No.IFU-COVIDIgG/IgM-01,Ver.1.5

CE

COVID-19（SARS-CoV-2）IgG/IgM Antibody Test Kit (Colloidal Gold)

Intended use

COVID-19（SARS-CoV-2）IgG/IgM Test is used for qualitative detection of novel coronavirus IgG/IgM antibodies in human serum, plasma and whole blood. After infection with the novel coronavirus, the common signs include respiratory symptoms, fever, cough, wheezing and dyspnea, etc. In more severe cases, the infection can lead to pneumonia, severe acute respiratory syndrome, kidney failure and even death. Coronaviruses can be expelled from the body through respiratory secretions, transmitted by oral fluids, sneezing, contact, and by airborne droplets.

Principle

COVID-19（SARS-CoV-2）IgG/IgM Test is the detection principle of colloidal gold marked recombinant novel coronavirus (COVID-19) antigen, while nitrocellulose membrane is coated with rat anti-human IgM, rat anti-human IgG and sheep anti-mouse polyclonal antibodies, when specimens containing IgM antibody with colloidal gold marked a novel coronavirus antigen form compounds, the compounds in rat anti-human IgM antibody was captured, presents the colored lines, if the specimen contains IgG antibody,And colloidal gold marked a novel coronavirus antigen form compounds, the compounds was caught the rat anti-human IgG antibody, presents the colored line, when specimens containing IgG and IgM at the same time, form 2 lines at T1 and T2, extra colloidal gold complexes and sheep anti-rat polyclonal antibody to form a line, as quality control line.When there is no IgG and IgM antibody in the sample, only the quality control line presents the color, which is negative.

Warnings and Precautions

1. This product is only used by professional institutions.For in vitro diagnostic use only. Operation should be carried out in strict accordance with the instructions, do not use expired or damaged products.
2. Only the diluent in the package can be used.
3. Do not use tap water, purified water and distilled water as negative controls.
4. The test device should be used within 1 hour after unsealing. If the ambient temperature is higher than 30°C or more humid, use immediately after tearing.
5. If there is no liquid migration in the test window within 30 seconds after adding the detection solution, add another 1 drop of detection solution.
6. Pay attention to the possibility of virus infection when collecting specimens, wear disposable gloves, masks, etc., after washing hands.
7. The test device is disposable. The test device and specimen after use shall be regarded as medical waste with biological infection risk and properly disposed of according to relevant national regulations.
8. False positive test results may be comes out if the person who have an allergic reaction or a high ferritin level.
9. In the early stage of infection, antibodies to the new coronavirus lgM and lgG that are not produced or have low titers will lead to negative results and should be reviewed within 7-14 days. During the re-examination, the last sample collected should be tested in parallel to confirm whether there is a serological positive or a significant increase in titer. Confirmation of infection with the new coronavirus should be performed in conjunction with the clinical manifestations of the patient or in combination with other methods.
10. Do not add too much sample, it should be controlled at about 10μl.
11. If using a dropper for sampling, the amount of sample is about 1 drop; if using a micro-sampling tube, take a 10μl scale line when s ampling, and then add it to the sample well of the reagent card.
12. The 10μl scale is the first scale from the lower end of the micro -sampling tube, and the upper end is coarse scale mark line，When sampling, the micro-sampling tube should be slightly tilted. After the sampling is completed, one end of the thick scale line is in serted into the rubber head, and then the sample is added.
13.It takes a while for humans to develop an immune response after infection with the new coronavirus. According to the seventh edition of the clinical diagnosis and treatment guidelines for new coronavirus pneumonia published by the Chinese government: New coronavirus-specific IgM antibodies usually appear after 3-5 days of onset, the recovery period of IgG antibody titer was 4 times or more higher than that of the acute phase. Testing is recommended to begin 5 days after infection.

Materials and Components

Materials provided

1. COVID-19 （ SARS-CoV-2 ） IgG/IgM Antibody test cassette(Contains 1 desiccant ,1 pcs test device)
2. Buffer: 1 bottle per box
3. Instruction: 1pcs per box
4.Dropper or micro-sampling tube

Materials required but not provided

Timer.
specimen collection container

Storage and Stability

1. The kit should be stored at room temperature (4-30°C).
2. Keep in a dry place away from light.
3. Do not freeze the test kit.
4. Expiry date: 24 months.Use within 1 hour after opening

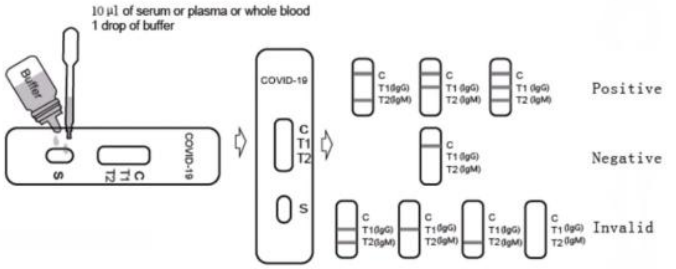
Specimen Collection and Preparation

1. COVID-19（SARS-CoV-2）IgG/IgM Test can be performed used on Whole Blood/ Serum/ Plasma.
2. Collection of serum/plasma specimens: serum and plasma should be separated as soon as possible after blood collection to avoid hemolysis.The separated serum and plasma should be tested as soon as possible within 8 hours. If it cannot be used immediately, it should be stored at 2℃ ~ 8℃ for 7 days.More than 7 days should be placed in -20℃ cryopreservation, can be stored for 6 months, before the test, pay attention to return to room temperature, avoid repeated freeze-thaw.
3. Venous whole blood collection: collect blood with anticoagulant tube, or first add anticoagulant (heparin and EDTA salt are recommended) into the blood collection vessel, then add the collected blood specimens and shake them well.It can be stored at room temperature for 8 hours. If it cannot be immediately detected, it can be stored at 2~8℃ for 7 days. The whole blood specimen of vein over 7 days is not suitable for this reagent.
4. Fingertip blood collection: blood should be taken immediately after the finger is punctured with a disposable blood collection needle to avoid coagulation.

Test Procedure

Read the instructions carefully before use and bring tests, buffer and specimens were restored to room temperature.

1. 10μl of serum/plasma/whole blood was absorbed and added to the specimen hole (S).
2. Add 1 drop of sample diluent to the test card specimen hole (S).
3.Wait for the colored line(s) to appear. The result should be read at 10-15 minutes. Do not interpret the result after 30 minutes.



Interpretation of Result

Positive：1. Two or three distinct lines appear. One line should always appear in the control line region (C), and another one or two apparent colored line(s) should appear in the test line region(s) (T1 and T2).
2. If a line appears on the quality control line, a line appears on the test line T1, and no sline appears on the test line T2, it indicates that IgG antibody is present in the specimen and no IgM antibody is present.
3. If a line appears on the quality control line, a line appears on the test line T2, and no sline appears on the test line T1, it indicates that IgM antibody is present in the specimen and no IgG antibody is present.。

Negative: One colored line appears in the control region (C). No Apparent colored lines appear in the test lines regions (T1 and T2).

Invalid: Control line(C) fails to appear. Insufficient specimen volume or incorrect procedural technologies are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

Note: The red line in the test line (T) can show different shades of color. However, even a very weak line should be judged as a positive result during the specified observation period, regardless of the color of the line.

Quality Control

A red line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume.

Limitations of Procedure

1. This product is only used for qualitative detection of new coronavirus (COVID-19) IgG / IgM antibodies in vitro.
2. This product is only used as a supplementary detection indicator for suspected cases of new coronavirus negative 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. It is limited to medical institutions. It is not suitable for general population screening and cannot be used for self-testing.
3. The negative result may be due to the lower antibody concentration than the analytical sensitivity of the product.
4. The accuracy of the test depends on the specimen collection process,improper specimen collection, improper specimen storage or repeated freezing and thawing of specimens will affect the test results.
5. It has been found in this product study that allergy or abnormal ferritin increase may lead to false positive, and its mechanism needs further study.

Performance index

1. **Physical characters**

1.1 Appearance: The test should be clean and complete, no burr, no damage and non-pollution. The shell of the test cassette should be flat, the upper and lower covers should be evenly closed, and there should be no obvious gap. The inner test strip should be firmly attached without waggle. The diluent should be clear and free of foreign matter.

1.2 Size: the size of the inner strip should not be less than 2.5mm.

1.3 Liquid migration speed should not be less than 10mm/min.

1.4 **2. Minimum detection limit：** The minimum test limit reference products S1 should be negative, S2 and S3 should be positive.

3. Negative compliance rate： 5 pieces of negative reference products of the test company shall be all negative, with a negative compliance rate of 100%.

4. Positive compliance rate： 5 pieces of positive reference products, each reference test one times and shall be all positive, with a positive compliance rate of 100%.

5. Repeatability: Test 1 piece of the enterprise positive reference, test it 10 times, the color should be consistent and all positive.

6. Specificity

6.1Shall not cross-react with avian influenza virus.

6.2Hemoglobin (20g/L), bilirubinuria (17.1mmol/L), sodium chloride (10 percents (w/v)) and bovine serum albumin (10percents (w/v)) has no effect on the detection results.

ANHUI DEEPBLUE MEDICAL TECHNOLOGY CO.,LTD.

4th Floor,D-1# Zone, Pearl Industrial Park, 106 Innovation Avenue,High-Tech Development Zone,230088 Hefei, Anhui,China

EC REP

Luxus Lebenswelt GmbH

Kochstr. 1, 47877, Willich,Germany

Instruction of symbols

CE	CE Mark	LOT	Batch number
	Consult instruction for use	IVD	IVD product
	For single use		Date of manufacture
30°C 4°C	Store between	Σ	Contains sufficient for <n> tests
	Manufacturer		Expire date
EC REP	European union representative		