BALLYA®
璞雅生物

COVID 19 Neutralizing Antibody Rapid Test

(Immunochromatography)

For in vitro diagnostic use only.

Cat. No.: CNA-19 / CNA-20 / CNA-21 / CNA-22 / CNA-23

Package: 1T, 5T, 10T, 20T, 50T

PRODUCT NAME

COVID 19 Neutralizing Antibody Rapid Test (Colloidal Gold)

INTENDED USE

This kit can detect circulating neutralizing antibodies against SARS-CoV-2 that block the interaction between the receptor binding domain of the viral spike glycoprotein (RBD) with the ACE2 cell surface receptor. The assay detects any antibodies in serum,plasma and whole blood that neutralize the RBD-ACE2 interaction.The test is both species and isotype independent.

TEST PRINCIPLE

This kit is a blocking colloidal gold detection tool, which mimics the virus neutralization process. The Kit contains two key components: Colloidal gold (Au) binds recombinant SARS-CoV-2 RBD fragment protein and human ACE2 receptor protein (HACE2). The protein-protein interaction between gold-labeled protein-SARS-CoV-2 RBD and ACE2 can be blocked by neutralizing anti-SARS-CoV-2 RBD antibody.

This Kit mimics the neutralization process of the virus and is detected by colloid gold immunochromatography. The Kit uses recombinant SARS-CoV-2 spinous process protein RBD labeled colloidal gold, and the recombinant human ACE2 protein is coated with nitrocellulose membrane (NC membrane). The interaction between RBD and ACE2 can be blocked by the SARS CoV-2 neutralizing antibody.This Kit uses the principle of colloid gold immunochromatography to qualitatively detect neutralizing antibody against novel coronavirus in human serum, plasma, whole blood or fingertip blood samples.

Key components:

Chloroauric acid, Gold-labeled recombinant SARS-CoV-2 RBD protein, gold-labeled chicken antibody, recombinant human ACE-2 receptor protein, goat anti-chicken antibody, nitrocellulose membrane, glass cellulose pad, absorbent paper, PVC backing card

MATERIALS SUPPLIED

Test Cassette
Disposable Venous Blood Lancet
Alcohol Pad
Dropper
Extraction Buffer Solution
Instruction For Use

MATERIAL REQUIRED BUT NOT PROVIDED

1. Clock or Timer
2. Gloves

WARNINGS AND PRECAUTIONS

1. This product is a single-use in vitro diagnostic reagent. Do not reuse it. Do not use it if it is expired.
2. Each component of the kit cannot be used in batches.
3. The positive result obtained by using this kit needs further confirmation by other methods.
4. Excessive temperature of the experimental environment should be avoided. The reaction temperature should be 10~30℃. The test cassette stored at low temperature should be recovery to room temperature before opening to

avoid moisture absorption.
5. The intensity of the color of the test line is not necessarily related to the concentration of the antigen in the sample, and the result interpreted after 15 minutes is invalid.
6. It is recommended to use fresh samples, do not use repeatedly freeze-thaw samples.
7. Avoid cross-contamination of samples by using a new plastic cup and pipette dropper for each sample.
8. The components of the kit and the waste produced by the test are treated as infectious pollutants.
9. For clinical reference only, and cannot be used as a basis for confirming or excluding cases alone.

STORAGE AND SHELF LIFE

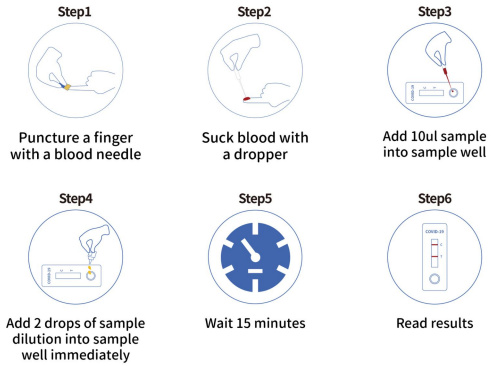
1. Store at 2℃ to 30℃ in the sealed pouch up to the expiration date (24 months).
2. Keep away from sunlight, moisture and heat.
3. DO NOT FREEZE.
4. Use it within 1 hour after opening. Production date, expiry date will be in the label.

SAMPLE COLLECTION

1. The recommended samples for this kit are serum, plasma and whole blood. Plasma and whole blood can be collected by blood collection tube or centrifuge tube with EDTA-2K or heparin sodium anticoagulant.
2. The samples collected with the correct medical technology should be returned to room temperature before testing. Jaundice, hemolysis, lipemia, and cloudy samples cannot be used. Severe hemolytic or heat-inactivated specimens are not recommended.
3. Samples should be tested as soon as possible. If the test cannot be completed within 8 hours, the samples can be stored at low temperature. Serum and plasma can be stored for 7 days at 2-8℃or for 6 months at -20℃, and whole blood can be stored for 3 days at 2-8℃. Do not freeze and thaw samples repeatedly.
4. Recovery the test kit and specimen to room temperature before start.

FINGERTIP BLOOD SPECIMEN COLLECTION

1. Wipe to clean the puncture site on your finger with the alcohol pad.
2. Remove the cap from safety lancet, push the lancet firmly against the puncture site.
3. Use the disposable pipette to draw the blood from puncture site.

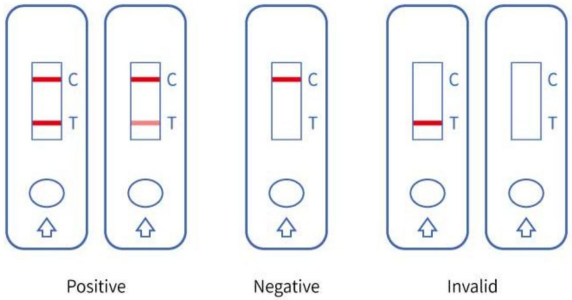


TEST PROCEDURE

1. Add 10ul sample into sample well
2. Add 2-3drops buffer into sample well
3. Wait for 15 minutes
4. Read results

INTERPRETATION OF RESULTS

Positive: T and C lines are visible
Negative: Only C line is visible
Invalid: No lines visible or only T line visible



CONTROL PROCEDURE

The test kit has its own built-in quality control indicator. After performing the test and no line in the Control area (C) of the reaction membrane is visible, the sample has not been added correctly or the test may have deteriorated.

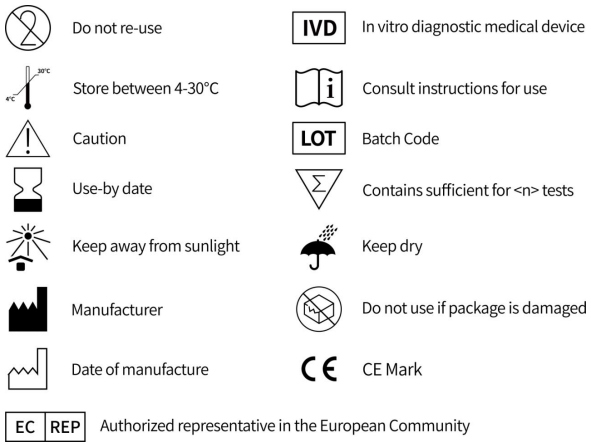
LIMITATIONS

1. This kit is only for the detection of neutralizing antibody against SARS-CoV-2.
2. The accuracy of the test depends on the sample collection, handing, storage and operation procedure. Improper sample collection, improper storage of samples, unfresh samples, or repeated freeze-thaw cycles of samples will affect the test results.
3. The test cassette only provides qualitative detection of neutralizing antibody against SARS-CoV-2 in the sample. If you need to detect the specific content of an indicator, please use the relevant professional instruments.
4. The test result of this kit is for clinical reference only and should not be used as the sole basis for clinical diagnosis and treatment. The clinical management of patients should be considered in combination with their symptoms/signs, medical history, other laboratory tests, and treatment responses.
5. Due to the limitation of the method of immunochromatography assay, its analytical sensitivity is generally lower than that of nucleic acid reagents. Therefore, the experimenters should pay more attention to the negative results and need to make a comprehensive judgment in combination with other test results. It is recommended to review the suspicious negative results by using nucleic acid detection or virus culture identification methods.
6. This test is only provided for use by clinical laboratories or to healthcare workers for point-of-care testing.
7. The test is for qualitative detection of neutralizing antibodies in human fingertip blood, serum and plasma specimens. It does not indicate the quantity of the antibodies. The intensity of the test line does not necessarily correlate to SARS-CoV-2 antibody titer in the specimen.
8. The test results should be interpreted at 15 minutes after addition of buffer. The test results should not be interpreted after 15 minutes.
9. Negative results do not preclude SARS-CoV-2 infection and immunity to SARS-COV-2 infection, it should not be used as the sole basis for patient management decisions. False positive results for antibodies may occur due to cross-reactivity from preexisting antibodies or other possible causes.
10. A negative result can occur if the quantity of antibodies for the SARS-CoV-2 virus present in the specimen is below the detection limit of the assay, or if the virus has undergone minor amino acid mutation(s) in the epitope recognized by the antibody used in the test.
11. Results from antibody testing should not be used to diagnose or exclude SARS-CoV-2 infection or to inform infection status.
12. A positive result may not indicate previous SARS-CoV-2 infection. Consider other information, including clinical history and local

disease prevalence, in assessing the need for a second but different serology test to confirm an immune response.

13. Not for the screening of donated blood.

INDEX OF SYMBOL



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