

Singclean®

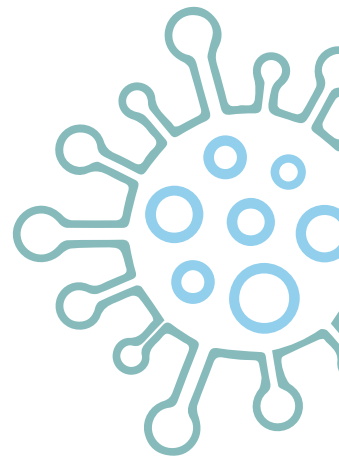
CE

COVID-19 Test Kit (Colloidal Gold Method)

One Step Coronavirus Antigen
Rapid Test Cassette
(Nasopharyngeal Swab)



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



Hangzhou Singclean Medical Products Co.,Ltd.

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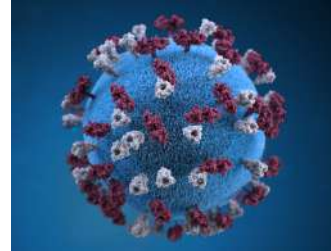
▶ Intended Use

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

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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 | Nasal Swab |
| 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 |

▶ Clinical Data


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

| | |
|--------------|---|
| Product Name | Singclean COVID-19 Test Kit |
| Sensitivity | $88/(88 + 11) \times 100\% = 88.89\%$ |
| Specificity | $138/(3 + 138) \times 100\% = 97.87\%$ |
| Accuracy | $(88 + 138)/240 \times 100\% = 94.17\%$ |

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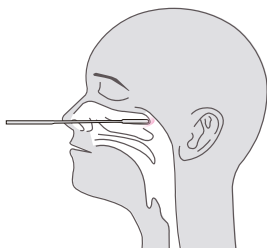
► Packing

| 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 (6 ml) | 600 pcs, L650*W270*H370mm |

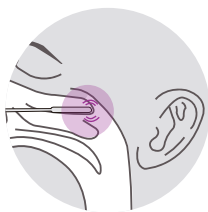
► Storage and Stability

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.

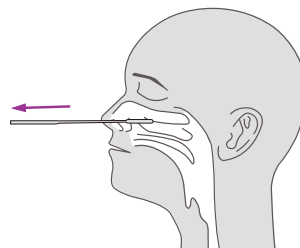
► Test Procedures



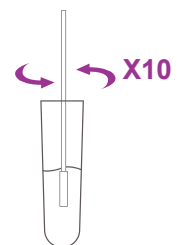
1. Insert a sterile swab into the nostril of the patient, reaching the surface of the posterior nasopharynx.



2. Swab over the surface of the posterior nasopharynx.



3. Withdraw the sterile swab from the nasal cavity.

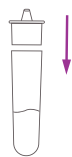


4. Insert the swab into an extraction buffer tube pre-added with 6 drops of extraction buffer, rotate the swab about 10 times.

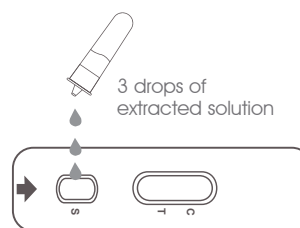


1min

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.



6. Press the dropper tip tightly onto the tube.



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



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 in the nasal cavity of the patient.
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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