BIOTIME

Xiamen Biotime Biotechnology Co.,Ltd.

Instructions for use

Catalog No.BT1301

PRODUCT NAME & MATERIAL

Name: SARS-CoV-2 IgG/IgM Rapid Qualitative Test

Material:
Material Provided
1. Test cartridge 25 tests/kit
2. Detection buffer 1 bottle/kit
3. Pipette 25/kit
4. Instructions for use 1 copy/kit

Material Required But Not Provided
1. Specimen collection containers
2. Timer

INTENDED USE

The Biotime SARS-CoV-2 IgG/IgM Rapid Qualitative Test is intended to qualify the SARS-CoV-2 IgG and IgM antibody in human plasma, serum or whole blood by colloidal gold immunochromatography assay. The test is used as an aid detection to SARS-CoV-2 infection and thus caused COVID-19 disease.

-Colloidal gold immunochromatography assay
-COVID-19 Disease
-SARS-CoV-2 infection

For in vitro diagnostic use only. For professional use only.

INTRODUCTION

The product is intended for in vitro detection of SARS-CoV-2 IgG/IgM antibody in human plasma, serum or whole blood samples.

SARS-CoV-2 belongs to the broad family of viruses known as coronaviruses. It is a positive-sense single-stranded RNA (+ssRNA) virus. Other coronaviruses are capable of causing illnesses ranging from the common cold to more severe diseases such as Middle East respiratory syndrome(MERS). It is the seventh known coronavirus to infect people, after 229E, NL63, OC43, HKU1, MERS-CoV, and the original SARS-CoV. Protein modeling experiments on the spike (S) protein of the virus suggest that it has sufficient affinity to the angiotensin converting enzyme 2 (ACE2) receptors of human cells to use them as a mechanism of cell entry. Studies have shown that SARS-CoV-2 has a higher affinity to human ACE2 than the original SARS virus strain. An atomic-level image of the S protein has been created using cryogenic electron microscopy.

SARS-CoV-2 infections cause COVID-19 disease. People who have confirmed COVID-19 have a range of symptoms, from people with little to no symptoms to people being severely sick and dying. Symptoms can include:fever, tiredness, and dry cough.. Some patients may have aches and pains, nasal congestion, runny nose, sore throat or diarrhea. These symptoms are usually mild and begin gradually. Some people become infected but don't develop any symptoms and don't feel unwell. Most people (about 80%) recover from the disease without needing special treatment. Around 1 out of every 6 people who gets COVID-19 becomes seriously ill and develops difficulty breathing. Older people, and those with underlying medical problems like high blood pressure, heart problems or diabetes, are more likely to develop serious illness. About 2% of people with the disease have died. People with fever, cough and difficulty breathing should seek medical attention.

Human-to-human transmission of the virus has been confirmed and occurs primarily via respiratory droplets from coughs and sneezes within a range of about 6 feet (1.8m). Viral RNA has also been found in stool samplesfrom infected patients. It is possible that the virus can be infectious even during the incubation period, but this has not been proven, and the WHO stated on 1 February 2020 that "transmission from asymptomatic cases is likely not a major driver of transmission" at this time. [1-24]

PRINCIPLE

This reagent is based on colloidal gold immunochromatography assay.

During the test, samples and detection buffer are applied to the test cartridges. If there is SARS-CoV-2 IgG or IgM in the sample, they combined with colloidal gold-labeled SARS-CoV-2 recombinant antigen forming IgM-virus antigen-colloidal gold complex (complex M) or IgG-virus antigen-colloidal gold complex (complex G).
During lateral flow, the complex M and complex G move along nitrocellulose membrane toward one end of the absorbent paper. When passing the line M (coated with anti-human IgM anbodies), the complex M is captured by anti-human IgM antibody resulting in coloring on line M; when passing the line G (coated with anti-human IgG anbodies), the complex G is captured by anti-human IgG antibody resulting in coloring on line G; when passing the line C, colloidal gold-labeled DNP is captured by quality-control antibody resulting in coloring on line C.

PRECAUTIONS

1. This reagent is used for in vitro diagnosis only, carefully read IFU and do not use expired products.
2. Safety precautions are essential, such as wearing protective clothing and gloves.
3. All blood samples (including the remaining samples after testing), used reagents and waste should be treated as infectious materials.
4. The reagent is for one-time use.
5. Please refer to Clinical management of severe acute respiratory infection when the SARS-CoV-2 infection is suspected— Interim guidance.

STORAGE AND STABILITY

1. Store the detection buffer at 2-30℃, the shelf life is 12 months tentatively.
2. Store the test cartridge at 2-30℃, the shelf life is 12 months tentatively.
3. Test Cartridge should be used right after opening the pouch.

SPECIMEN COLLECTION AND PREPARATION

1. The specimen type should be plasma, serum or whole blood.
2. The specimen collection container should be immune tube or pro-coagulant tube for serum or EDTA anticoagulant tube for plasma and whole blood .
3. Sample collection:
   a)The venipuncture for human plasma or serum collection method referring to the National Clinical Laboratory Procedures, if the sample can't be detected timely, it can be stored in refrigerator at 2-8℃ for 3 days，or at -20℃ for 3months.
   b)The venipuncture for human whole blood collection method referring to the National Clinical Laboratory Procedures, if the sample can't be detected timely, it can be stored in refrigerator at 2-8℃ for 3days, free of freeze thawing.
4. Separate the plasma or serum from blood as soon as possible to avoid hemolysis.

TEST PROCEDURE

The test should be operated at room temperature（~25℃）.

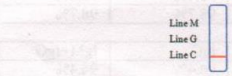
Step 1: Preparation
Take out the test kit, detection buffer and sample to be tested, balance them to room temperature.
Tear and open the aluminum foil bag, take the test cartridge out and put on the table horizontally.

Step 2: Sampling and Loading
Drip 1 drop (10~15uL) plasma, serum or whole blood with the pipette (provided within the kit) into the "S" well of the test cartridge. Then add 3 drops of detection buffer (~100uL) into the "D" well of the test cartridge.

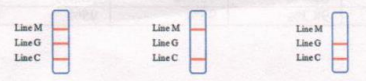
Step 3: Testing
Wait 10 min to allow the reaction completing and read the result visually afterward. Results should be read within 20 min.

INTERPRETATION OF THE RESULT

1. Negative result: there is coloration on line C only showing as following picture, suggesting that there is no SARS-CoV-2 IgG or IgM antibody in the sample.

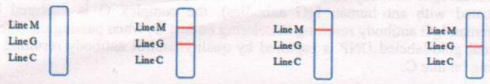


2. Positive result: the results show as following pictures. There is coloration on line C, line G and/or line M, showing as follow pictures, suggesting that there is SARS-CoV-2 IgG and/or IgM antibody in the sample.



IgG/IgM positive　　IgM positive　　IgG positive

3. Invalid result: there is no coloration on line C showing as following pictures, suggesting that invalid test or error operation.



LIMITATIONS OF PROCEDURE

1. The test sample should be plasma, serum or whole blood.

2. Human anti-mouse antibody (HAMA) may be present in patients who have received immunotherapy with a murine monoclonal antibody. This kit has been specially designed to minimize the effect of these antibodies on the test results. However, the test result must be carefully evaluated when patients are known to have these antibodies.[5,6]

3. Other factors also can induce the false results, include the technology, operational error and other sample factors.

4. The result is used as an aid detection only. A negative test results does not confirm the test subject does not carry the virus. It may due to the window period of detection or a poor immune response. While positive test results only indicates that the test subject was infected before test, it does not confirm that the test subject do carry the virus. The test result must be carefully evaluated along with other method or clinical symptoms.

5. The kit is not applicable for people who have received vaccination or treated with antibody drug to SARS-CoV-2 coronavirus since the SARS-CoV-2 IgG/IgM antibodies may not cause by virus infections in those cases.

6. The whole blood sample must be abandoned if its hematocrit ration is beyond normal range.

PERFORMANCE CHARACTERISTICS

Liquid velocity
No less than 10mm/min
Sensitivity
Test sensitivity control L03, L02 and L01 (10 replicates for each control), the results of testing L03 and L02 are positive and the results of testing L01 are negative
Accuracy
Positive coincidence: The positive results are 100% while testing 3 replicates with positive control P01~P03.
Negative coincidence: The negative results are 100% while testing 3 replicates with negative control N01~N10
Precision
The positive results are 100% while testing 10 replicates from same lot with positive control P01 and L02. There should be no significant difference of signal intensity for same lines between all test results of each control.
The negative results are 100% while testing 10 replicates from same lot with negative control N01. There should be no significant difference of signal intensity for same lines between all test results of each control.
Interference
No interfering is observed with interference substances listed below at the indicated concentration.

Bilirubin	15mg/dL	Triglyceride	400mg/dL
Hemoglobin	20g/dL	Rheumatoid factor	3250IU/mL

Cross reaction
No cross reaction is observed while testing clinical samples with common respiratory infections, including Pneumonia mycoplasma, Pneumonia chlamydia and other Coronaviruses (HKU1，OC43，NL63 and 229E). More than 5 clinical samples were tested for each of the above infections.
Cliniinical performance
Test with whole blood:

	IgM	IgG	IgM+IgG
Sensitivity	64.3%	96.4%	96.4%
Specificity	100%	98.7%	98.7%

Test with plasma:

	IgM	IgG	IgM+IgG
Sensitivity	67.9%	96.4%	96.4%
Specificity	96.7%	93.5%	93.5%

Test with serum）:

	IgM	IgG	IgM+IgG
Sensitivity	81.7%	95.8%	96.3%
Specificity	98.3%	95%	95%

SYMBOLS

Symbol	Description	Symbol	Description
REF	Catalogue number	IVD	In vitro diagnostic medical device
LOT	Lot number		Consult instructions for use
	Date of manufacture		Keep dry
	Expiry date		Keep away from sunlight
	Manufacturer	2℃ 30℃	Store at 2-30℃
	Do not re-use	EC REP	European authorized representative
CE	CE mark		

BIBLIOGRAPHY OF SUGGESTED READING

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