

Singclean[®]

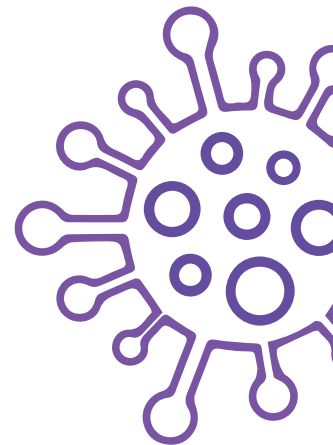
CE
1434

COVID-19 Test Kit
(Colloidal Gold Method)

For self-testing use
(Nasal Swab)

Top 10 in China Having CE Mark
for Rapid Covid-19 Antigen Self-Test

- Precise Rapid Sensitive
- For At-home Testing
- For Early Detection
- Able to Sell Across All EU Member States



Hangzhou Singclean Medical Products Co.,Ltd.

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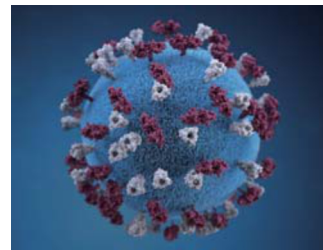
COVID-19 Test Kit (Colloidal Gold Method)

▶ Intended Use

COVID-19 Test Kit (Colloidal Gold Method) is a solid phase immunochromatographic assay for the rapid, qualitative detection of antigen to 2019 Novel Coronavirus in human nasal cavity. This test provides only a preliminary result for self-testing. 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

- For self-testing use
- 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

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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 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, nasal, saliva 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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COVID-19 Test Kit (Colloidal Gold Method)

▶ Product Information

Product Name	Singleclean COVID-19 Test Kit (For self-testing use)
Test Type	Antigen Test
Test Principle	Colloidal Gold Method
Sample Type	Nasal Swab
Sample Volume	3 Drops of Extracted Solution (about 100µl)
Qualitative /Quantitative	Qualitative
Test Time	15 mins
Operation Temperature	15-25°C
Storage Temperature	4-30°C

▶ PERFORMANCE CHARACTERISTICS

Clinical Sensitivity, Specificity and Accuracy

The results of the COVID-19 Test Kit (Colloidal Gold Method) were compared to results of RT-PCR assays for SARS-CoV-2 in nasal swab specimens. A total of 499 nasal cavity specimens were tested in this study. The COVID-19 clinical specimens contain specimens from individuals with symptoms within 7 days. The results of test reagent and control reagent both were 350 negative specimens and 149 positive specimens. The sensitivity and specificity calculated were valid in this study.

COVID-19 Test Kit vs PCR

Method	PCR results		Total	
	Positive	Negative		
COVID-19-Testkit	Positive	146	1	147
	Negative	3	349	352
Total	149	350	499	
Sensitivity	97.99%	95% confidence interval	94.25% - 99.31%	
Specificity	99.71 %	95% confidence interval	98.40% - 99.95%	
Accuracy	99.20 %	95% confidence interval	97.96% - 99.69%	

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▶ PACK FORMATS

- 1 test/box
- 20 tests/box

▶ MATERIALS SUPPLIED

- Sealed pouches each containing a test cassette, a desiccant
- Sampling cotton swabs (for nasal cavity sampling only)
- Antigen extract buffer
- Antigen extraction tube
- Paper workbench (The small one-test-box can be used as a workbench)
- Instructions for use

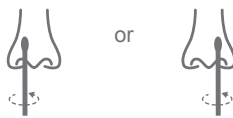
▶ MATERIALS REQUIRED BUT NOT PROVIDED

- 1. Specimen collection containers
- 2. Timer

▶ Test Procedures



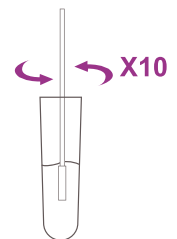
1. Remove the secretions on the surface of the anterior nasal cavity, keep the head slightly tilted.



2. Gently and slowly insert the swab through the nasal cavity (about 2-4cm). Rotate gently 5 times.



3. Gently rotate to remove the swab.



4. Put the swab specimen into the extraction tube pre-added with 6 drops of extraction buffer, rotate the swab about 10 times while pressing the swab head against the tube wall to release the antigen in the swab.



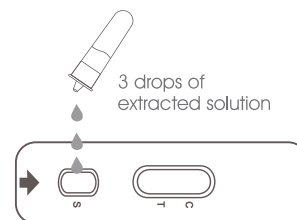
1 min

5. 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.



1 min

6. Press the dropper tip tightly onto the tube and wait for 1 minute



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



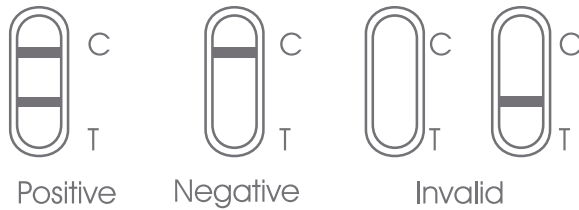
15 min

8. Read the test result in 15 minutes.

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▶ Result Interpretation



▶ Negative:

If only the C band is present, the absence of any burgundy color in the T band indicates that no COVID-19 (SARS-CoV-2) antigen is detected in the specimen. The result is negative.

If the test result is negative:

Continue to follow all applicable rules regarding contact with others and protective measures.

Even if the test is negative, an infection may be present.

In case of suspicion, repeat the test after 1 - 2 days, because the Coronavirus cannot be accurately detected at all stages of infection.

▶ COVID-19 Positive:

If the C and T band is present, the test indicates for the presence of COVID-19 (SARS-CoV-2) antigen in the specimen. The result is COVID-19 positive.

There is currently a suspicion of a COVID-19 infection.

Contact physician/family physician or local health department immediately.

Follow local guidelines for self-isolation.

Have a PCR confirmatory test performed.

▶ Invalid:

Control line 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. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

In case of an invalid test result:

Possibly advance warning due to incorrect test performance.

Repeat the test.

If test results are still invalid, contact a physician or a COVID-19- Test Center.

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▶ Limitations

1. Use fresh samples whenever possible.
2. Optimal assay performance requires strict adherence to the assay procedure described in this insert sheet. Deviations may lead to aberrant results.
3. A negative result for an individual subject indicates absence of detectable COVID-19 (SARS-CoV-2) antigen. However, a negative test result does not preclude the possibility of exposure to or infection with COVID-19.
4. A negative result can occur if the quantity of the COVID-19 (SARS-CoV-2) antigen present in the specimen is below the detection limits of the assay, or failed to collect the COVID-19 (SARS-CoV-2) antigen in the nasal cavity of the patient.
5. The test kit provides a presumptive diagnosis. A confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.
6. Only use for in vitro diagnostic, and cannot be reused.
7. The antigen extract buffer is used to extract specimens, and shall not be used internal or external by humans or animals. Swallowing will cause a serious accident. If happens, please seek medical attention immediately. The antigen extract is irritating to eyes and skin, if splashed into eyes accidentally, please rinse with water soon. If necessary, consult a doctor and maintain ventilation during the procedure.

▶ Warnings And Precautions

1. For non-professional self-testing use. Do not use after expiration date.
2. This package insert must be read completely before performing the test. Failure to follow the insert gives inaccurate test results.
3. Do not use it if the tube/pouch is damaged or broken.
4. Test is for single use only. Do not re-use under any circumstances.
5. Humidity and temperature can adversely affect results.

A decorative graphic consisting of several overlapping, wavy, horizontal bands in various shades of purple, ranging from light lavender to deep indigo. The bands flow across the page, creating a sense of movement and depth.

Importer:

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