1copy™ COVID-19 MDx Kit Professional Quick Start Guide

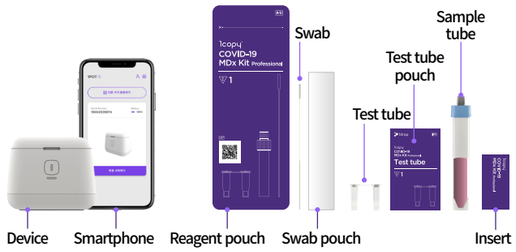
1drop

DR-M26-6048-E-00-07 Rev.07 Date 2021.07.09

1. Preparations

01 Wash hands thoroughly before you run a test.
When using this product, wear appropriate protective clothing, safety glasses and disposable gloves.

02 Before you begin a test, check all the components and place them on a flat, stable surface.



⚠ Caution
Make sure your smartphone battery is **at least 20%**.

03 Check the expiry date on the back of the reagent pouch.
Do not use products past their expiry dates.

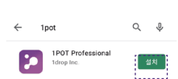
2. App Set up and Device Connection

04 Turn on your smartphone and go to the Apple App Store or Google Play Store.

GET IT ON Google Play Download on the App Store

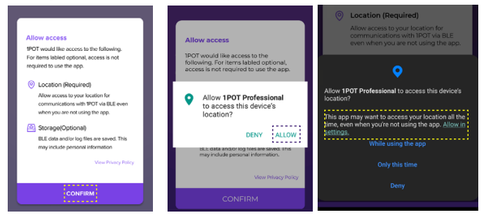
Download link

05 Type '1pot' and search for 1POT Professional app.



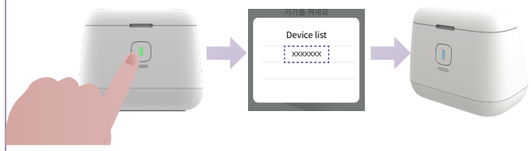
06 Install app.
Once fully installed, start the app.

07 When prompted to allow access to location of your device, tap either "Allow"(middle image) or "Allow access in settings" followed by "Always allow access"(last image).



⚠ Warning
Pop-up messages may vary depending on the smartphone specifications. Carefully read the pop-up messages displayed on your screen. Keep in mind that you may not be able to use the app if you do not select "Confirm", "Allow" or "Always allow".

08 When prompted to connect a new device, scan the QR code on the bottom of the device. Once you scan the QR code, you will be then prompted to turn on the device. Briefly press the button on the device to turn it on. When connected, the button on the device will display a blue light.



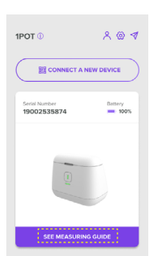
09 Once connected, tap "Allow" to allow access to photos, media and files on your device.

10 The serial number and the battery status of your device will be displayed on your screen. You are now ready to run a test.

⚠ Caution
The device will turn off automatically after it has been inactive for 5 minutes.

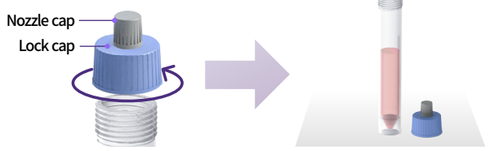
3. Sample Collection

11 Tap "See measuring guide" on the app to view instructions for collecting sample.

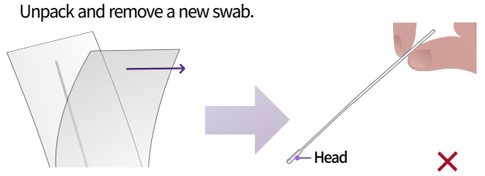


12 Unpack and remove the test tube. Tap the bottom of the test tube 3 times against a surface to make sure the freeze-dried reagents in the shape of white cotton are settled on the bottom.

13 Make sure that there is red solution in the sample tube and place it on a flat surface with the lock cap open.

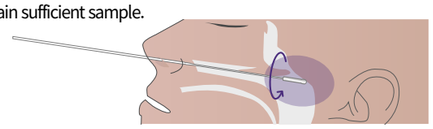


14 Unpack and remove a new swab.



⚠ Caution
Make sure the head of the swab does not touch your hand.

15 Insert the swab into a patient's nostril, parallel to the roof of his/her mouth and rotate more than 3 times in the inferior nasal turbinate to obtain sufficient sample.

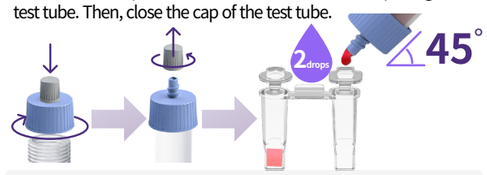


16 Submerge the tip of the swab into the sample tube and mix 15 times.
Then, dispose of the swab in the original reagent pouch.

15times

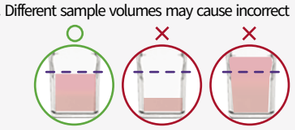
⚠ Caution
Do not swallow the solution or let them come into contact with your eye.

17 Close the lock cap of the sample tube, and open the nozzle cap. Tilt the sample tube to 45 degrees, and gently squeeze the sample tube to let 2 drops of solution each fall into the 2 openings of the test tube. Then, close the cap of the test tube.



⚠ Warning When transferring the sample solution, make sure it does not touch the walls of the test tube.

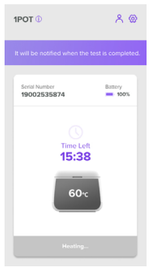
⚠ Warning Required sample volume for a test is 50μℓ. Make sure the solution fills up the bottom rectangular part of the test tube. Different sample volumes may cause incorrect results.



4. Testing

18 With the device turned on and smartphone connected, open the cover of the device and insert test tube.

19 Tap "Start Testing" on the app to start a test. Test process and remaining time will be displayed on screen.



Note
Test will run in the background.
You may use other apps. Testing will continue even if the device is disconnected from your smartphone.

⚠ Caution
Test may stop if the cover opens or the device tilts while running a test.

20 App screen will change 5 minutes before testing is completed.
You will be notified 5 minutes before test is completed, and a beep will sound from the device every minute.

21 Once testing is completed, take out the test tube and check the color of the reagent.

Positive **Negative**

5. Results interpretation

After testing is completed, leave the test tube at room temperature for about 3 to 5 minutes and examine the colors. The test tube has 2 types of reagents: test and control.

Test	Control	Result
●	●	Negative
●	●	Positive
●	●	Invalid
●	●	Invalid

6. Disposal

After you finish a test, seal and dispose of all the used components in the provided pouch.

⚠ Caution
- Do not open a test tube that has been used.
- If test result is positive, do not dispose of anything as regular waste. You must put everything in the provided pouch, seal and dispose as biomedical waste.

1copy™ COVID-19 MDx Kit Professional

CE IVD

1drop

Carefully read instructions below before you run a test.

REF M26590

Intended Use

The 1copy™ COVID-19 MDx Kit Professional is an *In vitro* diagnostic medical device intended to diagnose COVID-19 infection by detecting S gene and N gene of SARS-CoV-2 via loop-mediated isothermal amplification (LAMP) in upper respiratory specimens, nasopharyngeal swabs, collected from patients suspected of COVID-19.

Principle of the Assay

LAMP is a new and highly efficient amplification technique that utilizes Bst polymerase with strand displacement activity to anneal and extend genetic materials at a consistent temperature. Unlike the Taq polymerase used in conventional PCR, Bst polymerase has the 5' →3' Exonuclease activity and therefore can anneal and extend genetic material at a temperature near Tm value without changing the double helix structure of DNA via heating. Amplification starts with 4 to 6 primers in which the inner primer first binds and extends DNA followed by the binding of the outer primer, causing DNA strand displacement. The displaced single strand then serves as a template for DNA synthesis primed by more primers, which forms a loop starting at the 5' end, followed by an additional loop formation at the 3' end. LAMP method utilizes a DNA polymerase and a set of four specific primers that recognize a total of 6 distinct target sequences of DNA, which is comparably more specific than conventional PCR that only recognizes 2 specific target sequences. It not only decreases testing time by amplifying DNA in isothermal conditions but can also reduce several steps of conventional PCR such as the gel electrophoresis by using color dyes to confirm results with the naked eye. Because of such characteristics, it has been introduced in numerous papers as a field-friendly method that maintains the high sensitivity and specificity of molecular diagnostics without the need for high-cost equipment and can produce results rapidly.

Kit Contents (Materials Provided)

Product	Kit Contents	Quantity
1copy™ COVID-19 MDx Kit Professional	Sample Tube	1ea
	Test Tube	1ea
	Control Tube	1ea
	Swab	1ea

Materials Required but Not Provided

1. 1POT Professional (Product License No. IVD-21-290, Model name: MI01)
2. Mobile Application (1POT Professional, 1POT Professional for i)

Warnings and Precautions

1. The 1copy™ COVID-19 MDx Kit Professional is intended for *in vitro* diagnostic use only.
2. The 1copy™ COVID-19 MDx Kit Professional is intended for professional use by qualified and trained laboratory personnel specifically trained in handling clinical specimens and conducting molecular biological experiments.
3. Use the product according to the provided instructions. Operator must carefully read the manual prior to use.
4. Do not use expired components.
5. Do not use products that have been opened or with damaged packaging.
6. Do not mix reagents from different lots of 1copy™ COVID-19 MDx Kit Professional.
7. This product is used only for equipment manufactured by 1drop Inc., 1POT Professional.
8. Always wear laboratory gloves, lab coats, and protective goggles to protect against reagents or samples in use when handling the product.
9. Discard unused reagents, waste, standard and control according to local laboratory safety rules and guidelines.
10. Rinse immediately with water if reagent comes in to contact with the eyes.
11. Even if the test result is 'Positive', it should be interpreted by an experienced specialist by comprehensively reviewing various results such as the patient's symptoms.
12. Even if the test result is 'Negative', it should be interpreted by an experienced specialist by comprehensively reviewing various results such as the patient's symptoms, without excluding infection.
13. The usage of the specimen collection tool should follow the warnings and precautions below.
    ① Do not use the product that has been opened or with damaged packaging.
    ② This product is intended for single use only. Do not reuse to avoid risk of infection.
    ③ Use immediately after opening.
    ④ Check for damages before use. Do not use if there is any damage.
    ⑤ Be careful not to apply excessive force such as pressing strongly, when collecting specimen.
    ⑥ This product must be stored at room temperature away from direct sunlight.

Storage and Handling

1. The 1copy™ COVID-19 MDx Kit Professional is stable for 12 months at 1 ~ 30°C and should be stored away from direct sunlight.
2. Check the expiry date on the packaging before use.
3. This product is for single use only. Do not reuse.
4. Tool for specimens shall be stored and handled according to the details of their own license.

Procedure

Specimen collection and preparation

1. Use nasopharyngeal swab from human as a specimen.
2. Follow the local regulations of collection, storage, transport, and preparation of specimens.

Procedure

1. Preparation of the 1POT Professional
   ① Turn on the device by pressing the power button.
   ② Prepare the smartphone that has installed the 1POT Professional mobile application.
   ③ Run the mobile application and connect the device to the smartphone via Bluetooth.
   To connect the device, press and hold the power button of the device.
   When the Bluetooth connection is completed, a guide for preparing to run the device is displayed on the screen of a smartphone.
   ④ Open the cover of the device and prepare for specimen collection.
2. Test procedure
   ① Insert the swab soaked with the collected specimen in the sample tube and mix by rotating it more than 15 times. After mixing, the swab is placed in the pouch and discarded.
   ② Add the sufficiently mixed sample in the sample tube into the test tube and the control tube up to the marked portion (approximately 50μL), respectively.
   ③ Insert the test tube and control tube into each tube mounting section of the device and close the cover. When the cover of the device is closed, the test starts, according to the preset test conditions. Test conditions are 60°C, and 30 minutes.
   ④ While the device is running, the mobile application displays the remaining time out of the total set time.
   ⑤ When the set time is over, the mobile application switches to the test completion screen. Press the OK button to turn off the device.
   ⑥ When the test is completed, take out the test tube and control tube from the device and visually compare the color to judge the result.

Results Interpretation

When the isothermal amplification is complete, remove the tube from the 1POT Professional and visually compare the colors to determine the result. According to the criteria below, it is read as 'Positive', if the reaction result is yellow and 'Negative', if it is red.

	Color	Color Chart	Color code (HEX)
Positive	Yellow		#FFB500
Negative	Red		#AB2328

Interpretation criteria of positive, negative, and invalid

Example	Result Interpretation
 Positive  Negative	- Interpret the result as 'Positive' or 'Negative' by comparing the change in reagent color based on that presented in the color chart above. Note that turbidity can sometimes vary depending on the properties of the specimen. - If the color develops in completely different, retest should be performed.

Result		Interpretation of results
SARS-CoV-2	IC	
		COVID-19 Positive SARS-CoV-2 is detected
		COVID-19 Negative SARS-CoV-2 is not detected
		Invalid result Retest is recommended

Reference

1. Centers for Disease Control and Prevention. https://www.cdc.gov/coronavirus/2019ncov/index.html. Accessed February 9, 2020.
2. Centers for Disease Control and Prevention. Biosafety in Microbiological and Biomedical laboratories (refer to latest edition). http://www.cdc.gov/biosafety/publications/
3. Clinical and Laboratory Standards Institute. Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline. Document M29 (refer to latest edition).
4. Clinical and Laboratory Standards Institute. Collection, Transport, Preparation, and Storage of Specimens for Molecular Methods; Approved Guideline. CLSI Document MM13-A. Wayne, PA: Clinical and Laboratory Standards Institute; 2005.
5. World Health Organization. Laboratory Biosafety Manual. 3rd ed. Geneva, Switzerland: World Health Organization; 2004.

Glossary of Symbols

REF	Catalog Number	Σ	Contains sufficient for tests
CE	This product fulfills the requirement for directive on *in vitro* diagnostic medical devices (Conformite Europeenne)		Use By Date
			Manufacturer
			Consult instructions for use
IVD	*In-Vitro*-Diagnostic Medical Device		Temperature limitation
EC REP	Authorized representative in the European community		Caution
LOT	Batch Code		Keep away from sunlight

EC REP
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