SARS-CoV-2 IgM/IgG Antibody Rapid Test Kit

(Colloidal Gold Immunochromatography method)

CE IVD

Instruction For Use

【Product name】

Common name:
SARS-CoV-2 IgM/IgG Antibody Rapid Test Kit (Colloidal Gold Immunochromatography method)

【Package】

Cassette: 1 test/pouch, 20 tests /box, 40 tests /box.
Strip: 1 test/pouch;50 tests. Barrel: 50 tests /box,100 tests /box.

【Intended use】

The novel coronaviruses (SARS-CoV-2virus) belong to the βgenus of Corona Virus Family. COVID-19 is an acute respiratory infectious disease. People are generally susceptible to the virus infection. Currently,patients infected by the novel corona virus are the main route of Infection source. Asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7days. The main manifestations include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are also found in some cases.
SARS-CoV-2 IgM/IgG Antibody Rapid Test Kit (Colloidal Gold Immunochromatography method) is used for qualitative detection of SARS-CoV-2 virus specific IgM, IgG antibodies respectively in human whole blood/serum/plasma samples.The test device is intended for professional use only.

【Composition】

Main active materials:SARS-CoV-2 antigens, Monoclonal mouse anti-human IgM antibody, Monoclonal mouse anti-human IgG antibody, biotinylated BSA, Streptavidin.
Main raw and auxiliary materials: nitrocellulose film, colloidal gold binding pad, PVC base plate, absorbent paper, sample pad.

【Test principle】

SARS-CoV-2 IgM/IgG Antibody Rapid Test Kit (Colloidal Gold Immunochromatography method) use recombinant proteins of SARS-CoV-2 virus as gold nanoparticles labeling protein. Anti-human IgM mAb and Anti-human-IgG mAb are the coated on NC membrane separately as capture agents for IgM, IgG respectively . The assay method is capture immuno-assay by principle to test the specific IgM, IgG antibody for SARS-CoV-2 virus in clinical samples. Colloidal gold is labeled with SARS-CoV-2 antigen which binds IgM, IgG antibodies in specimen. NC membrane is coated with Anti-human IgM mAb (IgM test line), Anti-human-IgG mAb (IgG test line 2) and biotinylated BSA(quality control line C). Colloidal gold labeled streptavidin as control line labels. When the positive sample is tested, specific SARS-CoV-2 IgM, IgG antibody in the sample bind with the colloidal gold labeled SARS-CoV-2 antigens to form Immuno-complex. The complex moves forward along the strip through capillary force. When passing through the IgM test line, colloidal gold labeled SARS-CoV-2 antigen-IgM complex bind to the pre-coated anti-human IgM mAb to form a sandwich and a red color band appears. When passing through the IgG test line, colloidal gold labeled SARS-CoV-2 antigen-IgG antibody complex bind to the pre-coated Anti-human-IgG mAb to form a sandwich and a red color band appears, while the gold labeled streptavidin continues moving forward and reacts with the biotinylated BSA precoated on the N membrane of quality control zone. A visible red color band appears. Negative samples will be only colored at the quality control line.

【Precautions】

(1)For in vitro diagnostic use only.
(2)The test results should not be used as a sole basis for diagnosis or exclusion of COVID-19.
(3)Please read the instruction inserts carefully before performing the test.
(4)Do not reuse the test device.
(5)Do not use expired devices.
(6)Once open the pouch, the test should be carried out as soon as possible. The strip (or cassette) should be avoided long time exposure in the air because reagents could be destructed if it absorbs moisture.
(7)Do not use if the pouch is opened or damaged before testing.
(8)All samples and wastes shall be treated as infectious materials.
(9)The kit should be stored at room temperature.

【Material provided】

(1)Test device. The test strip (or cassette) is sealed in a foil pouch or 50 tests/barrel.
(2)Disposable plastic pipette.
(3)Sample diluent buffer.
Materials not provided:
(1) Alcohol Swipe paper.
(2) Disposable Lancet.

【Storage and stability】

(1)The test kit should be stored at 2°C-30°C. DO NOT FREEZE.
(2)The shelf-life of the kit is 24 months.

【Specimen preparation】

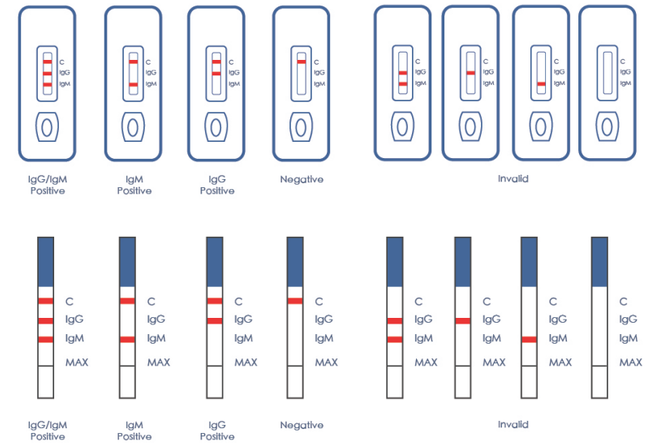
(1)Collection: The specimens are collected by the standard medical procedure. Whole blood/serum/plasma sample can be used directly after collection or separation.
(2)Storage: The serum/plasma specimen can be stored in the refrigerator for up to 7 days at 4 ℃. If needed store at - 20℃ or below for longer time. Avoid repeated freeze-thaw cycles.
(3)If serum/plasma specimen is refrigerated, it should be brought to room temperature before testing.Shake gently and mix well if there is sediment in the specimen. Sediment can be removed by centrifugation. Severe hemolysis or lipemia specimen should not be used.

【Test procedure】

(1)Test device and specimen should be brought to room temperature (15-30℃) prior to testing. Do not open pouches until ready to perform the assay.
(2)Take the test strips(or cassettes) out from the foil pouch/barrel.
(3)Slowly add 10 μl of whole blood/ serum / plasma specimen to the sample well (S) on cassette or sample area on strip with a pipette and two to three drops of sample dilution buffer from sample diluent bottle. Start time counting, and read the result within 10～15 minutes. Do not read results after 15 minutes.

【Interpretation of results】

POSITIVE
Two or three red lines appear, the control line (C) and the test lines (IgM, IgG or both).
1. Control line plus IgM: IgM positive.
2. Control line plus IgG: IgG positive.
3. Control line plus IgM and IgM: Both IgM and IgG positive.
NEGATIVE
Only control line (C) appears.
INVALID
If no red line appears in the position of control line (C), the test result is invalid regardless of color on the test line (IgM.IgG). Review the procedure and repeat the test with a new test device.



【Limitation of the procedure】

1. This device is only used for evaluation of SARS-CoV-2 IgM/IgG antibody status in human blood sample .
2. Diagnosis of COVID-19 should not made by use the antibody test result only.
3. Negative antibody test can not exclude SARS-CoV-2 infection.

【Performance】

(1)Sensitivity and Specificity.

SARS-COV-2 IgM/IgG Antibody Rapid Test	SARS-COV-2 RT-PCR Confirmed Cases		
	Positive	Negative	Total samples
IgG Positive	55	8	448
IgG Negative	5	380	
IgM Positive	45	6	
IgM Negative	15	382	
Total samples	60	388	

Sensitivity: IgG 91.6%; IgM 75%.
Specificity: IgG 97.9%; IgM 98.4%

(2) Cross Reactivity: No cross reactivity were observed with following microorganism positive sera: HCoV-OC43, HCoV-NL63, HCoV-229E, HCoV-HKU1, Influenza A,Influenza B,RSV, Parainfluenza, Adeno virus,.Mycoplama Pneumonia, Chlymedia Pneumonia,Rhinovirus, EBV,CMV,HIV,HBV,HCV.
(3) Interference: No interference were observed for following sera: Rheumatoid factor ⩽ 1900 IU/ml, Triglycerid ⩽3mMol/L ,Hemoglobin⩽ 10/L,Bilirubin⩽ 0.25mMol/L. HAMA, ANA,AMA.
(4) Interference of Common Drugs: No interference for following drugs were observed: Tobramycin Phenylephedrine Oxymetazoline NACL Beclomethasone Dexamethasone Flunisolide TriamcinoloneAcetonide Budesonide Mometasone FluticasonePropionate, Oseltamivir Levofloxacin Ceftriaxome Zanamivir IFN-α Ribavirin Peramivir Lopinavir Ritonavir Abidor Aithromycin
(5) Hook effect: High titer sera (IgM1:64,Ig G 1:256) has no hook effects observed.

【Reference】

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4. Wu Hua, Research and implementation of colloidal gold color recognition method, Xi'an University of Science&Technology, 2016.
5. Huang Pei. Establishment of a new rapid detection method for mers-cov, Jilin Agricultural University, 2018.
6. Huang Pei;Han qiuxue;Hu Xingxing.Preparation of the quantum dot immunochromatography test paper of the Middle East respiratory syndrome coronavirus, Chinese Journal of pathogenic biology, June 2018, 13 volumes 557-561.

【Interpretation of signs】

Symbol	Used for	Symbol	Used for
IVD	In vitro diagnostic instruments	®	Trademark
	Temperature limitation		Manufacturers
	The date of production		Expiry date
LOT	Product batch number		Do not reuse
	Not use if the package is damaged		

Manufacturer:
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EC REP

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