

# COVID-19 IgG/IgM antibody test solution



Accurate

Fast

Convenient



# COVID-19 IgG/IgM Rapid Test Device



25 Tests/kit



1 Test/kit

**Specimen types:** Wholeblood/Serum/Plasma

**Testing time:** 10 minutes

**Sensitivity:** IgG 99%; IgM 98%

**Specificity:** 100%

# Components of the Test kit



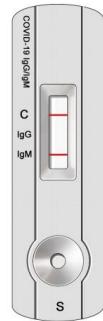
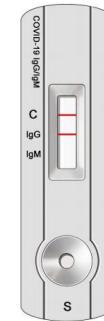
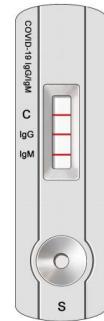
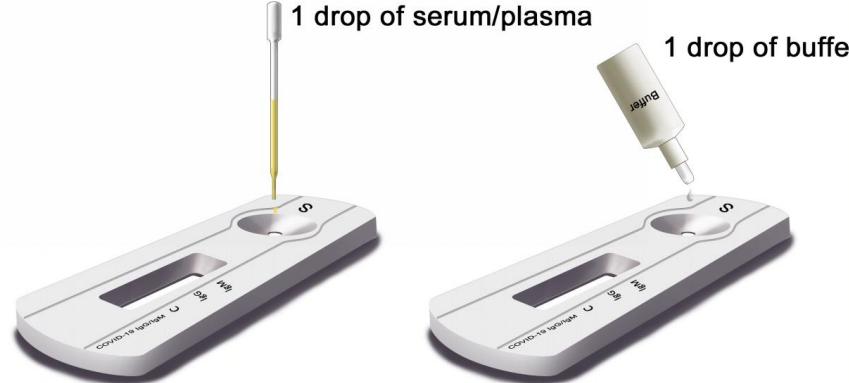
- 1 Package insert
- 1 Buffer
- 25 Test cassettes
- 25 Safty lancets
- 25 Alcohol pads
- 25 Droppers

# Components of the Test kit

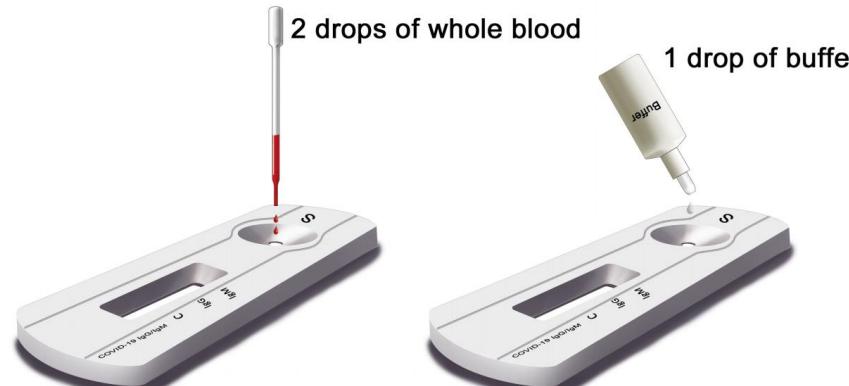


- 1 Buffer
- 1 Test cassette
- 1 Safty lancet
- 1 Alcohol pad
- 1 Dropper

# Quick reference guide

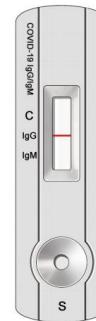


Positive



10-15 minutes

An arrow points to the right, indicating a time interval of 10-15 minutes between the two steps.



Negative



Invalid



# 营 业 执 照

(副 本)

统一社会信用代码 913301013219351652 (1/1)

名 称 杭州睿丽科技有限公司  
类 型 私营有限责任公司(自然人控股或私营性质企业控股)  
住 所 杭州经济技术开发区白杨街道 21 号大街 600 号 4 幢 506 室  
法定代表人 丁鹏飞  
注 册 资 本 肆佰伍拾万零玖佰陆拾元  
成 立 日 期 2015 年 01 月 08 日  
营 业 期 限 2015 年 01 月 08 日 至 长期  
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）



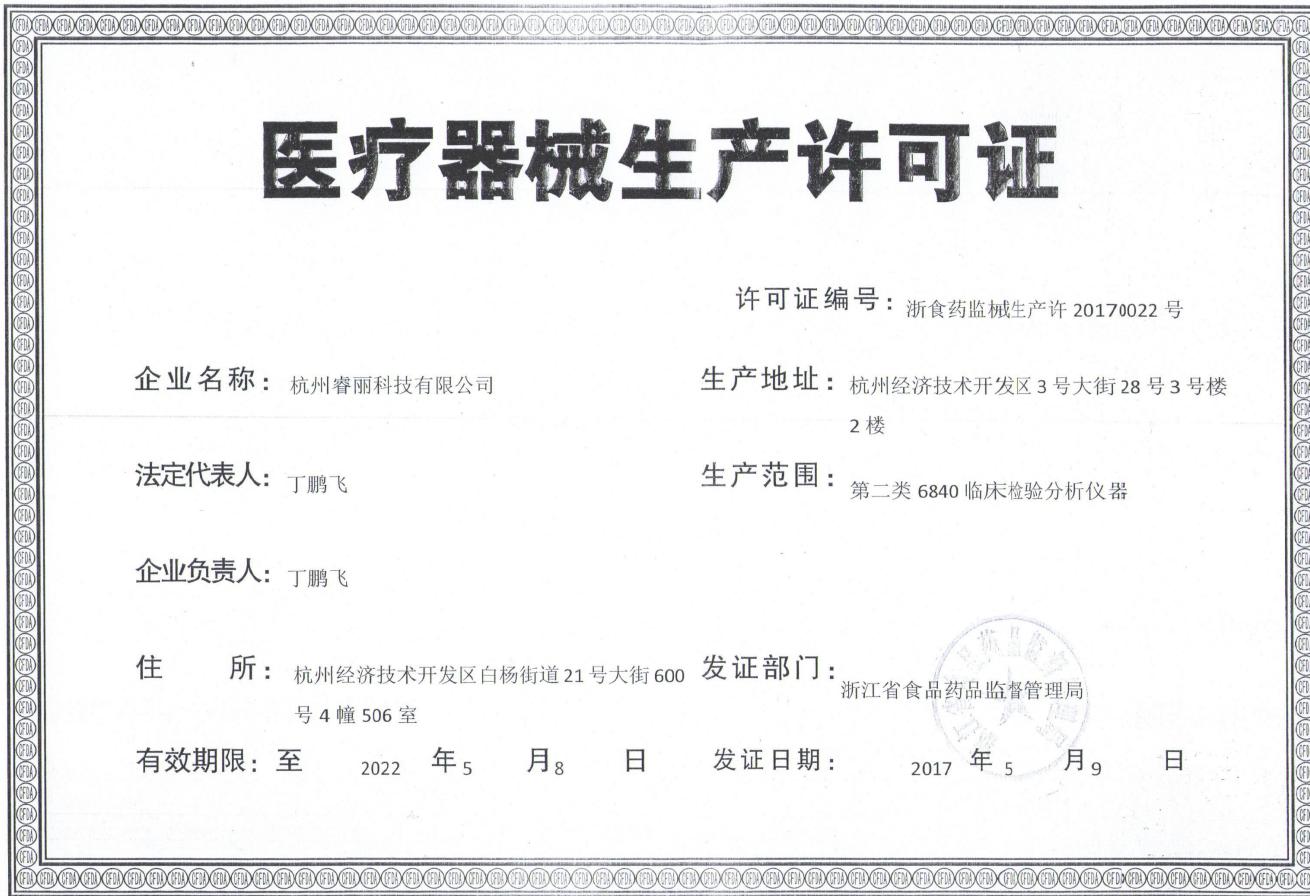
登记机关



2018 年 02 月 24 日

企业应当于每年 1 月 1 日至 6 月 30 日通过浙江省企业信用信息公示系统报送上年度年度报告

# Medical Device Manufacture License



# Quality System-ISO 13485: 2016

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

**DAkkS**  
Deutsche  
Akkreditierungstelle  
D-204-11321-01-00

**TÜV SÜD**  
Product Service

**Certificate**  
No. Q5 094846 0002 Rev. 01

**Holder of Certificate:** Hangzhou Realy Tech Co., Ltd.  
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:** 2023-01-23

**Date:** 2020-03-06   
Christoph Dicks  
Head of Certification/Notified Body

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

# Product Certifications



## Acknowledgment Letter

3/24/2020

Michael O'Neill  
ONeill Innovations  
14 John Davenport Drive NW  
Rome, GA 30165  
UNITED STATES

Dear Michael O'Neill:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has received your submission. This submission has been assigned the unique document control number below. All future correspondence regarding this submission should be identified prominently with the number assigned and should be submitted to the Document Control Center at the above letterhead address. Failure to do so may result in processing delays. If you believe the information identified below is incorrect, please notify the Program Operations Staff at (301) 796-5640.

Submission Number: PEUA200196  
Received: 3/24/2020  
Applicant: Hangzhou Realy Tech Co., Ltd  
Device: COVID-19 IgG/IgM Rapid Test(Colloidal Gold)

We will notify you when the review of this document has been completed or if any additional information is required. If you are submitting new information about a submission for which we have already made a final decision, please note that your submission will not be re-opened. For information about CDRH review regulations and policies, please refer to <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm>.

Sincerely yours,  
Center for Devices and Radiological Health

U.S. Food & Drug Administration  
10933 New Hampshire Avenue  
Silver Spring, MD 20993  
[www.fda.gov](http://www.fda.gov)

CE

US FDA

China FSC

中华人民共和国  
PEOPLES' 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 20200218 号

Certificate NO.: Zhejiang Food and Drug Administration Certificate No. 20200218

产品名称: 新型冠状病毒 (2019-nCoV) 抗体检测试剂盒 (胶体金法) 等产品, 见  
附件 (共 1 页)  
Product(s): 2019-nCoV IgG/IgM Rapid Test Device , etc. See Attachment (1 Page)

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

产地注册或备案凭证号: /  
Registration certificate(s): /

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: 杭州经济技术开发区白杨街道 21 号大街 600 号 4 楼 506 室  
Address of manufacturer: Room 506, #4Building, 600# 21st Baiyang Street, Hangzhou, Zhejiang 310018, P.R.China

生产许可证或备案凭证号: /  
Manufacturing License(s): /

兹证明上述产品未在中国注册, 尚未进入中国市场。该产品出口不受限制。  
This is to certify that the above product(s) are not registered in China and not distributed on the Chinese market. The exportation of the product(s) is not restricted.

证明书有效期至: 2022 年 03 月 23 日  
This certification valid until: 2022/03/23

备注: /  
Remark: /

浙江省药品监督管理局  
(浙江省药品监督管理局)  
2020年03月23日  
(出具单位盖章)  
Zhejiang Medical Products Administration  
2020年03月23日  
(出具单位盖章)

# Product Certifications



TRIM Reference: E20-50964  
(D20-524636)

**Notice under sections 41F1, 41F1F and 41FO of the Therapeutic Goods Act 1989**  
of decision to include the kind of device in the ARTG and impose conditions

Device Application / Submission ID:	IV-2020-IVA-05403-1 / DA-2020-02455-1
GMDN <sup>1</sup> :	Severe acute respiratory syndrome-associated coronavirus IVDs [C772]
Sponsor's Reference:	Covid-19 Rapid Testing Kit - Hangzhou Huanan Co.,Ltd
Device Name:	2019-nCoV/COVID-19 IgG/IgM Rapid Test Device
ARTG Entry:	To be confirmed, see next steps below

As a delegate of the Secretary of the Department of Health (the Secretary) for the purposes of section 41F1 of the Therapeutic Goods Act 1989 (the Act), I have made a decision to include the kind of device described above (COVID-19 IgG/IgM Rapid Test Device (GMDN: Severe acute respiratory syndrome-associated coronavirus IVDs [C772])) Class 3 in the Australian Register of Therapeutic Goods (ARTG).

Further, as a delegate of the Secretary for the purposes of section 41FO of the Act, I have decided to impose conditions on the inclusion of the Device in the ARTG.

**The conditions imposed on the Device are that:**

- The person (the sponsor) in relation to whom the Device is included in the ARTG may only supply the Device to:
  - laboratories that are accredited pathology laboratories; and/or
  - medical practitioners who are registered under a law of a State or Territory; and/or
  - health care professionals in residential and aged care facilities; and/or
  - Commonwealth, State or Territory department of health; and/or

<sup>1</sup> Information as stated in the application

<sup>2</sup> An automatic email should have been already sent to you informing you of the decision to include the Device in the ARTG

PO Box 100 Woden ACT 2606 ABN 40 030 406 004

Phone: 02 6232 8444 Fax: 02 6203 1605 Email: [pyb@tga.gov.au](mailto:pyb@tga.gov.au)

<http://www.tga.gov.au>

**TGA** Health Safety Regulation

Australia-TGA



**Elenco dei dispositivi medici**  
Ordine di inserzione:  
Denominazione fabbricante:  
Codice fabbricante:  
Pagine già / VMT Numero identificativo:  
Codice registro fabbricante:  
Denominazione modello:  
Codice fornito modello:  
Pagine già / VMT Numero identificativo:  
Codice registro e modello:  
Denominazione:  
Dispositivo medico registrato con attributo dal numero 001020e\_1902365  
Centro attribuito dal fabricante:  
Referenza del dispositivo:  
Ospitazione CDE:  
Designazione CDE:  
Classificazione CDE (se per dispositivo medico di classe, impostare solo le EFO)

Elenco dispositivi individuali									
Data aggiornamento 14/03/2020									
Aggiungi dispositivo ARTG									
Denominazione	REGISTRAZIONE	TIPO	RISPOSTA	DATA APPROVAZIONE	DATA REGISTRAZIONE	CLASSIFICA	DATA DI RICARICO	VALIDITÀ	REGISTRAZIONE
HUANAN CO., LTD	REGISTRAZIONE	TEST	SI	2020-03-03	2020-03-03	CLASSE 3	2020-03-03	2020-03-03	REGISTRAZIONE

<< Página 1 >> Mots, Pagina | Nov, Dispositivo(s)

Area sanitaria Dispositivi medici | Archivio banche dati

Stampa | Stampa il dataset



Bogotá DC, 6 de abril de 2020.

Señores  
**CI AGROSCIENCE COLOMBIA SAS.**  
Ciudad

Ref. Radicación de Trámite Virtual

Cordial saludo,

Mediante trámite virtual de fecha 06/04/2020 08:15 radicó solicitud de Registro Sanitario para el producto **RAPID TEST**, de origen China amparado en la emergencia sanitaria producida por el COVID-19 quedando radicado en nuestro sistema con el número 20200983467.

Toda notificación con relación a este proceso se realizará al correo electrónico registrado [comercial@agrosciencecolombia.com](mailto:comercial@agrosciencecolombia.com).

Cordialmente,

*Sergio Alfonso Troncoso Rizzo*

**SERGIO ALFONSO TRONCOSO RIZZO**  
DIRECTOR TECNICO MEDICAMENTOS Y DISPOSITIVOS MEDICOS

Carrera 10 No 64 – 28 PBX 2948700 – [www.invima.gov.co](http://www.invima.gov.co) - Bogotá

Italy MOH

Columbia MOH

# 2019-nCOV IgG/IgM Rapid Test Device Package Insert

FOR THE QUALITATIVE ASSESSMENT OF New Coronavirus (2019-nCOV) IgG/IgM IN HUMAN SERUM/PLASMA/WHOLE BLOOD.

For professional In Vitro Diagnostic Use Only

## INTENDED USE

The 2019-nCOV 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,serum,or plasma as an aid in the diagnosis of 2019-nCOV infections.

## SUMMARY

Coronavirus (CoV) belongs to the genus Nestovirus, Coronaviridae, and is divided into three genera:  $\alpha$ ,  $\beta$ , and  $\gamma$ . The genus  $\alpha$  and  $\beta$  are only pathogenic to mammals. The genus  $\gamma$  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), which 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 2019-nCOV virus envelope protein particles and anti-human IgG,anti-human IgM antibody conjugated gold particles coated on the membrane.

## PRECAUTIONS

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

## STORAGE AND STABILITY

- The original packaging should be stored at 4~30°C, 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°C or under high humidity conditions, should be used immediately once it is opened.

## SPECIMEN COLLECTION AND PREPARATION

- The 2019-nCOV IgG/IgM Rapid Test Device is intended for use with human whole blood, serum or plasma samples only.
- 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.
- 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.

- Containers containing anticoagulants such as EDTA, citrate, or heparin should be used for whole blood storage.
- 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.
- If specimens are to be shipped, pack them in compliance with all applicable regulations for transportation of etiological agents.
- Icteric, lipemic, hemolyzed, heat treated and contaminated sera may cause erroneous results.

## MATERIALS

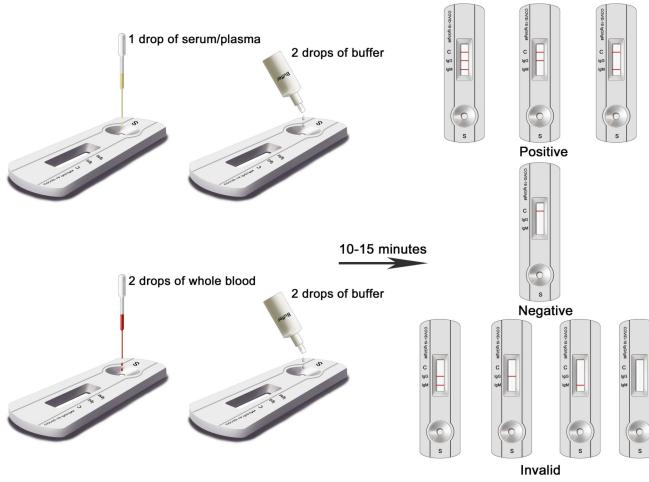
### Materials provided

- Test Devices
- Disposable plastic pipette
- Specimen collection containers
- Micropipette
- Lancets (for finger stick whole blood only)
- Buffer
- Package insert
- Centrifuge (for plasma only)
- Timer
- Alcohol pad

## DIRECTIONS FOR USE

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

- Bring the pouch to room temperature before opening. Remove the test device from the sealed pouch and use it as soon as possible.
- Place the test device on a clean and level surface.
- For Serum or Plasma Specimens:** Using the provided 5uL disposable pipette, and transfer 1 drop of serum/plasma to the specimen well of the test device, then add 2 drops of buffer and start the timer.
- For Whole Blood (Venipuncture/Fingerstick) Specimens:** Using the provided 5uL disposable pipette, and transfer 2 drop of whole blood (approximately 20uL) to the specimen well of the test device, then add 2 drops of buffer and start the timer.  
Note: Specimens can also be applied using a micropipette.
- Wait for the colored line(s) to appear. **Read results at 10 minutes. Do not interpret the result after 15 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 2019-nCOV-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 2019-nCOV-IgM antibodies and is indicative of primary 2019-nCOV 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 2019-nCOV 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

### Sensitivity and Specificity

The 2019-nCOV IgG/IgM Rapid Test Device has been compared to a leading commercial RT-PCR testing using clinical specimens. The results show that the 2019-nCOV IgG/IgM Rapid Test Device has a high sensitivity and specificity.

### For IgG testing

Method	RT-PCR		Total Results
	Results	Positive	
2019-nCOV IgG/IgM Rapid Test Device	Positive	48	48
	Negative	2	50
<b>Total Results</b>		<b>50</b>	<b>50</b>

Relative Sensitivity:48/50=96% (95%CI\*:86.3%-99.5%) \*Confidence Interval

Relative Specificity:50/50=100% (95%CI\*:92.9%-100%)

Accuracy:98/100=98% (95%CI\*: 93%-99.8%)

### For IgM testing

Method	RT-PCR		Total Results
	Results	Positive	
2019-nCOV IgG/IgM Rapid Test Device	Positive	46	46
	Negative	4	50
<b>Total Results</b>		<b>50</b>	<b>50</b>

Relative Sensitivity:46/50= 92% (95%CI\*:93%-99.8%) \*Confidence Interval

Relative Specificity:50/50=100% (95%CI\*: 92.9%-100%)

Accuracy: 96/100=96% (95%CI\*: 90.1%-98.9%)

## Cross-reactivity

The 2019-nCOV IgG/IgM Rapid Test Device has been tested for anti-influenza A virus, anti-influenza B virus, anti-RSV, anti-Adenovirus, HBsAg, anti-Syphilis, anti-HIV and anti-HCV positive specimens. The results showed no cross-reactivity.

## Interfering Substances

The following compounds have been tested using the 2019-nCOV IgG/IgM Rapid Test Device and no interference was observed.

Triglyceride: 100 mg/dL Ascorbic Acid: 20mg/dL Hemoglobin 1000mg/dL  
Bilirubin: 100mg/dL Total cholesterol: 6mmol/L

## 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 for use
LOT	Batch code	CE	Meet the requirements of EC Directive 98/79/EC
REF	Catalogue number		The number of test

## HANGZHOU REALY TECH CO., LTD.

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

Tel:+86-571-56050793

Fax:+86-571-56050794

Luxus Lebenswelt GmbH  
Kochstr.1,47877,Willich,Germany



Number:1101311601

Version:1.0

Effective Date:



Fight COVID-19 together!