RENDER

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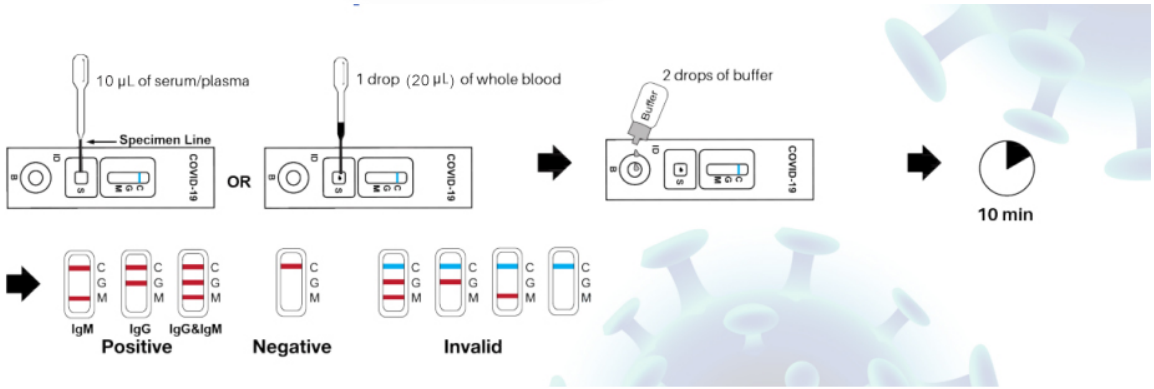
RENDER

COVID-19 IgM&IgG Test (Immunochromatography)



Disease background

In January 12, 2020, the novel coronavirus was named by WHO as COVID-19.

COVID-19 is mainly transmitted by droplet transmission, contact transmission and limited aerosol propagation. After COVID-19 viral infection, the virus has a incubation period of 1-14 days. Most patients show syndroms in 3-7 days. During the incubation period, close contacts without effective protection are also highly infectious. The virus has spread to tens of thousands of people and killed thousands of people in dozens of countries.

Symptomatic transmission of the disease

The range of reported diseases of COVID-19 ranges from mild symptoms to severe diseases and even death. The symptoms include fever, cough and shortness of breath.

Based on the current epidemiological, the virus is believed to be primarily transmitted from human to human, including close human to human contact (within about 6 feet), droplets produced when coughing or sneezing through an infected person, as these droplets may fall into the mouth or nose of a nearby person or may be inhaled into the lungs.

Product features

(1) Test sample: whole blood, serum and plasma
(2) Rapid screening of suspected cases in 5-10 minutes
(3) Reduce the risk of individual infection in hospital
(4) No need of instruments and equipment, suitable for on-site inspection
(5) Early diagnosis, early treatment and shortening the course of disease;
(6) Work of designated hospitals to alleviate epidemic situation

Test principle

The novel coronavirus COVID-19 IgG/IgM test kit (whole blood / serum / plasma) is a solid phase immunochromatography assay for rapid detection of COVID-19-spcific lgG and IgM antibodies in the blood.

In the process of infection, IgM&IgG are the first antibodies appearing in the human immune System. The detection of these antibodies can be used as an indirect method to exam COVID-19 in the period of acute infection.

The COVID-19-specific IgM&IgG antibodies have the advantages of high specificity, early diagnosis time and ability to determine whether the suspected person is infected. Therefore, the detection of COVID-19-specific IgM &IgG antibodies has important clinical significance, and is of great significance for effective control of large-scale transmission of COVID-19.

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RENDER

INSTRUCTION FOR USE

COVID-19 IgM & IgG Test (Immunochromatography)

【Reference Code】

320101701

【Packing Specifications】

20 T/Kit

【Intended Use】

This product is used for in vitro qualitative detection of COVID-19 IgM and IgG antibody in human serum, plasma or whole blood. Coronavirus belongs to coronaviridae, nidovirales and is divided into α, β and γ genuses. α and β genuses can only make mammal sick and y genus mainly causes birds to be infected. CoV is mainly transmitted through direct contacting secreta or transmitted byaerosol or spray. But there is also evidence certifying it can be transmitted by the fecal-oral route. By now, there has been already up to 7 types of HCoVs that can cause human respiratory disease:

HCoV-229E, HCoV-OC43, SARS-CoV, HCoV-NL63, HCoV-HKU1, MERS-CoV and SARS-CoV-2, so HCoV is the major causative agent to cause human respiratory tract infection. Therein, the COVID-19 was discovered due to 2019 viral pneumonia case in Wuhan, of which the clinical manifestation includes fever and fatigue, etc. constitutional symptoms, accompanied by dry cough and dyspnea, etc. It can evolve into severe pneumonia, respiratory failure, acute respiratory distress syndrome, septic shock, multiple organ failure and severe acid-base unbalance, etc. and even life-threatening.

【Test Principle】

This reagent applies the principle of colloidal gold immunochromatography. Colloidal gold-labeled recombinant COVID-19 antigen and colloidal gold-labeled chicken IgY antibody is entrapped in label pad;Mouse anti-Human IgM antibody (T1 line), Mouse anti-Human IgG antibody (T2 line) and Goat anti-Chicken IgY antibody (C line) is entrapped in nitrocellulose membrane.When appropriate amount of test specimen moves along the label pad and nitrocellulose membrane under the capillary action, if there are IgM antibodies in test specimen, they would combine with colloidal gold-labeled recombinant COVID-19 antigen and form immune complex which would be captured by the settled Mouse anti-Human IgM antibody in membrane, forming a magenta T1 line to display COVID-19 IgM antibody positive. If there are IgG antibodies in test specimen, they would combine with colloidal gold-labeled recombinant COVID-19 antigen and form immune complex which would be captured by the settled Mouse anti-Human IgG antibody in membrane, forming a magenta T2 line to display COVID-19 IgG antibody positive.If both line T1 and T2 display no color, the result is negative. There is also a quality control line C on the test card. No matter whether test line T1 and T2 appear, the magenta quality line should appear. The quality control line C is the immune complex color band for colloidal gold-labeled chicken IgY antibody and Goat Anti-Chicken IgY antibody. If the quality control line C doesn’t appear, it means the test result is invalid. The specimen needs to be tested again.

【Main Components】

Main components of this product include: Test card (20 tests), Sample diluent (1 bottle 3mL) and specification (1 copy).

1. The test card is composed of test strip and plastic shell. The main constituents of the test strip include:
   a. Colloidal gold-labeled COVID-19 antigen, chicken IgY antibody (coated on fiberglass);
   b. C line: Goat anti-Chicken IgY antibody (coated on nitrocellulose membrane);
   c. T line: Mouse anti-Human IgM /IgG antibody (coated on nitrocellulose membrane);
   d. PVC baseboard.
2. Sample diluent: CB solution.

【Storage Instructions】

1. Store at room temperature (2 - 30℃ or 35.6-86°F) in a dry place. Avoid direct sunlight.
2. 18 months of shelf life (date of manufacture to expiration date).

【Specimen Collection and Requirements】

1. Whole blood, serum or heparinized and EDTA.K2, heparin, sodium citrate treated plasma/whole blood can be tested.
2. Samples should be collected in an approved blood collection device. Contaminated samples should not be used.
3. Samples are recommended to be tested immediately after being collected. Serum/plasma samples should be separated as soon as possible after collection to avoid hemolysis. Extensively hemolyzed samples should not to be used.
4. Anticoagulant treated whole blood samples may be stored at 2-8℃ for up to 24 hours if not tested immediately.
5. Serum/plasma samples should be stored below –20℃ and subjected to one freeze thaw cycle to avoid analyte deteriorate.
6. Allow samples to warm to room temperature (20-25℃) before use.
7. Samples with extensive hemolysis or lipemia or high levels of bilirubin are not allowed to be used.

【Test Procedure】

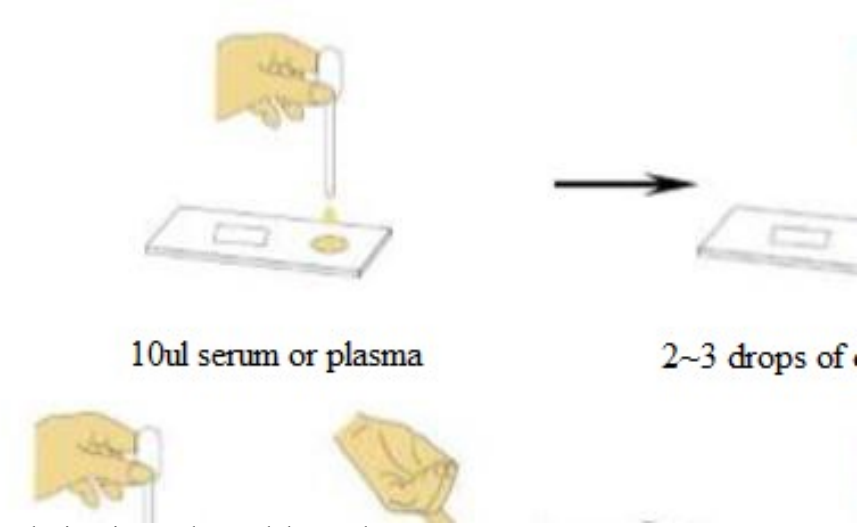
Step 1: Warm stored samples to room temperature before starting use;

Step 2: Remove a test card from the foil pouch. Follow the instruction of use;

(Caution: Keep the test card sealed in the protective foil pouch until just before use. The test card should be used within 1 hour once it is opened. If the temperature is higher than 30°C or under conditions of high humidity, it should be used immediately once the foil pouch is opened);

Step 3: Label the sample ID on the test card.;

Step 4: Add 10μL of sample (Serum/Plasma) or 20μL of whole blood to sample port and immediately add 2-3 drops (80-90μL) of sample diluent into the sample port.;



Step 5: Start 5-10 minutes of incubation time and record the result.

NOTE: The result will be invalid after 15 minutes. After observing and record the result, dispose of bio-hazardous materials should follow the practices of your institution. Discard all materials in a safe and acceptable manner and in compliance with all federal, state, and local requirements.

【Explanation of Test Result】

1. Negative result: if only the quality control line C appears and test line T1 and T2 show no color, it means no COVID-19 antibody is detected and the test result is negative (as shown in following figure).

2. Positive result:

2.1 If both quality control line C and T1 appear, it means the COVID-19 IgM antibody is detected and the test result is IgM antibody positive (as shown in following figure).

2.2 If both quality control line C and T2 appear, it means the COVID-19 IgG antibody is detected and the test result is IgG antibody positive (as shown in following figure).

2.3 If both quality control line C, T1 and T2 appear, it means the COVID-19 IgM and IgG antibody are detected and the test result is IgM and IgG antibody positive (as shown in following figure).

3. Invalid result: if quality control line C can't be observed, regardless of test line. The result is invalid. (as shown in following figure) The sample should be tested again.

【Limitation of the Test Method】

1. This reagent is for COVID-19 IgM/IgG antibody detection only. The test result is only for reference and shouldn't be used as the only basis for clinical diagnosis and treatment. Patients clinical management should be integrated with their symptoms/signs, medical history and other laboratory examination and therapeutic response, etc. conditions.
2. When the sample has insufficient antibody concentration it may result in negative result. It is suggested to carry out confirmation test according to patient's clinical conditions.

【Clinical Performance】

The COIVD-19 IgM/IgG Test has been evaluated with 264 clinical samples. Both 114 of COVID-19 negatives and 150 of COVID-19 positives were confirmed by RT-PCR and clinical diagnosis including chest CT and clinical signs etc.

The COVID-19 IgM test v.s. RT-PCR & clinical diagnosis

Test Method		RT-PCR& Clinical diagnosis		Total
		Positive	Negative	
COVID-19 IgM & IgG Test	Positive	132	6	138
	Negative	18	108	126
Total		150	114	264

The COVID-19 IgG test v.s. RT-PCR & clinical diagnosis

Test Method		RT-PCR& Clinical diagnosis		Total
		Positive	Negative	
COVID-19 IgM & IgG Test	Positive	126	3	129
	Negative	24	111	135
Total		150	114	264

The sensitivity of IgM test is 92% (138/150) and specificity is 94.7% (108/114) comparing with RT-PCR.

The sensitivity of IgG test is 86% (129/150) and specificity is 97.4% (111/114) comparing with RT-PCR.

The total clinical agreements of IgM & IgG are 90.9% (240/264) and 89.8% (237/264) respectively.

【Notes】

1. Before using this kit, make sure to read this specification carefully and strictly control reaction time. Operating not in accordance with the specification may result in inaccurate result;
2. Specimen test should be carried out in the laboratory with certain condition. All specimens and materials should be treated according to the laboratory practice for infectious diseases;
3. Beware of the product being affected with damp; don't open the aluminum foil bag before ready for test; don't continue to use those products with aluminum foil bag damaged or test card affected with damp for test;
4. Don't use other components to replace the one in the kit;
5. Don't test contaminated specimens;
6. Don't dilute specimen before test; otherwise, it may cause inaccurate result;
7. When COVID-19 antibody titer in the specimen is lower than the limit of detection, the kit may show negative result;
8. The specimen containing high titer heterophil antibody or rheumatoid factors may affect testing result.

【References】

1.Guidelines for Preparation of In Vitro Diagnostic Reagent Specification, No. 17, 2014

2.Diagnosis and Treatment of Scheme of Pneumonia Infected by COVID-19 (Tril Version Seven)

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【Explanation of Symbols on Label and Package】

	For single use only	
	Date of production	
	In vitro diagnostic medical device	
		

COVID-19 IgM & IgG Test (Immunochromatography)

Stability Study Report

1. The determination basis of stability study method

The stability test is based on " Registration Management Measures for IVD Reagents (Trial Implementation) " and "EN13640:2002" standard.

2. Stability Test Protocol

The stability study of kit is to evaluate its quality with the increase of storage time under specific storage condition, and determine its shelf life under specific storage condition base on the relevant data.

37℃ accelerated stability assessment is mainly based on "Chinese Biological Product Regulation"(2000 Edit), store the kits at 37℃ constant temperature for 25 days, test in different scheduled period within storage time; It should remain stable for over 20 days at 37℃ constant temperature.

Analog stability test during transportation process is to put 3 batches of finished products onto the company's van, investigate the stability of finished products under analog transportation conditions. After transported for 15 days, still store the kits at (2-30) ℃, test on day 5, day 10 and day 15 , it should be complied with the regulated requirements.

Stability Test under Storage Temperature after Unsealing of the pouch. The packing style of this detection kit is one detection device with one aluminum pouch, since it can not be reused after unsealing of the pouch, the stability test under storage temperature after unsealing of the pouch is not available.

3. Method and Process of Stability Study

3.1 37℃ Assessment of Accelerated Stability Test

3.1.1Test Materials

COVID-19 IgM & IgG Test (Immunochromatography), batches are:20200203; 20200204; 20200205. Internal QC controls: Internal QC panel (Batch is 202002)

3.1.2 Test Method

Select 180 tests for each batch from 3 batches of finished COVID-19 IgM & IgG Test (Immunochromatography). Store under 37℃ constant temperature for 25 days. Test every 5 days, means test on day 5,10,15 ,20, 25. Use the company's internal QC controls as the assessment samples; Test the items according to the criteria of the stability test, and to investigate the change range of the quality of kits with the increase of storage time. Finally collect the test results and make statistics.

3.1.3The criteria of the stability test

The kits should remain stable for over 20 days under constant storage temperature 37℃, means after being stored for 25 days under the specified conditions, the quality of kits must still meet the criteria of the finished products.

3.2 Analog Stability Test during Transportation Process

3.2.1Test Materials

COVID-19 IgM & IgG Test (Immunochromatography), batches are: 20200203; 20200204; 20200205. Internal QC controls: Internal QC panel (Batch is 202002)

3.2.2 Test Method

Select 120 tests for each batch from finished COVID-19 IgM & IgG Test (Immunochromatography), put 3 batches of finished products(180 tests for each batch) onto the company's van, to investigate the stability of finished products under analog transportation conditions. Restore the kits which have been stored 5 days,10 days, and 15 days on the company's van under （2-30）℃ temperature respectively. The main navigation route of the van covers National Highway, Express way, Township road etc. During testing, make daily records of every day's temperature and humidity as well as the daily mileage of the van. Use the company's internal QC controls as the assessment samples; Test the items according to the criteria of the stability test, and to investigate the change range of

the quality of kits with the increase of storage time. Finally collect up the test results and make statistics.

4 The criteria of stability test

4.1 Physical Inspection

4.1.1 Visual Test

Flat, the stickiness of materials should be fast, unabridged content.

4.2 Negative reference coincidence rate

Use the same batch of test kits to test 10 samples of internal control negative reference（N1～N10）, the test results of IgM & IgG should be negative, the negative coincidence rate should be 10/10;

4.3 Positive reference coincidence rate

Use the same batch of test kits to test 10 samples of internal control positive reference（P1～P10）,at least 8 / 10 IgM positives and 9 / 10 IgG positives should be tested .

4.4 Sensitivity reference

Use the same batch of test kits to test 3 samples of internal control sensitivity reference（C1～C3）, C1 should be tested both IgM and IgG strongly positive, C2 should be tested IgM moderately positive or weakly positive and IgG moderately positive, C3 should be tested IgM weakly positive or negative and IgG weakly positive.

4.5 Repeatability reference

Use 1 sample of internal control repeatability reference （J1）to do parallel tests on 10 test devices. The results should be coincident.

5 The Solution of Inconsistent Stability Test

The testing process is operated strictly as stated on user manual. The reason should be firstly found out if the testing result is not complied with the requirements. After finding out the reason, the inconsistent sample should be remeasured for 10 times and make determination based on the double test result. The environmental conditions of testing lab should be room temperature （18～

26）℃.

6 Assessment of Stability Test & Data Statistics

6.1 37℃ Accelerated Stability Test

Table 1 37℃ accelerated stability test result for Batch# 20200203

Test Item		Test Result										whether the require-ments are met, Yes/ No
37℃，Day 5												
Negative Reference	Test Sample	N1	N2	N3	N4	N5	N6	N7	N8	N9	N10	Yes
	IgM Test Result	-	-	-	-	-	-	-	-	-	-	
	IgG Test Result	-	-	-	-	-	-	-	-	-	-	
IgM & IgG Positive Reference	Test Sample	P1	P2	P3	P4	P5	P6	P7	P8	P9	P10	
	IgM Test Result	+	+	+	+	+	+	+	+	+	+	
	IgG Test Result	+	+	+	+	+	+	+	+	+	+	
Sensitivity Reference）	Test Sample	C1			C2			C3				
	IgM Test Result	+++			++			+				
	IgG Test Result	+++			++			+				
Intra-assay repeatability Reference（J1）	Test device	1	2	3	4	5	6	7	8	9	10	
	IgM Test Result	+	+	+	+	+	+	+	+	+	+	
	IgG Test Result	+	+	+	+	+	+	+	+	+	+	
37℃，Day 10												
Negative Reference	Test Sample	N1	N2	N3	N4	N5	N6	N7	N8	N9	N10	Yes
	IgM Test Result	-	-	-	-	-	-	-	-	-	-	
	IgG Test Result	-	-	-	-	-	-	-	-	-	-	
IgM & IgG Positive Reference	Test Sample	P1	P2	P3	P4	P5	P6	P7	P8	P9	P10	
	IgM Test Result	+	+	+	+	+	+	+	+	+	+	
	IgG Test Result	+	+	+	+	+	+	+	+	+	+	
Sensitivity Reference）	Test Sample	C1			C2			C3				
	IgM Test Result	+++			+			+				
	IgG Test Result	+++			++			+				
Intra-assay repeatability Reference（J1）	Test device	1	2	3	4	5	6	7	8	9	10	
	IgM Test Result	+	+	+	+	+	+	+	+	+	+	
	IgG Test Result	+	+	+	+	+	+	+	+	+	+	
37℃，Day 15												
Negative Reference	Test Sample	N1	N2	N3	N4	N5	N6	N7	N8	N9	N10	Yes
	IgM Test Result	-	-	-	-	-	-	-	-	-	-	
	IgG Test Result	-	-	-	-	-	-	-	-	-	-	
IgM & IgG Positive Reference	Test Sample	P1	P2	P3	P4	P5	P6	P7	P8	P9	P10	
	IgM Test Result	+	+	+	+	+	+	+	+	+	+	
	IgG Test Result	+	+	+	+	+	+	+	+	+	+	
Sensitivity Reference）	Test Sample	C1			C2			C3				
	IgM Test Result	+++			++			+				
	IgG Test Result	+++			++			+				

Intra-assay repeatability Reference（J1）	Test device	1	2	3	4	5	6	7	8	9	10	
	IgM Test Result	+	+	+	+	+	+	+	+	+	+	
	IgG Test Result	+	+	+	+	+	+	+	+	+	+	
37℃，Day 20												
Negative Reference	Test Sample	N1	N2	N3	N4	N5	N6	N7	N8	N9	N10	Yes
	IgM Test Result	-	-	-	-	-	-	-	-	-	-	
	IgG Test Result	-	-	-	-	-	-	-	-	-	-	
IgM & IgG Positive Reference	Test Sample	P1	P2	P3	P4	P5	P6	P7	P8	P9	P10	
	IgM Test Result	+	+	+	+	+	+	+	+	+	+	
	IgG Test Result	+	+	+	+	+	+	+	+	+	+	
Sensitivity Reference）	Test Sample	C1			C2			C3				
	IgM Test Result	+++			++			+				
	IgG Test Result	+++			++			+				
Intra-assay repeatability Reference（J1）	Test device	1	2	3	4	5	6	7	8	9	10	
	IgM Test Result	+	+	+	+	+	+	+	+	+	+	
	IgG Test Result	+	+	+	+	+	+	+	+	+	+	
37℃，Day 25												
Negative Reference	Test Sample	N1	N2	N3	N4	N5	N6	N7	N8	N9	N10	Yes
	IgM Test Result	-	-	-	-	-	-	-	-	-	-	
	IgG Test Result	-	-	-	-	-	-	-	-	-	-	
IgM & IgG Positive Reference	Test Sample	P1	P2	P3	P4	P5	P6	P7	P8	P9	P10	
	IgM Test Result	+	+	+	+	+	+	+	+	+	+	
	IgG Test Result	+	+	+	+	+	+	+	+	+	+	
Sensitivity Reference）	Test Sample	C1			C2			C3				
	IgM Test Result	+++			+			-				
	IgG Test Result	+++			++			+				
Intra-assay repeatability Reference（J1）	Test device	1	2	3	4	5	6	7	8	9	10	
	IgM Test Result	+	+	+	+	+	+	+	+	+	+	
	IgG Test Result	+	+	+	+	+	+	+	+	+	+	

Table 2 37℃ accelerated stability test result for Batch# 20200204

Test Item	**Test Result**										**whether the require-ments are met, Yes/ No**
37℃，Day 5											
Negative Reference	Test Sample	N1	N2	N3	N4	N5	N6	N7	N8	N9	N10	Yes
	IgM Test Result	-	-	-	-	-	-	-	-	-	-	
	IgG Test Result	-	-	-	-	-	-	-	-	-	-	
IgM & IgG Positive Reference	Test Sample	P1	P2	P3	P4	P5	P6	P7	P8	P9	P10	
	IgM Test Result	+	+	+	+	+	+	+	+	+	+	
	IgG Test Result	+	+	+	+	+	+	+	+	+	+	
Sensitivity Reference）	Test Sample	C1			C2			C3				
	IgM Test Result	+++			++			+				
	IgG Test Result	+++			++			+				

Intra-assay repeatability Reference（J1）	Test device	1	2	3	4	5	6	7	8	9	10	
	IgM Test Result	+	+	+	+	+	+	+	+	+	+	
	IgG Test Result	+	+	+	+	+	+	+	+	+	+	
37℃，Day 10												
Negative Reference	Test Sample	N1	N2	N3	N4	N5	N6	N7	N8	N9	N10	Yes
	IgM Test Result	-	-	-	-	-	-	-	-	-	-	
	IgG Test Result	-	-	-	-	-	-	-	-	-	-	
IgM & IgG Positive Reference	Test Sample	P1	P2	P3	P4	P5	P6	P7	P8	P9	P10	
	IgM Test Result	+	+	+	+	+	+	+	+	+	+	
	IgG Test Result	+	+	+	+	+	+	+	+	+	+	
Sensitivity Reference）	Test Sample	C1			C2			C3				
	IgM Test Result	+++			++			+				
	IgG Test Result	+++			++			+				
Intra-assay repeatability Reference（J1）	Test device	1	2	3	4	5	6	7	8	9	10	
	IgM Test Result	+	+	+	+	+	+	+	+	+	+	
	IgG Test Result	+	+	+	+	+	+	+	+	+	+	
37℃，Day 15												
Negative Reference	Test Sample	N1	N2	N3	N4	N5	N6	N7	N8	N9	N10	Yes
	IgM Test Result	-	-	-	-	-	-	-	-	-	-	
	IgG Test Result	-	-	-	-	-	-	-	-	-	-	
IgM & IgG Positive Reference	Test Sample	P1	P2	P3	P4	P5	P6	P7	P8	P9	P10	
	IgM Test Result	+	+	+	+	+	+	+	+	+	+	
	IgG Test Result	+	+	+	+	+	+	+	+	+	+	
Sensitivity Reference）	Test Sample	C1			C2			C3				
	IgM Test Result	+++			+			+				
	IgG Test Result	+++			++			+				
Intra-assay repeatability Reference（J1）	Test device	1	2	3	4	5	6	7	8	9	10	
	IgM Test Result	+	+	+	+	+	+	+	+	+	+	
	IgG Test Result	+	+	+	+	+	+	+	+	+	+	
37℃，Day 20												
Negative Reference	Test Sample	N1	N2	N3	N4	N5	N6	N7	N8	N9	N10	Yes
	IgM Test Result	-	-	-	-	-	-	-	-	-	-	
	IgG Test Result	-	-	-	-	-	-	-	-	-	-	
IgM & IgG Positive Reference	Test Sample	P1	P2	P3	P4	P5	P6	P7	P8	P9	P10	
	IgM Test Result	+	+	+	+	+	+	+	+	+	+	
	IgG Test Result	+	+	+	+	+	+	+	+	+	+	
Sensitivity Reference）	Test Sample	C1			C2			C3				
	IgM Test Result	+++			+			-				
	IgG Test Result	+++			++			+				
Intra-assay repeatability Reference（J1）	Test device	1	2	3	4	5	6	7	8	9	10	
	IgM Test Result	+	+	+	+	+	+	+	+	+	+	
	IgG Test Result	+	+	+	+	+	+	+	+	+	+	
37℃，Day 25												
Negative Reference	Test Sample	N1	N2	N3	N4	N5	N6	N7	N8	N9	N10	Yes
	IgM Test Result	-	-	-	-	-	-	-	-	-	-	
	IgG Test Result	-	-	-	-	-	-	-	-	-	-	
IgM & IgG	Test Sample	P1	P2	P3	P4	P5	P6	P7	P8	P9	P10	

Positive Reference	IgM Test Result	+	+	+	+	+	+	+	+	+	+	
	IgG Test Result	+	+	+	+	+	+	+	+	+	+	
Sensitivity Reference）	Test Sample	C1			C2			C3				
	IgM Test Result	+++			+			-				
	IgG Test Result	+++			++			+				
Intra-assay repeatability Reference （J1）	Test device	1	2	3	4	5	6	7	8	9	10	
	IgM Test Result	+	+	+	+	+	+	+	+	+	+	
	IgG Test Result	+	+	+	+	+	+	+	+	+	+	

Table 3 37℃ accelerated stability test result for Batch# 20200205

Test Item		**Test Result**										**whether the require-ments are met, Yes/ No**
37℃，Day 5												
Negative Reference	Test Sample	N1	N2	N3	N4	N5	N6	N7	N8	N9	N10	Yes
	IgM Test Result	-	-	-	-	-	-	-	-	-	-	
	IgG Test Result	-	-	-	-	-	-	-	-	-	-	
IgM & IgG Positive Reference	Test Sample	P1	P2	P3	P4	P5	P6	P7	P8	P9	P10	
	IgM Test Result	+	+	+	+	+	+	+	+	+	+	
	IgG Test Result	+	+	+	+	+	+	+	+	+	+	
Sensitivity Reference）	Test Sample	C1			C2			C3				
	IgM Test Result	+++			+			+				
	IgG Test Result	+++			++			+				
Intra-assay repeatability Reference （J1）	Test device	1	2	3	4	5	6	7	8	9	10	
	IgM Test Result	+	+	+	+	+	+	+	+	+	+	
	IgG Test Result	+	+	+	+	+	+	+	+	+	+	
37℃，Day 10												
Negative Reference	Test Sample	N1	N2	N3	N4	N5	N6	N7	N8	N9	N10	Yes
	IgM Test Result	-	-	-	-	-	-	-	-	-	-	
	IgG Test Result	-	-	-	-	-	-	-	-	-	-	
IgM & IgG Positive Reference	Test Sample	P1	P2	P3	P4	P5	P6	P7	P8	P9	P10	
	IgM Test Result	+	+	+	+	+	+	+	+	+	+	
	IgG Test Result	+	+	+	+	+	+	+	+	+	+	
Sensitivity Reference）	Test Sample	C1			C2			C3				
	IgM Test Result	+++			++			-				
	IgG Test Result	+++			++			+				
Intra-assay repeatability Reference （J1）	Test device	1	2	3	4	5	6	7	8	9	10	
	IgM Test Result	+	+	+	+	+	+	+	+	+	+	
	IgG Test Result	+	+	+	+	+	+	+	+	+	+	
37℃，Day 15												
Negative Reference	Test Sample	N1	N2	N3	N4	N5	N6	N7	N8	N9	N10	Yes
	IgM Test Result	-	-	-	-	-	-	-	-	-	-	
	IgG Test Result	-	-	-	-	-	-	-	-	-	-	

IgM & IgG Positive Reference	Test Sample	P1	P2	P3	P4	P5	P6	P7	P8	P9	P10	
	IgM Test Result	+	+	+	+	+	+	+	+	+	+	
	IgG Test Result	+	+	+	+	+	+	+	+	+	+	
Sensitivity Reference）	Test Sample	C1			C2			C3				
	IgM Test Result	+++			++			-				
	IgG Test Result	+++			++			+				
Intra-assay repeatability Reference（J1）	Test device	1	2	3	4	5	6	7	8	9	10	
	IgM Test Result	+	+	+	+	+	+	+	+	+	+	
	IgG Test Result	+	+	+	+	+	+	+	+	+	+	
37℃，Day 20												
Negative Reference	Test Sample	N1	N2	N3	N4	N5	N6	N7	N8	N9	N10	Yes
	IgM Test Result	-	-	-	-	-	-	-	-	-	-	
	IgG Test Result	-	-	-	-	-	-	-	-	-	-	
IgM & IgG Positive Reference	Test Sample	P1	P2	P3	P4	P5	P6	P7	P8	P9	P10	
	IgM Test Result	+	+	+	+	+	+	+	+	+	+	
	IgG Test Result	+	+	+	+	+	+	+	+	+	+	
Sensitivity Reference）	Test Sample	C1			C2			C3				
	IgM Test Result	+++			+			+				
	IgG Test Result	+++			++			+				
Intra-assay repeatability Reference（J1）	Test device	1	2	3	4	5	6	7	8	9	10	
	IgM Test Result	+	+	+	+	+	+	+	+	+	+	
	IgG Test Result	+	+	+	+	+	+	+	+	+	+	
37℃，Day 25												
Negative Reference	Test Sample	N1	N2	N3	N4	N5	N6	N7	N8	N9	N10	Yes
	IgM Test Result	-	-	-	-	-	-	-	-	-	-	
	IgG Test Result	-	-	-	-	-	-	-	-	-	-	
IgM & IgG Positive Reference	Test Sample	P1	P2	P3	P4	P5	P6	P7	P8	P9	P10	
	IgM Test Result	+	+	+	+	+	+	+	+	+	+	
	IgG Test Result	+	+	+	+	+	+	+	+	+	+	
Sensitivity Reference）	Test Sample	C1			C2			C3				
	IgM Test Result	+++			+			+				
	IgG Test Result	+++			++			+				
Intra-assay repeatability Reference（J1）	Test device	1	2	3	4	5	6	7	8	9	10	
	IgM Test Result	+	+	+	+	+	+	+	+	+	+	
	IgG Test Result	+	+	+	+	+	+	+	+	+	+	

6.2 Analog Stability Test during Transportation Process

Table 4 Test results for analog stability test during transportation process for Batch# 20200203

Test Item	Test Result	whether the require-ments are met, Yes/ No
Day 5		

Negative Reference	Test Sample	N1	N2	N3	N4	N5	N6	N7	N8	N9	N10	Yes
	IgM Test Result	-	-	-	-	-	-	-	-	-	-	
	IgG Test Result	-	-	-	-	-	-	-	-	-	-	
IgM & IgG Positive Reference	Test Sample	P1	P2	P3	P4	P5	P6	P7	P8	P9	P10	
	IgM Test Result	+	+	+	+	+	+	+	+	+	+	
	IgG Test Result	+	+	+	+	+	+	+	+	+	+	
Sensitivity Reference）	Test Sample	C1			C2			C3				
	IgM Test Result	+++			++			+				
	IgG Test Result	+++			++			+				
Intra-assay repeatability Reference（J1）	Test device	1	2	3	4	5	6	7	8	9	10	
	IgM Test Result	+	+	+	+	+	+	+	+	+	+	
	IgG Test Result	+	+	+	+	+	+	+	+	+	+	
Day 10												
Negative Reference	Test Sample	N1	N2	N3	N4	N5	N6	N7	N8	N9	N10	Yes
	IgM Test Result	-	-	-	-	-	-	-	-	-	-	
	IgG Test Result	-	-	-	-	-	-	-	-	-	-	
IgM & IgG Positive Reference	Test Sample	P1	P2	P3	P4	P5	P6	P7	P8	P9	P10	
	IgM Test Result	+	+	+	+	+	+	+	+	+	+	
	IgG Test Result	+	+	+	+	+	+	+	+	+	+	
Sensitivity Reference）	Test Sample	C1			C2			C3				
	IgM Test Result	+++			+			-				
	IgG Test Result	+++			++			+				
Intra-assay repeatability Reference（J1）	Test device	1	2	3	4	5	6	7	8	9	10	
	IgM Test Result	+	+	+	+	+	+	+	+	+	+	
	IgG Test Result	+	+	+	+	+	+	+	+	+	+	
Day 15												
Negative Reference	Test Sample	N1	N2	N3	N4	N5	N6	N7	N8	N9	N10	Yes
	IgM Test Result	-	-	-	-	-	-	-	-	-	-	
	IgG Test Result	-	-	-	-	-	-	-	-	-	-	
IgM & IgG Positive Reference	Test Sample	P1	P2	P3	P4	P5	P6	P7	P8	P9	P10	
	IgM Test Result	+	+	+	+	+	+	+	+	+	+	
	IgG Test Result	+	+	+	+	+	+	+	+	+	+	
Sensitivity Reference）	Test Sample	C1			C2			C3				
	IgM Test Result	+++			++			-				
	IgG Test Result	+++			++			+				
Intra-assay repeatability Reference（J1）	Test device	1	2	3	4	5	6	7	8	9	10	
	IgM Test Result	+	+	+	+	+	+	+	+	+	+	
	IgG Test Result	+	+	+	+	+	+	+	+	+	+	

Table 5 Test results for analog stability test during transportation process for Batch# 20200204

Test Item		Test Result										whether the require-ments are met, Yes/ No
Day 5												
Negative Reference	Test Sample	N1	N2	N3	N4	N5	N6	N7	N8	N9	N10	Yes
	IgM Test Result	-	-	-	-	-	-	-	-	-	-	
	IgG Test Result	-	-	-	-	-	-	-	-	-	-	
IgM & IgG Positive Reference	Test Sample	P1	P2	P3	P4	P5	P6	P7	P8	P9	P10	
	IgM Test Result	+	+	+	+	+	+	+	+	+	+	
	IgG Test Result	+	+	+	+	+	+	+	+	+	+	
Sensitivity Reference）	Test Sample	C1			C2			C3				
	IgM Test Result	+++			++			-				
	IgG Test Result	+++			++			+				
Intra-assay repeatability Reference（J1）	Test device	1	2	3	4	5	6	7	8	9	10	
	IgM Test Result	+	+	+	+	+	+	+	+	+	+	
	IgG Test Result	+	+	+	+	+	+	+	+	+	+	
Day 10												
Negative Reference	Test Sample	N1	N2	N3	N4	N5	N6	N7	N8	N9	N10	Yes
	IgM Test Result	-	-	-	-	-	-	-	-	-	-	
	IgG Test Result	-	-	-	-	-	-	-	-	-	-	
IgM & IgG Positive Reference	Test Sample	P1	P2	P3	P4	P5	P6	P7	P8	P9	P10	
	IgM Test Result	+	+	+	+	+	+	+	+	+	+	
	IgG Test Result	+	+	+	+	+	+	+	+	+	+	
Sensitivity Reference）	Test Sample	C1			C2			C3				
	IgM Test Result	+++			++			-				
	IgG Test Result	+++			++			+				
Intra-assay repeatability Reference（J1）	Test device	1	2	3	4	5	6	7	8	9	10	
	IgM Test Result	+	+	+	+	+	+	+	+	+	+	
	IgG Test Result	+	+	+	+	+	+	+	+	+	+	
Day 15												
Negative Reference	Test Sample	N1	N2	N3	N4	N5	N6	N7	N8	N9	N10	Yes
	IgM Test Result	-	-	-	-	-	-	-	-	-	-	
	IgG Test Result	-	-	-	-	-	-	-	-	-	-	
IgM & IgG Positive Reference	Test Sample	P1	P2	P3	P4	P5	P6	P7	P8	P9	P10	
	IgM Test Result	+	+	+	+	+	+	+	+	+	+	
	IgG Test Result	+	+	+	+	+	+	+	+	+	+	
Sensitivity Reference）	Test Sample	C1			C2			C3				
	IgM Test Result	+++			+			+				
	IgG Test Result	+++			++			+				
Intra-assay repeatability Reference（J1）	Test device	1	2	3	4	5	6	7	8	9	10	
	IgM Test Result	+	+	+	+	+	+	+	+	+	+	
	IgG Test Result	+	+	+	+	+	+	+	+	+	+	

Table 6 Test results for analog stability test during transportation process For Batch# 20200205

Test Item		Test Result										whether the require-ments are met, Yes/ No
Day 5												
Negative Reference	Test Sample	N1	N2	N3	N4	N5	N6	N7	N8	N9	N10	Yes
	IgM Test Result	-	-	-	-	-	-	-	-	-	-	
	IgG Test Result	-	-	-	-	-	-	-	-	-	-	
IgM & IgG Positive Reference	Test Sample	P1	P2	P3	P4	P5	P6	P7	P8	P9	P10	
	IgM Test Result	+	+	+	+	+	+	+	+	+	+	
	IgG Test Result	+	+	+	+	+	+	+	+	+	+	
Sensitivity Reference）	Test Sample	C1			C2			C3				
	IgM Test Result	+++			+			+				
	IgG Test Result	+++			++			+				
Intra-assay repeatability Reference（J1）	Test device	1	2	3	4	5	6	7	8	9	10	
	IgM Test Result	+	+	+	+	+	+	+	+	+	+	
	IgG Test Result	+	+	+	+	+	+	+	+	+	+	
Day 10												
Negative Reference	Test Sample	N1	N2	N3	N4	N5	N6	N7	N8	N9	N10	Yes
	IgM Test Result	-	-	-	-	-	-	-	-	-	-	
	IgG Test Result	-	-	-	-	-	-	-	-	-	-	
IgM & IgG Positive Reference	Test Sample	P1	P2	P3	P4	P5	P6	P7	P8	P9	P10	
	IgM Test Result	+	+	+	+	+	+	+	+	+	+	
	IgG Test Result	+	+	+	+	+	+	+	+	+	+	
Sensitivity Reference）	Test Sample	C1			C2			C3				
	IgM Test Result	+++			+			-				
	IgG Test Result	+++			++			+				
Intra-assay repeatability Reference（J1）	Test device	1	2	3	4	5	6	7	8	9	10	
	IgM Test Result	+	+	+	+	+	+	+	+	+	+	
	IgG Test Result	+	+	+	+	+	+	+	+	+	+	
Day 15												
Negative Reference	Test Sample	N1	N2	N3	N4	N5	N6	N7	N8	N9	N10	Yes
	IgM Test Result	-	-	-	-	-	-	-	-	-	-	
	IgG Test Result	-	-	-	-	-	-	-	-	-	-	
IgM & IgG Positive Reference	Test Sample	P1	P2	P3	P4	P5	P6	P7	P8	P9	P10	
	IgM Test Result	+	+	+	+	+	+	+	+	+	+	
	IgG Test Result	+	+	+	+	+	+	+	+	+	+	
Sensitivity Reference）	Test Sample	C1			C2			C3				
	IgM Test Result	+++			++			+				
	IgG Test Result	+++			++			+				
Intra-assay repeatability	Test device	1	2	3	4	5	6	7	8	9	10	
	IgM Test Result	+	+	+	+	+	+	+	+	+	+	

Reference（J1）	IgG Test Result	+	+	+	+	+	+	+	+	+	+	

6.3 Analysis for Stability Test Result

6.3.1After storing for 25 days under the temperature 37℃, all tested indexes of the detection kit meet the quality standards required for finished products. Based on the results of the accelerated stability assessment under temperature 37℃ , we can ressonably infer that the shelf life of this detection kit is 18 months under 2-30 ℃.

6.3.2the stability test under analog transportation process, the kits were transported under analog transportation condition for 5 days,10 days,15 days, all indexes meet the quality standards required for finished products.

6.4 Summary and Conclusion of stability assessment

In conclusion, we can see that all results of the our company’s developed COVID-19 IgM & IgG Test (Immunochromatography) by the accelerated stability under temperature 37℃ as well as analog stability test during transportation process exactly meet all the expected quality requirements, means under temperature 37 ℃ of destructive environment stored within 25 days and analog transported for 15 days, all tested indexes of the detection kit meet the quality standards required for finished products. Based on the results of the accelerated stability assessment under temperature 37℃ and the results of stability studies of other products, we can ressonably infer that the shelf life of this detection kit is 18 months under 2-30 ℃.

COVID-19 IgM&IgG Test Certificate of Analysis

Report No:2020031301

Product	COVID-19 IgM & IgG Test (Immunochromatography)		
Lot	20200313	Expiry date	2021.09.12
Batch	55 boxes	Sample Amount	2 boxes
Production Date	2020.03.13	Inspection Date	2020.03.13

1、 Test devices

Items	**CONTROLS**	**Acceptance range**		**Test result**
Sensitivity	C1	IgM	Strong Positive	Strong Positive
		IgG	Strong Positive	Strong Positive
	C2	IgM	Middle Positive or Week Positive	Middle Positive
		IgG	Middle Positive	Middle Positive
	C3	IgM	Week Positive or Negative	Week Positive
		IgG	Middle Positive	Middle Positive
Positive reference coincidence rate	P1-P10	IgM	At least 8/10	10/10
		IgG	At least 9/10	10/10
Negative reference coincidence rate	N1-N10	IgM	10/10	10/10
		IgG	10/10	10/10

2、Diluent Buffer (3mL/bottle)

Items	Acceptance range	Test result
Appearance	Colorless transparent liquid, No impurities	Colorless transparent liquid, No impurities
PH	9.6±0.2	9.61

Result：

■PASS □NG

Inspector	蒋浩	Check	柏宏瑶
Date	2020.03.13	Approve	

Material Safety Data Sheet

1. INFORMATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY

1.1 COMMERCIAL PRODUCT NAME: COVID-19 IgM & IgG Test (Immunochromatography)

1.2 COMPANY Shenzhen JetMay Care Limited

1.3 IN EMERGENCY Turn to nearest First Aid Station

2. COMPOSITION/INFORMATION ON INGREDIENTS KIT CONTENTS:

REAGENTS OR COMPONENTS	DESCRIPTION	CLASSIFICATION
1. Test devices (20)	Each foil pouch contains one single-use test device with one membrane strip.	NOT DANGEROUS
2. Diluent Buffer (3mL/vial)	One bottle containing a buffered saline solution with Na_2CO_3 and Na_2HCO_3.	NOT DANGEROUS

Make reference to safety data sheet of dangerous chemical compounds and preparations written according to 67/548/CE and 88/379/CE directives and following modifications and amendments.

3. HAZARDS IDENTIFICATION

The usual precautions taken when handling chemicals should be observed.

4. FIRST AID MEASURES

Eye contact: flush eyes with water.
Skin contact: wash off with water.
Ingestion: seek medical advice.
Direction for physician: symptomatic treatment by a physician

5. FIRE-FIGHTING MEASURES

Extinguishing media: no restriction.
Thermal decomposition: dangerous decomposition is not anticipated.

6. ACCIDENTAL RELEASE MEASURES

After spillage: dilute liquid with water and absorb.
Absorbent material: no restriction.
Special measures to limit damage are not necessary.

7. HANDLING AND STORAGE

7.1 HANDLING No special requirements.

7.2 STORAGE Store in tightly closed containers under cool conditions.
Do not store together: no restriction

8. EXPOSURE CONTROL/PERSONAL PROTECTION

TLV: no

Respiratory protection: none

Eye protection: no

Hand protection: disposable gloves. Wash hands before breaks and at the end of work

9. PHYSICAL AND CHEMICAL PROPERTIES

ITEM	DESCRIPTION	PROPERTIES
9.1 APPEARANCE	1.Each foil pouch contains one single-use test device with one membrane strip.	cassette
	2. Diluent Buffer (3ml/vial) , One bottle containing a buffered saline solution with Na_2CO_3 and Na_2HCO_3.	liquid
9.2 COLOUR	1.Each foil pouch contains one single-use test device with one membrane strip.	white
	2. Diluent Buffer (3ml/vial) , One bottle containing a buffered saline solution with Na_2CO_3 and Na_2HCO_3.	colorless
9.3 SMELL	1.Each foil pouch contains one single-use test device with one membrane strip.	odorless
	2. Diluent Buffer (3ml/vial) , One bottle containing a buffered saline solution with Na_2CO_3 and Na_2HCO_3.	odorless
9.4 pH	N.D.	
9.5 MELTING POINT	N.D.	
9.6 BOILING POINT	N.D.	
9.5 MELTING POINT	N.D.	
9.7 IGNITION TEMPERATURE	N.D.	
9.8 FLASH POINT	N.D.	
9.9 EXPLOSION LIMIT	N.D.	
9.10 VAPOR TENSION	N.D.	

9.11 DENSITY	N.D.	
9.12 VAPOR PRESSURE	N.D.	
9.13 SOLUBILITY IN WATER	N.D.	

10. STABILITY AND REACTIVITY

Hazardous reactions: none known when used appropriately.
Hazardous decomposition products: no

11. TOXICOLOGICAL INFORMATION

LD50 oral: not known.
LD50:not known.
LD50 skin: not known.
LD50 inhalation: not known.
Toxicological information: toxification has so far not become known.

12. ECOLOGICAL INFORMATION

No data yet available.

13. DISPOSAL CONSIDERATION

Used reagents must be disposed of in accordance with local, national and federal regulations.

14. TRANSPORT INFORMATION

This product is not subject to current regulations for transportation of hazardous goods.

15. REGULATORY INFORMATION

This Product does not require special labeling, in accordance with the appropriate EEC directives related to dangerous

16. OTHER INFORMATION

This product is intended for IN VITRO diagnostic use only. NOT FOR USE IN HUMANS. The information herein is believed to be correct as of the date hereof and excludes any guarantee related with the final use given to the product.

Released: March 13, 2020

CE RENDER

INSTRUCTION FOR USE

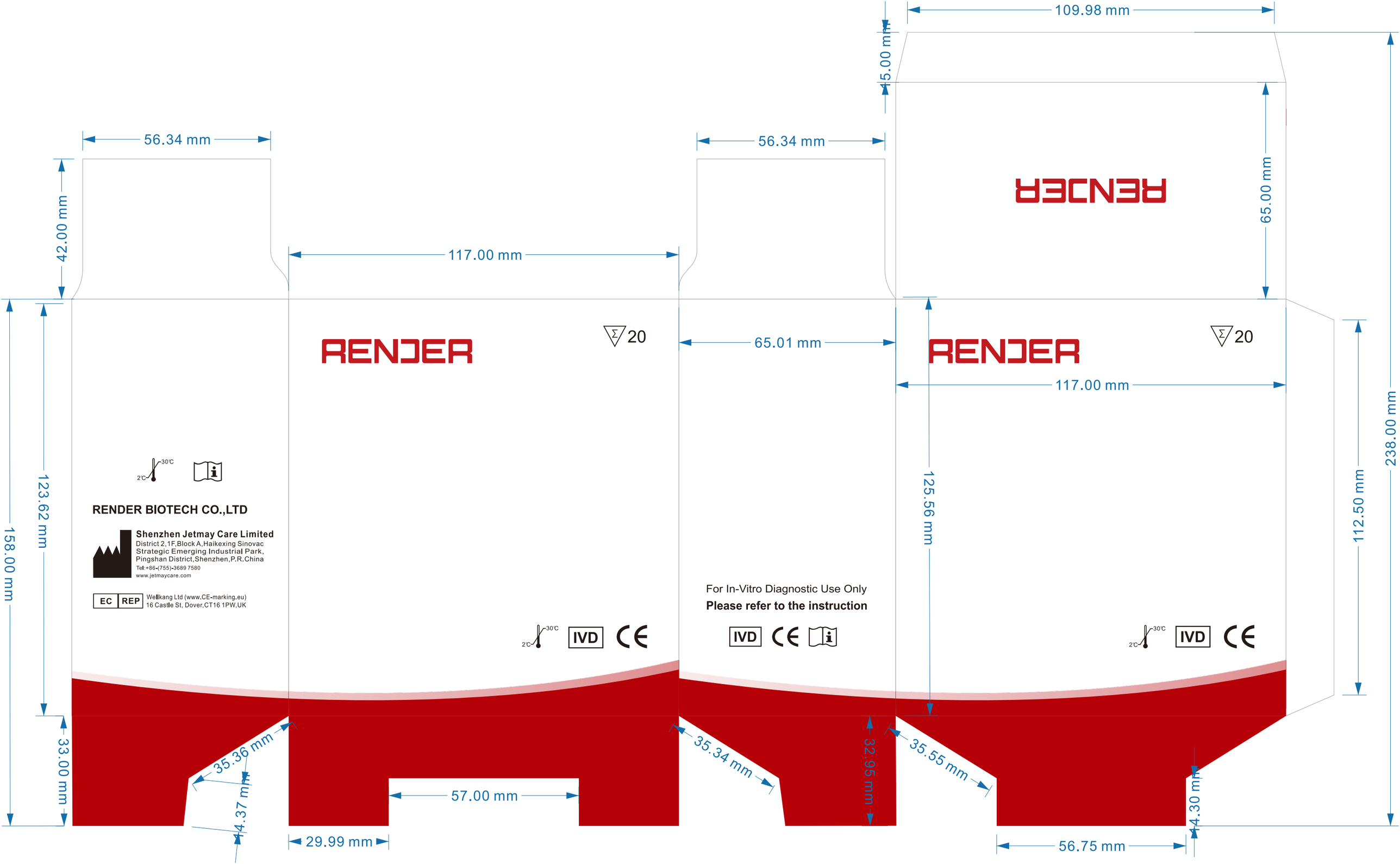
COVID-19 IgM & IgG Test (Immunochromatography)

【Packing Specifications】

20 T/Kit

【Intended Use】

This product is used for in vitro qualitative detection of COVID-19 IgG and IgM antibody in human serum, plasma or whole blood. Coronavirus belongs to coronaviridae, nidovirales and is divided into α, β and γ genuses. α and β genuses can only make mammal sick and γ genus mainly causes birds to be infected. CoV is mainly transmitted through direct contacting secreta or transmitted by aerosol or spray. But there is also evidence certifying it can be transmitted by the fecal-oral route. By now, there has been already up to 7 types of HCoVs that can cause human respiratory disease: HCoV-229E, HCoV-OC43, SARS-CoV, HCoV-NL63, HCoV-HKU1, MERS-CoV and SARS-CoV-2, so HCoV is the major causative agent to cause human respiratory tract infection. Therein, the COVID-19 was discovered due to 2019 viral pneumonia case in Wuhan, of which the clinical manifestation includes fever and fatigue, etc, constitutional symptoms, accompanied by dry cough and


109.98 mm
15.00 mm
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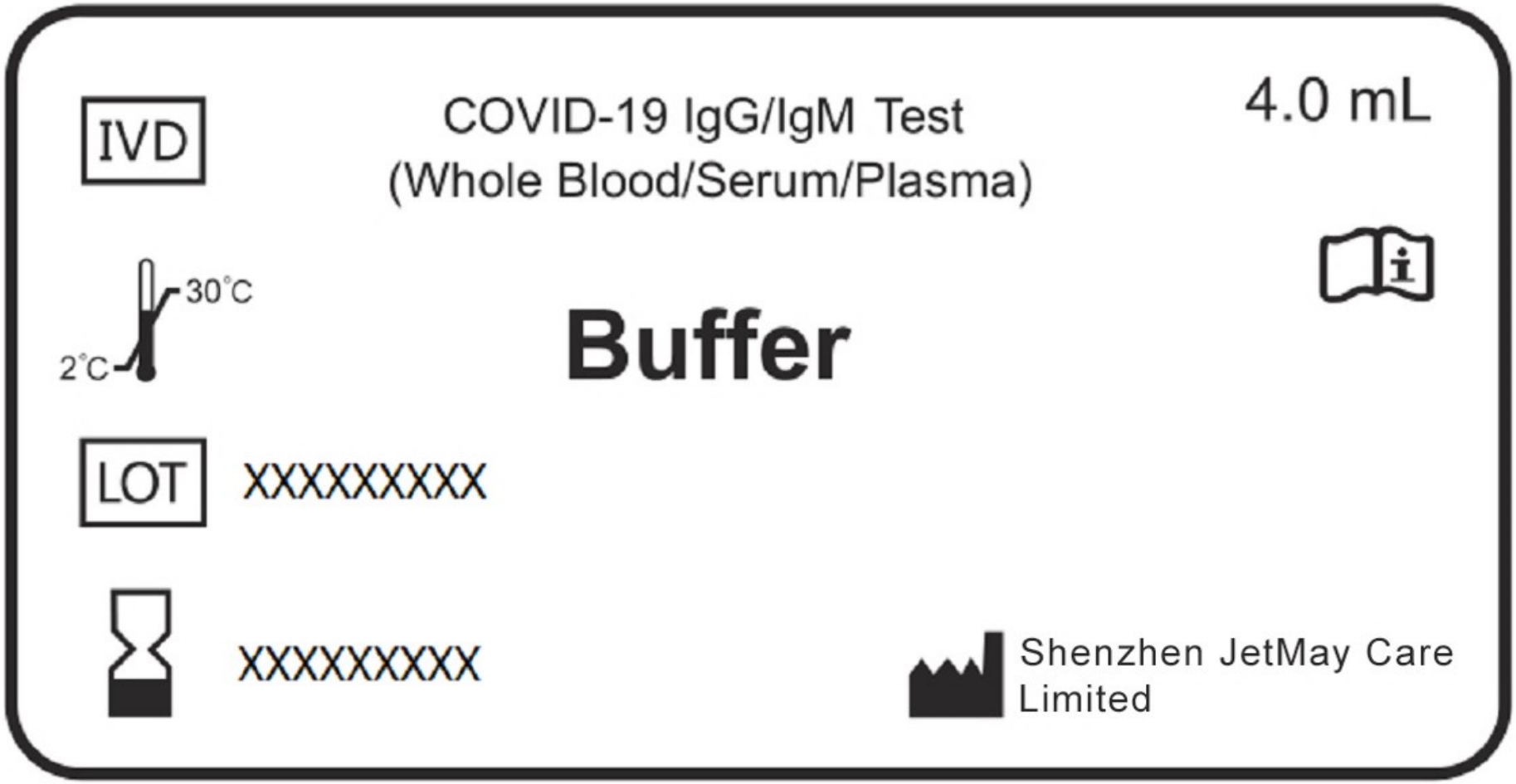
123.62 mm
125.56 mm
112.50 mm
30℃
2℃
RENDER BIOTECH CO.,LTD
Shenzhen Jetmay Care Limited
District 2,1F,Block A,Haikexing Sinovac
Strategic Emerging Industrial Park,
Pingshan District,Shenzhen,P.R.China
Tel:+86-(755)-3689 7580
www.jetmaycare.com
EC REP
Wellkang Ltd (www.CE-marking.eu)
16 Castle St, Dover,CT16 1PW,UK
For In-Vitro Diagnostic Use Only
Please refer to the instruction
IVD
CE
33.00 mm
35.36 mm
4.37 mm
57.00 mm
29.99 mm
35.34 mm
32.95 mm
35.55 mm
4.30 mm
56.75 mm


IVD
COVID-19 IgG/IgM Test
(Whole Blood/Serum/Plasma)
4.0 mL
30°C
2°C
Buffer
LOT
XXXXXXXXX
XXXXXXXXX
Shenzhen JetMay Care
Limited

尺寸：43-22mm

RENDER

Company Profile

Founded in 2010, Render has been determined to be respectable provider for high-tech medical devices and solutions from China, we are committed to produce and deliver Innovative, high-quality, cost-effective medical devices to serve healthcare, making it more elegant, accessible and affordable.

Headquarter based in Shenzhen, Render possesses the first-class professional R&D team in Shenzhen. Customer-oriented and aspirated to advanced technology, we focus on innovation in the field of In-Vitro Diagnostics, covering Microbiology, Hemostasis, Urine Analysis and Immunoassay.

With diligent team and always listening to needs of customers, we are at our steady growing steps. Through our subsidiaries and distributor partners worldwide, Render products and services can be found in more than 49 countries and regions in Asia Pacific, Middle East, Africa, South America as well as part of Europe. Our QMS is compliant with ISO13485 standard, All products are CE, ISO, FSC and CFDA certificated.

After the outbreak of COVID-19 at end of year 2019, we invested the new project of COVID-19 IgG&IgM Test kits. The kits had been well approved in the well known hospitals in Wuhan which is the first place virus found. Comparing with the nucleic acid testing and similar brands, the technical advantages of Render COVID-19 IgG&IgM Test kits includes the following: (1) Test sample: serum and plasma (2) Rapid screening of coronavirus in 10 minutes(3) Reduce the risk of individual infection in hospital (4) No need for instruments and equipment, suitable for on-site inspection (5) Early diagnosis, early treatment and shortening the course of disease; (6) Work of designated hospitals to alleviate epidemic situation

Company Vision

To be the respectable provider for high-tech healthcare solution from China.

Company Mission

Dedicated in innovation and quality for efficient healthcare solution to promote life quality of mankind.

Core Value

Dependable

BUREAU VERITAS
Certification

Shenzhen JetMay Care Limited

DISTRICT 2, 1F, BLOCK A, HAIKEXING SINOVAC STRATEGIC EMERGING INDUSTRIAL PARK, PINGSHAN DISTRICT, SHENZHEN, P.R. CHINA

Certified site:
DISTRICT 2, 1F, BLOCK A, HAIKEXING SINOVAC STRATEGIC EMERGING INDUSTRIAL PARK, PINGSHAN DISTRICT, SHENZHEN, P.R. CHINA

Bureau Veritas Italia S.p.A. certifies that the Management System of the above organisation has been audited and found to be in accordance with the requirements of the management system standards detailed below

EN ISO 13485:2016

Scope of certification

Design, manufacture and sales of the colloidal gold & fluorescence-based immunoassay reagents and devices, which is intended to measure the concentration of biomarkers in human whole blood/serum/plasma and urine, as an aid in clinical assessment of cardiovascular diseases and early bacterial infection and sepsis.

Certificate awarded in conformity with the requirements of ACCREDIA DT 02-DC Rev.00

Original cycle start date:	**04/02/2020**
Expiry date of previous cycle:	**N.A.**
Certification / Recertification Audit date:	**22/12/2019**
Certification / Recertification cycle start date:	**04/02/2020**

Subject to the continued satisfactory operation of the organization's Management System, this certificate expires on: **03/02/2023**

Certificate No. - Version: IT296208 - 1 Revision date: **04/02/2020**

GIORGIO LANFAFRE – Local Technical Manager

Certification body address:
Bureau Veritas Italia S.p.A., Viale Monza, 347 - 20126 Milano, Italia

Further clarifications regarding the scope of this certificate and the applicability of the management system requirements may be obtained by consulting the organisation. To check this certificate validity please refer to the website www.bureauveritas.it

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SQQ N° 009A