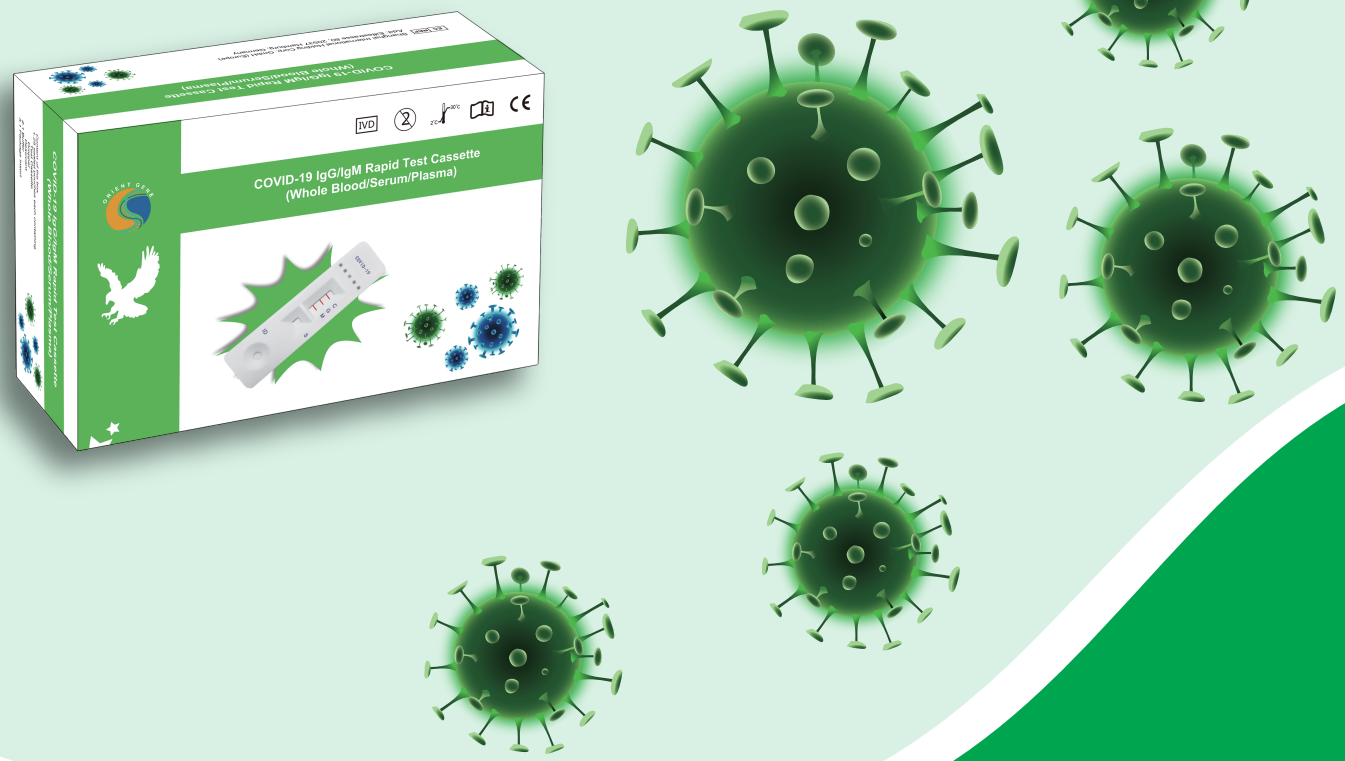


COVID-19 IgG/IgM Rapid Test

COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) is a solid phase immunochromatographic assay for the rapid, qualitative and differential detection of IgG and IgM antibodies to 2019 Novel Coronavirus in human whole blood, serum or plasma.

Zhejiang Orient Gene Biotech Co., Ltd
Add: 3787#, East Yangguang Avenue, Dipu Street,
Anji , Huzhou, Zhejiang, China
Tel: +86-572-5303755/5303756
Fax: +86-572-5226222
Web: http: //www.orientgene.com

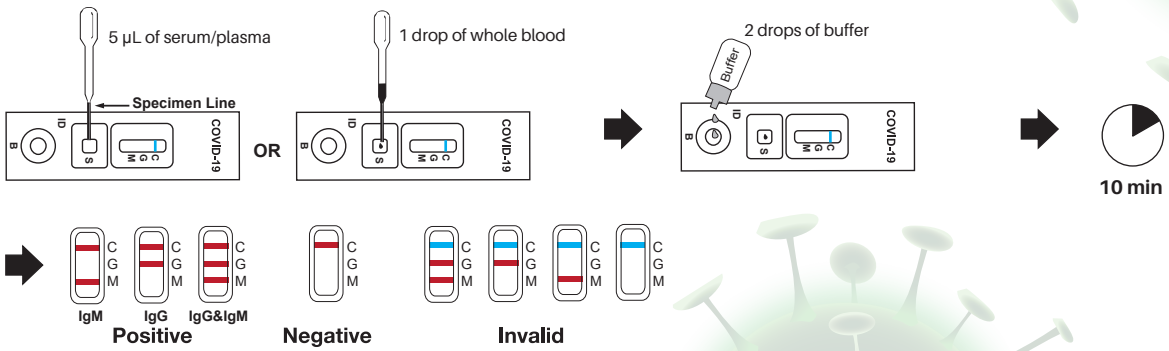
Key Facts of COVID-19

- The 2019 new coronavirus pneumonia(NCP), or"COVID-19", was discovered for the 2019 Wuhan Viral Pneumonia case in China and was named by the world Health Organization on January 12, 2020.
- For confirmed coronavirus disease 2019 (COVID-19) cases, reported illnesses have ranged from mild symptoms to severe illness and death. Symptoms can include:
  - Fever
  - Cough
  - Shortness of breath
- The virus is thought to spread mainly from person-to-person.
  - Between people who are in close contact with one another (within about 6 feet).
  - Via respiratory droplets produced when an infected person coughs or sneezes.
  - These droplets can land in the mouths or noses of people who are nearby or possibly be inhaled into the lungs.

Features & Benefits

- Fast results as soon as 2-10 minutes
- Facilitates patient treatment decisions quickly
- Simple, time-saving procedure
- Little specimens, only 5 μL of serum/plasma or 10 μL of whole blood specimens
- All necessary reagents provided & no equipment needed
- High sensitivity and specificity

Test Procedure & Interpretation



Ordering Information

Product Description	Specimen	Catalog No.	Format	Kit Size
COVID-19 IgG/IgM Rapid Test	Whole Blood/Serum/Plasma	GCCOV-402a	Cassette	25 Tests/Kit

Confirmation

of EU product notifications submitting

Herewith we confirm that

Shanghai International Holding Corp. GmbH (Europe)
Eiffestraase 80, 20537 Hamburg, Germany

has taken over the function of an European Authorised Representative according to the requirements of IVD Directive 98/79/EC for:

Zhejiang Orient Gene Biotech Co., Ltd
3787#, East Yangguang Avenue, Dipu Street,
Anji 313300, Huzhou, Zhejiang, China

for their in-vitro diagnostic device:
1) Coronavirus Ag Rapid Test Cassette (Swab)
2) COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma)
3) SARS-CoV-2 Detection Kit (Fluorescence PCR)

and has submitted the product notifications at the relevant German Competent Authority according to Article 10(3) of the above mentioned IVD Directive and all supporting technical documents are deposited in our office. The product notifications are estimated to be completed within 3 months.

14 February 2020

Shanghai International Holding Corporation GmbH (Europe) Eiffestrasse 80 20537 Hamburg

Mr. Jin Liang
-- on behalf of --
Shanghai International Holding Corp. GmbH (Europe)

浙江东方基因生物制品有限公司
Zhejiang Orient Gene Biotech Co.,LTD

CE-DOC-OG127
version 1.0

EC Declaration of Conformity

In accordance with Directive 98/79/EC

Legal Manufacturer: *Zhejiang Orient Gene Biotech Co., Ltd*

Legal Manufacturer Address: *3787#, East Yangguang Avenue, Dipu Street, Anji 313300, Huzhou, Zhejiang,China*

Declares, that the products
Product Name and Model(s)

COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma)	GCCOV-402a

Classification: *Other*
Conformity assessment route: *Annex III (EC DECLARATION OF CONFORMITY)*

We, the Manufacturer, herewith declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In-Vitro Diagnostic Medical Devices.

We hereby explicitly appoint

EC Representative's Name: Shanghai International Holding Corp. GmbH (Europe)

EC Representative's Address: Eiffestrasse 80, 20537 Hamburg，Germany

to act as our European Authorized Representative as defined in the aforementioned Directive.

I, the undersigned,hereby declare that the medical devices specified above conform with the directive 98/79/EC on in vitro diagnostic medical devices and pertinent essential requirements

Date Signed: February 12, 2020

ZHEJIANG ORIENT GENE BIOTECH CO., LTD 330523 102391

Joyce Pang

Name of authorized signatory: Joyce Pang
Position held in the company: Vice-President

COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma)

CE

INTENDED USE

COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) is a solid phase immunochromatographic assay for the rapid, qualitative and differential detection of IgG and IgM antibodies to 2019 Novel Coronavirusi in human whole blood, serum or plasma. This test provides only a preliminary test result. Therefore, any reactive specimen with the COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) must be confirmed with alternative testing method(s) and clinical findings.

INTRODUCTION

Coronaviruses are enveloped RNA viruses that are distributed broadly among humans, other mammals, and birds and that cause respiratory, enteric, hepatic, and neurologic diseases. Seven coronavirus species are known to cause human disease. Four viruses - 229E, OC43, NL63, and HKU1 - are prevalent and typically cause common cold symptoms in immunocompetent individuals.4 The three other strains - severe acute respiratory syndrome coronavirus (SARS-CoV), Middle East respiratory syndrome coronavirus (MERS-CoV) and 2019 Novel Coronavirus (COVID-19) - are zoonotic in origin and have been linked to sometimes fatal illness. IgG and IgM antibodies to 2019 Novel Coronavirus can be detected with 1-3 weeks after exposure. The seroconversion rate and the antibody levels increased rapidly during the first two weeks,some patients with negative nucleic acid findings could be screened out through antibody testing. Combining RNA test and antibody test significantly raised the sensitivity for detecting patients. The antibody detection be an important supplement to RNA detection during the illness course.

PRINCIPLE

The COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) is a lateral flow immunochromatographic assay. The test uses anti-human IgM antibody (test line IgM) , anti-human IgG (test line IgG) and rabbit IgG (control line C) immobilised on a nitrocellulose strip. The burgundy colored conjugate pad contains colloidal gold conjugated to recombinant COVID-19 antigens conjugated with colloid gold (COVID-19 conjugates). When a specimen followed by assay buffer is added to the sample well, IgM &/or IgG antibodies if present, will bind to COVID-19 conjugates making antigen antibodies complex. This complex migrates through nitrocellulose membrane by capillary action. When the complex meets the line of the corresponding immobilized antibody (anti-human IgM &/or anit-human IgG) the complex is trapped forming a burgundy colored band which confirm a reactive test result. Absence of a colored band in the test region indicates a non reactive test result.

To serve as a procedural control, a colored line will always change from blue to red in the control line regin, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

MATERIALS SUPPLIED

25 sealed pouches each containing a test cassette, a dropper and a desiccant
1 Buffer
1 package insert

MATERIAL REQUIRED BUT NOT PROVIDED

1. Specimen collection containers
2. Lancets (for fingerstick whole blood only)
3. Centrifuge (for plasma only)
4. Timer
5. Heparinized capillary tubes and dispensing bulb (for fingerstick whole blood only)

STORAGE AND STABILITY

The kit can be stored at room temperature or refrigerated (2-30°C). The test device is stable through the expiration date printed on the sealed pouch. The test device must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

WARNINGS AND PRECAUTIONS

1. For professional In Vitro diagnostic use only. Do not use after expiration date.
2. This package insert must be read completely before performing the test. Failure to follow the insert gives inaccurate test results.
3. Do not use it if the tube/pouch is damaged or broken.
4. Test is for single use only. Do not re-use under any circumstances.
5. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens.
6. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
7. Humidity and temperature can adversely affect results.
8. Do not perform the test in a room with strong air flow, ie. electric fan or strong air-conditioning.

SPECIMEN COLLECTION

1. COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) can be performed using either whole blood, serum or plasma.
2. Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.
3. Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days. For long term storage, specimens should be kept below -20°C. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.
4. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
5. If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.

TEST PROCEDURE

Allow test cassette, specimen,buffer and/or controls to equilibrate to room temperature (15-30°C) prior to testing.

1. Remove the test cassette from the sealed foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
2. Place the test device on a clean and level surface.

For Serum or Plasma Specimens:

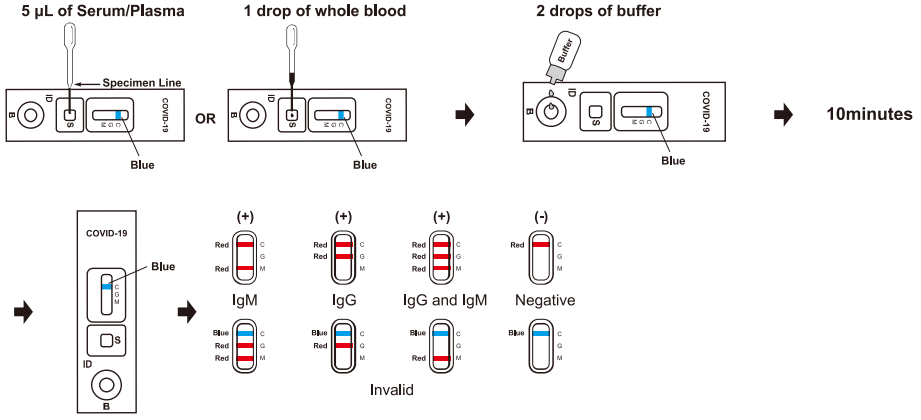
With a 5 µL mini plastic dropper provided, draw serum/plasma specimen to exceed the specimen line as showed in the following image and then transfer drawn serum/plasma specimen into the sample well (S). Then add 2 drops (about 80µL) of sample buffer to the buffer well (B) immediately. Avoid air bubbles.

Note: Practice a few times prior to testing if you are not familiar with the mini dropper. For better precision, transfer specimen by pipette capable to deliver 5 µL of volume.

For Whole Blood Specimen:

Hold the 5 µL mini plastic dropper vertically and transfer 1 drop of whole blood (about 10µL) to the specimen well(S) of the test device, then add 2 drops (about 80µL) of sample buffer to the buffer well (B) immediately. Avoid air bubbles.

3. Wait for the colored line(s) to appear. After 2 minutes, if the red colour has not moved across the test window or if blood is still present in the specimen well (S), add 1 additional drop of the sample buffer to the buffer well (B).
4. The result should be read in 10 minutes. Positive results may be visible as soon as 2 minutes. Do not interpret the result after 15 minutes.



INTERPRETATION OF RESULTS

NEGATIVE: The colored line in the control line region (C) changes from blue to red. No line appears in the test line regions M or G. The result is negative.

IgM POSITIVE:

The colored line in the control line region (C) changes from blue to red, and a colored line appears in test line region M. The result is anti-COVID-19 IgM positive.

IgG POSITIVE:

The colored line in the control line region (C) changes from blue to red, and a colored line appears in test line region G. The result is anti-COVID-19 IgG positive.

IgG and IgM POSITIVE:

The colored line in the control line region (C) changes from blue to red, and two colored lines appear in test line regions M and G. The result is anti-COVID-19 IgM and IgG positive.

INVALID:

Control line is still completely or partially blue, and fails to completely change from blue to red. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

QUALITY CONTROL

A procedural control is included in the test. A red line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique.

Control standards are not supplied with this kit; however it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS

1. Use fresh samples whenever possible. Frozen and thawed samples (especially repeatedly) contain particles that can block the membrane. This slows the flow of reagents and can lead to high background color, making the interpretation of results difficult.
2. Optimal assay performance requires strict adherence to the assay procedure described in this insert sheet. Deviations may lead to aberrant results.
3. A negative result for an individual subject indicates absence of detectable anti-COVID-19 antibodies. However, a negative test result does not preclude the possibility of exposure to or infection with COVID-19.
4. A negative result can occur if the quantity of the anti-COVID-19 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.
5. Some specimens containing unusually high titer of heterophile antibodies or rheumatoid factor may affect expected results.
6. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the result of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

PERFORMANCE CHARACTERISTICS

Clinical Performance

The COVID-19 IgG/IgM Rapid Test (Whole Blood/Serum/Plasma) has been evaluated with the 113 blood samples obtained from patients exhibiting pneumonia or respiratory symptoms. The results were compared to RT-PCR or clinical diagnosis (including chest Computed Tomography and clinical signs etc.) of “Diagnosis and treatment of novel coronavirus pneumonia”.

Regarding the IgM test, the result comparison to RT-PCR.

Method		RT-PCR		Total
		Positive	Negative	
COVID-19 IgG/IgM Rapid Test	Positive	87	0	87
	Negative	12	14	26
Total		99	14	113

Regarding the IgG test, we have counted the positive rate of the 36 of 113 patients during the convalescence period.

Method		Number of patients during the convalescence period	Total
COVID-19 IgG/IgM Rapid Test	Positive	35	35
	Negative	1	1
Total		36	36

The sensitivity of IgM test is 87.9% (87/99) and specificity is 100%(14/14) comparison to RT-PCR.

The sensitivity of IgG test is 97.2% (35/36) during the convalescence period,and specificity is 100%(14/14).

REFERRENCE

1. Weiss SR, Leibowitz JL. Coronavirus pathogenesis. Adv Virus Res 2011; 81: 85-164.
2. Masters PS, Perlman S. Coronaviridae. In: Knipe DM, Howley PM, eds. Fields virology. 6th ed. Lippincott Williams & Wilkins, 2013: 825-58.
3. Su S, Wong G, Shi W, et al. Epidemiology, genetic recombination, and pathogenesis of coronaviruses. Trends Microbiol 2016; 24: 490-502.
4. Cui J, Li F, Shi ZL. Origin and evolution of pathogenic coronaviruses. Nat Rev Microbiol 2019; 17: 181-192.

INDEX OF SYMBOLS

	Consult instructions for use		Tests per kit	EC REP	Authorized Representative
IVD	For *in vitro* diagnostic use only		Use by		Do not reuse
2°C~30°C	Store between 2~30°C	LOT	Lot Number	REF	Catalog#

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REF GCCOV-402a

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B21855-02