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CE

COVID-19 Antigen Test Kit (Colloidal Method)

One Step Coronavirus Antigen Rapid Test Cassette
(Nasopharyngeal Swab and Saliva Swab)



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

Hangzhou Singclean Medical Products Co.,Ltd.

Singclean®

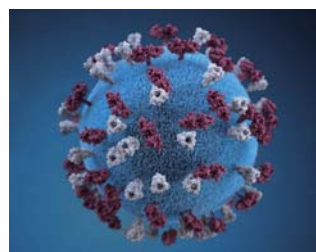
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▶ Introduction

To help stop the spread of COVID-19, Singclean Medical has developed two kinds of COVID-19 Antigen Test Kits, nasopharyngeal swab and saliva swab which are solid phase immunochromatographic assays for the rapid, qualitative detection of antigen from COVID-19 in human nasopharyngeal and saliva swab specimen. The 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



▶ Comparison Between Nasopharyngeal Swab and Saliva Swab

Singclean COVID-19 Antigen Test Kit	Nasopharyngeal Swab	Saliva Swab
Similarities	<ul style="list-style-type: none">• Quick: results ready in 15 minutes• Affordable: no need for instrument• Accurate diagnostic tool for active infection• Easy to administer and read results• Enable testing on a massive scale	
Differences	Sensitive: Detect the antigen more quickly when viral load is low in the early stage of infection.	Non-invasive: More comfortable than nasopharyngeal swab

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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, easy for healthcare professionals to use	No special facilities needed, easy for healthcare professionals to use
Cost	High	Low	Low
Sample requirement	Saliva, nasal, oral or anal swabs	Whole blood, serum & plasma	Nasopharyngeal 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.

► 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.

(For saliva test, after opening the sealed pouch, use the test as soon as possible within 60 minutes.)

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▶ Product Information

Product Name	Singclean COVID-19 Antigen Test Kit	
Sample Type	Nasopharyngeal Swab	Saliva Swab
Test Principle	Colloidal Gold Method	
Sample Volume	3 Drops of Extracted Solution (about 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	
Specification	1 test/box 20 tests/box	1 test/box 20 tests/box 50 tests/box 100 tests/box

▶ Clinical Data for Nasopharyngeal Swab

Calculate the sensitivity/specificity/accuracy compared with the control reagent.

Method	PCR		Sum
	Positive	Negative	
Singclean COVID-19 Test Kit	Positive	3	209
	Negative	306	309
Sum	209	309	518
Sensitivity	$206/(206+3) \times 100\% = 98.56\%$	95% confidence level	95.87%-99.51%
Specificity	$306/(3+306) \times 100\% = 99.03\%$	95% confidence level	97.18%-99.67%
Accuracy	$(206+306)/518 \times 100\% = 98.84\%$	95% confidence level	97.50%-99.47%

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Materials Supplied

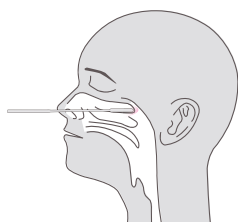
Test Cassette
Cotton Swab
Antigen Extraction Buffer
Antigen Extraction Tube
Paper Workbench
Instruction for Use

Material Required but Not Provided

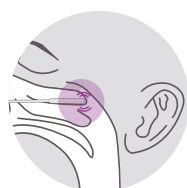
Timer

Test Procedures

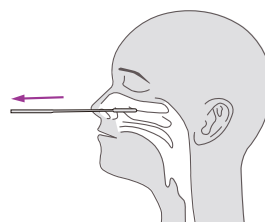
Nasopharyngeal Swab Specimen Collection



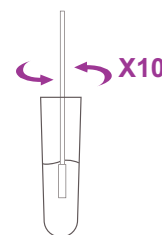
Insert a sterile swab into the nostril of the patient, reaching the surface of the posterior nasopharynx.



Swab over the surface of the posterior nasopharynx.



Withdraw the sterile swab from the nasal cavity.

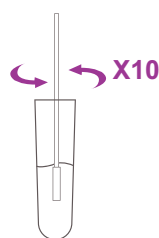


Place the antigen extraction tube on the workbench. Insert the swab into an extraction buffer tube pre-added with 6 drops of extraction buffer, rotate the swab about 10 times.

Saliva Swab Specimen Collection



DO NOT eat, drink, smoke, brush teeth for 30 minutes before collecting saliva. Remove the swab package, keep the sponge 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 12 drops of extraction buffer, rotate the swab about 10 times.

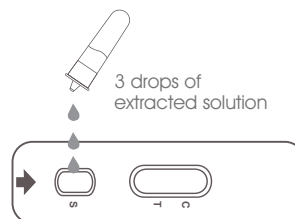


1 min

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.



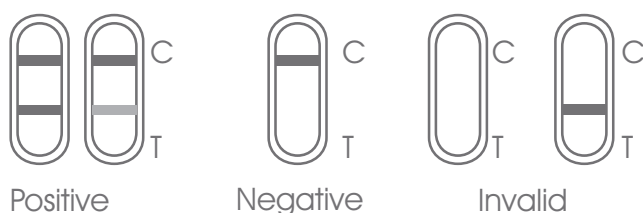
15 min

Read the test result in 15 minutes.

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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 (SARS-CoV-2) antigen in the specimen. The result is COVID-19 positive.

Negative:

If only control line (C) appears, the result indicates that no COVID-19 (SARS-CoV-2) antigens are detected in the specimen. The result is COVID-19 negative.

Invalid:

If control line (C) doesn't appear after performing the test, the result is considered invalid. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for the failure of control line. Review the procedure and repeat the test with a new test kit.

▶ Limitations

1. Use fresh samples whenever possible.
2. Positive results do 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.
4. Negative results do 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. For a more accurate test result, repeat the tests or confirmed with other testing methods and clinical findings is recommended.

▶ 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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