TEST CORONAVIRUS

COVID 19 – 2 SEROLÓGICO

COVID-19

About Realy

The company was established in 2015 and is located in Baiyang Street. It is a high-tech enterprise integrating R & D, production and sales of high-end medical diagnostic equipment and supporting diagnostic reagents. It is composed of high-educational biomedical industry high-tech talents and management talents. It has a complete R & D team engaged in the development and application of medical equipment and supporting reagents, and is an international leader in technology and operations. The company currently has 60 employees, including 30 with a bachelor's degree or above, accounting for 50% of the total number, 16 Ph.D. R & D staff, accounting for 26% of the total number, reasonable professional configuration, each with its own specialties. As the first domestic R & D company for home-grade POCT products, realy Technology's one-step operation, intelligent identification, rapid acquisition of test results within 15 minutes, and compatibility with detection of nearly 30 immune markers, not only suitable for bedsides in large and medium-sized hospitals The rapid diagnosis of critically ill patients is also suitable for the comprehensive immunoquantitative analysis and testing of small and medium-sized hospitals' clinical departments and grassroots hospitals. It is also suitable for the immediate testing and health monitoring of common chronic diseases in families with chronic diseases. At present, the company has listed the first domestic POCT product in May 2017. There are more than 30 POCT rapid diagnostic reagent products registered in CFDA. The inspection items cover cardiovascular and cerebrovascular diseases, infectious diseases, kidney disease, diabetes, health checkups and women. In the fields of obstetrics and other fields, in the future, it will become one of the most comprehensive companies in the domestic POCT product line. At present, the company's R & D and production have passed the ISO13485: 2003 quality management system certification of TUV in Europe, and a number of products have been awardedin Europe CE registration. Realy Technology is actively deploying sales channels in multiple regions at home and abroad. Its main business is rapidly expanding in 30 provinces, municipalities and autonomous regions across the country and sales coverage has been achieved in Asia, the European Union, and South America. Innovate real-time diagnosis and lead smart medicine. Realy Technology will continue to provide high-quality products and services for human health, realize self-health management for everyone, health for the body, happiness for the family and a better life.

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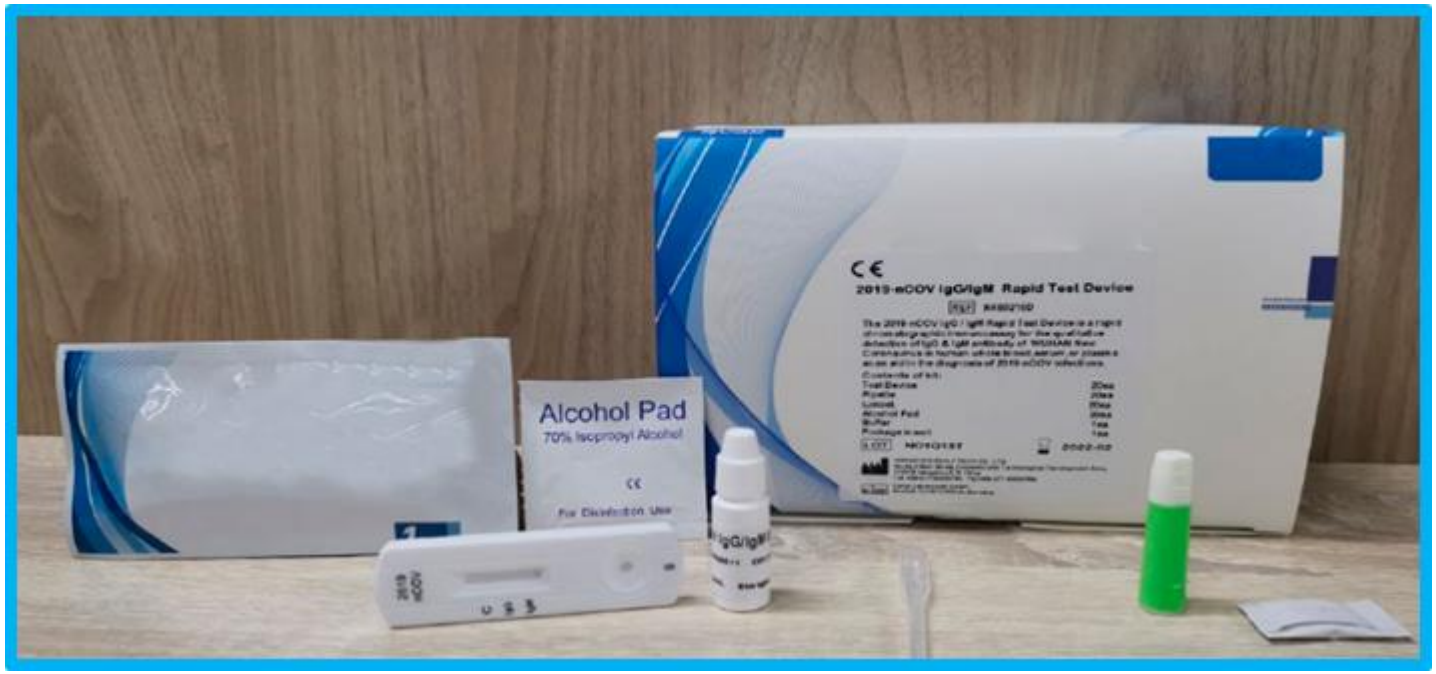


CE/FDADate /Declarationof Conformity

CE EC Declaration of Conformity CE

in accordance with Directive 98/79/EC

Manufacturer:

Name:
Address: 4th Floor, #12 Building, Eastern Medicine Town, Xiasha Economic&Technology Development, 310018 Hangzhou, Zhejiang, P.R.China

Product/s	*Catalogue number*
2019-nCOV IgG/IgM Rapid Test Device	K460216D

Category: Other Devices (All devices except Annex II and self-testing devices)

Conformity assessment route: Annex III, except Point 6, of Directive

Applicable Standards: EN ISO 13485:2016; EN ISO 15223-1:2016; EN ISO 14971:2012 ;EN ISO 13612:2002; EN ISO 17511:2003; EN ISO 18113-1:2011; EN ISO 18113-2:2011, EN ISO 18113-3:2011; EN ISO 23640:2015; EN 62366:2008.

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.

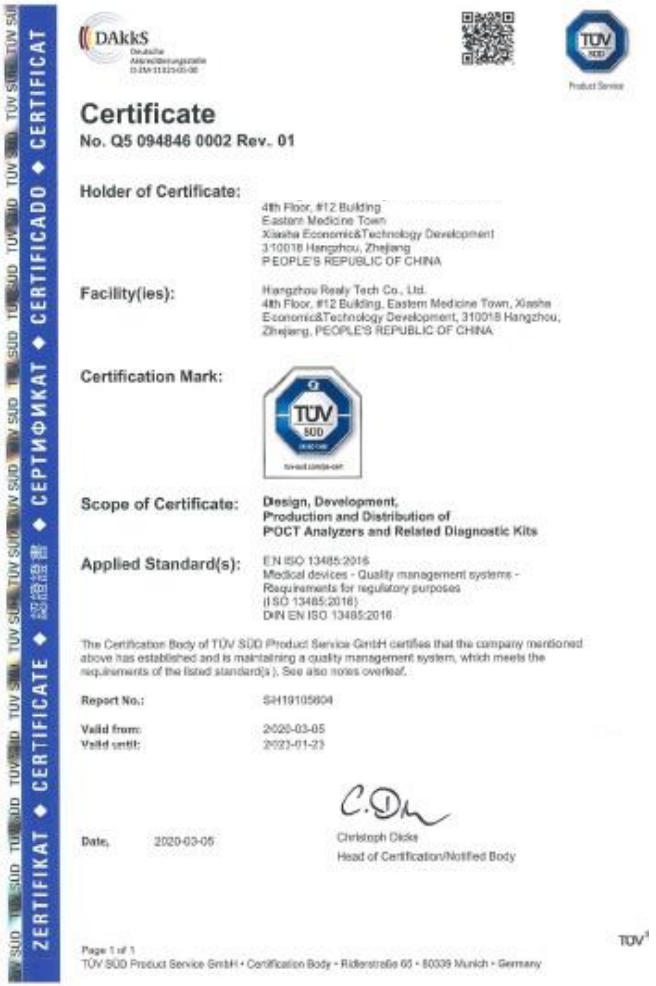
We hereby explicitly appoint Luxus Lebenswelt GmbH, located at Kochstr. 1, 47877, Willich, Germany to act as our European Authorised Representative as defined in the aforementioned Directive.

Hangzhou — Dean

(Place and date of issue) (Signature and position)

Signed for and on behalf of the manufacturer

Certificate



ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS

Certificate

No. Q5 094846 0002 Rev. 01

Holder of Certificate:
4th Floor, #12 Building
Eastern Medicine Town
Xiasha Economic&Technology Development
310018 Hangzhou, Zhejiang
PEOPLE'S REPUBLIC OF CHINA

Facility(ies):
Hangzhou Realy Tech Co., Ltd.
4th Floor, #12 Building, Eastern Medicine Town, Xiasha Economic&Technology Development, 310018 Hangzhou, Zhejiang, PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

Scope of Certificate: **Design, Development, Production and Distribution of POCT Analyzers and Related Diagnostic Kits**

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: SH19105604
Valid from: 2020-03-05
Valid until: 2021-01-23

Date, 2020-03-05

Christoph Dicke
Head of Certification/Notified Body

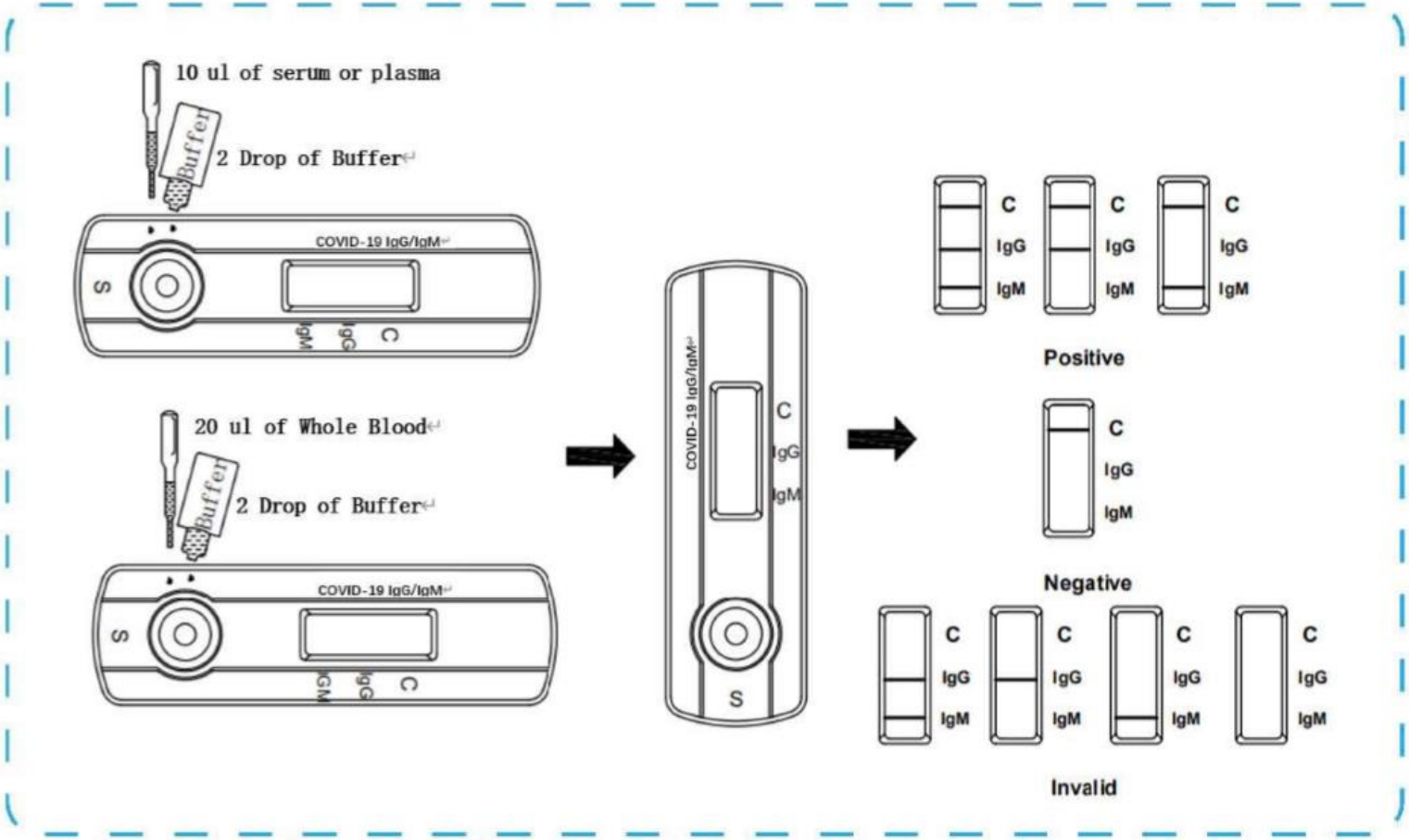
Page 1 of 1
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

MEW CORONAVIRUS (COVID-19)
IgG / IgM Rapid Test

The novel coronavirus (nCoV-2019) outbreak in Wuhan, China has spread rapidly nationwide, with some cases occurring in other parts of the world. Although most patients present with mild febrile illness with patchy pulmonary inflammation, a significant portion develop severe acute respiratory distress syndrome (ARDS), with a current case fatality of 2.3-3%.

The New Coronavirus（COVID-19）IgG/IgM Rapid Test Device is a rapid chromatographic immunoassay for the qualitative detection of IgG & IgM antibody of WUHAN New Coronavirus in human whole blood .in human whole blood ,serum ,or plasma as an aid in the diagnosis of COVID-19 infections.

Directions for use:



Features:

- ***China CDC verified*** (compare with Real-time PCR method)
- Specimen types: Whole blood/Serum/Plasma
- Testing time: 10-15 minutes
- Sensitivity: 92.5%

Selling permission in manufacturing country and sold

统一社会信用代码
91330101321935165 2 (1/1)

营业执照

（副本）

名　　称　杭州睿丽科技有限公司
类　　型　有限责任公司（自然人投资或控股）
法定代表人　丁鹏飞
经营范围　技术开发、技术服务、技术咨询、成果转让；计算机软硬件、计算机信息技术、生物医学仪器、实验室仪器与耗材、化学试剂（除化学危险品及易制毒化学品）；销售：第一类医疗器械、第二类医疗器械；货物及技术进出口（法律、行政法规禁止经营的项目除外，法律、行政法规限制经营的项目取得后方可经营）。（依法须经批准的项目，经相关部门批准后方可开展经营活动）

注册资本　[illegible]
成立日期　2015 年 01 月 06 日
营业期限　2015 年 01 月 06 日 至 长期
住　　所　浙江省杭州经济技术开发区白杨街道 21 号大街 600 号 4 幢 506 室

登记机关　杭州市市场监督管理局

2020 年 01 月 17 日

国家企业信用信息公示系统网址：http://www.gsxt.gov.cn　　市场主体应当于每年 1 月 1 日至 6 月 30 日通过国家企业信用信息公示系统报送公示年度报告。　　国家市场监督管理总局监制

医疗器械生产许可证

许可证编号：[illegible]

企业名称：[illegible]　　生产地址：[illegible]

法定代表人：丁鹏飞　　生产范围：[illegible]

企业负责人：丁鹏飞

住　　所：[illegible]　　发证部门：[illegible]

有效期限：至 2022 年 5 月 8 日　　发证日期：2017 年 5 月 9 日

国家食品药品监督管理总局制

Selling permission in manufacturing country and sold

Medical device production license

Company Name:

Legal representative: DING PENGFEI

General manager: DING PENGFEI

License number: 浙食药监械生产许 20170022 号

Production address: No.28,3 Main Street, Economic and Technological Development Zone, 310018 Hangzhou, P. R China

Production range: The second type of 6840 clinical laboratory analysis equipment

Address: Room 506, Building 4, No. 600, No. 21, Baiyang Street, Hangzhou Economic Development Zone, Hangzhou, P. R China

Issuing Department: Zhejiang Food and Drug Administration

杭州睿丽科技有限公司 Hangzhou Realy Tech Co., Ltd

Validity period: Until May 8, 2022

Date of issue: May 9, 2017

中华人民共和国 PEOPLE' S REPUBLIC OF CHINA 医疗器械产品出口销售证明 CERTIFICATE FOR EXPORTATION OF MEDICAL PRODUCTS

证书编号：浙杭食药监械出 20200303 号
Certificate NO.: 浙杭食药监械出 20200303 号

产品名称：见附件（共 1 页）
Product(s): See Attachment (1 Page)

规格型号：见附件（共 1 页）
Model: See Attachment (1 Page)

产品注册或备案凭证号：见附件（共 1 页）
Registration certificate(s): See Attachment (1 Page)

生产企业：杭州睿丽科技有限公司
Manufacturer: HANGZHOU REALY TECH CO.,LTD.

生产企业住所：杭州下沙经济技术开发区东部医药港小镇12号楼4楼，310018
Address of manufacturer:4th Floor,#12 Building,Eastern Medicine town,Xiasha Economic & TechnologyDevelopment 310018 Hangzhou, Zhejiang PEOPLE' S REPUBLIC OF CHINA

生产许可或备案凭证号：
Manufacturing License(s):

该产品出口不受限制，出口医疗器械的企业应当保证其出口的医疗器械符合进口国（地区）的要求。
The exportation of the product(s) is not restricted. The exporter should assure that exporting medical devices meeting requirements of the importing country(region).

证明有效日期至：2022 年 02 月 26 日
This certification valid until: 2022/02/26

备注：
Remark:

Zhejiang Food and Drug Administration
（浙江省食品药品监督管理局）
2020 年 03 月 27 日

1

附件 ATTACHMENT

证书编号：浙杭食药监械出 20200303 号 （共 1 页 第 1 页）
Certificate NO.: 浙杭食药监械出 20200303 号 （Page 1 of 1 Page）

序号 SN	产品名称 Product(s)	规格型号 Model	产品注册或备案凭证号 Registration certificate(s)
1	新冠状病毒IgG/Ig抗体检测试剂盒（胶体金法） 2019-nCOV IgG/IgM Rapid Test Device	K460216D	\
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INSTRUCTION

New Coronavirus（COVID-19） IgG / IgM Rapid Test Device Package Insert

FOR THE QUALITATIVE ASSESSMENT OF COVID-19 IgG/IgM IN HUMAN SERUM/PLASMA/WHOLE BLOOD.

For professional In Vitro Diagnostic Use Only

INTENDED USE

The New Coronavirus（COVID-19）IgG/IgM Rapid Test Device is a rapid chromatographic immunoassay for the qualitative detection of IgG & IgM antibody of WUHAN New Coronavirus WUHAN IgM in human whole blood ,serum ,or plasma as an aid in the diagnosis of COVID-19 infections.

SUMMARY

Coronavirus (CoV) belongs to the genus Nestovirus, Coronaviridae, and is divided into three genera: α, β, and γ. The genus α and β are only pathogenic to mammals. The genus γ mainly causes bird infections. CoV is mainly transmitted through direct contact with secretions or through aerosols and droplets. There is also evidence that it can be transmitted through the fecal-oral route.

So far, there are 7 types of human coronavirus (HCoV) that cause human respiratory diseases: HCoV-229E, HCoV-OC43, SARS-CoV, HCoV-NL63, HCoV-HKU1, MERS-CoV and new coronaviruses (2019) , Is an important pathogen of human respiratory infections. Among them, the new coronavirus (2019) was discovered due to Wuhan virus pneumonia cases in 2019. The clinical manifestations are systemic symptoms such as fever and fatigue, accompanied by dry cough and dyspnea, etc., which can rapidly develop into severe pneumonia, respiratory failure, and acute breathing. Distress syndrome, septic shock, multiple organ failure, severe acid-base metabolism disorders, etc. are even life-threatening.

PRINCIPLE

This kit uses immunochromatography. The test card contains: 1) colloidal gold-labeled recombinant new coronavirus antigen and quality control antibody gold markers; 2) two detection lines (G and M lines) and one quality Control line (C line) of nitrocellulose membrane. The M line is immobilized with a monoclonal anti-human IgM antibody for detecting a new coronavirus IgM antibody; the G line is immobilized with a reagent for detecting a new coronavirus IgG antibody; and the C line is immobilized with a quality control antibody.

When an appropriate amount of the test sample is added to the sample hole of the test card, the sample will move forward along the test card under the action of the capillary. If the sample contains an IgM antibody, the antibody will bind to the colloidal gold-labeled new coronavirus antigen. The immune complex will be captured by the anti-human IgM antibody immobilized on the membrane to form a purple-red M line, showing that the new coronavirus IgM antibody is positive.

If the sample contains an IgG antibody, the antibody will bind to the colloidal gold-labeled new coronavirus antigen, and the immune complex will be captured by the reagent immobilized on the membrane to form a purple-red G line, indicating that the new coronavirus IgG antibody is positive.

If the test lines G and M are not colored, a negative result is displayed. The test card also contains a quality control line C. The fuchsia quality control line C should appear regardless of whether a test line appears. The quality control line is a color band of the quality control antibody immune complex. If the quality control line C does not appear, the test result is invalid, and the sample needs to be tested again with another test card.

REAGENTS

The test contains COVID-19 virus envelope protein particles and anti-human IgG,anti-human IgM antibody conjugated gold particles coated on the membrane.

PRECAUTIONS

1.For professional *in vitro* diagnostic use only. Do not use the kit beyond the expiration date.
2.Do not eat, drink or smoke in the area where the specimens or kits are handled.
3.Do not use the test if the pouch is damaged.
4.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.
5.Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
6.The used test should be discarded according to local regulations.

STORAGE AND STABILITY

- The original packaging should be stored at 4~ 30 ℃, to avoid light, keep dry.
- 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, especially at temperatures above 30℃ or under high humidity conditions, should be used immediately once it is opened.

SPECIMEN COLLECTION AND PREPARATION

1.The COVID-19 IgG/IgM Rapid Test Device is intended for use with human whole blood, serum or plasma specimens only.
2.Only clear, non-hemolyzed specimens are recommended for use with this test. Serum or plasma should be separated as soon as possible to avoid hemolysis.
3.Perform testing immediately after specimen collection. Do not leave 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, serum or plasma 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 after collection. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.

4.Containers containing anticoagulants such as EDTA, citrate, or heparin should be used for whole blood storage.
5.Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Avoid repeated freezing and thawing of specimens.
6.If specimens are to be shipped, pack them in compliance with all applicable regulations for transportation of etiological agents.
7.Icteric, lipemic, hemolyzed, heat treated and contaminated sera may cause erroneous results.

MATERIALS

Materials provided

- Test Devices
- Disposable plastic pipette
- Buffer
- Package insert

Materials required but not provided

- Specimen collection containers
- Micropipette
- Lancets (for finger stick whole blood only)
- Centrifuge (for plasma only)
- Timer

DIRECTIONS FOR USE

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

1.Bring the pouch to room temperature before opening. Remove the test device from the sealed pouch and use it as soon as possible.

2.Place the test device on a clean and level surface.

For Serum or Plasma Specimens:

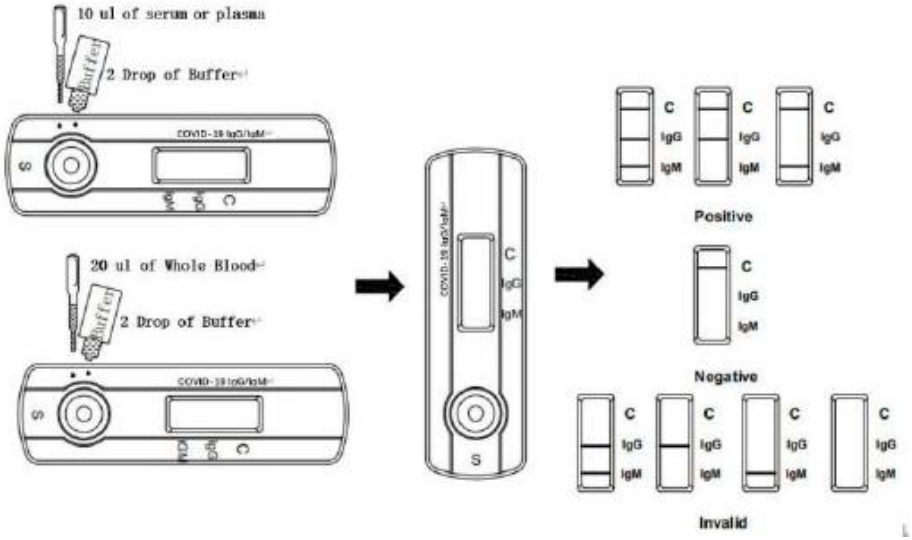
Using the provided 10uL disposable pipette, draw the specimen up to the Fill Line, and transfer 1 drop of serum/plasma (approximately 5uL),to the specimen well of the test device, then add 3 drops of buffer and start the timer.

For Whole Blood (Venipuncture/Fingerstick) Specimens:

Using the provided 10uL disposable pipette, and transfer 2 drop of whole blood (approximately20μL) to the specimen well of the test device, then add 3 drops of buffer and start the timer.

Note: Specimens can also be applied using a micropipette.

3. Wait for the colored line(s) to appear. Read results at 15 minutes. Do not interpret the result after 20 minutes.



INTERPRETATION OF RESULTS

IgG POSITIVE: *The colored line in the control line region (C) appears and a colored line appears in test line region IgG. The result is positive for COVID-19-IgG antibodies.

IgM POSITIVE: *The colored line in the control line region (C) appears and a colored line appears in test line region IgM. The result is positive for COVID-19-IgM antibodies and is indicative of primary Dengue infection.

IgG AND IgM POSITIVE: *The colored line in the control line region (C) appears and two-colored lines should appear in test line regions IgG and IgM. The color intensities of the lines do not have to match. The result is positive for IgG & IgM antibodies.

***NOTE:** The intensity of the color in the test line region(s) IgG and/or IgM will vary depending on the concentration of COVID-19 antibodies in the specimen. Therefore, any shade of color in the test line region(s) IgG and/or IgM should be considered positive.

NEGATIVE: The colored line in the control line region (C) appears. No line appears in test line regions IgG or IgM.

INVALID: There is no line appear in the c region.

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 device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

QUALITY CONTROL

Internal procedural controls are included in the test. A color line appearing in the control region (C) is an internal positive 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.

PERFORMANCE CHARACTERISTICS

Clinical Sensitivity, Specificity and Accuracy

COVID-19 IgG/IgM Rapid Test Device has been evaluated with specimens obtained from a population of symptomatic and asymptomatic individuals. Results were confirmed by PCR Test..

Method	COVID-19 IgG/IgM Rapid Test		
PCR	Results	IgM	IgG
Positive	14	14	0
	17	17	17
	3	0	3
	3	0	0
Negative	30	0	0

SYMBOLS

Symbol	Meaning	Symbol	Meaning
IVD	In vitro diagnostic medical device		Storage temperature limit
	Manufacturer	EC REP	Authorized representative in the European Community
	Date of Manufacture		Use by date
	Do not reuse		Consult instruction foe use
LOT	Batch code	CE	Meet the requirements of EC Directive 98/79/EC

ORANGE_fish

SANITARY SOLUTIONS

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