

Singclean®

GT GOOD
TEST

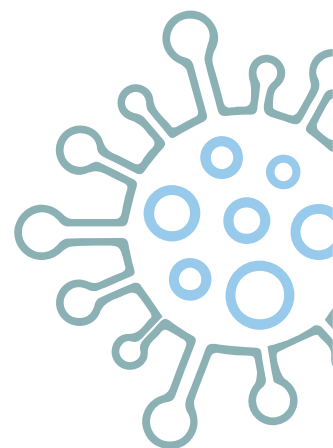


COVID-19 Test Kit (Colloidal Gold Method)

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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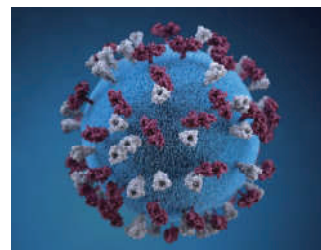
COVID-19 Test Kit (Colloidal Gold Method)

▶ Intended Use

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 Test Kit (Colloidal Gold Method) must be confirmed with alternative testing method(s) and clinical findings.

▶ Main Symptoms of COVID-19

- ☒ Fever
- ☒ Fatigue
- ☒ Cough
- ☒ Shortness of Breath



▶ Features

- Results ready in 15 minutes
- With a high level of accuracy that's comparable to nasopharyngeal swab testing
- Easy to administer and read results
- Affordable, no need for instrument, highly portable
- Enable testing on a massive scale
- Will not require health care workers to be put at risk. Sampling can be done by patients
- Non-invasive: More comfortable than COVID-19 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	10-15 minutes	10-15 minutes
Facility requirement	PCR Laboratory, complex	No special facilities needed, easy for healthcare professionals to use	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. Although antigen tests are less accurate than (PCR) tests, antigen tests are cheaper and faster to run.

► 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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COVID-19 Test Kit (Colloidal Gold Method)

Product Information

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

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		99.57 %	95% confidence interval	98.59% ~ 99.96%

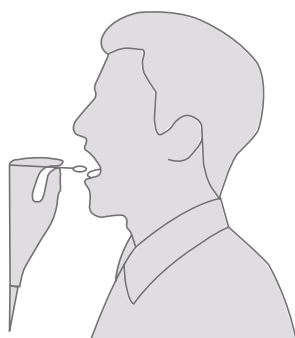
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Specimen Collection

1. Singclean COVID-19 Test kit can be performed using a saliva swab.
2. Testing should be performed immediately after specimen collection.
3. Bring specimens to room temperature prior to testing.
4. If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.

Specimen collection,



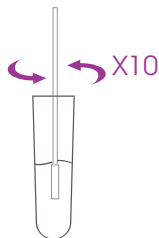
DO NOT eat, drink, smoke, brush teeth for 30 minutes before collecting saliva. Remove the swab package, keep the tip on the tongue until the tip being fully soaking by saliva (at least two minutes).

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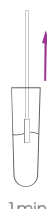


COVID-19 Test Kit (Colloidal Gold Method)

Test Procedures



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

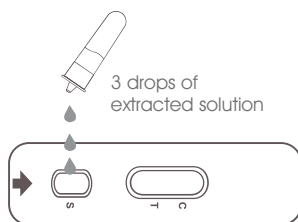


1min

2. 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.



3. Press the dropper tip tightly onto the tube.



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



15 min

5. Read the test result in 15 minutes.

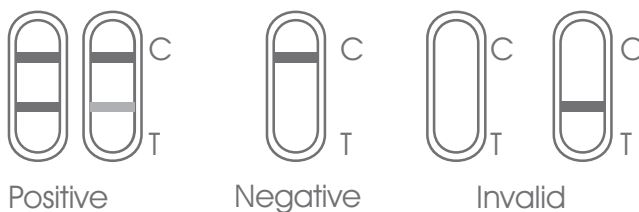
Packing

Specification	Picture	Package Contents	Carton
20 tests/kit		1 Instruction 1 Paper Workbench 20 Test Kits 20 Swabs 20 Extraction Tubes and Dropper Tips 20 Bottles of Extraction Buffer	600 pcs, L650*W270*H370mm
1 test/kit		1 Instruction 1 Test Kit 1 Swab 1 Extraction Tube and Dropper Tip 1 Extraction Buffer	400 pcs, L520*W380*H500mm

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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.



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