



1DROP SARS-CoV-2 antigen test V.2

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¹1DROP

Version 2

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Works for me

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ABSTRACT

Our capillary-driven microfluidic chips automatically detect multiple SARS-CoV-2 antigens after the addition of a few drops of saliva, triggering a cascade of events powered by capillary forces. We integrate biochemical reagents directly on the microfluidic chips, avoiding the need for peripheral equipment for fluid control. Thus, detection of SARS-CoV-2 can be done at the patient's side by simply adding sample to the chips, with minimal hands-on time, faster results, and increased sensitivity of fluorescence assays. The use of saliva as a sample matrix avoids painful sample-collection procedures and the need for trained medical staff.

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GUIDELINES

For in vitro diagnostic use

For use with the 1DROP Analyzer

This test is designed only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens.

Store kit at 2-30°C.

Do not reuse any 1DROP SARS-CoV-2 antigen test components.

Freshly collected specimens should be processed as soon as possible, but no later than one hour after

specimen collection.

MATERIALS TEXT

Consumables in 1DROP SARS-CoV-2 antigen test kit
1DROP SARS-CoV-2 antigen test Chip
Collection Tube, 50 mL
Reagent Tube, 2 mL, containing Buffer
Calibrated disposable Pipette
Equipment
1DROP Analyzer
Watch or timer

List of Material required for 1DROP SARS-CoV-2 antigen test protocol

SAFETY WARNINGS


The 1DROP SARS-CoV-2 antigen test kit is stable until the expiration date marked on the outer packaging and container.

BEFORE STARTING

All components must be at room temperature before use.

Refrain from consuming food or beverage (including water) for 30 minutes before providing a saliva sample.

Sample collection

- 1 Collect patient saliva in the Collection Tube. Saliva must be collected until the amount reaches above the  1 mL line.

Device preparation

1m

- 2 Switch on the 1DROP Analyzer with the side switch.
- 3 Scan the Chip on the scanner of the 1DROP Analyzer.
- 4 Follow instructions on the screen to enter patient ID.

Sample preparation


1m

5



Use the Pipette to transfer  500 µl of saliva to the Reagent Tube containing the Buffer.

To transfer the patient sample:

1. Firmly squeeze the top bulb of the Pipette.
2. Still squeezing, place the Pipette tip into the saliva sample.
3. With the Pipette tip still in the sample, release pressure on the bulb to fill the Pipette up to  500 µl
4. Place the Pipette in the Reaction Tube containing the Buffer.

5. Firmly squeeze the bulb to empty the contents of the Pipette in the Reaction Tube.

6 

Pipette up and down the reagent mix in the Reagent Tube 5 times.

Test Procedure 16m


7 

Just prior to loading the sample, pipet up and down two more times the prepared sample in the Reagent Tube.

8 

Fill the Pipette and transfer **4 drops** to the loading pad of the Chip.

1. Apply light pressure to the Pipette bulb, to dispense the liquid drop by drop and stop pressing after the fourth drop is out.

9 Once the sample have been loaded, start a timer for  **00:15:00** .

10 

After 15 minutes, insert the Chip in the 1DROP Analyzer slit and press "Start" on the screen.
The result will be displayed on the 1DROP Analyzer screen.

Display	Interpretation
CoV2 Positive	Positive Test for SARS-CoV-2 (antigen detected).
CoV2 Negative	Presumptive Negative Test for SARS-CoV-2 (no antigen detected).
Invalid Test	Test is invalid.*

1DROP Analyzer result display

* Repeat the test with another Chip  **go to step #6** (same sample mix can be reused).

11 Once the results have been read, remove the Chip from the 1DROP Analyzer and switch off the Analyzer.

12 Once done, discard the Chip, the Pipette, the Collection Tube, and the Reagent Tube as biohazard waste.