No.IFU-COVIDIgG/IgM-01,Ver.1.2

CE

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

(Colloidal Gold)

For professional in vitro diagnostic use only.

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. For professional 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, and diluent in different batches cannot be mixed.
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 occur if the person have an allergic reaction or a high ferritin level.

Materials and Components

Materials provided
1. COVID-19（SARS-CoV-2）IgG/IgM Antibody test cassette (Contains 1 desiccant ,1 pcs test device, 1 dropper)
2. Buffer: 1 bottle per box
3. Instruction: 1 pcs per box

Materials required but not provided
1. Timer
2. 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.

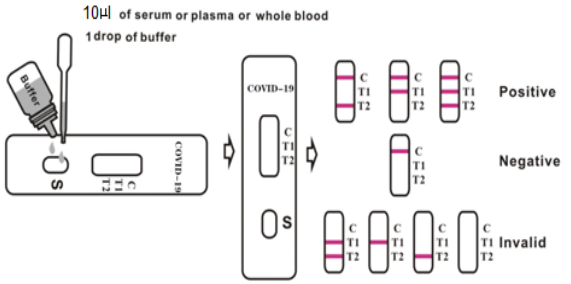
Specimen Collection and Preparation

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 used for qualitative testing only.
2. The test results of this product are for reference only, not as the sole basis for diagnosis and treatment, and should be confirmed in combination with clinical symptoms or other conventional testing methods.
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.
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
6.1 Cross Reaction: This product do not cross-react with the positive specimens including vice influenza virus antibodies, influenza a virus, influenza b virus antibodies, pneumonia chlamydia, mycoplasma pneumoniae antibody, adenovirus antibody, respiratory syncytial virus antibody, hepatitis b surface antibody, hepatitis c virus antibody, treponema pallidum antibody, human immunodeficiency virus (HIV) antibodies, EB virus antibody, measles virus, CMV antibodies, enterovirus type 71, mumps virus antibody, varicella - zoster virus.
6.2 There is no cross-reaction between RF, ANA and AMA.
6.3 Interfering substance:
(1) When bilirubin concentration ≤250μmol/L, hemoglobin content ≤9g/L, triglyceride content ≤15mmol/L, content of rheumatoid factor ≤80IU/mL, titer of ANA ≤1:240, anti-mitochondrial antibody (AMA) ≤80U/mL, content of mouse IgG ≤ 1000μg/mL, there will be no interference with the test results of this product.
(2) The commonly used antiviral drugs epiztin acid (≤4mg/L), ribavirin (≤40mg/L), interferon (≤200mg/L), oseltamivir (≤30mg/L), abidol (≤40mg/L), levofloxacin (≤200mg/L), azithromycin (≤100mg/L), ceftriaxone (≤400mg/L), meropenan (≤200mg/L) has no interference in the detection of this product.
7. Hook effect: No hook effect was found in the test results of this product within the titer range of clinically positive samples of the novel coronavirus antibody.
8. The minimum detection limit and reproducibility of 10 samples of clinically positive serum of COVID-19 novel coronavirus were studied. The results all meet the requirements.
9. Clinical performance
The experimental in vitro diagnostic reagents were compared with the clinical diagnostic criteria of the marketed same methodology products and the novel coronavirus pneumonia. The test results showed that the clinical sensitivity of the product was 89.67% (95%ci :83.55%, 90.85%) and the specificity was 99.33% (95%ci :98.12%, 99.32%).In addition, the homologous serum/plasma and whole blood samples of 160 subjects (72 positive and 88 negative) were selected for comparative test. The results showed that with the serum/plasma test results as the reference, the positive compliance rate of the whole blood test was 92.28% (95%ci: 87.52% ~ 97.11%), the negative compliance rate was 100.00% (95%ci: 96.21% ~ 100.00%), and the total consistency rate was 97.25% (95%ci: 93.55% ~ 99.01%). After preliminary evaluation, it is basically confirmed that the clinical performance of the product can meet the emergency needs of epidemic situation.

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EC REP

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IVD

30°C
4°C

Instruction of symbols

CE	CE Mark	LOT	Batch number
	Consult instruction for use	IVD	IVD product
	For single use		Date of manufacture
	Store between		Keep away from sunlight
	Manufacturer		Expire date
EC REP	European union representative		Protect against moisture
REV.	Date of last revision		