Singclean®

COVID-19 Test Kit (Colloidal Gold Method)

One Step Coronavirus Antigen Rapid Test Cassette

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

Hangzhou Singclean Medical Products Co.,Ltd.

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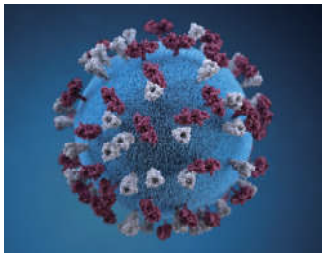
Intended Use

Singclean COVID-19 Test Kit (Colloidal Gold Method) is a solid phase immunochromatographic assay for the rapid, qualitative detection of antigen from COVID-19. 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.

This rapid antigen test kit is the second test kit developed by Singclean Medical for COVID-19 testing on the basis of Colloidal Gold Method after Singclean COVID-19 IgG/IgM Test Kit, an antibody test, was launched globally in March.

Main Symptoms of COVID-19

- ☑ Fever
- ☑ Fatigue
- ☑ Cough
- ☑ Shortness of Breath



Features

- Results ready in 15 minutes
- Accurate diagnostic tool for active infection
- Easy to administer and read results
- Affordable, no need for instrument, highly portable
- Enable testing on a massive scale
- For healthcare workers use only

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Comparison Among Different Testing Methods for COVID-19

Singclean®	PCR Nucleic Acid Test	Antibody Test	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, easy for healthcare professionals to use
Cost	High	Low	Low
Sample requirement	Saliva, nasal, oral or anal swabs	Whole blood, serum & plasma	Nasal or throat swabs
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.

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Product Information

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

Clinical Data

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

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

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Specimen Collection

1. Singclean COVID-19 Test kit can be performed using the following three samples, including I.) Nasal swab, II .) Oropharyngeal swab and It can also be performed using III.) Nasopharyngeal 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,

I.) Nasal Swab collection (Recommended for self-testing)

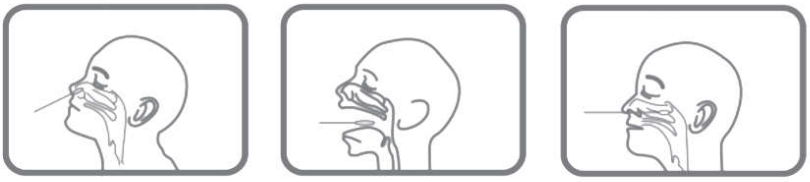
It is important to gain as much secretion as possible. Insert a sterile swab (stick) into the nostril. The sterile swab (stick) should be inserted into 2.5cm (1 inch) from the edge of the nostril. Hit the swab 5 times along the mucous membrane inside the nostrils to ensure that both mucus and cells are collected. Repeat this procedure for the second nasal stick to ensure that a sample is taken from both nasal cavities. When removing the tampon, please do not touch the swab.

II.) Oropharyngeal swab collection (Recommended for self-testing)

It is important to gain as much secretion as possible. Insert a sterile swab (stick) into the neck, which is essential secretion from the red area of the throat and maxillary mandies to take a sample from the neck. Moderately you will test the bilateral cervical tonsils and the stench of the throat to get a sample. When removing the tampon, please do not touch the swab.

III.) Nasopharyngeal swab collection (Recommended for professional use)

It is important to gain as much secretion as possible. Insert a sterile swab (stick) into the nostril, which during visual inspection nostrils are the most hidden part. Push the swab into the posterior part of the nasal cavity. Turn the swab 10 times and then remove it from the nostril. When removing the tampon, please do not touch the swab. Use nasopharyngeal swab only if you are a trained health care professional, or if this test can be made by a trained professional.



Nasal swab | Oropharyngeal swab | Nasopharyngeal swab

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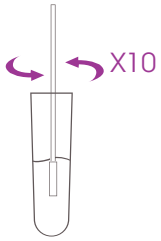
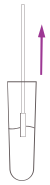
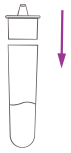
Test Procedures



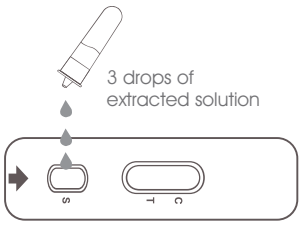
1. Insert the swab into an extraction buffer tube pre-added with 6 drops of extraction buffer, rotate the swab about 10 times.



2. Leave the swab in the extraction tube for 1minute. 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.

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 1 Bottle of Extraction Buffer (5 ml)	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 Negative Invalid

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

1. This test is not for at home testing, and should only be operated by healthcare workers.
2. 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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