COVID-19 IgG/IgM Rapid Test Kit (Colloidal Gold)

Instructions for Use (IFU)

【PRODUCT NAME】

COVID-19 IgG/IgM Rapid Test Kit (Colloidal Gold)

【PACKAGE AND SPECIFICATION】

20Tests/box (1Test/bag ×20 Bags) 、40 Tests /box (1Test / bag ×40 Bags)

【INTENDED USE】

For in vitro qualitative determination of the content of COVID-19 IgG/IgM antibody in human serum, plasma and whole blood. This test is only provided for use by clinical laboratories or to healthcare workers for point-of-care testing, and not for at home testing.

A positive test result requires further confirmation, and a negative test result cannot rule out the possibility of infection. The test results of this kit are only for clinical reference. It is recommended to conduct a comprehensive analysis of the patient's condition in combination with clinical manifestations and other laboratory tests.

For in vitro diagnostic use only. For professional use only

【TEST PRINCIPLE】

In this kit, IgG antibody and IgM antibody of novel coronavirus (COVID-19) were detected by immunocapture method. Mouse anti-human IgM antibody, mouse anti-human IgG antibody and goat anti-chicken IgY antibody were coated with cellulose nitrate membrane. Recombinant novel coronavirus antigen and chicken IgY antibody labeled by colloidal gold are as tracers.

Add the sample to the sample loading well of test strip; and the sample flows through the blood filter film (filter red blood cells).If the sample contains the novel coronavirus IgM antibody, it can combine with colloidal gold labeled novel coronavirus antigen to form a complex, which is captured by the mouse anti-human IgM antibody coated with colored band (M line).If the sample contains the novel coronavirus IgG antibody, it can combine with colloidal gold labeled novel coronavirus antigen to form a complex, which is captured by the mouse anti-human IgG antibody coated with colored band (G line). The colloidal gold labeled chicken IgY antibody is bound to the goat anti- chicken IgY antibody coated with a colored band (C line), which acts as a control line.

【COMPONENT】

COMPONENT	20Tests/box	40Tests/box	Main components
Test Kit	20Tests/box (1Test/bag ×20 Bags)	40Tests/box (1Test/bag ×40Bags)	The detection lines were coated with mouse anti-human IgM antibody and mouse anti-human IgG antibody, the control line was coated with goat anti-chicken antibody, Recombinant novel coronavirus antigen and chicken IgY antibody labeled by colloidal gold are as tracers.
Desiccant	20 pouchs	40 pouchs	Silica Gel
Sample Diluent	1Bottle(4mL)	2Bottles(8mL)	Solution of trimethylaminomethane hydrochloride(0.02M Tris-HCl)

【STORAGE AND STABILITY】

1. Store at 4~30ºC in the sealed pouch up to the expiration date, and the validity is tentatively 12 months. Do not freeze.
2. The test cassette should be used within 1 hour after taking out from the aluminum foil bag. Sample diluent should be re-capped in time after use.
3. Keep away from sunlight, moisture and heat.

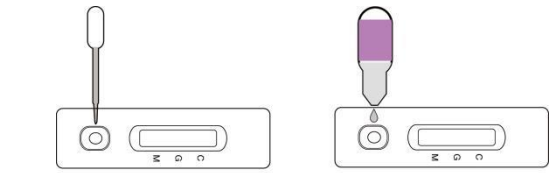
【SPECIMEN COLLECTION AND PREPARATION】

1. The recommended samples for this kit are serum, plasma, whole blood. Plasma and whole blood can be collected by blood collection tube or centrifuge tube with EDTA-2K or heparin sodium anticoagulant.

2. The samples collected with the correct medical technology should be returned to room temperature before testing. Jaundice, hemolysis, lipemia, and cloudy samples cannot be used. Severe hemolytic or heat-inactivated specimens are not recommended.
3. Samples should be tested as soon as possible. If the test cannot be completed within 8 hours, the samples can be stored at 4℃perature. Serum samples and plasma samples can be stored for 7 days at 4℃ or for 6 months at -20℃, and whole blood can be stored for 3 days at 4℃. Do not freeze and thaw samples repeatedly.

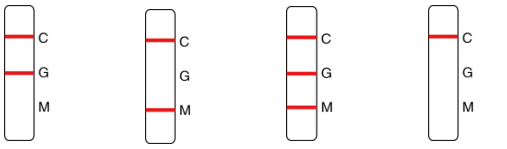
【TEST METHOD】

1. Remove test kit, specimen to room temperature. Tear off the foil pouch, take out the test strip/cassette and place the test kit on a clean and level surface.
2. Add 20μL whole blood or 10μL serum (or plasma) into sample well using a calibrated pipet. Then add 70 μL (2 drops) of the Sample Diluent. For each individual's specimen, use a separate tip and Cassette.
3. Read the test results between 15 and 20 minutes. Do not read the results after 20 minutes.

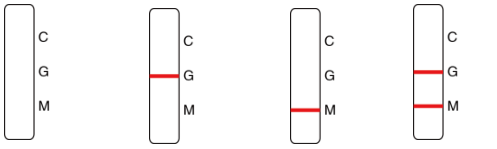


Add specimen into sample well

Add diluent (70μL/2 drops) into sample well



Positive (+) Positive (+) Positive (+) Negative (-)



Invalid(x) Invalid(x) Invalid(x) Invalid(x)

(The picture is for reference only)

【INTERPRETATION OF TEST RESULTS】

1. IgG POSITIVE: Two lines appear. One colored line should be in the control line region (C), and a colored line appears in IgG test line region. The result is positive for SARS-COV-2 virus specific-IgG and is probably indicative of secondary SARS-COV-2 infection.
2. IgM POSITIVE:Two lines appear. One colored line should be in the control line region (C), and a colored line appears in IgM test line region. The result is positive for SARS-COV-2 virus specific-IgM antibodies and is indicative of primary SARS-COV-2 infection.
3. IgG and IgM POSITIVE: Three lines appear. One colored line should be in the control line region (C), and two colored lines should appear in IgG test line region and IgM test line region. The color intensities of the lines do not have to match. The result is positive for IgG & IgM antibodies and is indicative of secondary SARS-COV-2 infection.

   NOTE: The intensity of the color in the IgG and/or IgM test line region(s) will vary depending on the concentration of SARS-COV-2 antibodies in the specimen. Therefore, any shade of color in the IgG and/or IgM test line region(s) should be considered positive.
4. NEGATIVE: One colored line should be in the control line region (C). No line appears in IgG and IgM test line region(s).
5. INVALID: Control line fails to appear. Insufficient buffer volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the procedure with a new test cassette. If the problem persists, discontinue using the test kit immediately and contact your

local distributor.

6. Result determination time: The result should be judged within 15~20 minutes after the sample is added into the sample loading well, and the result displayed after 20 minutes is invalid.

【LIMITATIONS OF TEST METHOD】

1. This product is only suitable for qualitative test and auxiliary diagnosis.
2. The test results are only for clinical reference and should not be the only basis for clinical diagnosis and treatment. The clinical management of patients should be considered in combination with their symptom, physical signs, medical history, other laboratory tests, therapeutic reaction, and epidemiological information.
3. The hemolytic, lipemia, jaundice, and contaminated samples may affect the test results. Such samples should be avoided.
4. During early infection, when IgG/IgM isn't formed or the concentration is very low, it will cause a negative result. If there is a suspected infection, it's recommended to retest in 7-14 days. Test the second sample simultaneously with the first sample under the same conditions to determine whether exist seroconversion in first infection or an elevation in antibody titer.
5. We do not test all types of collection tubes that may be used for this kit; therefore, for blood sample collection tubes from different manufacturers, different results may be obtained due to different raw materials and additives. Each laboratory shall make its own judgment on the suitability of the blood collection tubes.

【PERFORMANCE CHARACTERISTICS】

1. Positive conformity rate: testing positive reference material of the company, there is no false negative result.
2. Negative conformity rate: testing negative reference material of the company, there is no false positive result.
3. Limit of detection: testing the the detection limit reference material of the company, S1 should be positive, S2 should be negative or positive, and S3 should be negative.
4. Repeatability: testing two copies of the repeatability reference materials of the company, each test is repeated 10 times, all should be positive.
5. Clinical Performance

The clinical performance of the COVID-19 IgG/IgM Rapid Test Kit was evaluated by testing a total of 400 clinical samples from individual patients: serum samples, plasma samples and whole blood samples (EDTA, heparin, and citrate). The samples were collected from patients at three sites in China at a time when the acute SARS-CoV-2 infection was prevalent.

Study Results

Across all study sites, serum and plasma samples from a total of 182 patients with positive PCR comparator results and 218 patients with negative PCR comparator results were tested with the Anti-SARS-CoV-2 Rapid Test. Overall study results are shown in Table 1 below.

Table 1. Overall Clinical Study Results for all time periods from symptom onset

Reagent test results		PCR Comparator		Subtotal
		positive	negative	
positive	IgG+/IgM+	148	0	148
	IgG-/IgM+	4	4	8
	IgG+/IgM-	18	5	23
negative	IgG-/IgM-	12	209	221
Subtotal		182	218	400

Positive Percent Agreement (PPA)= (IgM positive or IgG positive)/(PCR positive)

Positive Percent Agreement (PPA)= 170/182 (93.41%)

Negative Percent Agreement: (NPA) = (IgM negative and IgG negative)/(PCR negative)

Negative Percent Agreement (NPA)= 209/218 (95.87%)

6. Assay Cross Reactivity Cross-reactivity of the COVID-19 IgG/IgM Rapid Test Kit was evaluated using serum or plasma samples (collected before August 2019) which contain antibodies to the pathogens listed below. No IgM or IgG false positivity was found with the following:

Table 2: Cross-reactivity Results

IgM/IgG potential cross-reactant			
Potential cross-reactants	No. of samples	Potential cross-reactants	No. of samples
Anti-Flu A (IgM/ IgG)	10	Human coronavirus panel (IgM/ IgG)	10
Anti-Flu B (IgM / IgG)	10	EB Virus antibody (IgM/ IgG)	10
anti-HKU1 (beta coronavirus)	10	HIV-1 and HIV-2	10
anti-OC43 (beta coronavirus)	10	Adenovirus (IgM/ IgG)	10
anti-NL63 (alpha coronavirus)	10	Human Metapneumovirus (hMPV) (IgM/ IgG)	10
anti-229E (alpha coronavirus)	10	Parainfluenza virus 1-4 (IgM/ IgG)	10
anti-rhinovirus (IgM/ IgG)	10	Enterovirus (IgM/ IgG)	10
anti-HCV (IgM/ IgG)	10	Rhinovirus (IgM/ IgG)	10
anti-HBV (IgM/ IgG)	10	Streptococcus pneumoniae (IgM/ IgG)	10
ANA	10	Mycobacterium tuberculosis (IgM/ IgG)	10
anti-respiratory syncytial virus (IgM/ IgG)	10	Mycoplasma pneumoniae (IgM/ IgG)	10
anti-Haemophilus influenzae. (IgM/ IgG)	10		

7. Potentially Endogenous Interfering Substances Low titer COVID-19 antibody positive serum samples and COVID-19 antibody negative serum samples were spiked with one of the following substances to specified concentrations and tested in multiple replicates. No false positivity or false negativity was found with the following:

Bilirubin Conjugated	0.3 mg/mL	Antibody (HAMA) Human Serum Albumin	50 mg/mL
Hemoglobin	8 mg/mL	Levofloxacin	200 mg/L
Human Anti-mouse	780 ng/mL	α-IFN	200 mg/L
Bilirubin Unconjugated	0.4 mg/mL	Abidol	50 mg/L
Triglycerides	15 mg/mL	Tobramycin	10 mg/L
Cholesterol	5 mg/mL	Ribavirin	40 mg/L
Rheumatoid Factor	2000 IU/mL	Ceftriaxone	420 mg/L
Histamine hydrochloride	4 mg/L	Meropenem	210 mg/L
Oseltamivir carboxylate	1 mg/L	Human IgM	0.5 mg/mL

Zanamivir	1 mg/L	Human IgG	9 mg/mL

【PRECAUTIONS】

1. This product is only used for in vitro diagnosis, not for other purposes; do not use expired reagents.
2. All reagent components, samples and various wastes should be treated as infectious agents. At the same time, this product is a one-time use product, and it should be destroyed centrally in accordance with the local infectious disposal law or laboratory regulation.
3. Proper specimen collection, storage and transport are critical to the performance of this test.
4. Testing should be applied by professionally trained staff working in certified laboratories or clinics at which the sample(s) is taken by qualified medical personnel.
5. Please read the instructions carefully before operation, and follow the instructions. During use, all laboratory reagent handling precautions must be followed.
6. Please use fresh samples as much as possible, and avoid using samples contaminated with bacteria, hemolysis, jaundice, or excessive blood lipid.
7. The results of this kit are invalid after 20 minutes.

【WARNINGS】

1. This test has not been reviewed by the FDA.
2. Negative results do not rule out COVID-19 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals.
3. Results from antibody testing should not be used as the sole basis to diagnose or exclude COVID-19 infection or to inform infection status.
4. Positive results may be due to past or present infection with non-COVID-19 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E.
5. Not for the screening of donated blood .
6. Do not smoke, drink, or eat in areas where specimens or kit reagents are being handled.
7. Dispose of all specimens and materials used to perform the test as biohazardous waste.
8. Handle the negative and positive controls in the same manner as patient specimens for operator protection.
9. Do not perform the test in a room with strong air flow, i.e. an electric fan or strong air-conditioning.

【EXPLANATION OF LABELS】

IVD	In Vitro Diagnostic Use		See Instruction for Use	REF	Catalog #
LOT	Batch Number		Expiry Date		Manufacturing Date
	Do not reuse	4℃ 30℃	Store between 4～30℃		Keep away from Sunlight
	Keep Dry		Manufacturer	EC REP	EU Authorized Representative
CE	CE Mark				

【BASIC INFORMATION】

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【DATE OF APPROVALAND AMENDMENT OF IFU】： June-2020