
新型冠状病毒（2019-nCoV）IgM/IgG抗体检测试剂盒
（胶体金免疫层析法）
用户使用手册
稀释液

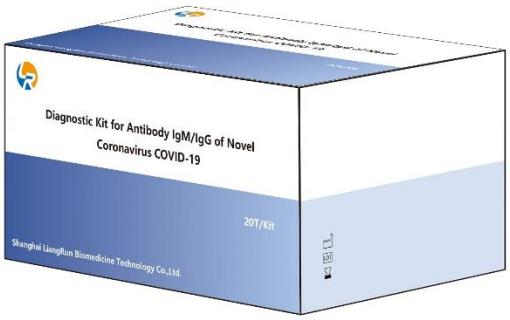
20
LO
210217
消毒用
Alcohol Prep Pad
酒精棉片
70-75% Alcohol
稀释液

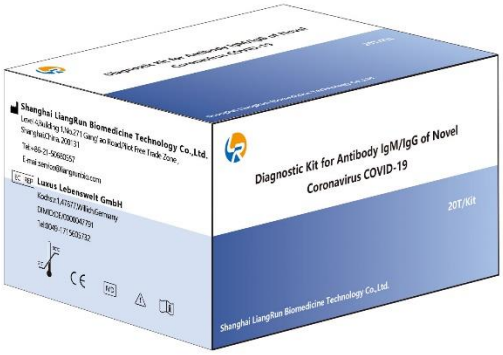
Shanghai LionRun

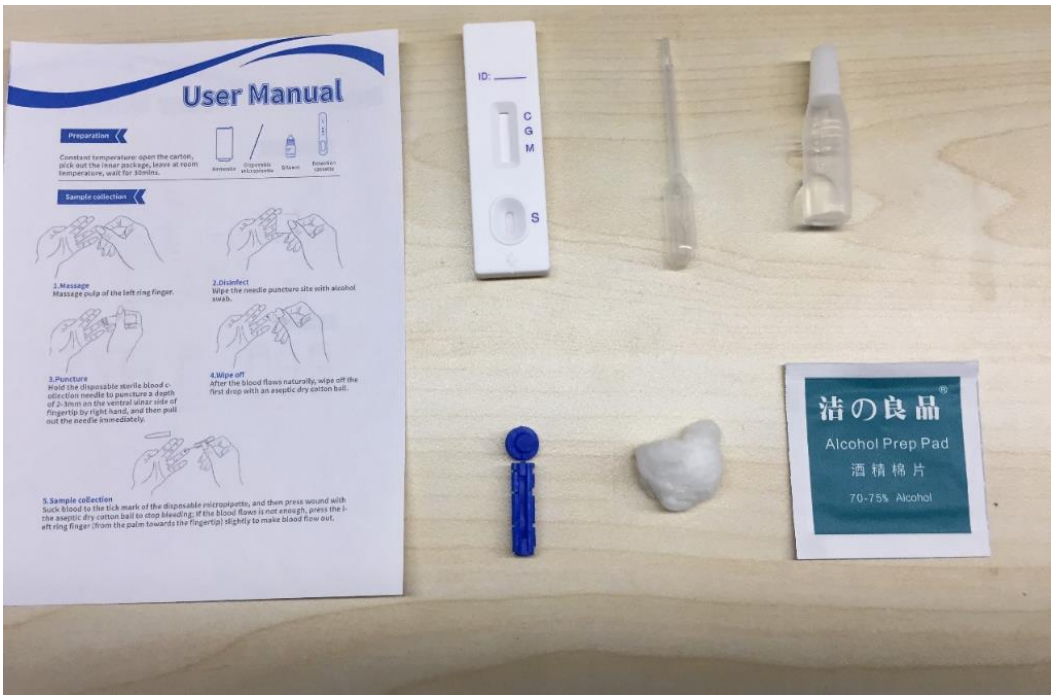
Diagnostic Kit for IgM/IgG Antibody of SARS-CoV-2

Introduction

Product:







Packaging specifications:

NO.	Packing Specifications	Product size (mm)			Packing Dimension (mm)			N.W.	G.W.
		L	W	H	L	W	H	KG	KG
1	20kit.	160	120	90	425	300	255	6.4	7.4
2	50kit.	160	120	90	590	350	450	16	17.5

TÜVRheinland®

CE Technical Documentation Review Report

Applicant:	**Core Technology Co., Ltd.** Room 100, C Building, No. 29 Life Park Road, Changping District, 102206 Beijing, China
Report Number:	**50348936 001**
Examination intent:	Examination the completeness of the Technical Documentation according to the requirements of the In Vitro Diagnostic Medical Devices Directive 98/79/EC Annex III
Product(s):	**COVID-19 IgM/IgG Ab Test**
Type(s)/Model(s):	Strip, Cassette
Classification:	Other IVD products (according to manufacturer's declaration)
Examination period:	Mar.05.2020
Date of expiry:	May.26.2024
Review result:	During the examination of the provided Technical Documentation (CORE-CE-COVID IgM/IgG, Revision V1.1, Dated 2020-Mar-04) no Non-compliance according to the requirements of the In Vitro Diagnostic Medical Devices Directive 98/79/EC Annex III was detected.

TÜV Rheinland (China) Ltd.
Yuhong CHEN
Manager
Medical Services

Rev.01, 2002-10-10

Unit 707, AVIC Bldg., No. 10B, Central Road, East 3rd Ring Road, Chaoyang District, Beijing, 100022, P.R.China
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e-mail: info@bj.chn.tuv.com Internet: http://www.chn.tuv.com

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Classification:	Other IVD products (according to manufacturer's declaration)
Examination period:	Mar.05.2020
Date of expiry:	May.26.2024
Review result:	During the examination of the provided Technical Documentation (CORE-CE-COVID IgM/IgG, Revision V1.1, Dated 2020-Mar-04) no Non-compliance according to the requirements of the In Vitro Diagnostic Medical Devices Directive 98/79/EC Annex III was detected.

TÜV Rheinland (China) Ltd.
Yuhong CHEN
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Tel: (8610)6566 6660 Fax: (8610)6566 6667
e-mail: info@bj.chn.tuv.com Internet: http://www.chn.tuv.com

CERTIFICATE OF CONFORMITY

Certificate No.	:	ZUOCE200309610
Company Name	:	Shanghai Liangrun Biomedicine Technology Co.,Ltd.
Company Address	:	Level 4 , Building 1, No.271 Gang'ao Road, Pilot Free Trade Zone, Shanghai, China
Product Name	:	Diagnostic Kit for Antibody IgM/IgG of Novel Coronavirus COVID-19
Related Directives and Annex	:	98/79/EC In Vitro Diagnostic Medical Directive
Related Standards	:	EN ISO 13485:2016; EN ISO 14971:2012; EN 1041:2008; EN ISO 18113-2:2011; EN 13612: 2002; ISO 15223-1:2012; EN ISO 14155:2011; ISO 13640:2002; ISO 23640:2011 EN 980:2008
Examination Intent	:	*Examination the completeness of the Technical Documentation according to the requirements of the In Vitro Diagnostic Medical Directive 98/79/EC Annex III*
Review result	:	*During the examination of the provided Technical Documentation (No.:LR-TCF-001, Revision: A/0, dated 2020-MAR-06), no Non-compliance according to the requirements of the In Vitro Diagnostic Medical Directive 98/79/EC Annex III was detected.*
Valid From	:	03.09.2020
Valid Until	:	03.08.2025

CE

Authorized Signer :

Wallace Xu

Job Title : Certification Manager

ZUOCE CERTIFICATION & TESTING CENTER CHINA BRANCH

Date of Issue : 2020-03-09

00130152000040O

上海市电子证照库
zwdtcert.sh.gov.cn

7/8

医疗器械出口备案表

编号： 沪浦 20200038

生产企业名称	上海良润生物医药科技有限公司		
生产地址	上海市浦东新区外高桥自贸区		
是否具有第三方认证	是	第三方认证机构	莱茵技术（上海）有限公司
认证证书编号	SX601285120001	认证证书有效期	2021-04-22
联系方式	18896516122		
出口产品名称	新型冠状病毒（2019-nCoV）Ig[illegible]测试剂盒		
出口企业名称	上海良润生物医药科技有限公司		
出口企业地址	中国（上海）自由[illegible]路 251 号 1 幢 4 层		
销往国家（地区）	欧洲/非洲/美[illegible]/韩国/伊朗		
是否境外委托境内生产	否	是否获准境外上市	是
境外委托企业名称	POWERFUL BIOTECHNICALS LIMITED		
境外委托企业地址	AJELTAKE ROAD,AJELTAKE ISLAND, MAJURO,REPUBLIC OF THE MARSHALL ISLANDS		
出口合同编号	[illegible]R[illegible]10401	出口合同期限	2023-03-06
产品规格	20 人份/盒	包装规格	20 人份/盒
出口数量	100 万人份		

申请出口备案产品未取得国内医疗器械注册证/备案凭证，属于接受境外企业委托生产在境外上市销售的医疗器械。

本企业承诺保证所生产出口的医疗器械符合进口国（地区）的要求，所提交的全部备案资料真实有效，并承担一切法律责任。

法定代表人（签字）

（企业盖章）

年 月 日

[illegible]部门（盖章）：

备案日期： 2020 年 03 月 12 日

1.生产企业应当于产品出口前，填写本表向生产地址所在区（县）药品监督管理部门备案。

2.本表按实际内容填写，不涉及的可缺项。

统一社会信用代码

91310000781742111

证照编号：41000000201911260009

营业执照

扫描二维码登录“国家企业信用信息公示系统”了解更多登记、备案、许可、监管信息。

中国（上海）自由贸易试验区

名　　称　上海良润生物医药科技有限公司

类　　型　有限责任公司（自然人投资或控股的法人独资）

法定代表人　何林富

经营范围　从事医疗器械专业领域的技术开发、技术服务、技术转让、技术咨询，医疗器械生产（详见许可证），医疗器械的销售，从事货物及技术的进出口业务，转口贸易，区内企业间的贸易及贸易代理 。【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　人民币5882.3530万元整

成立日期　2013年09月09日

营业期限　2013年09月09日 至 2043年09月08日

住　　所　中国（上海）自由贸易试验区港澳[illegible]1幢4层全部位

登记机关

2019 年 11 月 26 日

医疗器械生产许可证

许可证编号：沪食药监械生产许20172468号

企业名称：上海良润生物医药科技有限公司

生产地址：中国（上海）自由贸易试验区港澳路271号1幢4层全部位

法定代表人：何林富

生产范围：详见医疗器械生产产品登记表

企业负责人：何林富

住　　所：中国（上海）自由贸易试验区港澳路271号1幢4层全部位

发证部门：上海市食品药品监督管理局

有效期限：至　2022　年　11　月　14　日

发证日期：　2018　年　10　月　08　日

国家药品监督管理局制

2019-nCOV IgG/IgM Rapid Test Cassette（Colloidal Gold Immunochromatography）

Package Insert

[PRODUCT NAME]

2019-nCOV IgG/IgM Rapid Test Cassette（Colloidal gold immunochromatographic assay）

[PACKING]

20 Test / Unite

[INTENDED USE]

2019-nCoVs IgG/IgM Rapid Test Cassette (GICA) is a solid phase immunochromatographic assay for the rapid, qualitative and differential detection N Protein of IgG and IgM antibodies to 2019-nCoVs in human whole blood, serum or plasma，Applicable to the auxiliary diagnosis and screening of patients with new 2019-nCoVs disease.

The test detects protein 2019-nCoV of IgG and IgM antibodies by using 2019-nCov protein as antigen. IgM is the first antibody that appears in the body's immune system and is usually produced 3 to 7 days after exposure. IgM can be used to reflect whether the body is in an acute infection state and is an important indicator for early diagnosis. IgG is the main antibody produced by the re-immune response. It has high affinity, is widely distributed in the body and has a higher content and has important immune effects. The detection of total antibodies in patients with 2019-nCoVs infection can reflect the production of antibodies at different infection periods, reducing the impact of the single detection window period. At the same time, the detection target is increased compared to the single target, which can significantly improve the detection rate and reduce missed diagnosis.

[PRINCIPLE]

The 2019-nCoV IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) is a lateral flow immunochromatographic assay. The test uses mouse anti-human IgM antibody (test line IgM) , mouse anti-human IgG (test line IgG) immobilized on a nitrocellulose strip membrane. The

burgundy colored conjugate pad contains colloidal gold conjugated to recombinant 2019-nCoV antigens conjugated with colloid gold (2019-nCoV conjugates) and IgG-gold conjugates. When a specimen followed by assay buffer is added to the sample well, IgM &/or IgG antibodies if present, will bind to 2019-nCoV 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 are active test result. Absence of a colored band in the test region indicates a non-reactive test result.

The test contains an internal control (C band) which should exhibit a burgundy colored band on any of the test bands. Otherwise, the test result is invalid.

[MATERIALS SUPPLIED]

COMPONENTS		20 test/unit	Composition
1. Test Cassette		20x	Nitrocellulose membrane, N protein, S protein, mouse anti-human IgM antibody, mouse anti-human IgG antibody, anti-N protein antibody, anti-S protein antibody, tetra chloroauric acid, etc.
2. Diluent Buffer		100uL×20 vial	Phosphate buffer, Tween-20, etc.
3. Blood Collection Set	Lancets（ for fingerstick whole blood only）	20 x	Sterile lancet.
	Alcohol Pad	20 x	75% Alcohol cotton tablets, sterile dry cotton balls
	Disposable Pipette	20uL×20	Aseptic tubing

[STORAGE AND STABILITY]

The kit can be stored in dark place at room temperature or refrigerated (2-30°C) for 18 months.

Manufacturing date and expiration date are printed on the label.

[SPECIMEN COLLECTION AND PREPAREATION]

1. 2019-nCoV IgG/IgM Rapid Test Cassette can be performed using either whole blood, serum or plasma.

2. Serum and plasma specimens may be stored at 2-8℃for up to 3 days after sealing. For 6 month storage s, specimens should be kept at -20℃. For 48 month storage s, specimens should be kept below -70℃. Specimens (-20℃) The test results are stable within 3 times of freezing and thawing, but it is still recommended to avoid repeated freezing and thawing. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed, mixed well and equilibrate to room temperature prior to testing. Specimens should not be frozen and thawed repeatedly. Whole blood or Whole blood collected by fingerstick must be tested within 8 hours.

3 To collect Fingerstick Whole Blood Specimens:

3.1 Wash the patient’s hand with soap and warm water or clean with an alcohol pad. Allow to dry.

3.2 Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.

3.3 Puncture the skin with a sterile lancet. Wipe away the first sign of blood.

3.4 Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.

3.5 Add the Fingerstick Whole Blood specimen to the test by using a disposable micropipette:

3.6 Touch the end of the disposable micropipette to the blood until filled to approximately 20 μL. Press the wound with sterile dry cotton ball (cotton swab).

[TEST PROCEDURE]

1. Test Preparation: allow test cassette, specimen, buffer and/or controls to equilibrate to room temperature (15-30°C) prior to testing, it may take 30 minutes.
2. Assay steps; use a 20μl pipette to draw 10μl of plasma (serum) or 20μl of whole blood

(Fingerstick Whole Blood) dropwise into the sample application area, then add 2 ~ 3 drops of diluent and start timing. Wait for the purple-red band to appear The results should be interpreted within 10-20 minutes, and the interpretation results will be invalid after 20 minutes.

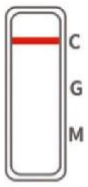
[QUALITY CONTROL]

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.

NEGATIVE:

If only the C band is present, the absence of any burgundy color in the both T bands (IgG and IgM) indicates that no anti-2019-nCoV antibodies are detected in the specimen. The result is negative.



Negative

IgM POSITIVE:

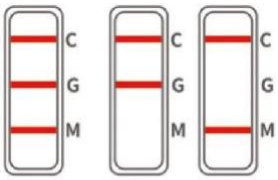
In addition to the presence of C band, if only IgM band is developed, the test indicates for the presence of IgM anti-2019-nCoV in the specimen. The result is IgM anti-2019-nCoV positive.

IgG POSITIVE:

In addition to the presence of C band, if only IgG band is developed, the test indicates for the presence of IgG anti-2019-nCoV in the specimen. The result is IgG anti-2019-nCoV positive.

IgG and IgM POSITIVE:

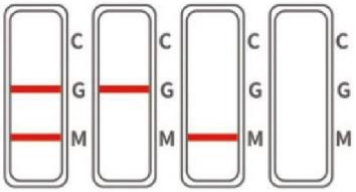
In addition to the presence of C band, both IgG and IgM bands are developed, the test indicates for the presence of both IgG and IgM anti-2019-nCoV in the specimen. The result is IgG and IgM anti-2019-nCoV positive.



Positive

INVALID:

Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure.



Invalid

[LIMITATIONS]

1. The 2019-nCOV IgG/IgM Rapid Test Cassette is for in vitro diagnostic use only.

2. This test should be only used for detection of IgG and IgM antibody to 2019-nCOV in whole blood, serum or plasma specimens. Neither the quantitative value nor the rate of increase in the concentration of IgG or IgM antibodies to 2019-nCOV can be determined by this qualitative test.

3. The 2019-nCOV IgG/IgM Rapid Test Cassettewill only indicate the presence of IgG and IgM antibodies to 2019-nCOV in the specimen and should not be used as the sole criteria for the diagnosis of 2019-nCOV infections. As with all diagnostic tests, all results must be considered with other clinical information available to the physician.

4. If the test result is negative and clinical symptoms persist, additional follow-up testing using other clinical methods is suggested. A negative result at any time does not preclude the possibility of 2019-nCOV infection

[PERFORMANCE CHARACTERISTICS]

1.Appearance and character

The outer packaging box should be flat, without damage, and the text and external identification should be clear; the packaging of the test card should be sealed without damage; the packaging of the diluent should be sealed without leakage.

2. Consistent rate

2.1 Negative consistent rate: The kit detects 10 new reference antibodies of the company's new coronavirus (2019-nCoV) antibody, and the consistent rate should be 100%.

2.2 Positive coincidence rate: The kit detects the enterprise's new coronavirus (2019-nCoV) IgM antibody positive reference product and the enterprise's new coronavirus (2019-nCoV) IgG antibody positive reference product, and the consistent rate should be 100%.

3. Reproducibility

3.1 Negative Repeat Rate: Use the kit to test the same enterprise negative reference 10 times. The negative repeat rate should be 100%.

3.2 Positive repetition rate: Use the kit to detect the same company's new coronavirus (2019-nCoV) IgM antibody positive reference and IgG antibody positive reference 10 times each.The positive repetition rate should be 100%.

4. Batch difference

Use 3 lot kits to detect the same company's new coronavirus (2019-nCoV) IgM antibody positive reference and IgG antibody positive reference 10 times each, and the positive repeat rate should be 100%.

5. Thermal stability

Take the validity period of the kit at 37 ℃ for 3 days, and check itsconsistent rate and repeatability. It should meet the requirements of 2 and 3.

[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. Specimens storage: 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.

[REFERENCES]

[1] Huang C, Wang Y, Li X, et al. Clinical features of patients infected with 2019 novel coronavirus in Wuhan, China[J]. The Lancet, 2020.

[2] Xu X, Chen P, Wang J, et al. Evolution of the novel coronavirus from the ongoing Wuhan outbreak and modeling of its spike protein for risk of human transmission[J]. Science China Life Sciences, 2020: 1-4.

[3] Chan J F W, Yuan S, Kok K H, et al. A familial cluster of pneumonia associated with the 2019 novel coronavirus indicating person-to-person transmission: a study of a family cluster[J]. The Lancet, 2020.

[4] Zhu N, Zhang D, Wang W, et al. A novel coronavirus from patients with pneumonia in China, 2019[J]. New England Journal of Medicine, 2020.

[5] Zhou L, Liu H G. Early detection and disease assessment of patients with novel coronavirus

pneumonia[J]. Chinese journal of tuberculosis and respiratory diseases, 2020, 43: E003.

【BASIC INFORMATION】

Company name: S&R Medical Appliance Company Limited

Registered address: 30/F, Two Chinachem Central, 26 Des Voeux Road Central, Central, Hong Kong

Production address: 30/F, Two Chinachem Central, 26 Des Voeux Road Central, Central, Hong Kong

Email: SRMedApp@outlook.com

Название копании: Shanghai Liangrun Biomedicine Technology Co.Ltd

Имя директора: YuKan