BZ COVID-19 Neutralizing Ab Test

In vitro diagnostic medical devices

Intended Use

The product is used for the qualitative detection of human serum, plasma samples of Corona Virus (COVID-19) Neutralizing antibody. It is only used as a supplementary test for the nucleic acid test of novel coronavirus or in cooperation with nucleic acid test in suspected cases It cannot be used as a basis for the diagnosis and exclusion of pneumonia caused by novel coronavirus infection, and is not suitable for general screening for medical institution use only, and biosecurity protection should be done in laboratory when testing of novel coronavirus. The results of this kit are only for clinical reference the test result is positive, further confirmation is needed If the test result is negative, the possibility of infection cannot be excluded. Comprehensive analysis of the patient's condition should be carried out in combination with clinical symptoms and other laboratory tests.

Introduction

Coronavirus is a single-stranded positive-sense RNA virus with an envelope of about 80 to 120 nm in diameter. Its genetic material is the largest of all RNA viruses and is an important pathogen of many domestic animals, pets, and human diseases. It can cause a variety of acute and chronic diseases. Common signs of a person infected with a coronavirus include respiratory symptoms, fever, cough, shortness of breath, and dyspnea. In more severe cases, infection can cause pneumonia, severe acute respiratory syndrome, kidney failure, and even death. The 2019 new coronavirus, or "SARS-CoV-2 (COVID-19)", was discovered because of Wuhan Viral Pneumonia cases in 2019, and was named by the World Health Organization on January 12, 2020, confirming that it can cause colds and the Middle East Respiratory Syndrome (MERS) and more serious diseases such as acute respiratory syndrome (SARS). This kit is helpful for the auxiliary diagnosis of coronavirus infection. The test results are for clinical reference only and cannot be used as a basis for confirming or excluding cases alone.

Test principle

The BZ COVID-19 Neutralizing Ab Test detects SARS-CoV-2 neutralizing antibodies in human serum, plasma using a competitive immunochromatographic assay. Colloidal gold-labeled Chicken IgY and COVID-19 spike protein RBD proteins were applied to a conjugation pad, and Goat anti-Chicken IgY and human Angiotensin Converting Enzyme2 (hACE2) proteins were fixed on a nitrocellulose membrane, respectively, and the control ("C") and Make a test group ("T") line. The protein interaction between the COVID-19 spike protein RBD and hACE2 can be blocked by neutralizing the SARS CoV 2 RBD.When testing negative samples, the COVID-19 spike protein RBD labeled with colloidal gold was coated on the test line for human Angiotensin Converting. It binds to the Enzyme2 (hACE2) protein, resulting in a red detection line on the T line.

When a positive sample is placed in the sample well, the COVID-19 spike protein RBD labeled with colloidal gold present in the sample is mixed with the neutralizing antibody in the positive sample and does not bind to the human Angiotensin Converting Enzyme2 (hACE2) protein coated on the test line. These results should be interpreted 10 to 15 minutes after the start of the test.

Principal component (25tests/kit)

Components	Quantity	Storage
Test Cassette with Desiccant	25 EA	2~30℃
Sample Buffer	1 bottle (3mL)	
Instruction For Use	1 EA	

MATERIALS REQUIRED (BUT NOT PROVIDED)

Sample collection device Precision pipette capable of delivering 40ul disposable tips
Gloves. Clock or timer.

WARNINGS AND RECAUTIONS

1. For professional in vitro diagnostic use only.
2. Do not reuse.
3. Do not use if the product seal or its packaging is compromised.
4. Do not use after the expiration date shown on the box.
5. Do not mix and interchange different specimens
6. Wash hands thoroughly after finishing the tests.
7. Clean up spills thoroughly with appropriate disinfectants.
8. Handle all specimens as if they contain infectious agents.
9.. Observe established precautions against microbiological hazards throughout testing procedures
10. Dispose of all specimens and used devices in a proper bio-hazard container.
11. The handling and disposal of the hazardous materials should follow local, regional or national regulations. Keep out of children's reach.
12. It is not possible to diagnose SARS-CoV-2 infection only with the result of this product, and it must be confirmed with a RT-PCR product approved for permission or emergency use, and the final decision by a doctor considering clinical symptoms, etc.
13. This product only checks for the presence of specific antibodies against SARS-CoV-2, and this product alone cannot be used to diagnose SARS-CoV-2 infection.
14. If the concentration of SARS-CoV-2 antibody in the sample is below the detection limit of the test, or if it is improperly collected or transported, a false negative result may be produced. Therefore, SARS-CoV-2 infection cannot be ruled out as a negative result.
15. Even if this product is tested positive, it is not possible to rule out duplicate infection by other pathogens.
16. This product only checks for specific antibodies to SARS-CoV-2, and there is no correlation between the strength (or measured value) of the test line and the titer of the SARS-CoV-2 specific antibody.
17. If there is a mutation in the site to which the antibody contained in this product binds, it may be evaluated as negative.
18. The results of this product cannot be used to determine the SARS-CoV-2 infection status (initial, recovery, etc.).

Storage conditions and expiry date

1. 2~30°C dry, keep away from light, valid for 12 months.
2. The product should be stored in dry condition under 2~30°C and kept away from light. Under the condition of 18~30°C, the humidity is below 60%, use within 1 hour after opening Humidity above 60% it should be used immediately
3. Production date and validity penod are shown in the label

Sample requirements

1. The Serum, plasma samples can be collected by vein in a conventional manner
   Above sample can be placed under 2~8°C for 5 days. Samples under-20°C can be stored for at least 3 months
2. Samples should avoid hemolysis or repeated freezing-thawing. If the sample is turbid or has precipitation, it should be centrifuged or filtered to clarify before testing

SPECIMEN PREPARATION

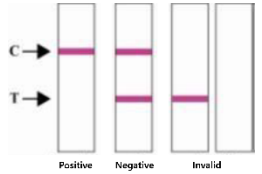
For Serum, plasma samples, collect blood in a tube without anticoagulant and allow it to clot.

Test procedure

This package insert must be read completely before performing the test. Please restore the test card, sample diluent and sample lo 18~30℃ before inspection
Test procedure is as follows:

1. Remove the test card from the aluminum foil bag, mark the sample and put it on the horizontal worktable
2. Sample Test
   Take 25 uL serum, plasma samples to be directly added to the add hole or the bottom of the indicator arrow, and then add the sample buffer 40uL (about 1 drop)
3. Read the results after 10 minutes. Result should be read at 10-15minutes

Interpretation of assay result



1. Positive : C line appears; T line does not appear, indicating a positive result for COVID-19 neutralizing antibody is detected in the sample.
2. Negative : C line appears and T line appears, indicating a negative result for COVID-19 neutralizing antibody.
3. Invalid : C line does not appear. Repeat with a new test kit. If the test still fails, please contact the distributor with the lot number.

QUALITY CONTROL

Although the testing device contains an internal quality control (purple colored band in the control region), good laboratory practice recommends the daily use of an outside control to ensure proper testing device performance. Quality control samples should be tested according to the standard quality control requirements established by your laboratory.

Limitations of the test method

1. The product is only used for the detection of serum, plasma.
2. This product inspection result is only for clinical reference should not serve as the only basis for clinical diagnosis and treatment. The clinical management of patients should be combined with its symptoms or signs, other medical history and laboratory examination, treatment response and epidemiological information such as the comprehensive consideration
3. A negative test does not rule out the possibility of viral infection
4. The target detection object of this product is the antibody of the target Virus, which does not directly reflect the presence or absence of the virus in the sample
5. Because the concentration level at which neutralizing antibodies are protective is unknown, positive neutralizing antibody tent does not imply the ability to protect individuals from Corona Virus (COVID-19) infection

Product performance Indicator

1. Smooth appearance, solid material attachment, complete contents, complete packaging no damage, clearly identifiable signs, no impurities were found in the sample extract
2. Test Strip width conform to 35 ± 0.2mm
3. The moving speed of sample diluent ≥10mm per minute
4. Compliance rate of positive quality control products, inspection 10 positive quality control products, PI ~ P3 Corona Virus (COVID-19) neutralizing antibody is required to be positive.

Description of Symbol Used

Symbol	Description	Symbol	Description
REF	Catalogue number	⚠	Caution
LOT	Batch code		Manufacturer
	Use-by date		Consult instructions for use
	Upper limit of temperature		

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