SARS-COV-2 Neutralizing Antibody Rapid Test Kit (Colloidal Gold)

Instruction for Use

Read this instruction carefully before use

A rapid test for the qualitative detection of SARS-COV-2 Neutralizing Antibody in serum,plasma and whole blood specimens.For professional medical institutions use only,Not for self testing.

PRODUCT NAME

SARS-COV-2 Neutralizing Antibody Rapid Test Kit (Colloidal Gold)

SPECIFICATION

25 tests/kit, 5 tests/kit, 1 test/kit

INTENDED USE

The SARS-CoV-2 Neutralizing Antibody Rapid Test Kit (Colloidal Gold) is a lateral flow chromatographic immunoassay for the qualitative detection of Novel coronavirus Neutralizing Antibody in human serum,plasma and whole blood. It is suitable for the auxiliary diagnosis of SARS-COV-2 Neutralizing Antibody after vaccine.

INTRODUCTION

A robust serological test to detect neutralizing antibodies to SARS-CoV-2 is urgently needed to determine not only the infection rate, herd immunity and predicted humoral protection, but also vaccine efficacy during clinical trials and after large-scale-vaccination. SARS CoV-2 Neutralizing Antibody Rapid Test Kit (Colloidal Gold) is a lateral flow chromatographic immunoassay for the semi-qualitative detection of neutralizing Antibody after vaccination or after the infection with SARS-CoV-2 virus. in human serum, plasma and whole blood. The SARS-CoV-2 neutralizing antibodies are the protective antibodies which produced by the human body after vaccination or infection with SARS-CoV-2 virus. Not all the antibody which produced by human body are the neutralizing antibody. Only the antibody have protective function can be named neutralizing antibody.

PRINCIPLE

The SARS CoV-2 Neutralizing Antibody Rapid Test (Colloidal Gold) is a lateral flow chromatographic immunoassay. The test cassette consists of: 1)a burgundy colored conjugate pad containing SARS-COV-2 S-RBD antigen conjugated with colloid gold (SARS CoV-2 conjugates) and mouse IgG-gold conjugates, 2) a nitrocellulose membrane strip containing a test band (T band) and a control band (C band). The test band is pre-coated with Mouse anti-human IgG antibody for capture bind to RBD with neutralizing antibody , in order to detection the RBD antibody in serum, plasma and whole blood. The C band is pre-coated with goat anti mouse IgG.

When an adequate volume of test specimen is dispensed into the sample well of the test cassette, the specimen migrates by capillary action across the cassette. If there is antibody producing after vaccine, the RBD antibody will be conjugated with RBD antigen, than the Mouse anti-human IgG antibody can bind to RBD antigen with Neutralizing Antibody. So the test line will be colored. If no antibody produced, the RBD antigen will not bind to Mouse anti-human IgG antibody , the test line will not be colored. These combo cassette can distinguish the source of the antibody, which is very important for detecting the effect of the vaccine.

MAIN COMPONENTS

Materials Provided

Components	25 tests/kit	5 tests/kit	1 tests/kit
Cassettes	25 cassettes with dependent sealed foil pouch	5 cassettes with dependent sealed foil pouch	1 cassette with dependent sealed foil pouch
Sample Diluent Solution	25tubes(300ul/ tube)	5tubes(300ul/ tube)	300ul/tube
Dropper	25 pcs	5 pcs	1 pcs
Lancet	25 pcs	5 pcs	1 pcs
Alcohol pad	25 pcs	5 pcs	1 pcs
Package insert	1	1	1

Main ingredients of test cassettes:

SARS-COV-2 RBD Recomninant Antigen, Goat anti-rabbit IgG polyclonal antibody, Mouse anti-human IgG Antibody, rabbit IgG, Colloidal gold conjugate, Other test device support; one desiccant

Main ingredients of Sample Diluent Solution:

Neutral salt buffer

Reagents of different batch numbers cannot be used interchangeably.

MATERIALS REQUIRED BUT NOT PROVIDED

Timer for timing use

PRECAUTIONS

- Read this IFU carefully before use.
- Do not spill solution into the reaction zone.
- Do not use test if pouch is damaged.
- Do not use test kit after expiration date.
- Do not mix Sample Diluent Solution and Transfer Tubes from different lots.
- Do not open the Test Cassette foil pouch until ready to perform the test.
- Do not spill solution into the reaction zone.
- For professional use only.
- For in-vitro diagnostic use only
- Do not touch the reaction zone of the device to avoid contamination.
- Avoid cross-contamination of samples by using a new specimen collection container and specimen collection tube for each sample.
- All patient samples should be treated as if capable of transmitting disease. Observe established precautions against microbiological hazards throughout testing and follow standard procedures for proper disposal of specimens.
- Do not use more than the required amount of liquid.
- Bring all reagents to room temperature (15~30°C) before use.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when testing.
- Evaluate the test result after 20 minutes and not beyond 30 minutes.
- Store and transport the test device always at 2~30°C.

STORAGE AND STABILITY

- The kit should be stored at 2~30°C, valid for 12months.
- The test must remain in the sealed pouch until use.
- Do not freeze.
- Cares should be taken to protect components in this kit from contamination.
- Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

SPECIMEN COLLECTION AND HANDLING

Consider any materials of human origin as infectious and handle them using standard biosafety procedures.

Plasma

1.Collect blood specimen into a lavender, blue or green top collection tube (containing EDTA, citrate or heparin, respectively in Vacutainer®) by veinpuncture.
2.Separate the plasma by centrifugation.
3.Carefully withdraw the plasma into new pre-labeled tube.

Serum

1.Collect blood specimen into a red top collection tube (containing no anticoagulants in Vacutainer®) by veinpuncture.
2.Allow the blood to clot.
3.Separate the serum by centrifugation.
4.Carefully withdraw the serum into a new pre-labeled tube.
5.Test specimens as soon as possible after collecting. Store specimens at 2°C to 8°C if not tested immediately.
6.Store specimens at 2°C to 8°C up to 5 days. The specimens should be frozen at -20°C for longer storage

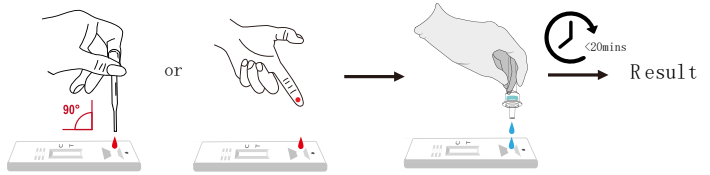
Blood

Drops of whole blood can be obtained by either finger tip puncture or veinpuncture. Do not use any hemolized blood for testing.

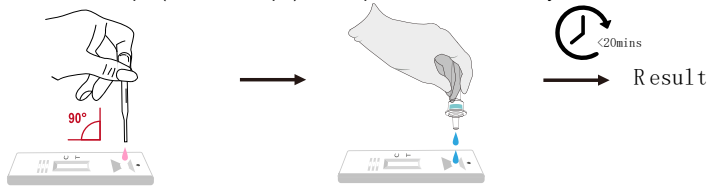
Whole blood specimens should be stored in refrigeration (2°C-8°C) if not tested immediately. The specimens must be tested within 24 hours of collection.Avoid multiple freeze-thaw cycles. Prior to testing, bring frozen specimens to room temperature slowly and mix gently. Specimens containing visible particulate matter should be clarified by centrifugation before testing.

ASSAY PROCEDURE

Step 1: Bring the specimen and test components to room temperature if refrigerated or frozen. Once thawed, mix the specimen well prior to assay.
Step 2: When ready to test, open the pouch at the notch and remove device. Place the test device on a clean, flat surface.
Step 3: Be sure to label the device with specimen's ID number.
Step 4: For whole blood test
- Apply 1 drop of whole blood (about 30-35 μL) into the sample well.
- Then add 2 dropS (about 60-70 μL) of Sample Diluent immediately.



For serum or plasma test
- Fill the pipette dropper with the specimen.
- Holding the dropper vertically, dispense 1 drop (about 30-35 μL) of specimen into the sample well making sure that there are no air bubbles.
- Then add 2 dropS (about 60-70 μL) of Sample Diluent immediately.

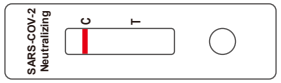


Step 5: Set up timer.
Step 6: Results can be read in 20 minutes. Positive results can be visible in as short as 1 minute.
Don't read results after 30 minutes.To avoid confusion, discard the test device after interpreting the result.

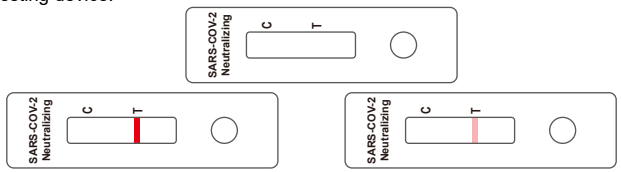
RESULT INTERPRETATION

POSITIVE: Two distinct red lines appear. One line should be in the control region(C) and the other line should be in the test region(T).

NEGATIVE: One red line appears in the control region(C). No red line appears in the test region(T).The negative result does not indicate the absence of analyses in the sample, it only indicates the level of tested analyses in the sample is less than cut-off level.



INVALID: No colored lines appear, or control line fails to appear, indicating that the operator error or reagent failure. Verify the test procedure and repeat the test with a new testing device.



NOTE:

The intensity of the color in test region (T) may vary depending on the concentration of aimed substances present in the specimen. Therefore, any shade of color in the test region should be considered positive. Besides, the substances level cannot be determined by this qualitative test.Insufficient specimen volume, incorrect operation

procedure, or performing expired tests are the most likely reasons for control band failure.

PERFORMANCE CHARACTERISTICS

1. Clinical Performance For neutralizing antibody Test

A total of 600 clinical samples were test by the SARS CoV-2 neutralizing antibody Rapid Test compared with the virus neutralizing antibody test(VNT).The samples were serum, plasma , venipuncture or finger peripheral blood.The results are showed in the following table:

	SARS CoV-2 Neutralizing Antibody Rapid Test		
BESTest	Positive	Negative	Total
Positive	197	3	200
Negative	1	399	400
Total	198	402	600
Relative Sensitivity: 98.5%; Relative Specificity:99.75%; Overall agreement: 99.33%			

2. Cross-reactivity

This kit has no cross reactivity with HCoV-229E, HCoV-OC43, HCoV-NL63, SARS, HCoV-HKU1, MERS-CoV, Influenza(A/B), Adenovirus, Parainfluenza virus, M.Pneumonia, Measles, Streptococcus Pneumoniae, Staphylococcus aureus, EBV, Coxsachie virus, AIV H7N9, AIV H5N1.

3.HOOK Effect:

This kit no hook effect in the detection of strong clinical samples of the SARS-COV-2 neutralizing antibody.

4.Interference Specificity:

This kit no interference with HAMA, Human serum Albumin, Antinuclear antibody, Antimitochondrial antibody, Cholesterol, Bilirubin conjugated, Lipids, Hemoglobin, Bilirubin unconjugated, Rheumatoid factor, et al.

QUALITY CONTROL

1.Internal procedural controls are included in the test. A colored band appearing in the control region (C) is considered an internal positive procedural control. It confirms sufficient specimen volume and correct procedural technique.

2.External controls are not supplied with this kit. It is recommended that positive and negative controls be tested as as a good laboratory practice to confirm the test procedure and to verify proper test performance.

TEST LIMITATIONS

1.This product is only used for testing individual serum, plasma or whole blood samples.

2.This kit is semi-quantiative test and cannot quatify the concentration of the SARS-COV-2 neutralizing antibody.

3.The result of this kit was only used to determine the neutralizing antibody, and can be used to evaluate the immune effect of vaccination or the presence of neutralizing antibody after infection with SARS-COV-2 Virus. This kit can not be applicable to the evaluation of protective ability after vaccination or after infection with SARS-COV-2 virus.

4.This kit is semi-quantitative test and can not quantify the concentration of the SARS-COV-2 neutralizing antibody.

5.The target of this product is the SARS-COV-2 Neutralizing Antibody, which does not directly reflect the presence of the Novel Coronavirus in the sample.

NOTICE

1.This product is used for in vitro diagnosis only.

2.Must strictly follow the instructions for operation and interpretation of the results.

3.The product is qualitatively tested, and the result cannot be used as a quantitative basis.

4.The reagent, straw for single person one-time use, cannot be reused.

5.The samples stored at low temperature should be balanced to room temperature and fully mixed before testing.

6.Samples and waste must be treated as a potential source of infection and the desiccant in the foil bag is not edible.

7.The samples stored at low temperature should be balanced to room temperature and fully mixed before testing.

8.Samples and waste must be treated as a potential source of infection and the desiccant in the foil bag is not edible.

SYMBOLS

Symbol	Used For	Symbol	Used For
	Use-by date		Consult instructions for use
	Batch code		In vitro diagnostic medical device
	Temperature limit		Manufacturer
	Please don't reuse it		Keep away from sunlight
	Don’t use the product when the package is damaged		Keep dry
	Date of manufacture		Tests per kit
	CE Mark		Biological Risks
	Authorized representative in the European Community		

BASIC INFORMATION

Ningbo BESTest Bio-technology Co.,Ltd.
Address: No.80 building, No.777, Qing Feng Road, Cicheng Town,Jiangbei District, Ning Bo, Zhejiang, China 315033
Tel: 0086 571 2799 8736

SUNGO Europe B.V.
Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands.