COVID-19 Neutralizing Antibody Test Cassette (Immunochromatography) Instruction For Use

CE IVD

【Product name】

Common name:
COVID-19 Neutralizing Antibody Test Cassette (Immunochromatography)

【Package】

1 test/box, 30 tests/box, 40 tests/box, 50 tests/box, 100 tests/box。

【Intended use】

This product is used to detect COVID-19 neutralizing antibody in human serum, plasma and whole blood.
The novel corona viruses belong to the β genus. COVID-19 is an acute respiratory infectious disease.People are generally susceptible.Currently,the patients infected by the novel coronavirus are the main source of infection;asymptomatic infected people can also be an infectious source.Based on the current epidemiological investigation,the incubation period is 1 to 14 days,mostly 3 to 7days.The main manifestations include fever,fatigue and dry cough.Nasal congestion,runny nose,sore throat,myalgia and diarrhea are found in a few cases.
Neutralizing antibody is a kind of antibody produced by the body stimulated by the envelope or capsid antigen of the virus, which can bind to the virus and make it lose its infectivity. Neutralizing antibodies against COVID-19 S1 protein RBD can be combined with COVID-19 RBD region, blocking RBD and ACE2 receptor binding, thereby blocking viruses from invading human cells. Neutralizing antibodies against RBD are the most important, diverse and active antibodies against virus.

【Principle】

The reagent is based on the principle of immunochromatography and competitive method. It is used to detect whether there is COVID-19 neutralizing antibody in human blood samples (including serum, plasma and whole blood). Precoat colloidal gold labeled covid-19 S-RBD protein and colloidal gold labeled streptavidin on glass fiber, ACE2 and bio-BSA coated on the nitrocellulose membrane in the test area (t line) and quality control area (C line) respectively. The neutralizing antibody in the sample competes with ACE2 to bind S-RBD labeled with colloidal gold. The sample diffuses upward due to the fine capillary force. When the sample passing through the label pad, if there is no neutralizing antibody in the sample, there is no substance combining with labeled S-RBD, The labeled S-RBD will be combined with ACE2, and the red line with the same color as the control area (C line) appeared in the test area (t line), indicating that the result is negative.If the sample contains neutralizing antibody, labeled S-RBD will be bound by neutralizing antibody, If the colloidal gold labeled S-RBD is partially bound by the neutralizing antibody in the sample, ACE2 in the test area (t line) will react with labeled S-RBD which is not bound to the tested substance, resulting in a weaker color of band than that in the quality control area (C line); If all of the labeled S-RBD is bound to neutralizing antibodies in the sample to be tested, there is no colloidal gold labeled S-RBD binding to ACE2 in the test area, and the T line does not develop color.T-line showed no color or the color was obviously weaker than the quality control line, both indicated that the neutralizing antibody of the sample were positive.The red band displayed in the quality control area (line C) is the standard to judge whether the chromatographic process is normal or not, and also serves as the internal control standard of the reagent.

【Main components】

The cassette is mainly composed of a single-pack test card (1 test card, 1 desiccant), sample diluent, and dropper.

1.Test card: the test card is made up of test strips and plastic cassette. The test strips are made up of nitrocellulose membrane, sample pad, binding pad, absorbent paper, PVC board and other supporting materials. It contains labeled COVID-19 S-RBD protein and streptavidin, and is coated with ACE2 and bio-BSA.
2.Sample diluent: the main component is phosphate buffer.
Note: The components of cassettes with different lot numbers should not be mixed to avoid incorrect results.

【Storage conditions and period of validity】

The product should be stored at 2 ℃ ~ 30 ℃ and its validity is 24 months.
It should be used within 30 minutes after the aluminum foil bag opening, and the bottle cap should be tightened immediately after using the sample diluent, and placed in a cool place.
Production date, expiration date: see product label.

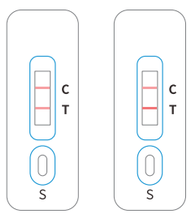
【Sample requirements】

1. The applicable sample type of this product is serum, plasma or whole blood. The plasma sample can be treated with heparin sodium or EDTA anticoagulant.
2. Serum and plasma samples can be stored for 7 days at 2-8℃ or 24 days at -20℃ if they cannot be detected in time after collection.
3. Frozen serum and plasma samples should be completely melted, rewarming and mixed evenly before use. Aviod to repeat freezing and melting by all means.
4. The sediment and suspended matter in the sample may affect the test results and remove them by centrifugation.
5. Severe hemolytic, lipidemic or turbid samples should not be used.

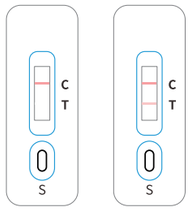
【Test method】

Please read this instruction carefully before operation.
1. Take out the sample to be tested (serum / plasma / whole blood) and test reagent and fully recover to room temperature.
2. Take out the test cassette from the aluminum foil bag and place it horizontally on a dry surface.
3. Slowly add the sample(serum / plasma / whole blood:25μl) into the adding well, or draw the sample with a dropper into the adding well. After 10minutes, add 1-2 drops of sample diluent(about 40-80 μl)into the sample well.
4. Observe the results within 10-15 minutes after adding the sample diluent, and after 15 minutes the results are invalid.

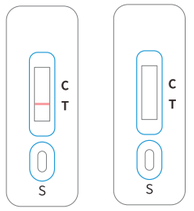
【Interpretation of test results】



SARS-COV-2 Neutralizing Antibody Negative:
If the chromaticity of the quality control line (line C) is as same as test line (line T), or the chromaticity of the test line (line T) is higher than the quality control line (line C), it indicates that no neutralizing antibodies are detected.
It was guided that there is no neutralizing antibody in the body. Maybe the body was not vaccination not yet or it need to vaccination once more.

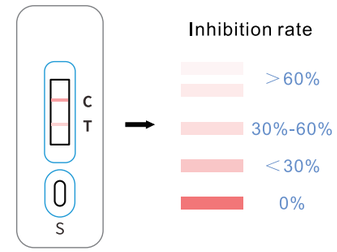


SARS-COV-2 Neutralizing Antibody Positive:
COVID-19 neutralizing antibody positive (+): only quality control line (line C) shows color, or the chroma of test line (line T) is weaker than that of quality control line (line C).
Before making a formal diagnosis of the positive test results, the positive test results should be reconfirmed by alternative test methods and clinical results.



INVALID RESULT:
If the quality control line (C line) is not colored, the test is invalid, and it is recommended to retest. Pay particular attention to whether the sample volume is enough.

Value Results	Results	Tset Result Interpretation
0% Signal Inhibition	Negative	Neutralizing antibodies for SARS-CoV-2 are not detected
＜30% Signal Inhibition	Positive	Neutralizing antibodies for SARS-CoV-2 are detected
30% ⩽Signal Inhibition ⩽60%	Positive	Neutralizing antibodies for SARS-CoV-2 are detected
＞60% Signal Inhibition	Positive	Neutralizing antibodies for SARS-CoV-2 are detected



【Limitations of test methods】

1. This product can only detect COVID-19 neutralizing antibody in human blood samples, and cannot accurately measure the content of neutralizing antibody in samples.
2. Failure to comply with the specifications may adversely affect test performance or cause invalidate test results.
3. Improper sample collection, improper sample storage or repeated freezing and melting will affect the test results.
4. The cassette is only used to detect COVID-19 neutralizing antibodies in human serum, plasma and whole blood. It can not be guaranteed by using other samples or solutions.
5. Due to the limitation of the detection methodology, the presence of interfering substances in the sample may affect the detection results.

【Product performance index】

1. Clinical Performance For neutralizing antibody Test
A total of 276 clinical samples were test by the COVID-19 Neutralizing Antibody Test Cassette (Fortune Bio) compared withSARS-CoV-2 Surrogate Virus Neutralization Test Kit(GenScript).The results are showed in the following table:

SARS-CoV-2 Neutralizing Antibody Test

COVID-19 Neutralizing Antibody Test Cassette	SARS-CoV-2 Surrogate Virus Neutralization Test Kit		
	Positive	Negative	Total
Positive	66	14	80
Negative	4	192	196
Total	70	206	276

Positive coincidence rate:66/(66+4)*100%=94.3%
Negative coincidence rate:192/(192+14)*100%=93.2%
Total coincidence rate:(66+192)/276*100%=93.5%

2. Cross reactivity and interference specificity: The COVID-19 Neutralizing antibody Test Cassette has no cross-reactive and interference withHCoV-OC43 , HCoV-NL63, HCoV-229E, HCoV-HKU1, Influenza A, InfluenzaB, Parainfluenza, RSV, Adenovirus, Mycoplasma, Pneumonia, Chlamydia, Pneumonia, Rhinovirus, HIV, EB virus, CMV, HBV, HCV, Syphilis, Albumin, Acetaminophen, Atropine, Aspirin, Ascorbic acid, Bilirubin, Creatinine, Caffeine, EDTA, Hemoglobin, Heparin Sodium, Glucose, Salicylic acid, AMA, ANA, HAMA, HSV-1, HSV-2, Azithromycin, Parainfluenza, Rheumatoid factor, Syphilis, Triglycerid, VZV.

【Attention】

1. Read the product manual carefully before operation, and carry out the experiment in strict accordance with the requirements of the cassette manual.
2. All used samples, testing reagents and consumables should be regarded as infectious products and should be treated as medical waste.
3. This product is an in vitro diagnostic reagent, only suitable for the detection of human serum, plasma and whole blood samples.
4. Collect fresh blood samples for testing. If the samples are placed for a long time, grow bacteria and have peculiar smell, the test results may be inaccurate.
5. Do not use expired, damaged or contaminated products.
6. This product is only for one-time use, do not reuse.
7. Improper collection, storage or transportation of samples may lead to wrong test results.
8. Please observe the results within 10-15minutes. After 15 minutes, the results are invalid and need to be retested.
9. If the quality control line does not develop color, the test result is invalid and should be retested.
10. The aluminum foil bag contains desiccant and should not be used for other purposes.
11. Please do not use if the aluminum foil bag is damaged or the product is damaged before use.
12. Avoid testing in the environment with too high temperature; test cassettes stored below room temperature should be restored to room temperature before opening the aluminum foil bag to avoid moisture absorption.
13. The test sample is blood, it should be regarded as infectious products. The operation should follow the infectious disease laboratory operation specification and pay attention to the biological safety operation.

【Interpretation of signs】

Symbol	Used for	Symbol	Used for
IVD	In vitro diagnostic instruments	®	Trademark
	Temperature limitation		Manufacturers
	The date of production		Expiry date
LOT	Product batch number		Do not reuse
	Not use if the package is damaged		

Manufacturer:
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