

CLEO™ Typhi / Paratyphi Molecular Test

Instruction for Use

REF CL1107

RUO

Intended Use

The CLEO™ Typhi / Paratyphi Molecular Test kit is a molecular test for the qualitative detection of nucleic acid from the *Salmonella Typhi* (typhoid) and *Salmonella Paratyphi* (paratyphoid). This kit is research use only.

Principles of the Procedure

The CLEO™ Typhi / Paratyphi Molecular Test kit uses fluorescence-probe based loop-mediated isothermal amplification (Probe-LAMP) technology to detect *Salmonella Typhi* and *Salmonella Paratyphi* genome. Isothermal amplification takes place in a disposable CLEO™ Test Cartridge. Isothermal amplification is performed in a disposable CLEO™ test cartridge. Genes are amplified through isothermal amplification from the sample in the cartridge, and when the target-specific probe binds to the amplified gene, a fluorescent signal is generated, which is measured by the fluorometer in the CLEO™ ONE instrument. Test results are immediately available through automated analysis in the CLEO™ ONE app.

Storage & Handling

- Store all components between 4 - 25 °C (39.2 - 77 °F).
- 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 tubes and test cartridges that are wet, have leaked, or have spilled.
- Do not use the test cartridge if its pouch is punctured or not completely sealed. The test cartridge contains freeze-dried reagents that are sensitive to moisture.
- Do not use the test kit whose valid dates have expired.
- All components other than the CLEO™ ONE device are single-use and should be disposed of after the test is completed.
- Follow all instructions in the manual.

Operating Conditions

- The test should be operated at 4 to 25°C (39.2 to 77°F), otherwise results may be inaccurate or inaccurate.
- 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

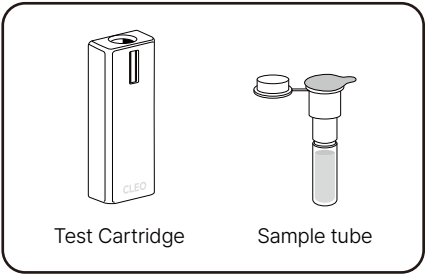


- For research use only. Do not for diagnostic use.
- Do not use the product for any other purpose.
- Test the sample as soon as possible after preparation.
- Failure to follow the instructions for use may result in invalidation of test performance or results.
- Use only the test components provided. Do not mix with components from other tests.
- The kit is for single use only. Do not reuse used kits.
- Do not swallow the contents of the kit.
- Keep out of reach of children.
- Do not get the solution in the sample tube on your skin or eyes or swallow it. If contact occurs, rinse with water. If irritation persists, seek medical attention. If swallowed: Contact a poison control center/doctor if you feel unwell.
- Report any serious incident involving the device to the relevant authorities and the manufacturer.

Kit Contents

1. Materials (Provided)

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



2. Required but Not Provided

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

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

Test Procedure

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

1. 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.

2. 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: To connect via Bluetooth, your tablet and device must be within 5 meters.



Main menu



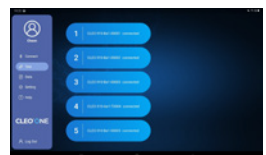
Orange is ready for connect
Blue is the connected slot

3. Input test information

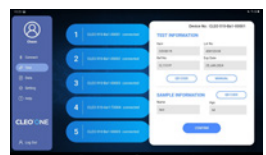
- Select <Test> item in the left menu of the app.
- Select the desired device slot from the testable device list.
- If the test information input window appears, scan the QR code printed on the kit package with the tablet camera and enter the test information.
- If the test information is entered, check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

4. Prepare the sample

- Place the swab sample you want to test in the LB medium, write the sample name, and culture at 37 °C for 4-6 hours with shaking (180-250 rpm).
- Using a pipette, place 100ul of cultured sample into the sample tube and heat it at 100 degrees for 5 minutes using a heating block.
- Carefully remove the sample tube from the heating block and let it cool at room temperature for 5 to 10 minutes.

CAUTION: When removing the sample tube from the heating block, be careful not to get burned as the bottom of the tube is very hot.



Heating the sample (100°C /5 min.) & Cooling for 5 min/RT

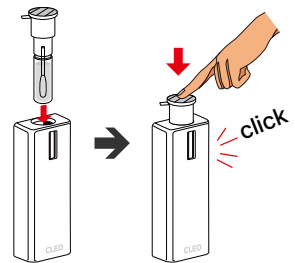
5. Prepare test cartridge

- After opening the test cartridge, insert the prepared sample tube into the tube insertion port and firmly press the top of the tube until you hear a 'click' sound to attach it.

CAUTION: If the sample tube is not properly attached, you will not hear a 'click' sound. Please press it firmly until you hear a sound.

- Place the cartridge on a flat table and wait for about 30 seconds. At this time, check the transparent part on the back of the cartridge to see if the solution in the sample tube moves into the cartridge and the test reagent (white bead) is dissolved well.

CAUTION: If the solution does not move into the cartridge, gently tap the bottom of the cartridge 2-3 times to help the solution move.

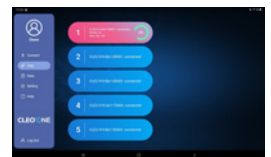
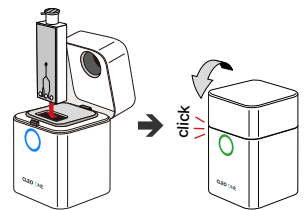


6. Run test

- Insert the test cartridge into the CLEO™ ONE device. After confirming that the LED on the front turns green, close the device lid until you hear a 'click' sound.
- If the lid is closed properly, the test will start automatically and the green LED on the front of the device will blink.
- The test takes 30 minutes.

CAUTION: If the device LED does not blink green, the test has not started, so take out the test cartridge and reinsert it.

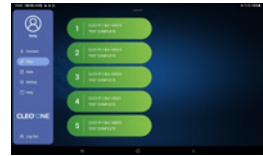
CAUTION: Do not turn off the device and tablet while the test is in progress, and keep the tablet close to the device at all times to avoid losing the Bluetooth connection.



Test progress on the screen.

7. 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)

8. 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.

S.Typhi	S. Paratyphi	IC	Results
+	+	+	<i>S. Typhi</i> detected
+	-	+	<i>S. Paratyphi</i> detected
-	+	+	<i>S. Typhi</i> & <i>S. Paratyphi</i> detected
-	-	+	Negative
-	-	-	Invalid / Retest

INVALID

- The test result is invalid, and the test has not been made properly.
- Cause: Insufficient sample collection test procedure error, Bluetooth disconnection, or unstable connection between the device and the app.
















<What to do>

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

9. 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

Symbol	Meaning	Symbol	Meaning
	Rsearch use only		Catalog number.
	Caution		Use-by date
	Instructions for use		Do not re-use
	Manufacturer		Contents sufficient for <n> tests
	Consult instruction for use		Batch code
	Keep dry		Temperature limit
	UDI(Unique Device Identification)		Do not use if package is damaged
	Keep away from sunlight		



Wizbiosolutions Inc.

#1103, 1405, 1406, A-dong, 14, Sagimakgol-ro 45beon-gil,
Jungwon-gu, Seongnam-si, Gyeonggi-do, Republic of Korea
B237~B242, 14, Galmachi-ro 288beon-gil, Jungwon-gu,
Seongnam-si, Gyeonggi-do, Republic of Korea

Tel : (82) 70-7603-5066

Fax: (82) 31-624-3066

e-mail: support@wizbiosolution.com

www.wizbiosolution.com



This User manual may be used only for its intended purpose. It may not be reproduced in whole or in part or be translated into another language without our express, prior written consent.

© 2024 Wizbiosolutions Inc. All rights reserved. CLEO is trademark of Wizbiosolutions Inc.