

# COVID-19 (SARS-CoV-2) Antigen Test Kit

## Instruction for Use

- Self-test used on-site or at home
- Please read the instruction for use before use.

### [Product name]

COVID-19 (SARS-CoV-2) Antigen Test Kit

### [Specification]

1 Test/Kit

### [Intended use]

This kit is intended for in vitro qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in nasal swabs from individuals suspected of COVID-19. The kit is intended for layperson use and for people age 7 years or above, children 7–14 years of age should be tested by an adult (over 18 years old). People over 65 years of age should seek help with the test.

COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifestations include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases.

### [Kit components]

- 1 Antigen test cassette
- 1 Antigen extract R1
- 1 Sample swab
- 1 Antigen extraction tube (with dropper head)
- 1 Instruction for use
- 1 Biohazard waste bag

### [Test principle]

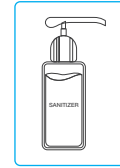
This kit employs immunochromatography for detection. The specimen will move forward along the test cassette under capillary action. If the SARS-CoV-2 viral antigen is present, it will be bounded to the colloidal gold-labeled SARS-CoV-2 specific antibodies. The immune complex will be captured by coronavirus monoclonal antibody fixed in the T (Test) line. If the specimen is SARS-CoV-2 positive, both the T (Test) line and C (Control) line will become visible. If the specimen is SARS-CoV-2 negative, the C (Control) line will become visible but the T (Test) line will be invisible. The C line must be visible if the test has been performed correctly.

### [Storage & stability]

1. Store at 2°C–30°C, and it is valid for 12 months. DO NOT FREEZE.
2. After the aluminum foil bag is unsealed, the test cassette should be used as soon as possible.

### [Preparatory steps]

1. Disinfect the surface where you will open the test kit. Remove and lay out contents of the test kit on a clean, flat surface.
2. Please blow your nose and clear the nostril before taking the test.
3. Wash hands with soap and water. If soap and water are not available, use hand sanitizer. Dry your hand completely before taking the test.
4. You need to prepare a timer or any device with timer function.

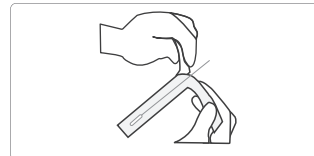


### [Test methods]

1. Press along the dotted line of the tube stand. Place the extraction tube on the tube stand. Twist the tip to open the Antigen extract R1 container, place the Antigen extract R1 container downward to allow the solution to drip into the extraction tube without touching the edges of extraction tube. Add the **entire contents** to the extraction tube by squeezing the R1 container.



2. Collect the sample:



A. Remove the swab from the package. **Do not touch the soft end (swab head)** with your hands or anything else.



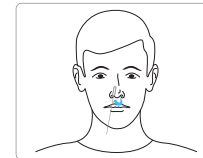
B. Insert the entire soft end of the swab into your nostril (about **1.5–2.0 cm**).



C. Slowly rotate the swab, gently press against the inside of your nostril at least **5** times for a total of **15** seconds. Get as much nasal secretion as possible on the soft end of the swab.

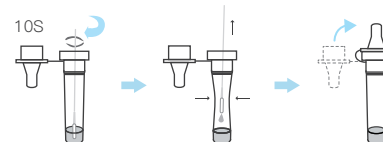


D. Gently remove the swab.

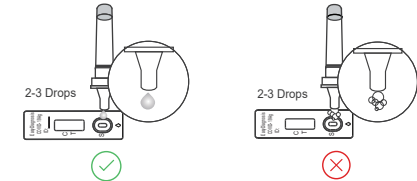


E. Using the same swab, repeat steps **B–D** in your other nostril with the same end of the swab.

3. Put the swab specimen into the extraction tube, rotate the swab in the liquid for about **10** seconds, and press the swab head against the tube wall to release the specimen in the swab.



4. Squeeze the swab over the head while taking the swab out of the extraction tube to remove as much liquid as possible from the swab. **Put the swab after use into the biohazard waste bag.**
5. Install the dropper head on the extraction tube, unseal the package and take out the antigen test cassette.
6. Add **2–3** drops into the specimen well of the test cassette, and start the timer. The drops should be liquid not foams/bubbles. If the drop is foam/bubbles, add another drop.



7. Read the result in 15 minutes. Strong positive results can be reported within 15 minutes, however, negative results must be reported after 15 minutes, and the results after 25 minutes are no longer valid.

8. The antigen test cassette, antigen extract R1, antigen extraction tube (with dropper head) and sample swab after use should be placed in the biohazard waste bag and disposed of with household waste.

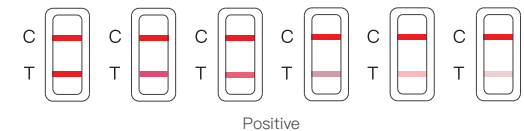


9. Wash hands or re-apply hand sanitizer after taking the test.

### [Interpretation of test results and instructions for actions]

- **Positive result:** if both the C line and the T line appear (as shown in the figure below), novel coronavirus antigen has been detected and the result is positive. **Look very closely! The T line can be very faint. Any pink/purple line visible here indicates a positive result.**

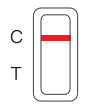
Here are some examples of the colors of T line.



Positive

A positive test result suggests there is currently a suspicion of COVID-19 infection, if your test result is positive, you should immediately contact a doctor/family doctor or the local health authority and ask for their professional opinions, you should comply with local self-isolation guidelines and have a COVID-19 nucleic acid PCR confirmatory test carried out to confirm the infection.

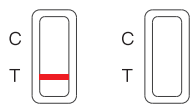
- **Negative result:** if there is only a C line (as shown in the figure below), the T line is colorless, indicating that novel coronavirus antigen has not been detected and the result is negative.



Negative

A negative test result does not rule out possibility of infection, an infection may be present even if your test result is negative. You should continue to comply with all applicable rules regarding contact with others and protective measures. In case of suspicion, please repeat the test after 1 – 2 days, as the novel coronavirus may not be detected accurately in all phases of an infection.

• **Invalid result:** if the C line is not observed, it will be invalid regardless of whether there is T line (as shown in the figure below), and the test should be repeated.



Invalid

An invalid test result is possibly caused by faulty test execution, please repeat the test; If test result is still invalid, contact a doctor or COVID-19 test center for their professional opinions and immediately contact the manufacturer or local supplier.

#### [Benefits and Limitations]

##### Benefits:

1. This test kit can be transported and stored at room temperature and is valid for 12 months.
2. This test kit is user-friendly, does not require professional testing equipment and can be used by non-professionals on-site or at home. The results can be observed with the naked eye in only 15 minutes.
3. The test result from this test can help your healthcare provider make informed recommendations for your treatment / care and help limit the spread of COVID-19 to your family and others around you.

##### Limitation:

1. This test kit is used for in vitro diagnosis only.
2. This test kit is only used to detect human anterior nasal swab extracts. The results of other specimens may be inaccurate.
3. This test kit is only used for qualitative detection and cannot indicate the level of novel coronavirus antigen in the specimen.
4. This test kit is only a clinical auxiliary diagnostic tool. If the result is positive, it is recommended to use other methods for further examination in time and the doctor's diagnosis shall prevail.

#### [Clinical performance]

Contrast Results Statistics of Clinically Confirmed/Excluded Results (202 anterior nasal swabs)

Evaluation Reagent	Clinical Confirmed/Excluded Results (RT-PCR CT≤32)		Total
	Confirmed	Excluded	
Positive	98	0	98
Negative	4	100	104
Total	102	100	202

##### Result calculation:

- (1) Clinical sensitivity: 96.1%, 95% confidence interval: [90.4%, 98.5%].
- (2) Clinical specificity: 100.0%, 95% confidence interval: [96.0%, 100.0%].
- (3) Clinical accuracy: 98.0%, 95% confidence interval: [95.0%, 99.2%].

#### [Precautions]

1. The antigen test cassette, antigen extract R1, antigen extraction tube (with dropper head) and sample swab after use should be placed in the biohazard waste bag and disposed of with household waste.
2. Read the instructions carefully before using the kit, and strictly control the reaction time. If you do not follow the instructions, you may get inaccurate results.
3. Protect from moisture, do not open the aluminum foil bag before it is ready for testing. Do not use when the aluminum foil bag is damaged or the test cassette is damp.
4. Please use it within the validity period.
5. Wait all reagents and specimens back to room temperature (15 ~ 30 °C) before use.
6. The product contains animal sourced antibodies and the antigen extract R1 contains casein. Do not touch the test strip in the middle of the test cassette and try to avoid touching the liquid of the antigen extract R1.
7. Do not replace the components in this kit with components in other kits.
8. Do not dilute the specimen for testing, otherwise you may get inaccurate results.
9. The kit shall be stored in strict accordance with the conditions specified in this Instruction for Use. Please do not store the kit under freezing conditions.
10. The test methods and results must be interpreted in strict accordance with this Instruction for Use.

#### [Index of Symbols]

	Temperature Limit		Use-by date
	Batch/Lot code		In vitro diagnostic medical device
	Manufacturer		Catalogue number
	Contains sufficient for <N> tests		Consult instructions for use
	Do not re-use		CE Certification
	Date of manufacture		CE Certification
	Do not use if package is damaged		Sterilized using irradiation
	Authorized representative in the European Community		Biological hazard

#### [Date of Instruction for use compilation/approval]

V1.0 05.19.2021

V1.1 07.13.2021

#### [INFORMATION INQUIRIES AND GENERAL INFORMATION]



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#### [SWAB INFORMATION]



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