CE IVD

SARS-CoV-2 Neutralizing Antibody Rapid Test Cassette
(Colloidal Gold Method)

【Product Name】

SARS-CoV-2 Neutralizing Antibody Rapid Test Cassette (Colloidal Gold Method)

【Package specification】

1 Test/bag, 1/20/30/50/100 Tests/Kit

【Intended Use 】

This kit is intended for qualitative detection of SARS-CoV-2 neutralizing antibody in human serum, plasma or whole blood specimen. This kit is intended for use as an aid in identifying individuals with an adaptive immune response to vaccination or natural infection.

Neutralization antibody is a soluble protein secreted by adaptive immune response cells. It specifically binds to the receptor binding domain (RBD) of the virus, thus blocking the binding of the RBD to angiotensin converting enzyme 2 (ACE2) on the surface of human cells. Through the above process, neutralizing antibodies can prevent genetic materials of virus from entering cell for proliferation, thus preventing virus from infecting cell and neutralizing virus toxicity.

【Principle】

This kit applied the chromatographic immunoassay technology is a blocking detection tool. Using purified receptor binding domain (RBD), protein from the viral spike (S) protein and the host cell receptor ACE2, this kit is designed to mimic the virus-host interaction by direct protein-protein interaction on the test strip. If there are neutralizing antibodies to SARS-CoV-2 in the specimen and their concentration exceed the limit of detection, the antibodies will bind to RBD marker and block RBD binding to the ACE2 in the test area (T line), not showing a red reaction line, it indicate a positive in neutralizing antibodies; otherwise, it is negative. The quality control area (C line) should be colored to indicate that the test is valid.

【Components】

The kit consists of test card, diluent (dropper), desiccant.

1. Test card: SARS-CoV-2 neutralizing antibody test strip and plastic cassette. The test strip is made up of nitrocellulose membrane (T line is coated with recombinant human ACE2 protein, and C line is coated with rabbit anti-chicken IgY) , sample pad, binding pad (sprayed with Colloidal Gold labeling recombinant RBD antigen and chicken IgY) , absorbent paper and PVC board.
2. Diluent (dropper): buffer containing phosphate (pH6.5-8.0).
3. Desiccant: a bag containing silica.

Note: Do not mix the component of kits from different lot in order to avoid error test result.

【Storage & Expiry】

The unopened kit should be stored at 2~30℃, and the validity period is 12 months. When open the foil bag, The test card should be used within one hour. It should be covered and put in the dark once open the bottle of diluent.

Production date and expiry date are shown on the label.

【Specimen Requirements】

Human serum, plasma or whole blood specimen can be used in the test.

Serum/plasma specimen: the Specimen should be tested after collection. If they cannot be tested timely, they should be stored at 2℃ ~8℃ or kept at -20℃ for no more than 3 days. Before test, it should be restored to room temperature. Avoid repeated freezing and thawing. It is not recommended to use specimen with severe hemolysis or heat inactivation.

Whole blood specimen: the Specimen should be tested after collection. If they cannot be tested timely, they should be stored at 2 ℃ ~8 ℃ less than 7 days.

【Test Procedure】

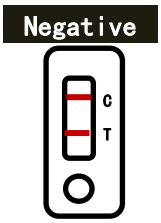
Please read the instruction before use. The test card and other materials shall be restored to room temperature before test. The test shall be conducted at room temperature.

1. Open the aluminum foil bag along the tearing line, take out the test card and lay it flat.
2. Drian 20uL serum/plasma/whole blood specimen with a pipette into the specimen well on the test card, and then drian about 80uL (2 drops) specimen diluent with a pipette into the specimen well.
3. Read the result visually within 10 minutes. The result read after 20 minutes has no clinical significance.

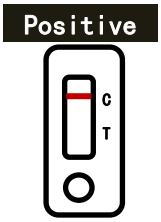
【Explanation of test results】

As shown in Figures, the test results are as follows:

1. **Negative:** clear red C line and red T line appear in the reaction well indicate a negative in neutralizing antibodies.



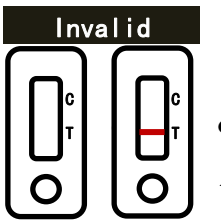
2. **Positive:** only a clear red C line appears in the C line.



3. **Invalid: any case listed below indicate a invalid test,** you need to find the cause and retest.

   1) no reaction line appears in the reaction wells;

   2) only T line appears in the reaction well.



【Limitations】

The test results are only used as an assisted clinical diagnosis. They are not the only reference for clinical diagnosis. The clinician should also make a comprehensive judgment based on the patient's physical condition, medical history, and other diagnostic items and diagnostic methods.

1. This kit is only for detection of specimen from serum, plasma and whole blood.

2. The accuracy of test depends on the specimen collection. Inappropriate collect, storage or repeated freeze-thaw cycle of specimen would affect the test result.

3. This kit is only for qualitative diagnosis of total neutralizing antibodies to SARS-CoV-2 in the serum, plasma and whole blood specimen and cannot determine the concentration of antibodies. Please use other devices for quantitative diagnosis.

4. The test results of this kit are only for clinical reference, and shall not be the only basis for clinical diagnosis and treatment. The clinical management of patients should be considered comprehensively in combination with their symptoms/signs, medical history, other laboratory tests and treatment reactions.

5. Positive results may be due to current or past infection with non-SARS-COV-2 corona virus strains, such as SARS-COV-1, HKU1, NL63, OC43, or 229E. NDH SARS-CoV-2 Neutralizing Antibody Rapid Test Cassette is known to cross-react with SARS-CoV-1 neutralizing antibodies.

6. Analysis of possibilities for false negative

a) Inappropriate specimen treatment or preservation, such as high temperature or repeated freeze-thaw cycle, may cause inactivation of neutralizing antibodies, leading to the false negative result.

b) The time is too short since vaccination (within two weeks) for the body to produce enough neutralizing antibodies, which may lead to false negative result.

【Performance Indicators】

1. Positive reference rate: 100 positive specimens of SARS-CoV-2 neutralizing antibodies were detected,

all results should be positive.

2. Negative reference rate: 100 negative specimens of SARS-CoV-2 neutralizing antibodies were detected, all results should be negative.

3. Minimum detection limit: the National Standard for SARS-CoV-2 Neutralizing Antibodies were detected, greater than or equal to 10U/mL was positive, or else was negative.

4. Precision: one positive specimen of SARS-CoV-2 neutralizing antibodies was detected for 10 times, all results should be positive.

5. Analytical specificity:

a) This product has no cross reaction with positive specimens from SARS-CoV-2 nucleoprotein antibody, Para influenza virus antibody, influenza A virus antibody, influenza B virus antibody, Chlamydia pneumonia antibody, Mycoplasma pneumonia antibody, adenovirus antibody, respiratory syncytial virus antibody, hepatitis B virus antibody, hepatitis C virus antibody, Treponema palladium antibody, human immunodeficiency virus antibody, EB virus antibody, measles virus antibody, cytomegalovirus antibody and enterovirus 71 antibody.

b) It would not interfere with the test results of the SARS-CoV-2 antibodies when the bilirubin concentration was less than 200 mol/L, the hemoglobin concentration was less than 10g/L, the triglyceride concentration was less than 15mmol/L, the rheumatoid factor concentration was less than 100IU/ml, the anti-mitochondrial antibody (AMA) was less than 70U/ml, and the IgG content of mice was less than 1000ug/ml.

【Precautions】

1. This kit is for disposable use. Do not re-use it or use it after expiry.

2. Avoid high temperature during test. The test card and diluent shall be restored to room temperature before use to avoid excessive humidity.

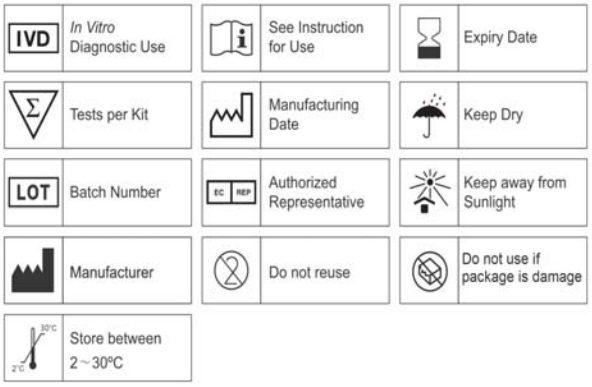
3. Do not mix components from different batches. Do not mix with components from other manufacturers.

4. After test, the used test card, diluent, desiccant shall be treated as biomedical waste.

5. The desiccant in the aluminum foil pouch, which shall not be taken internally.

6. Do not use repeated freeze-thaw specimen. Please restore the specimen to room temperature before test.

7. The specimen shall be regarded as infectious product, and the operation shall be in accordance with the operation specifications of infectious disease laboratory.



【Manufacturer】

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【Manual Approved/Amended Date】

Approval Date: January 2021