GB's QUIK
COVID-19 Antibody IgG/IgM Detection Kit
(Colloidal Gold Lateral Flow Method)

GENUINE BIOSYSTEM

INTENDED USE

This product is used for in vitro qualitative detection of COVID-19 (SARS-CoV2) IgG/IgM antibodies in human serum, plasma or whole blood samples.

The coronavirus belongs to the new coronavirus of the genus β, which has an envelope, the particles are round or oval, often polymorphic, and the diameter is 60 ~ 140nm. Its genetic characteristics are significantly different from SARSr-CoV and MERSr-CoV. Current research shows that it has more than 85% homology with bat SARS-like light viruses. [1] There are three proteins on the surface of the coronavirus envelope: Spike Protein (S), Envelope Protein (E) and Membrane Protein (M). After the virus invades the human body, it produces specific antibodies, which can be detected by immunochromatography. This kit is only used as a supplementary indicator for suspected cases of new coronavirus nucleic acid detection or used in conjunction with nucleic acid detection in the diagnosis of suspected cases. It cannot be used as a basis for the diagnosis and exclusion of pneumonitis infected by new coronavirus. check.

PRINCIPLE

This assay uses colloidal gold immunochromatographic technology to detect COVID-19 IgM / IgG antibodies. The test card is coated with colloidal gold-labeled COVID-19 protein, anti-human IgG antibody (detection line, 1 line area), anti-human IgM antibody (detection line, 2 line area) coated on a nitrocellulose membrane, and Sheep anti-mouse IgG polyclonal antibody (quality control line, C line area).

During detection, the IgM / IgG antibodies (specific IgM / IgG antibodies and non-specific IgM / IgG antibodies) in the sample to be tested are bound to the colloidal gold-labeled COVID-19 protein; under the action of chromatography, The film is moved. If the test sample contains COVID-19 IgM / IgG antibody, it will be captured by the anti-human IgM / IgG antibody coated on the nitrocellulose membrane in the T-line area, forming a visible red band; The test sample does not contain the COVID-19 IgM / IgG antibody, so no red band appears in the T-line area; the free colloidal gold-labeled COVID-19 protein or immune complex continues to migrate forward with the C-line area coated goat A murine IgG polyclonal antibody bound and a red band appeared. The red band on line C is the criterion for determining whether the tomographic process is normal.

MAIN COMPONENTS

COMPONENTS	QTY
Test Casette	25 Nos
Diluent Buffer	1 Vial
Sample Dropper	25 Nos

STORAGE CONDITION AND STABILITY

1.The original package is stored at 2℃~30℃ protected from light and dry.

2. The validity period is tentatively set for 6 months. The reagent should be should be used as soon as possible.

3.See the kit label for the production date and expiration date.

SAMPLE REQUIRED

1. Sample type: human serum, plasma or whole blood (anticoagulant: EDTA, heparin, sodium citrate).

2. Sample collection: sample collection according to the requirements of the permit.

3. Sample storage: Serum or plasma samples can be stored for 3 days at 2℃~ 8 ℃, long-term storage below -20 ℃. It is recommended that whole blood samples be stored at 2℃ to 8℃ and tested within 3 days; do not store frozen. A special library or counter should be set up to keep specimens separately. Avoid repeated freeze-thaw cycles during specimen transport. [1]

TEST PROCEDURE

1. **Prepare**

1.1 Read the instructions carefully, and restore the test card and dilution to 20℃ ~ 30℃

1.2 Remove the test card from the single package and lay it flat on the test bench.

2. **Detection**

2.1 Adding samples

Serum / plasma sample: Take one drop (or) 10μL of serum or plasma sample, add it to the well of the test card, add 2 drops of sample dilution, and start timing detection;

Whole blood sample: Take two drop (or) 20μL of serum or plasma sample, add it to the well of the test card, add 2 drops of sample dilution, and start timing detection;

2.2 Timing test: Start timing after the sample is added, and detect it in 3 ~ 15 minutes; observe and record the result when it is for 15 minutes; Please do not read the result after 15 minutes.

INTERPRETATION OF RESULTS

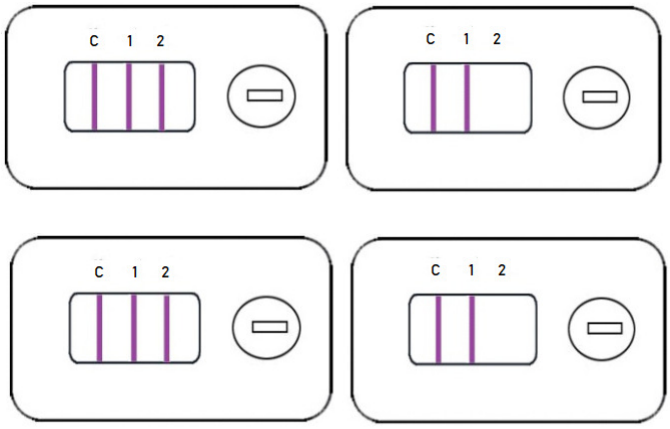

Figure - 1 Figure- 2

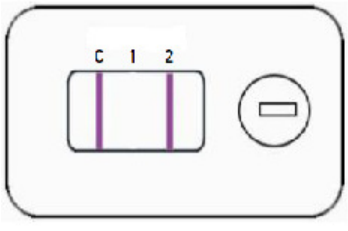

Figure - 3

2. **Negative:** As shown in Figure ④, only a clear red C line appears in the reaction well;

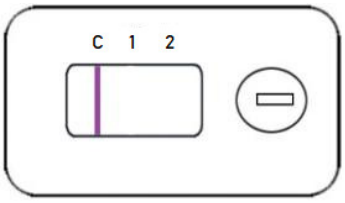

Figure - 4

3.**Invalid:** as shown in Figure ⑤, only red T1 and T2 lines appear in the reaction well; as shown in Figure ⑥, only T1 lines appear in the reaction well; as shown in Figure ⑦, only T2 lines appear in the reaction well; As shown in Figure ⑧, no reaction line appears in the reaction wells, which indicates that the test is invalid. You need to find the cause and retest.

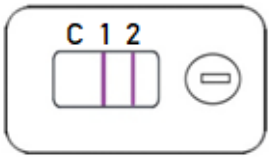

Figure-5

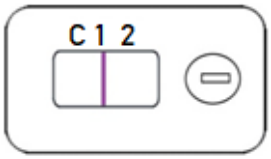

Figure-6

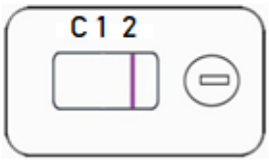

Figure-7

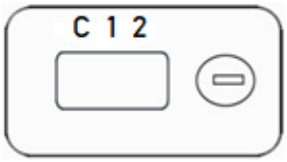

Figure-8

A positive antibody test not only occurred in the primary infection, but also increased the reactivity of IgM / IgG antibodies in the secondary infection. The test object of this kit is COVID-19 IgM / IgG antibody, and the results cannot indicate whether there is a new coronavirus in the sample.

LIMITATION

1.This kit is a qualitative detection reagent. The results are visually interpreted. The interpretation of the test results will be affected by human factors (such as visual differences) and the testing environment (such as temperature and brightness). In order to reduce the difference, the test should be performed under the same conditions as much as possible.

2. Because the new coronavirus protein shares some epitopes with other viruses (such as SARS-CoV and MERS-CoV, etc.), cross-reactions with other virus infections may produce false positive results.

3. The study found that the effect of this kit on rheumatoid factors will lead to false positive results.

4.In the early stage of infection, if COVID-19 IgM / IgG antibody is not produced or the titer is very low, it will lead to a negative result. It is recommended that the patient re-examine within 7 to 14 days. During the re-examination, the last sample collected is tested in parallel to confirm whether there is a serological positive .

5.Patients whose immune function is impaired or receiving immunosuppressive therapy have limited reference value for serological antibody detection.

6. Hemolytic, sticky, high-fat, long bacteria and contaminated samples cannot be used for the detection of this kit.

7. Hemoglobin (≤50mg / mL), bilirubin (≤0.1mg / mL), and triglycerides (≤ 10mg / mL) have no effect on the measurement results.

8. This product has no cross-reactions to the following: ① endemic human coronavirus (HKU1, OC43, NL63 and 229E); ② H1N1 (new H1N1 influenza virus (2009), seasonal H1N1 influenza virus), H3N2, H5N1 H7N9, influenza B Yamagata, Victoria, respiratory syncytial virus, rhinovirus A, B, C group, adenovirus 1, 2, 3, 4, 5, 7, 55, enterovirus A, B, C, D group EB virus, measles virus, human cytomegalovirus, rotavirus, norovirus, mumps virus, varicella-zoster virus; ③Mycoplasma pneumoniae.

PERFORMANCE INDEX

1. Appearance: the outer package is complete, no damage, no pollution, and the label is clear and legible
2. Net content: The net content of the dilution should not be less than the indicated value.
3. Film strip width: should not be less than 2.5mm.
4. Liquid migration speed: The liquid migration speed should not be less than 10mm / min.
5.Negative and positive reference rate: The negative and positive reference rate of testing enterprises (-/-) ≥ 9/10; positive rate (+ / +) ≥ 9/10.
6. Repeatability: The repeatable reference product of the enterprise shall be tested, and the response results shall be consistent, and the color rendering shall be uniform.
7. Detection limit: the detection limit reference product of the detection enterprise, and the results should meet the requirements of the detection limit reference product.
8. Analysis specificity: detection of human IgG antibody, human IgM antibody interference factors, the result should be negative

PRECAUTION

1. For in vitro diagnostic use only.
2. Test cards and straws are disposable test supplies and cannot be reused.
3. The use of this kit and the waste after use have potential biosafety risks. Use and disposal of waste in accordance with the requirements of the Regulations on Biological Safety Management of Pathogen Microbial Laboratories to prevent pollution to people and the environment harm.
4. Due to the different sample titres, the red lines of the test line will show different shades of color, all indicating positive results. The depth of the test line color cannot be used as a basis for judging the antibody titer in the sample.
5. Products that leak or leak due to transportation, or reagents that have not been maintained in accordance with the instructions during transportation and storage must not be used.
6. Avoid direct contact with skin and eyes. Do not swallow.

REFERENCES

1. Technical Guide for 2019-nCoV Laboratory (the 4th Edition), Ministry of Health, PRC
2. Guidelines for public protection of pneumonia due to novel coronavirus infection, Chinese CDC.
3. N Zhu, D Zhang, W Wang,et. A novel coronavirus from patients with pneumonia in China, 2019[J].New England Journal of Medicine,.2020. DOI: 10.1056/NEJMoa2001017
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4. JRE Bridgen, DAT Cummingset.Novel coronavirus COVID-19: early estimation of epidemiological parameters and epidemic predictions [J], medRxiv,2020.

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