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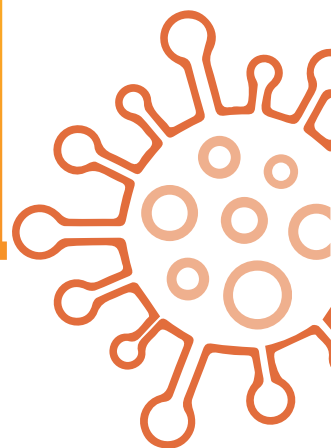
CE

COVID-19 Antigen Test Kit (Colloidal Method)

One Step Coronavirus Antigen Rapid Test Cassette
(Saliva Swab)



- Precise Rapid Sensitive
- For Massive Scale Testing
- For Early Detection



Hangzhou Singclean Medical Products Co.,Ltd.

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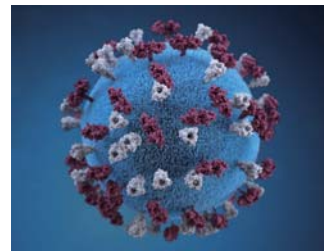
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▶ Introduction

Singclean COVID-19 Antigen Test kit (Saliva Swab) is a solid phase immunochromatographic assay for the rapid, qualitative detection of antigen to 2019 Novel Coronavirus in human saliva. This test provides only a preliminary test result. Therefore, any reactive specimen with the COVID-19 Antigen Test kit (Colloidal Gold) must be confirmed with alternative testing method (s) and clinical findings.

▶ Main Symptoms of COVID-19

- Fever
- Fatigue
- Cough
- Shortness of Breath



▶ Features

- Quick: Results ready in 15 minutes, help with the global shortage of swabs and PPE
- Accurate: With a high level of accuracy that's comparable to nasopharyngeal swab testing
- Non-invasive: More comfortable than COVID-19 nasopharyngeal swab
- Safe: Will not require health care workers to be put at risk. Sampling can be done by patients
- Affordable: No need for instrument

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► Comparison Among Different Testing Methods for COVID-19

Singclean®	PCR Nucleic Acid Test	Singclean Antibody Test	Singclean Antigen Test
Clinical Value	Diagnosis, gold standard	Auxiliary diagnosis	Diagnosis and screening
When to take the test	Early stage of infection	Late or recurrent stage of infection	Early stage of infection
Result time	6 hours	15 minutes	15 minutes
Facility requirement	PCR Laboratory, complex	No special facilities needed	No special facilities needed
Cost	High	Low	Low
Sample requirement	Saliva, nasal, oral or anal swabs	Whole blood, serum & plasma	Nasopharyngeal swab, Nasal swab and saliva swab
Storage	Cold chain	Room Temperature	Room Temperature
Sensitivity	High; false positive is unlikely, false negative could happen.	Moderate; false positive and false negative could happen.	Moderate; false positive is unlikely, false negative could happen and negative result can be confirmed with PCR testing.

► Clinical Data

A total of 397 samples were tested in this study
COVID-19 Antigen Test Kit vs PCR

Method		PCR results		Total
		Positive	Negative	
COVID-19 Antigen Test kit	Positive	167	1	168
	Negative	0	229	229
Total		167	230	397
Sensitivity		>99.99%	95% confidence interval	97.75% ~100%
Specificity		99.57 %	95% confidence interval	97.58% ~ 99.92%
Accuracy		99.75 %	95% confidence interval	98.59% ~ 99.96%


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▶ Product Information

Product Name	Singclean COVID-19 Antigen Test Kit
Sample Type	Saliva Swab
Test Principle	Colloidal Gold Method
Sample Volume	3 Drops of Extracted Solution (100 μ l)
Qualitative/Quantitative	Qualitative
Test Time	15 mins
Operation Temperature	15-30°C
Storage Temperature	4-30°C
Shelf Life (Unopened)	24 months

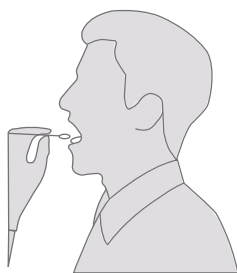
▶ Packing

Specification	Package Contents	Picture (take 1pc/box as an example)
1 test/box	1.Swab	
20 tests/box	2.Antigen Extraction Tube & Tube Tip	
50 tests/box	3.Antigen Extraction Buffer	
100 tests/box	4.Instruction for Use	
	5.Paper Workbench (the box of 1pc can be used as the workbench)	
	6.Test Kit	

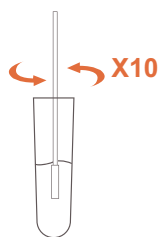
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▶ Test Procedures



DO NOT eat, drink, smoke, brush teeth for 30 minutes before collecting saliva. Remove the swab package, keep the tip on the tongue until the tip being fully soaking by saliva (at least two minutes).



Place the antigen extraction tube on the workbench. Insert the swab into an extraction buffer tube pre-added with the whole bottle of extraction buffer, rotate the swab about 10 times.

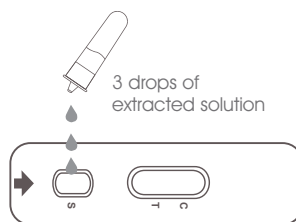


1 min

Leave the swab in the extraction tube for 1 minute. Remove the swab while squeezing the tip of the swab to extract the liquid from the swab.



Press the dropper tip tightly onto the tube.



Apply 3 drops of extracted solution to the specimen well of the test device.



15 min

Read the test result in 15 minutes.

▶ Storage and Stability

The kit can be stored at room temperature or refrigerated (4-30°C). The test device is stable through the expiration date printed on the sealed pouch. The test device must remain in the sealed pouch until use.

DO NOT FREEZE.

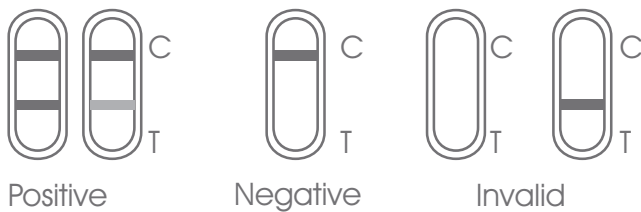
Do not use beyond the expiration date.

After opening the sealed pouch, use the test as soon as possible within 60 minutes.

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▶ Result Interpretation



Positive:

If both control line (C) and test line (T) appear, the result indicates the presence of COVID-19 antigen in the specimen. The result is COVID-19 positive.

Negative:

If only control line (C) appears, the result indicates that no COVID-19 antigens are detected in the specimen. The result is COVID-19 negative.

Invalid:

Control line (C) fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test cassette.

▶ Limitations

1. Use fresh samples whenever possible.
2. A positive result does not rule out bacterial infection or co-infection with other viruses.
3. A negative result can occur if the quantity of the COVID-19 antigen present in the specimen is below the detection limits of the assay, or failed to collect the COVID-19 antigen in the saliva of the patient.
4. A Negative result does not rule out infection with COVID-19 and should not be used as the final or sole basis for treatment or patient management decisions. Negative results should be considered in the context of a patient's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19.

▶ Warnings

Optimal assay performance requires strict adherence to the assay procedure described in this insert sheet. Inadequate or inappropriate sample collection, storage, and transport may cause false test results.

Dedicated to Healthcare Improvement



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