Version: DR0004-A01

【Product Name】
COVID-19 Total Antibodies Rapid Test

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

【Intended Use】
The COVID-19 Total Antibodies Rapid Test is a lateral flow immunoassay intended for the qualitative detection of total antibodies to SARS-CoV-2 in human serum, plasma or whole blood. The COVID-19 Total Antibodies Rapid test is intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2 virus or vaccine. The COVID-19 Total Antibodies Rapid test should not be used to diagnose or exclude acute SARS-CoV-2 infection.
For in vitro diagnostic use only.
For professional use only.

【Summary】
The product is intended for in vitro detection of SARS-CoV-2 total antibodies in human serum, plasma 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.

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.

【Test Principle】
This reagent is based on a lateral flow immunoassay.
During the test, specimens are applied to the test cartridges. If SARS-CoV-2 antibody is present in the specimen, they combined with colloidal gold-labeled SARS-CoV-2 recombinant antigen forming antibody-virus antigen-colloidal gold complex (complex T).
During lateral flow, the complex T move along nitrocellulose membrane toward one end of the absorbent paper. When passing through the line T (coated with same SARS-CoV-2 recombinant antigen), the complex T is captured by recombinant antigen resulting in coloring on line T; when passing through the line C, colloidal gold-labeled DNP is captured by quality-control antibody resulting in coloring on line C.

【Precautions and Warnings】
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.

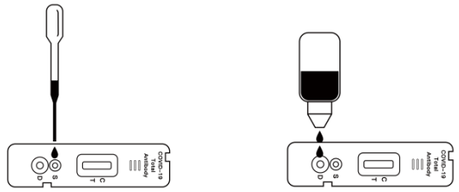
【Components】
1. 1 test/kit
   Test cartridge: 1 test/kit
   Detection buffer: 1 bottle/kit
   Pipette: 1/kit
   Instructions for Use: 1 copy/kit
2. 5 tests/kit
   Test cartridge: 5 tests/kit
   Detection buffer: 1 bottle/kit
   Pipette: 5/kit
   Instructions for Use: 1 copy/kit
3. 20 tests/kit
   Test cartridge: 20 tests/kit
   Detection buffer: 1 bottle/kit
   Pipette: 20/kit
   Instructions for Use: 1 copy/kit
4. 25 tests/kit
   Test cartridge: 25 tests/kit
   Detection buffer: 1 bottle/kit
   Pipette: 25/kit
   Instructions for Use: 1 copy/kit
5. 50 tests/kit
   Test cartridge: 50 tests/kit
   Detection buffer: 2 bottles/kit
   Pipette: 50/kit
   Instructions for Use: 1 copy/kit

【Material Required】(But Not Provided)
1. Specimen collection containers
2. Timer

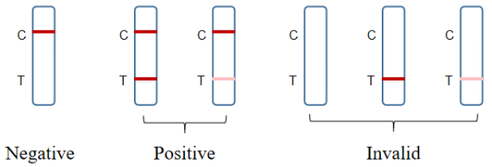
【Storage and Stability】
1. Store the detection buffer, at 2-30℃, the shelf life is 24 months tentatively.
2. Store the test cartridge at 2-30℃, the shelf life is 24 months tentatively.
3. Test Cartridge should be used right after opening the pouch.

【Specimen Collection and Preparation】
1. The specimen type should be serum, plasma or whole blood.
2. The specimen collection container should be immune tube or pro-coagulant tube for serum, EDTA anticoagulant tube for plasma and whole blood.
3. 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 detected timely, it can be stored in refrigerator at 2-8℃ for 14 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 3 days, free of freeze thawing.
4. Separate the serum or plasma from blood as soon as possible to avoid hemolysis.

【Test Procedure】
The test should be operated at room temperature(15~30℃).
Step 1: Preparation
Take out the test kit and specimen to be tested, then balance them to room temperature(15~30℃).
Tear and open the aluminum foil bag, take the test cartridge out and put them on the table horizontally.
Step 2: Sampling and Loading
Drip 1 drop (10~15ul) specimen(serum, plasma or whole blood) with the pipette (provided within the kit) into the “S” well of the test cartridge. Then add 2 drops of detection buffer (~80uL) into the “D” well of the test cartridge.
Insure that there is no bubble emerging during the process.
Step 3: Testing
Wait 10 min to allow the reaction completing 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, suggesting that there is no SARS-CoV-2 antibodies in the specimens.
2. Positive result: the results show as following pictures. There is coloration on line C and line T, suggesting that there are SARS-CoV-2 antibodies in the specimens.
3. Invalid result: there is no coloration on line C, suggesting that invalid test or error operation.



【Performance Characteristics】
Liquid velocity
No less than 10mm/min
Sensitivity
Test sensitivity control L03, L02 and L01 (3 replicates for each control), all results of testing L03 and L02 should be positive and all results of testing L01 should be negative
Accuracy
Positive coincidence: Results should be all positive while testing positive control P01～P03.
Negative coincidence: Results should be all negative while testing negative control N01～N10.
Precision
The positive results are 100% while testing 10 replicates of 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 of 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.

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

	Whole Blood	Plasma	Serum
Sensitivity	97.5% (118/121)	98.4% (189/192)	97.9% (188/192)
	95% CI: 92.4%~99.4%	95% CI: 95.1%~99.6%	95% CI: 94.4%~99.3%
Specificity	98.5% (203/206)	99.1% (636/642)	99.2% (637/642)
	95% CI: 95.5%~99.6%	95% CI: 97.9%~99.6%	95% CI: 98.1%~99.7%

【Limitations】
1. Use of COVID-19 Total 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.
4. It is not known at this time if the presence of antibodies to SARS-Cov-2 confers immunity to re-infection.
5. COVID-19 Total Antibodies Rapid Test does not distinct classes of antibodies. User should aware different classes of antibodies may exist in specimen, however, the COVID-19 Total Antibodies Rapid Test does not specify any class.
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 presence of antibodies in the specimen from test subject, it does not confirm that the test subject does or does not carry the virus, and it does not confirm if the antibodies result from vaccination of virus infection. The test result must be carefully evaluated along with other method or clinical symptoms.
9. The whole blood sample should not be used if its hematocrit ration is beyond normal range.
10. 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.
11. 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. False positive results 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.

12. Positive results may be due to past or present infection with non-SARS-Cov-2 coronavirus strains, such as coronavirus SARS, MERS, HKU1, NL63, OC43, or 229E.
13. Not for the screening of donated blood.

【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】

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

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EC REP

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UDXBIO

COVID-19 Total Antibodies Rapid Test

Instructions for Use

For Professional Use

CE

IVD

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