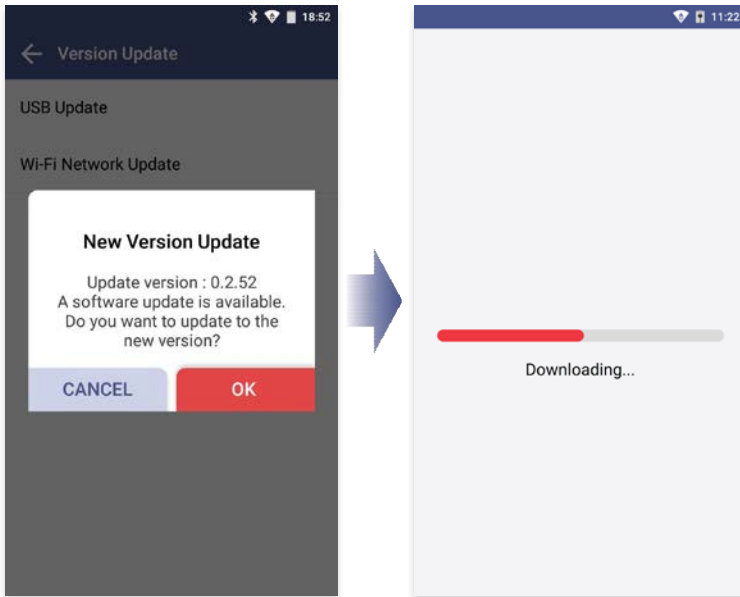
· The update starts when Sampinute™ Analyzer's battery level is 15% or higher.

· Unstable wireless network connectivity may cancel the update.

· If the update continuously fails, please contact the system administrator.

8-3. Device Registration

STEP 1 Settings ⟶ Device Registration

a. Input the admin password to access device registration menu.

b. Enter the hospital code on the device registration screen.

c. Type the hospital code and touch the '**DONE**' button. The device will try to access the hospital server.
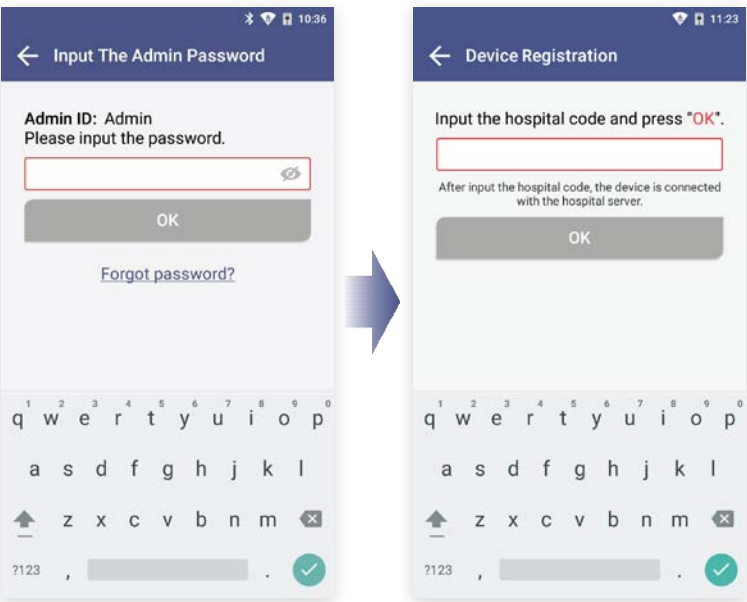
*If you have already registered the device during initial setup, you do not need to set it up again.

STEP 2 Registration Completed

When registration is completed:

a. The message 'Successfully registered' is displayed.

b. Touch the '**DONE**' button to proceed to settings screen.
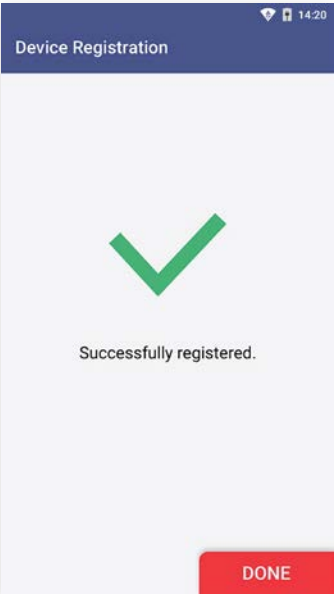
8-4. Auto Power Off Settings

a. Select the 'Power Off Settings' button.
b. Input the admin password.
c. Select 'Power Off'
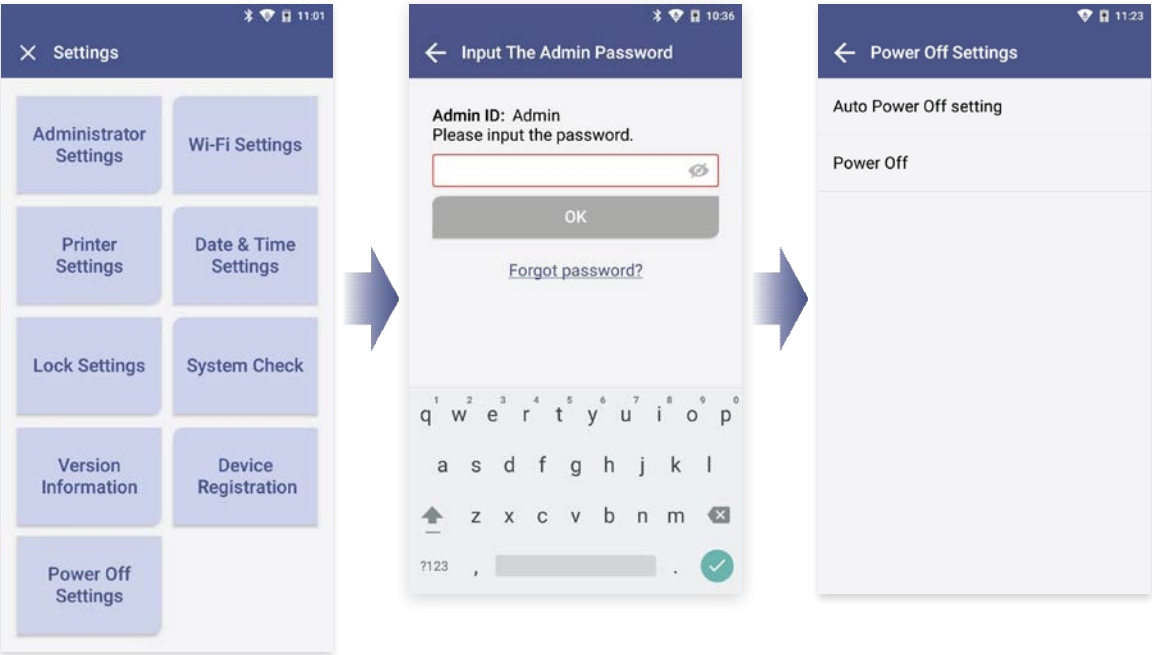
Option 1. On/Off Setting of Auto Power Off
Select on or off by touching **[Auto Power Off Settings ⟶ On/Off]** to enable or disable the function.
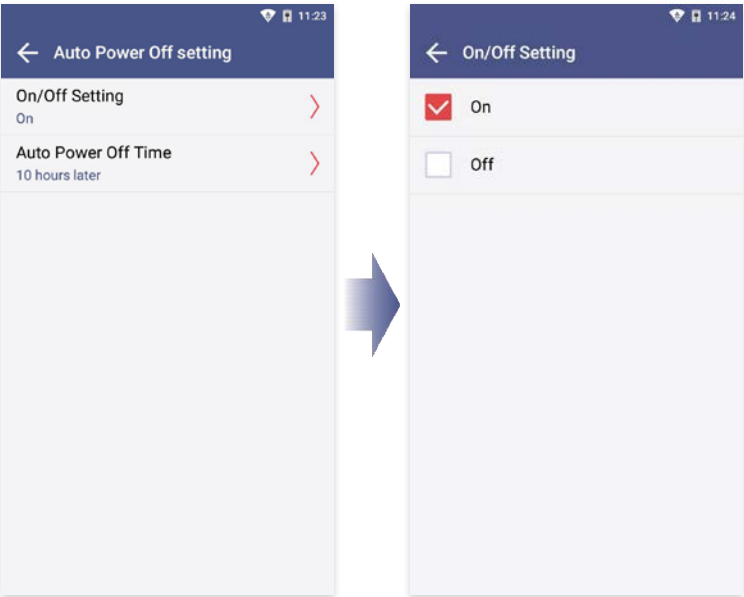
· Default auto power off time is 10 hours when the function is enabled 'On'.
· Auto power off time can be changed by selecting Auto Power off Time.

8-4. Auto Power Off Settings

On/Off setting ⟶ Select the 'On' button ⟶ Select the 'Auto power off time'
After selecting the duration time for the screen to be displayed, the device will be automatically turned off after that duration time.
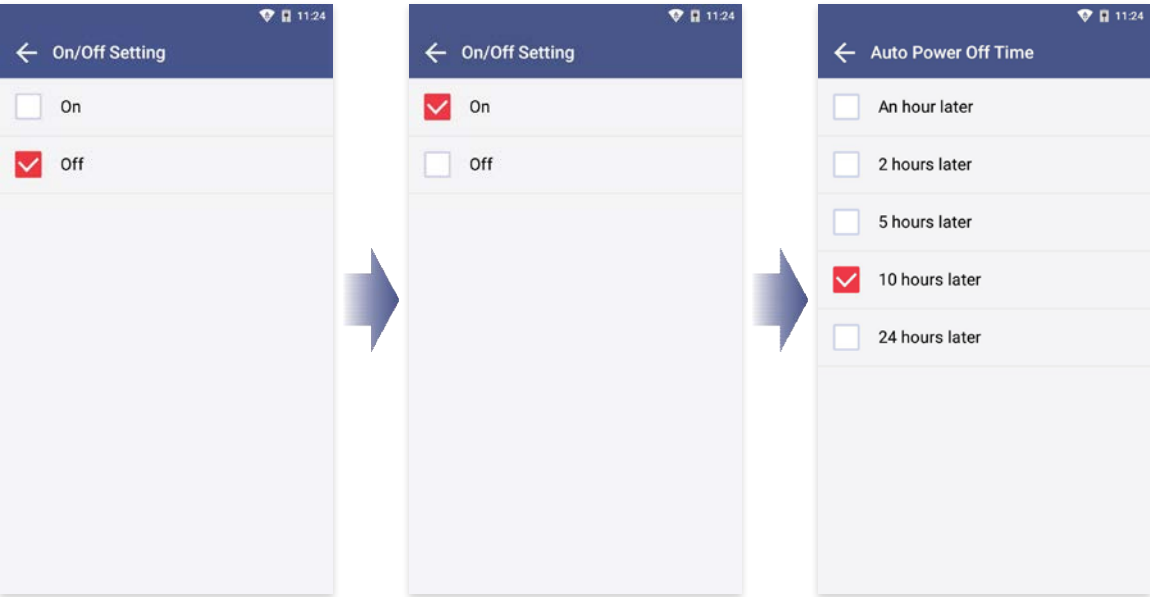
Option 2. Power Off
a. Select the '**Power off**' button.
b. Touch the '**YES**' button to finally turn the power of the device off.
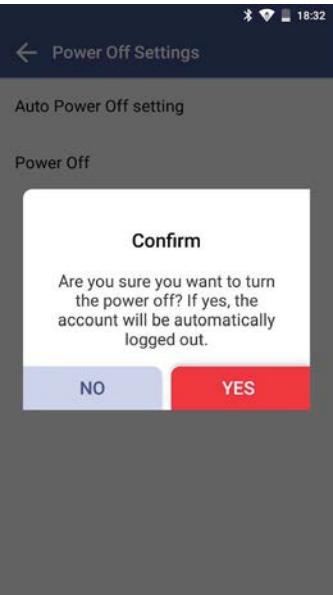
· It is recommended to turn Sampinute™ Analyzer off, if the instrument is not used for a long period of time.

· If you turn off the analyzer for a long time, time settings of the device may be initialized. Time is automatically set up, once the instrument is connected to Wi-Fi.

8-5. Cleaning

Clean the analyzer periodically with a soft and dry cloth.

Clean the analyzer periodically with a soft and dry cloth. Do not use highly corrosive cleaning solution or chemicals, or a cleaning tissue contains chemical substances that may damage the device.

*Make sure to turn off when cleaning the device.

Test Tray Cleaning

The blood, moisture or dust that enters the tray may lead to failure of the Sampinute™ Analyzer. Wipe the tray carefully with an alcohol-moistened swab if needed.

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

8-6. Storage Requirements

· Protect the device from dust and do not expose it to direct sunlight.

· Recommended temperature and humidity for storage condition are as follows:
  [Temperature] -10 - 45℃ (14 - 113℉)
  [Humidity] 10 - 80%

· Avoid storage places prone to tremors or that could cause falling.

9. Error Messages
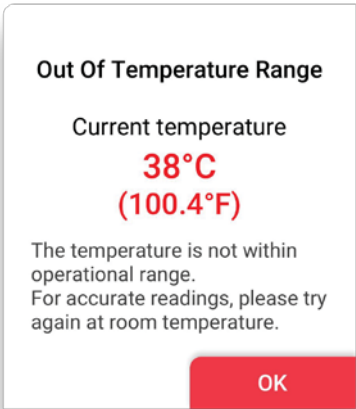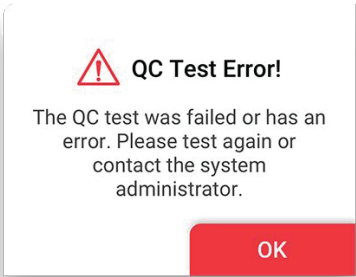
9-1. Notifications

Error Notifications	Descriptions and Solutions
Please input the admin password.	Admin password is not inputted. Displayed when touching the '**OK**' button without having entered the admin password. Solution: Input the admin password and then touch the '**OK**' button.
Please input the hospital code.	Hospital code is not inputted. Displayed when touching the '**DONE**' button without having entered the hospital code. Solution: If a hospital code is required, contact the administrator. Input the hospital code and then touch the '**DONE**' button.
Unregistered hospital code. Please contact administrator.	Unregistered hospital code Displayed when unregistered hospital code is entered. Solution: If a hospital code is required, contact the administrator. Input registered hospital code. If the issue persists, contact the administrator.
Failed to connect to network. Please try again.	No response from server Displayed when device registration fails due to lost network connection or other errors which make server communication unavailable. Solution: Either try to connect again at a later time or connect to another network.
Unknown error. Please try again.	Wi-Fi communication error The alert pop up when Wi-Fi communication is failed. Solution: Try again. If the issue persists, then contact the administrator.
Please try again after connecting to a network.	No Wi-Fi connection Displayed when device requests server communication for Wi-Fi connection. Solution: Connect to a Wi-Fi.
Low battery. 14% of the battery level is remaining. The remaining battery must be 15% or higher to run the analyzer. Please connect the analyzer to a power source.	Low battery Displayed when touching the low-battery icon on the home screen. Solution: Connect to a power adapter.

Error Notifications	Descriptions and Solutions
Please perform the system check and the QC test prior to sample tests as instructed in the manual.	System check and QC test not performed Displayed when touching '**RUN TEST**' without having performed system check and QC test. Solution: Perform system check and QC test if required.
The system check was failed. Please check the results again. Contact the system administrator.	Displayed when touching the system check warning ▨ icon on the home screen under the condition that the system check was failed. Solution: Perform system check. **[Settings screen → System Check → ▨ System Check]**
Either the QC test was failed or no tests have been performed within the set QC interval. Please check the results again.	Displayed when touching QC! icon on the home screen under the condition that either the QC test was failed or no analyses have been run within the set QC interval. Solution: Perform the QC test.
The temperature is not within operational range. (Current temperature: 38°C/100.4°F)	Inappropriate temperature Displayed when touching the temperature icon on the home screen which pops up when temperature is out of range for testing. Solution: Re-locate device in an environment of operational range (15-30°C / 59-86°F).
The admin account automatically logged out.	Administrator account logout Displayed when administrator account logs out before power off or reboot.
Please input the master password.	Master password has not been entered. Displayed when the '**OK**' button is touched without master password input. Solution: Enter the master password.
Incorrect password. Please input the master password again.	Password input error Displayed when the correct password has not been entered. Solution: Enter the correct password.
The fan is activated due to increased internal temperature of the analyzer.	Fan activated Displayed when the fan is activated by the Celltrion Sampinute™ Analyzer's temperature sensor operation.
Invalid ID. Please check the ID again.	Wrong operator ID Displayed when wrong operator ID is entered. Solution: Enter the correct ID.

Error Notifications	Descriptions and Solutions
Please input the operator ID.	Operator ID has not been entered. Displayed when touching 'OK' without entering the operator ID. Solution: Enter the operator ID.
Please input the patient code.	Patient code has not been entered. Displayed when touching 'OK' without entering the patient code. Solution: Enter the patient code.
Please insert test cartridge in the tray.	Tray ejection failure Displayed when a cartridge is not inserted in the tray within the specified time period. Solution: Insert the cartridge immediately upon request.
Please remove the cartridge	Cartridge is not removed. Displayed when cartridge is not removed upon request. Solution: Remove the cartridge.
Incorrect password. Please input the password correctly.	Current password mismatch. Displayed when you do not enter currently set password. Solution: Enter the currently set password.
The new password and re-entered password do not match. Please input the passwords again.	New password mismatch Displayed on the Change Administrator Password screen when newly entered password does not match with the one typed in the new password confirm box. Solution: Ensure both passwords entered are the same.
Please input the new admin password.	New administrator password has not been entered. Displayed when a new administrator password has not been entered in the password setting screen. Solution: Enter new administrator password.
Please disconnect the device first and then try connecting the device.	Bluetooth disconnection Displayed when a new Bluetooth printer connection is requested while the analyzer is connected to a Bluetooth printer. Solution: Connect to the appropriate Bluetooth printer.
Please remove the USB port first and then try connecting the device.	USB disconnection Displayed when a Bluetooth printer connection is requested while the analyzer is connected to a USB mobile printer. Solution: Either disconnect the Bluetooth or the USB printer.

9-2. Error pop-ups

Error pop-ups	Descriptions and Solutions
Out Of Temperature Range Current temperature **38°C** **(100.4°F)** The temperature is not within operational range. For accurate readings, please try again at room temperature. **OK**	Inappropriate temperature **Case1.** Pops up when the '**RUN TEST**' button is touched on the home screen, or the '**RUN QC TEST**' button is touched. **Case2.** Pops up when the temperature is out of test range after the '**RUN TEST**' or "**RUN QC TEST**" button has been touched. Solution: Move the device to the recommended operating temperature (15-30°C, 59-86°F) and wait until device temperature decreases to below 30°C (86°F).
⚠ **Battery Low!** Low battery. 14% of the battery level is remaining. The remaining battery must be 15% or higher to run the analyzer. Please connect the analyzer to a power source. **OK**	Low battery **Case1.** Pops up when the '**RUN TEST**' button is touched on the home screen, or the '**RUN QC TEST**' button is touched at 14% battery level. **Case2.** Pops up when the battery level is 14% and the user touched Next to proceed to the next level of the QC test. Solution: Connect the analyzer to a power source.
⚠ **QC Test Error!** The QC test was failed or has an error. Please test again or contact the system administrator. **OK**	QC Test error Pops up when the '**RUN TEST**' button is touched on the home screen under the condition that QC lock settings are turned '**ON**', and/or the QC TEST result is '**Fail**'. Solution: Conduct the test again. If the QC test is a fail, then contact the system administrator.

Error pop-ups	Descriptions and Solutions

⚠ **System Check Error!**

The system check was failed
or has an error.
Please test again or contact the
system administrator.

OK

System Check Error
Pops up when the '**RUN TEST**' button is touched on the home screen under the condition that the system check result is '**Fail**'.

Solution: Conduct system check again. If the system check is a fail, then contact the system administrator.

Contact System Administrator

If you forgot your admin password,
contact the system administrator.
- e-mail: support@bbbtech.com
- Tel: +82-070-4407-8808

OK

Contact the system administrator.
Pops up upon selecting '**Forgot password?**'

Solution: Contact the system administrator.

⚠ **Error!**

Invalid QR code. Please scan the
test cartridge QR code again.

OK

Invalid cartridge QR code
Pops up when an invalid QR code is scanned.

Solution: Scan a valid QR code.

⚠ **Error!**

The test cartridge has been expired.
Please use a new test cartridge.

OK

Expired cartridge QR code
Pops up when expired cartridge QR code is scanned.

Solution: Scan a new cartridge of valid expiry date.

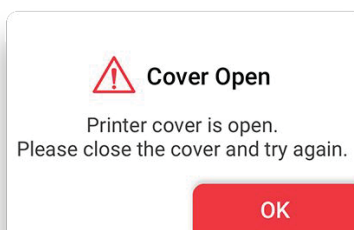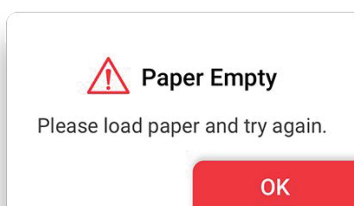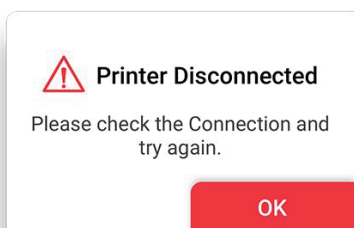| Error pop-ups	Descriptions and Solutions
⚠ Error! The wrong type of cartridge scanned. Please check the type of cartridge and scan the cartridge QR code again. **OK**	The QR code of the check cartridge is scanned. Pops up when the check cartridge's QR code is scanned instead of the test cartridge. Solution: Scan the QR code of a test cartridge.
⚠ Error!(ER1) Please contact the system administrator. **OK**	Tray ejection failure Pops up within 10 seconds after tray ejection fails. Solution: Contact the system administrator.
⚠ Error! The test cartridge has already been used. Please use a different test cartridge. **OK**	Pops up when a used cartridge is inserted. Solution: Remove used cartridge and insert a new cartridge.
⚠ **Insufficient Sample** Please try again with enough volume (at least 50 µL). If failure persists for the third time, try again with a new cartridge. **OK**	Insufficient sample Pops up when a sample test fails due to errors associated with timeout, insufficient test sample injection, etc. Solution: Insert at least 50 µL of the sample again into the inlet. If failure persists for the third time, insert a new cartridge.

Error pop-ups	Descriptions and Solutions
⚠ **Cover Open** Printer cover is open. Please close the cover and try again. **OK**	Pops up when the printer cover is open. Solution: Close the printer cover.
⚠ **Paper Empty** Please load paper and try again. **OK**	Pops up when there is no paper left in the printer. Solution: Re-fill printer with paper.
⚠ **Printer Disconnected** Please check the Connection and try again. **OK**	Printer disconnection Pops up when the printer is not connected and the user touches the '**Print**' button. Solution: Ensure that the printer is connected.
⚠ **Error!(ER203)** There was an error proceeding the analysis. Please retry the test or contact the system administrator. **OK**	Analysis failure Pops up when analysis is failed. Solution: Either try the analysis again or contact the administrator.

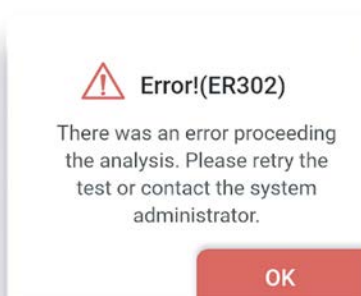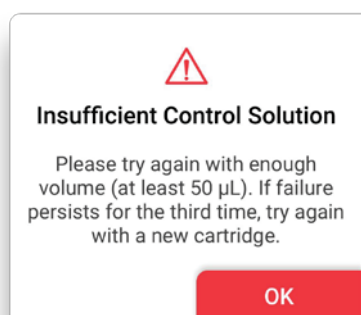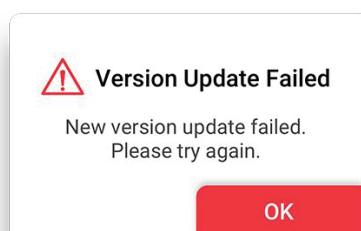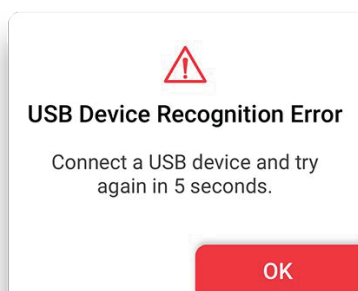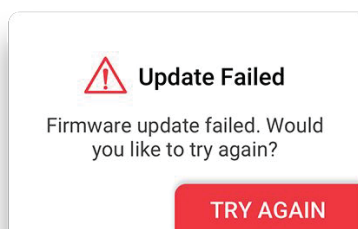| Error pop-ups	Descriptions and Solutions
⚠ Error!(ER302) There was an error proceeding the analysis. Please retry the test or contact the system administrator. **OK**	Analysis failure Pops up when analysis is failed. Solution: Either try the analysis again or contact the administrator.
⚠ **Insufficient Control Solution** Please try again with enough volume (at least 50 μL). If failure persists for the third time, try again with a new cartridge. **OK**	Insufficient solution Pops up when a solution test fails due to either timeout, insufficient solution injection, or solution reading failure. Solution: Insert at least 50 μL of the control solution again into the inlet. If failure persists for the third time, insert a new cartridge.
⚠ Error! The wrong type of cartridge scanned. Please scan check cartridge QR code. **OK**	The QR code of the test cartridge is scanned. Pops up when the QR code of the test cartridge is scanned during the System Check process. Solution: Scan the QR code of a check cartridge.
⚠ **Version Update Failed** New version update failed. Please try again. **OK**	New version installation failure Pops up upon new version installation failure during software update. Solution: Re-try version update.

⚠️

USB Device Recognition Error

Connect a USB device and try
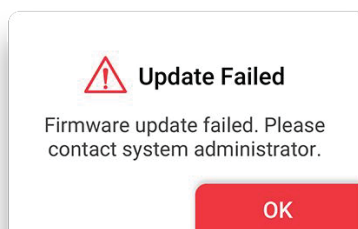again in 5 seconds.

OK

USB Device Connection Error
The alert pops up when USB is removed or
disconnected during software update.

Solution: Connect the USB device and try
again in 5 seconds.

⚠ **Update Failed**

Firmware update failed. Would
you like to try again?

TRY AGAIN

Pops up when the firmware update fails.

Solution: Try updating the firmware again.

⚠ **Update Failed**

Firmware update failed. Please
contact system administrator.

OK

Repetitive update failure
Pops up when the firmware update fails
more than 3 times.

Solution: Contact the system administra-
tor.

⚠ **Battery Low!**

Battery too low to allow update.
Please connect the charger and
update when battery level is
more than 15%

OK

Low battery during software update
Pops up upon touching '**Update**' when
battery level is 14 % or lower.

Solution: Connect the device to a charger.

10. Technical Information

Model Name	MB-100
CPU	MT8163B (Quad core)
Display type	5.5" HD display, Touch screen
Memory capacity	8GB ROM / 1GB RAM
Battery	Main battery : 2,700mAh 3.8V Sub battery : 2,500mAh 14.4V (3.7V 18650 4cell)
Power	rating : 12VDC, 1.5A plug interface : 5.5mm * 2.5mm
Dimension/weight	114 x 206 x 86mm / 1,300g
OS	Android 7.0
LOT reading	QR Code
Operating temperature (Device without a cartridge)	-10 - 45℃ (14 - 113˚F)
Storage environment	-10 - 45℃ (14 - 113˚F), less than 80% of relative humidity
Wi-Fi	2.4GHz (IEEE 802.11/b/g/n)
Bluetooth	4.0
USB port	USB A
Software version	v1.0.0
Firmware version	MBMP100
FCC ID	2AKGP-MB100

11. Product Warranty

Product Warranty

Manufacturer guarantees to the original Purchaser of Sampinute™ Analyzer that the Instrument is free from material defects in material and workmanship for a period of one (1) years from the date of the original purchase. This warranty does not guarantee the uninterrupted operation of the Instrument. Manufacturer's only liability and Purchaser's exclusive remedy under this warranty is that during the warranty period Manufacturer shall replace or repair, at no charge, and at the Manufacturer's sole discretion, any and all part of the Instrument proven to be defective. MANUFACTURER MAKES NO OTHER WARRANTIES AND EXPRESSLY EXCLUDES ANY IMPLIED WARRANTY OF MERCHANTABILITY, NONINFRINGEMENT OR FITNESS FOR A PARTICULAR USE. IN NO EVENT SHALL Manufacturer or distributor BE LIABLE FOR ANY INCIDENTAL, INDIRECT, SPECIAL, CONSEQUENTIAL OR EXEMPLARY DAMAGES, INCLUDING, BUT NOT LIMITED TO, DAMAGES FOR LOSS OF USE OR REVENUE, OR PROFITS IN CONNECTION WITH OR ARISING OUT OF MANUFAC-TURER'S PROVISION OF THE INSTRUMENT, OR PURCHASER'S USE OF THE INSTRUMENT.

Tampering with any portion of the Instrument, abusing the Instrument or using the Instrument in a manner inconsistent with its User Manual will void this warranty. This warranty does not apply to any component that is damaged by improper storage in environmental conditions outside the recommended range, accident, or that is subject to alteration, misuse, tampering or abuse. Purchaser must file a warranty claim in writing and within the applicable warranty period to the USA Distributor.

Please contact – Celltrion USA, Inc. Customer Service Center, Sampinute@celltrion.com

Distributor Information

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www.bbbtech.com

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