Version: DR0002-A01

【PRODUCT NAME】
COVID-19 IgM/IgG Antibodies Rapid Test

【PACKING】
1 test/kit，5 tests/kit，20 tests/kit，25 tests/kit，50 tests/kit

【INTENDED USE】
The COVID-19 IgM/IgG Antibodies Rapid Test assay is a lateral flow immunoassay intended for qualitative detection and differentiation of IgM and IgG antibodies to SARS-Cov-2 in human serum, plasma (potassium EDTA), and venous whole blood. The SARS-Cov-2 IgM/IgG Antibodies Rapid Test assay is intended as an aid in identifying individuals with an adaptive immune response to COVID-19, indicating recent or prior infection.IgM and IgG antibodies to SARS-Cov-2 are generally detectable in blood several days after initial infection, although the duration of time antibodies are present post-infection is not well characterized. Individuals may have detectable virus present for several weeks following seroconversion. The test is used as an aid detection to SARS-CoV-2 infection and thus caused COVID-19 disease.

The COVID-19 IgM/IgG Antibodies Rapid Test is for in vitro diagnostic use only and for professional use only.

【SUMMARY】
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.

SARS-Cov-2 infections cause COVID-19 disease. People who have confirmed COVID-19 have a range of symptoms, from little to no symptoms to severe illness and death. 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. People with fever, cough and difficulty breathing should seek immediate 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). It is possible that the virus can be infectious even during the incubation period.

After SARS-Cov-2 infection, anti-SARS-Cov-2 antibodies will appear in the blood of human body resulting from adaptive immune response in most individuals. Usually IgM antibodies can be detected 5~10 day after symptom onset, and IgG can be detected several days later.

【TEST PRINCIPLE】
This test is based on colloidal gold immunochromatography assay.

During the test, specimens and detection buffer are applied to the test cartridges. If there are SARS-Cov-2 S1 protein IgG or IgM antibodies in the specimens, they combine with colloidal gold-labeled SARS-Cov-2 S1 protein 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 the nitrocellulose membrane toward the end of the absorbent paper. When passing the line M (coated with anti-human IgM antibodies), 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 antibodies), the complex G is captured by anti-human IgG antibody resulting in coloring on line G; when passing the line C, colloidal gold-labeled control molecule is captured by quality-control antibody resulting in coloring on line C.

【COMPONENTS】
1. 1 test/kit
   Test cartridge 1/kit
   Detection buffer 1 bottle/kit (enough for 1test)
   Pipette 1/kit
   Instructions for use 1 copy/kit
2. 5 tests/kit
   Test cartridge 5/kit
   Detection buffer 1 bottle/kit (enough for 5 tests)
   Pipette5/kit
   Instructions for use 1 copy/kit
3. 20 tests/kit
   Test cartridge 20/kit
   Detection buffer 1 bottle/kit (enough for 20 tests)
   Pipette 20/kit
   Instructions for use 1 copy/kit
4. 25 tests/kit
   Test cartridge 25/kit
   Detection buffer 1 bottle/kit (enough for 25 tests)
   Pipette 25/kit
   Instructions for use 1 copy/kit
5. 50 tests/kit
   Test cartridge 50/kit
   Detection buffer 2 bottles/kit (enough for 50 tests)
   Pipette 50/kit
   Instructions for use 1 copy/kit

【MATERIALS REQUIRED BUT NOT PROVIDED】
1. Specimen collection tubes
2. Timer

【STORAGE AND STABILITY】
1. Store the detection buffer at 2-30℃, the shelf life is 24 months tentatively.
2. Store the test cartridge at 2-30℃, the shelf life is 24months tentatively.
3. Test Cartridge should be used in 1 hour after opening the pouch.

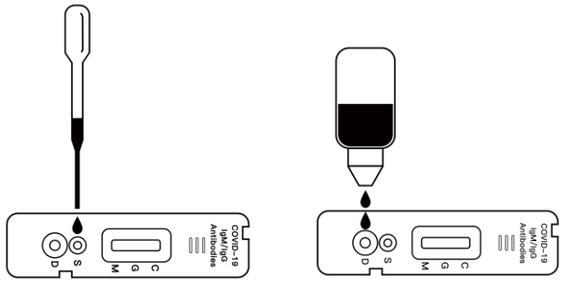
【PRECAUTIONS AND WARNINGS】
1. This reagent is used for in vitro diagnosis only, please do not use expired products.
2. All blood samples (including the remaining samples after testing), used reagents and waste should be treated as infectious materials.
3. Test is for single use only. Do not re-use under any circumstances.
4. Do not use any other reagents from different lots in this test.
5. Once the cartridge is removed from the pouch, use the cartridge as soon as possible to avoid being humidified. The cartridge is sensitive to humidity as well as to heat.
6. Professionals must handle the potentially contaminated materials safely according to local and state requirements.

【SAMPLE COLLECTION AND PREPARATION】
1. The specimen type should be plasma, serum or venous whole blood.
2. The COVID-19 IgM/IgG Antibodies Rapid Test has not been evaluated with fingerstick specimens. This test is not authorized for use with finger stick blood.
3. The specimen collection container should be immune tube or pro-coagulant tube for serum or EDTA anticoagulant tube for plasma and whole blood.
4. Sample collection:
   a)The venipuncture for human serum or plasma collection method referring to the National Clinical Laboratory Procedures, if the sample can't be tested in a timely manner, it should be stored in refrigerator at 2-8℃ for up to 14 days，or at -20℃ for up to 3 months.
   b) The venipuncture for human whole blood collection method referring to the National Clinical Laboratory Procedures, if the sample can't be tested immediately after collection, it should be stored in refrigerator at 2-8℃ for up to 3days. Do not freeze.
5. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Serum and plasma specimens cannot be frozen and thawed more than 3 times.
6. Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.
7. Do not use samples demonstrating gross lipemia, gross hemolysis or turbidity in order to avoid interference on result interpretation.
8. If specimens are to be shipped, they should be packed in compliance with federal regulations for transportation of etiologic agents.

【TEST PROCEDURE】
The test should be performed at room temperature（15-30℃）.

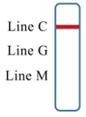
Step 1: Preparation
Take out the test kit, detection buffer, and sample to be tested and balance them to room temperature.
Tear and open the aluminum foil pouch, take the test cartridge out, and put it on the table horizontally.

Step 2: Sampling and Loading
Use the pipette (provided within the kit) to take specimen from the original specimen container and add 1 drop (10~15uL) specimen (plasma, serum or venous whole blood) into the "S" well of the test cartridge. Then add 2 drops of detection buffer (~100uL) using the drip bottle containing detection buffer into the "D" well of the test cartridge.

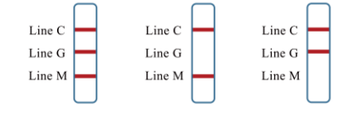


Step 3: Testing
Wait 10 min to allow the reaction to complete and read the result visually afterward. Results should be read between 10 and 20 min.

【RESULT INTERPRETATION】
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.

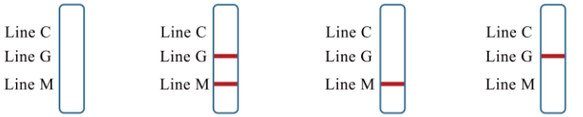


2. Positive result: the results show as following pictures. There is coloration on line C, line G and/or line M, showing as follow pictures, suggesting that there is SARS-Cov-2 IgG and/or IgM antibody in the sample.



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.



【PERFORMANCE CHARACTERISTICS】
Liquid velocity
No less than 10mm/min

Sensitivity
Test sensitivity controls L01, L02 and L03 in 20 replicates:
The results of both IgG and IgM are 100% positive while testing L01.
The results of both IgG and IgM are no less than 95% positive while testing L02.
The results of testing L03 can be negative or positive.

Accuracy
Positive coincidence: The positive controls P01, P02 and P03 in triplicates:
The results of both IgG and IgM are 100% positive while testing P01.
The results of IgG are 100% positive and IgM are 100% negative while testing P02.
The results of IgM are 100% positive and IgG are 100% negative while testing P03.
Negative coincidence: The results of both IgG and IgM are 100% negative while testing 3 replicates with negative control N01~N10.

Precision:
Intra-Lot Precision:
a)The positive results of both IgG and IgM are 100% while testing 10 replicates from same lot with precision control C01. There should be no significant difference of signal intensity for same lines between all test results of each line.
Inter-Lot Precision:
b)The positive results of both IgG and IgM are 100% while testing 10 replicates from same lot with precision control C01. There should be no significant difference of signal intensity for same lines between all test results of each line.

Interference
No interfering is observed with interference substances listed below at the indicated concentration.

Interference substances	Concentration	Interference substances	Concentration	Interference substances	Concentration
Bilirubin	15mg/dL	Triglyceride	400mg/dL	ANA	200mg/mL
Hemoglobin	20g/dL	Rheumatoid factor	3250IU/mL	Cholesterol	100mmol/L

Cross reaction
No cross reaction is observed while testing clinical samples with common respiratory infections, including Adenovirus, human MPV, Influenza A/B, Parainfluenza virus, 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.

Clinical performance
Test with whole blood:

	IgM	IgG	IgM+IgG
Sensitivity	69.7% (62/89)	96.6% (86/89)	96.6% (86/89)
	95%CI（58.9%-78.7%）	95%CI（89.8%-99.1%）	95%CI（89.8%-99.1%）
Specificity	99.6% (235/236)	98.7% (233/236)	98.7% (233/236)
	95%CI（97.3%-99.9%）	95%CI（96.0%-99.7%）	95%CI（96.0%-99.7%）

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Instructions for Use

For Professional Use

CE

IVD

Test with plasma:

	IgM	IgG	IgM+IgG
Sensitivity	64.5% (78/121)	96.7% (117/121)	96.7% (117/121)
	95%CI（55.2%-72.8%）	95%CI（91.2%-98.9%）	95%CI（91.2%-98.9%）
Specificity	100% (405/405)	98.8% (400/405)	98.8% (400/405)
	95%CI（98.8%-100%）	95%CI（97.0%-99.5%）	95%CI（97.0%-99.5%）

Test with serum:

	IgM	IgG	IgM+IgG
Sensitivity	68.6% (83/121)	97.5% (118/121)	97.5% (118/121)
	95%CI（59.4%-76.6%）	95%CI（92.4%-99.4%）	95%CI（92.4%-99.4%）
Specificity	99.3% (402/405)	99.0% (401/405)	99.0% (401/405)
	95%CI（97.7%-99.8%）	95%CI（97.3%-99.7%）	95%CI（97.3%-99.7%）

【LIMITATIONS】

1. Use of COVID-19 IgM/IgG Antibodies Rapid Test is limited to laboratory personnel who have been trained. Not for home use.
2. Results should only be used in conjunction with other clinical and laboratory data.
3. The test specimens should be plasma, serum or venous whole blood. Do not use with finger stick samples.
4. It is not known at this time if the presence of antibodies to SARS-Cov-2 confers immunity to re-infection.
5. SARS-Cov-2 IgG antibodies may be below detectable levels in patients who have been exhibiting symptoms for less than 15 days. SARS-Cov-2 IgM antibodies may be below detectable levels in patients who have been exhibiting symptoms for less than 8 days.
6. 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.
7. Other factors also can induce the false results, include the technology, operational error and other patient and clinical factors.
8. This test should not be used to diagnose or exclude acute SARS-Cov-2 infection. The result of this assay is used as an aid for detection of antibodies only. A negative test result does not confirm the test subject does not carry the virus. A negative result may be due to the specimens' collection early after symptom onset or a poor immune response. While positive test results only indicate that the test subject has been infected previously, it does not confirm that the test subject does or does not carry the virus. The test result must be carefully evaluated along with other method or clinical symptoms.
9. The kit should not be used to evaluate an immune response in people who have received vaccination or treated with antibody therapy to SARS-Cov-2 coronavirus since the SARS-Cov-2 IgM/IgG antibodies may not be caused by natural viral infection in those cases.
10. The whole blood sample should not be used if its hematocrit ration is beyond normal range.
11. The test is limited to the qualitative detection of antibodies specific for the SARS-Cov-2 virus. The intensity of the test line does not necessarily correlate to SARS-Cov-2 antibody titer in the specimen. This test cannot be used as a quantitative test.
12. A negative result for individual subject indicates absence of detectable anti-SARS-Cov-2 S1 protein antibodies. Negative results do not preclude SARS-Cov-2 infection and should not be used as the sole basis for patient management decisions, IgM antibodies may not be detected in the first few days of infection; the sensitivity of the COVID-19 IgM/IgG Antibodies Rapid Test early after infection is unknown. False positive results for IgM and IgG antibodies may occur due to cross-reactivity from pre-existing antibodies or other possible causes. Positive results must be confirmed with another available method and interpreted in conjunction with the patient's clinical information. A negative result can occur if the quantity of the anti-SARS-Cov-2 antibodies present in the specimen is below the detection limits of the assay, or the antibodies that are detected are not present during the stage of disease in which a sample is collected.
13. Positive results may be due to past or present infection with non-SARS-Cov-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E.
14. Not for the screening of donated blood.

【BIBLIOGRAPHY】

1. HAMA Interference with Murine Monoclonal Antibody-Based Immunoassays. Journal of Clinical Immunoassay,1993,16:294-299.
2. The Nature of Heterophilic Antibodies and the Role in Immunoassay Interference. Journal of Clinical Immunoassay,1992,15:108-114

【SYMBOL】

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	30℃ 2℃	Store at 2-30℃
	Do not re-use	EC REP	European authorized representative
CE	CE Mark		

【GENERAL INFORMATION】

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EC REP
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