

Singclean[®]



Singclean COVID-19 Neutralizing Antibody Test Kit

Precise Rapid Sensitive



Hangzhou Singclean Medical Products Co.,Ltd.



Intended Use

COVID-19 Neutralizing Antibody Test Kit (Colloidal Gold) is a solid phase immunochromatographic assay for the rapid, qualitative detection of Neutralizing Antibody of COVID-19 in human whole blood/serum/plasma. This test provides only a preliminary test result.

What Are Neutralizing Antibodies

Infection with COVID-19 initiates an immune response, which includes the production of antibodies in the blood. The secreted antibodies provide protection against future viral infections, because they will stay in the circulatory system from months to years after infection, and will quickly and strongly bind to the pathogen to block cellular infiltration and replication. These antibodies are named neutralizing antibodies.


The Significance of Neutralizing Antibody Testing

COVID-19 Neutralizing Antibody is a crucial marker for assessing the effectiveness of the COVID-19 vaccines and can be seen as indicators of immunity. And COVID-19 Neutralizing Antibody Test Kit is for detecting neutralizing antibodies in samples from individuals after vaccine injection or recovered from COVID-19.

If an individual is infected with COVID-19, the Neutralizing Antibodies will appear soon.

The time taken for the Neutralizing Antibodies to appear after vaccine injection depends on vaccine effectiveness. Neutralizing Antibodies normally appear within 28 days with COVID-19 mRNA vaccine, and 42 days with inactivated COVID-19 vaccine.

A rapid detection of neutralizing antibodies can help with vaccine development, plasma therapy, and immunology study.



Product Information

Product Name	Singclean COVID-19 Neutralizing Antibody Test Kit
Test Type	Antibody Test
Test Principle	Colloidal Gold Method
Sample Type	Whole blood/Serum/Plasma
Sample Volume	1 Drop
Qualitative/Quantitative	Qualitative
Test Time	10 mins
Operation Temperature	15-30°C
Storage Temperature	4-30°C
Shelf Life (Unopened)	2 years

Features

- Accurate serology test for Neutralizing Antibodies detection
- Easy to administer and read results
- Results ready in 10 minutes
- Enable testing on a massive scale
- Affordable, no need for instrument, highly portable
- For healthcare workers use only

Packing

Specification	Pictures	Package Contents
1 test/box 20 tests/box 50 tests/box 100 tests/box		Test Kit Dropper Lancet (for finger stick whole blood only) Sterilizing Tablet (for finger stick whole blood only) Buffer Instruction for Use

Storage and Stability

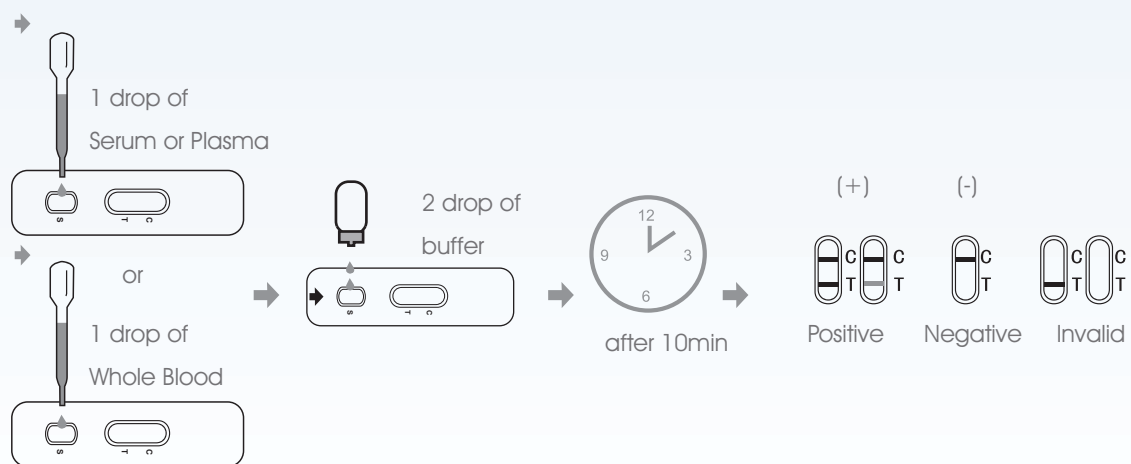
The kit can be stored at room temperature or refrigerated (4-30°C). The test device is stable through the expiration date printed on the sealed pouch. The test device must remain in the sealed pouch until use.

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.

Test Procedures



INTERPRETATION OF RESULTS

NEGATIVE:

If only the C band is present, the absence of any burgundy color in the T band indicates that no COVID-19 Neutralizing Antibody is detected in the specimen. The result is negative.

POSITIVE:

In addition to the presence of C band, if T band is developed, the test indicates for the presence of COVID-19 Neutralizing Antibody in the specimen. The result is COVID-19 Neutralizing Antibody positive.

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.



Limitations

1. A positive test result indicates that there are COVID-19 neutralizing antibodies in the sample, and a positive reaction can be generated after infection with the COVID-19 or injection of the COVID-19 vaccine. It needs to be analyzed based on the individual situation of the user.
2. A positive COVID-19 neutralizing antibody test result only indicates that the tested person has neutralizing antibody of COVID-19 in the blood, but it does not mean that the tested person will be protected from the COVID-19 infection. Please pay attention to maintain personal protective measures in a crowded environment.
3. A negative result only indicates that there is no COVID-19 neutralizing antibody that reaches the test concentration in the specimen, and other cellular immunity and mucosal immunity cannot be ruled out.
4. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should be made by a doctor after evaluating the results of other clinical and laboratory tests.

Warnings

1. This test is only used to detect the COVID-19 Neutralizing Antibodies and is not used to diagnose an active infection.
 2. Use fresh specimen whenever possible.
 3. Optimal assay performance requires strictly adherence to the assay procedure described in Instruction for use. Deviations may lead to aberrant results.
 4. All samples and reaction waste should be treated as the source of infection, and the operators should take necessary protective measures.
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Dedicated to Healthcare Improvement



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