

CLEO™ COVID-19 Molecular Test



For *in vitro* diagnostic use.
For professional use only.

Instruction for Use

REF CL1101P

Intended Use

The CLEO™ COVID-19 Molecular Test is a molecular *in vitro* diagnostic test for the qualitative detection of nucleic acid from the novel coronavirus SARS-CoV-2 that causes COVID-19. This test is authorized for professional use only with anterior nasal (nasal) swab samples from the suspected of COVID-19.

Principles of the Procedure

The CLEO™ COVID-19 Molecular Test uses fluorescence reverse transcription loop-mediated isothermal amplification (RT-LAMP) technology to conduct in the Open Reading Frame 1ab (ORF1ab) and N (Nucleocapsid) regions of the SARS-CoV-2 genome. The CLEO™ test also identifies nucleic acids from human genes that serve as controls for samples. Isothermal amplification takes place in a disposable CLEO™ Test Cartridge. The gene is amplified by isothermal amplification from the sample in the cartridge, and when the SARS-CoV-2 specific probe is bound to the amplified gene, a fluorescence signal is generated, which is measured by the fluorescence meter in the CLEO™ ONE device. The measured result value is transmitted to the CLEO™ ONE app, and through the app's analysis algorithm, you can check whether you are infected with COVID-19.

Storage & Handling

- Store all components between at 39.2 °F to 77 °F (4 °C to 25 °C).
- Do not open components until you are ready to perform testing.
- Open all packages carefully to avoid losing any small components.
- Do not use sample tube and Test Cartridge that are wet, have leaked or spilled.
- Do not use the Test Cartridge if its pouch is punctured or not completely sealed. The Test Cartridge contains a freeze-dried reagents that is sensitive to moisture.
- Do not use the CLEO™ COVID-19 Test whose components valid date are expired.
- All components other than the CLEO™ ONE device are single-use and should be disposed after the test is completed.
- Follow all instructions carefully as shown in the CLEO™ ONE app.
- Use only the plastic stick of swab with your hands to avoid any contamination on the tip of swab.

Operating Conditions

- The test should be operated between 39.2 °F to 77 °F (4 °C to 25 °C).
- Failure to do so may yield invalid or inaccurate results.
- The test is best used in a room with adequate lighting and away from direct sunlight. Failure to do so may result in an inability to see the results on the test.
- The CLEO™ ONE device must be placed on a flat surface and should not be moved during operation. Failure to do so may yield invalid or inaccurate results.

- If a power failure occurs or the CLEO™ ONE device is unplugged while the Test Tube is in the CLEO™ ONE device, the test result is invalid and the user should be retested following the retest procedure.

Warnings and Precautions



- For *in vitro* diagnostic use only. for professional use only
- Do not use the product for any other purpose.
- This product is approved only for the detection of nucleic acid of SARS-CoV-2, and it is not detected against other viruses or pathogens.
- For the latest information on COVID-19, please visit: <https://www.cdc.gov/coronavirus/2019-ncov/index.html>
- The strength of the test line does not necessarily correlate with the amount of SARS-CoV-2 virus in the sample.
- Samples should be tested immediately after the samples are collected.
- Failure to follow the instruction manual may cause invalidated test performance or results.
- Use only provided test components. Do not use swabs from other tests. Do not reuse the components. Only CLEO™ ONE device can be reused to test other samples.
- A positive result indicates the presence of SARS-CoV-2 RNA.
- Do not swallow.
- Keep out of reach of children.
- Avoid contact with skin and eyes.
- Do not apply the Sample Tube directly to the skin or mucous membranes or ingestion. In case of contact with the body, wash off with water. If irritation persists, go to see a doctor. IF SWALLOWED: Call a poison center/doctor if you feel unwell.
- Any significant incidents related to the device should be notified to the competent authorities and manufacturers.

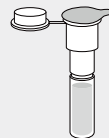
Kit Contents

1. Materials (Provided)

- Test Cartridge 10
- Sample tube 10
- Nasal swab 10
- Instruction for use 1



Test Cartridge



Sample tube



Nasal swab

NOTE : Make sure all the components are present and that the CLEO™ ONE app is compatible to your mobile or tablet device.

2. Required but Not Provided

- CLEO™ ONE device (Model number : CL0001P1, separate purchase is required)
- CLEO™ ONE app (Provided separately)

Test Procedure

Make sure you have all kit components ready for testing and check that items are not damaged.


01 Power on & Login

- Connect the power adaptor to CLEO™ ONE device. The power is on when an **Orange light** appears around the front button of the test device.
- After running the <CLEO™ ONE app> on the tablet, log in by entering your ID and password.

Note: If you do not have an account, please create a user account and log in.



02 Bluetooth connect

- Press the  **'Connect'** button in the menu of the app.
- From slots 1 to 10, press the slot you want to connect.
- If you select one of the list of connectable devices displayed in the pop-up window, the device is automatically connected.
- When the device and tablet are properly connected, the color of the corresponding slot changes from **orange** to **blue**, and at the same time, the color of the button on the front of the device changes from **orange** to **blue**.

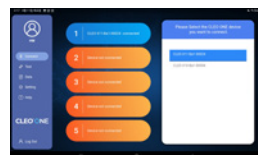
CAUTION:



The tablet must be placed within 1 meter (or 3.5ft)-distance to the device in order to establish the connection through Bluetooth.




Screen after login



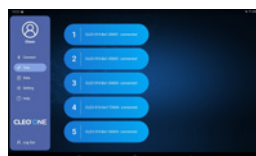
Orange is ready for connect
Blue is the connected slot

03 Input test information

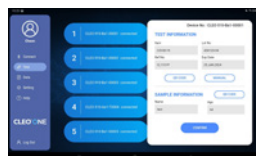
- Select  **Test** item in the left menu of the app.
- Select the desired device slot from the testable device list.
- If the test information input window appears, scan the QR code printed on the kit package with the tablet camera and enter the test information.
- If the test information is entered, check if it matches the contents of the kit.
- Enter sample information.

NOTE: If you use an expired cartridge, the test will not proceed.

NOTE: If the kit's QR code is damaged and it is impossible to enter the QR code, you can enter the test information directly by selecting the manual.



Testable list

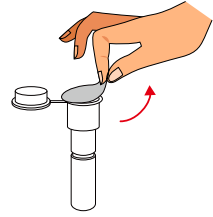


Test information input window

04 Prepare Sample tube & Swab

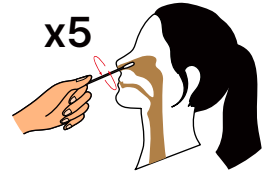
- Open the sample tube by peeling off its foil seal. Do NOT spill or touch the liquid.
- Open the nasal swab packaging from the stick end and take out the swab. Do NOT touch the swab tip.

NOTE: The swab is sterile. Do NOT use the swab if it touches anything or is damaged.



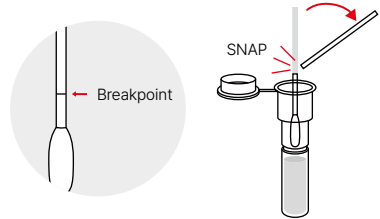
05 Collect nasal sample

- Insert the soft end of the swab into nostril. Slowly rotate the swab, gently rubbing it along the inner side of nasal passage at least 5 times.
- Repeat the same procedure in the other nostril.



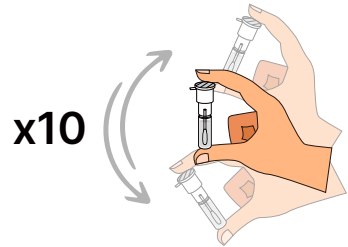
06 Insert into Sample tube

- Insert the swab into the sample tube.
- Find the breakpoint and snap off the swab.
- Close the tube cap securely.



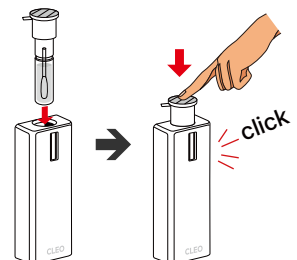
07 Shake the sample tube

- Shake the sample tube at least 10 times



08 Combine Sample tube & Test Cartridge

- Open the test cartridge pouch and take out the cartridge.
- Insert the pre-processed sample tube into the inlet of the test cartridge and press the top of the tube until it's 'click'.
- Check the transparent side of the cartridge to see if the solution in the sample tube moves into the chamber and dissolves the test reagent well.



09 Wait for 1 minute

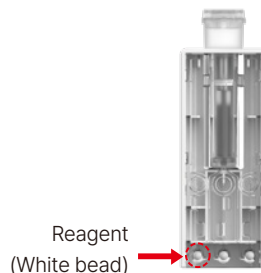
- After combining the sample tube and cartridge, leave it for 1 minute to check if the reagent dissolves well.

TIP: If the sample does not move to the reagent within 30 seconds, please tap the cartridge lightly on the floor 2-3 times to move the sample.

NOTE: Do not leave the combined cartridge unattended for more than 5 minutes.

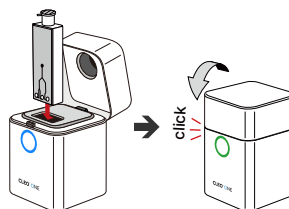


CAUTION: If the reagent does not dissolve properly, the experiment fails.



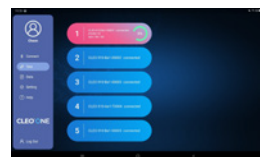
10 Insert the test cartridge into the CLEO™ ONE

- Open the lid of the device, insert the test cartridge into the cartridge slot.
- When the light turns **green**, please close the lid.
- When the lid is properly closed, the test will start automatically and the **green** circular button on the instrument will **blink**. It means the test starts properly.
- In the app, the corresponding slot turns **pink** and shows the test progress.
- The test takes 30 minutes.



CAUTION: Do not turn off the device and tablet while the test is in progress, and keep the tablet close to the device at all times to avoid losing the Bluetooth connection.

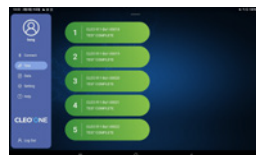
CAUTION: If the green light does not blink on the circular button, the test has not started. Open the lid of the device, check the cartridge and sample tube if they are well combined. Then, close the lid completely and check if the green light blinks. If the green light does not blink again, please contact our customer center.



Test progress on the screen.

11 Test Complete

- When the test is completed, the color of the corresponding slot changes to **green** and a message indicating test completion is displayed.
- Press the front button of the device to open the lid and take out the cartridge and tube
- When the cartridge is taken out of the device, the button color turns **blue**.



Test completed (Green)

12 Read Results

- To check the test results, select **Data** from the left menu and check the test results.
- Click the test result to see more detailed test results.

POSITIVE

- COVID-19 (SARS-CoV-2) virus RNA was detected in the sample. This means that you may currently be infected with COVID-19.

NEGATIVE

- This means that the COVID-19 virus was not detected in the sample.
- However, if the amount of COVID-19 virus RNA in the sample is below the test limit, it may be negative, so infection with COVID-19 cannot be completely ruled out.

INVALID

- The test result is not valid, and the diagnosis of COVID-19 has not been made properly.
- Cause: Insufficient sample collection test procedure error Bluetooth disconnection or unstable connection between device and smartphone.

<What to do>

- Perform a retest using a new kit
- Reread the quick guide and user manual carefully before retesting.



Test Result List



Detailed view of test result

13 Finishing Up

- When the test is completed, unplug the CLEO™ ONE device from the power source.
- Take out the test cartridge from the CLEO™ ONE device. Do NOT take out the sample tube from the test cartridge. The tube must stay inside the test cartridge.
- Place the Test Cartridge containing the sample tube and swab into the provided disposable bag.
- Dispose of the bag as general waste.

Symbol Glossary



CE marking



Catalogue number



in-vitro diagnostic use only



Batch code



Instructions for use



Manufacturer



Use-by date



Authorized EC Representative
in the European Community



Do not re-use



Caution



Temperature limitation



Keep away from sunlight



Do not use if package is
damaged



UDI(Unique Device
Identification)



Contents sufficient for
<n> tests



Technical Support



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