CE IVD

SARS-CoV-2 IgG/IgM Rapid Test Cassette
(Colloidal Gold Method)

【Product Name】

SARS-CoV-2 IgG/IgM Rapid Test Cassette (Colloidal Gold Method)

【Package specification】

20/40/50/100 Tests/Box

【Intended Use 】

This kit is used for in vitro qualitative diagnostic of SARS-CoV-2 IgG/IgM in human serum, plasma or whole blood specimen. It is intended for use of screening test and aid in the diagnosis of SARS-CoV-2 virus infections. This kit is for professional in vitro diagnosis only.

【Principle】

This kit applies the chromatographic immunoassay technology to capture the SARS-CoV-2 IgG/IgM antibodies in human serum, plasma or whole blood specimen. If there is SARS-CoV-2 antibodies IgG/IgM in the specimen and its concentration exceed the limit of detection, the antibodies will bind to antigen marker and be captured by the second antibody (Anti IgM μ-chain antibody / anti IgG antibody) in the G line or M line, showing a red reaction line, it indicates a positive in SARS-CoV-2 IgG and/or IgM; 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 IgG/IgM antibodies test strip and plastic cassette. The test strip is made up of nitrocellulose membrane (G line is coated with mouse anti-human IgG antibody, M line is coated with mouse anti-human IgM μ-chain antibody, and C line is coated with rabbit anti-chicken IgY), sample pad, binding pad (sprayed with Colloidal Gold labeling recombinant SARS-CoV-2 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】

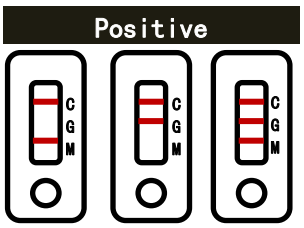
Please read the instruction before use. The test card and other materials shall be restored to room temperature before test. The test shall be conducted at room temperature.

1. Open the aluminum foil bag along the tearing line, take out the test card and lay it flat.
2. Drip 10ul serum/plasma/whole blood specimen with a pipette into the specimen well on the test card, and then drip about 100ul (2 drops) specimen diluent with a pipette into the specimen well.
3. Read the result visually within 15minutes. The result read after 20 minutes has no clinical significance.

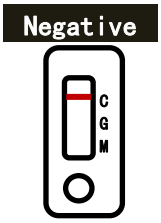
【Explanation of test results】

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

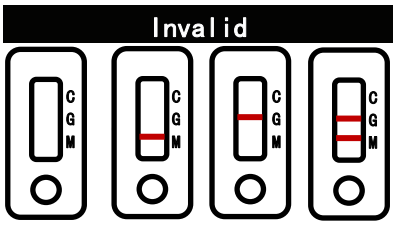
1. **Positive:** clear red C line and red M line appear in the reaction well indicate a positive in SARS-CoV-2 IgM; clear red C line and red G line appear in the reaction well indicate a positive in SARS-CoV-2 IgG; clear red C line, red G and M lines appear in the reaction well indicate a positive in SARS-CoV-2 IgM and IgG.



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



3. **Invalid: any case listed below indicate an invalid test,** you need to find the cause and retest.
   1)no reaction line appears in the reaction wells
   2) only M line appears in the reaction well
   3) only G line appears in the reaction well
   4)only red G and M Lines appear in the reaction



【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 SARS-CoV-2 IgG/IgM 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. Due to limitation of the methodology of antibody detection kit, it is recommended to use nucleic acid detection or virus culture identification method to confirm positive test results.

6. Analysis of possibilities for false negative

a) Inappropriate specimen collection, transit or treatment, or extreme low concentration of antibodies in specimen may lead to false negative result.

b) The mutation of virus gene may lead to the change of antibody determinants, which may lead to false negative result.

c) The best specimen type and the best sampling time (peak virus titer) after infection have not been verified. Therefore, it is possible to avoid false negative when samples are collected from same patient in several times and multiple locations.

【Performance Indicators】

1. Positive reference rate: three positive specimens of SARS-CoV-2 antibodies were detected; all results should be positive.

2. Negative reference rate: three negative specimens of SARS-CoV-2 antibodies were detected; all results should be negative.

3. Minimum detection limit: three positive specimens of SARS-CoV-2 antibodies with minimum detection limit (S1-S3) were detected, S1 result is negative, S2

and S3 are positive.

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

5. Analytical specificity:

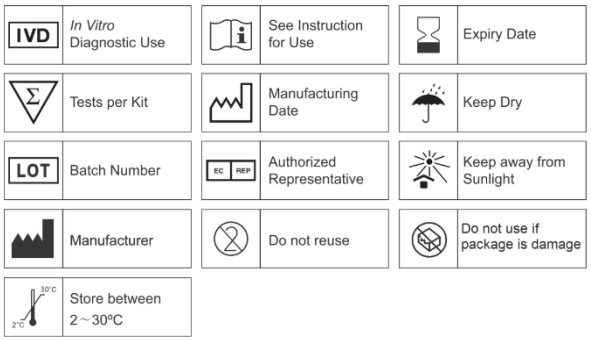
a) This product has no cross reaction with positive specimens from human local coronavirus (HKU1,OC43, 229E) antibody, Para influenza virus antibody, influenza A virus antibody, influenza B virus antibody, Chlamydia pneumonia antibody, Mycoplasma pneumonia antibody, adenovirus antibody, respiratory syncytial 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 250 mol/l, the hemoglobin concentration was less than 9g/l, the triglyceride concentration was less than 15mmol/l, the rheumatoid factor concentration was less than 80IU/ml, the antinuclear antibody (ANA) titer was less than 1:249, the anti-mitochondrial antibody (AMA) was less than 80U/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. After test, the used test card, diluent, desiccant shall be treated as biomedical waste.
4. The desiccant in the aluminum foil pouch, which shall not be taken internally.
5. Do not use repeated freeze-thaw specimen. Please restore the specimen to room temperature before test.
6. The specimen shall be regarded as infectious product, and the operation shall be in accordance with the operation specifications of infectious disease laboratory.
7. If you have any questions or suggestions during the use of this kit, please contact the manufacturer.

【Definition of Symbols】



【Manufacturer】

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EC REP

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【Manual Approved/Amended Date】

Approval Date: May 2020