深圳市绿诗源生物技术有限公司
Green Spring Shenzhen Lvshiyuan Biotechnology Co.,ltd.

# Covid-19 IgG/IgM Rapid Test Kit Solution

Shenzhen Lvshiyuan Biotechnology CO.,Ltd.

# Contents



# Enterprise Information

Shenzhen Lvshiyuan Biotechnology Co., Ltd. was established in 2003. It is a company dedicated to food and drug safety, clinical diagnosis, public safety and other fields, founded by well-known senior scholars who have studied in the United States for many years. It integrates research and development, production, sales, service, and information. It is a national high-tech enterprise integrated with construction and integration, and has established cooperative relations with China Agricultural University, Huazhong Agricultural University, Harbin Veterinary Research Institute and other universities and biotechnology research institutions. The company develops the most advanced diagnostic reagents for animal diseases, food safety testing reagents, human disease diagnostic reagents, environmental monitoring reagents, new enzyme preparations, microbial preparations, protein products, nucleotide products, green aquatic drugs, small molecule antigen antibodies, genes Recombinant antigens, antibodies and other biochemical products are mainly used to serve the world with advanced international corporate business philosophy, strong R & D strength, standardized production standards, sound sales network, perfect technical service system and extensive domestic and foreign cooperation networks. Committed to the global industrialization of biological agents.

Lvshiyuan Biological R & D Center is located in Shenzhen National Marine Biological Industrial Park. It has gathered a group of professional R & D and production teams with doctoral and master's degrees as the backbone of the business, with a bachelor's degree or above accounting for more than 95%. Kits, colloidal gold test strips, biosensors, cell engineering, enzyme engineering, genetic engineering and other technology research and development and production platforms, currently developed rapid detection kits for veterinary drug residues (eg, clenbuterol detection kits, chloramphenicol Detection kit, nitrofuran-type detection kit), animal disease diagnostic reagents (eg: Toxoplasma gondii antibody detection kit, blue ear disease detection kit, swine fever virus detection kit), special tools for molecular biology A series of products such as enzymes and green aquatic drugs have been widely used in state agencies, enterprises and scientific research units.

Shenzhen Lvshiyuan Biotechnology Co., Ltd. is one of the largest and most complete manufacturers of food safety testing kits and animal disease diagnostic kits in China. Its product technology has reached the domestic first-class and world-leading level, and has taken the lead in the world. Developed 35 kinds of food safety detection kits such as furacillin metabolite detection kit, furantoin metabolite rapid detection kit, 20 kinds of animal disease diagnosis kits, and 8 kinds of colloidal gold rapid detection cards. In order to meet the needs of market development, Hundreds of kits are under development and will soon be on sale.

Food safety testing kits and animal disease diagnostic kits are exported to more than 30 countries and regions such as the United States, Europe, and Southeast Asia. The product quality and technical level are fully affirmed and recognized by foreign government units and food processing enterprises.

The 21st century is the era of high-tech biotechnology. With the goal of "creating a green earth, derived from your cooperation with us", we adhere to the business philosophy of "biotechnology serving humanity" and provide customers with leading biotechnology products and Comprehensive technical services.

# Development history of the enterprise

1. In December 2003, the company was formally established. In the early days of the company's establishment, relying on the technology of independent intellectual property rights, it successfully developed more than 10 varieties of kits, including products such as clenbuterol kits.
2. In 2006, the world's first commercial production of furacicillin and toxin metabolite detection kit opened the prelude to entering the field of biological diagnostics;
3. In January 2007, Clenbuterol test kit passed the Guangzhou Ministry of Agriculture ' s Livestock and Poultry Product Quality Supervision and Inspection Center. In December of the same year, Clenbuterol test kit passed the Ministry of Agriculture ' s Livestock and Poultry Product Quality Supervision and Inspection Center. The first to develop furacicin kit and furantoin kit, which are more than one year ahead of other colleagues in the world.
4. In April 2007, the company successfully passed ISO9001: 2000 quality management system certification.
5. In March 2007, the company successfully registered as a Shenzhen government procurement supplier.
6. In 2008, our company successfully developed the test kit for flufenib, which is still the world's exclusive production. The number of kits has reached about 30, including animal disease diagnosis and veterinary drug residue detection kits, which rank among the top in the country.
7. In 2008, the foreign trade business started, and the US FDA, EU Reference Materials and Measurement Research Institute, and the United Nations Food and Agriculture Agency and other authoritative agencies have cooperated with our company;
8. In February 2009, the Clenbuterol test kit produced by the company was successfully filed with the Ministry of Agriculture of the People's Republic of China. Twelve types of kits have passed the preliminary examination and approval by the Intellectual Property Office; Clenbuterol kits have passed the announcement of the "Veterinary Drug Residue ELISA Kit Recording" by the Ministry of Agriculture.
9. In 2009, the company began to set up branches in Heilongjiang and Beijing.
10. In 2010, the product range was more extensive, with 50 varieties of kits, and products such as rapid test cards were also developed. About 10 new products are developed each year. At the same time, CE, FDA and other international certifications of the products are in progress.
11. 11.In 2011, 9 products, including the Clenbuterol Kit and Furacicillin Kit, passed the trial stage of the Intellectual Property Office, and will soon receive patent certificates.
12. September 2011 Toxoplasma gondii detection kit products passed the examination by the Intellectual Property Office, and issued a patent certificate.
13. From 2012 to 2013, the company re-developed product research and development and successfully applied for 5 Shenzhen Municipal Government projects. Complete the construction of R & D center, quality inspection department and GMP workshop. In the food safety and animal disease diagnosis industry, it has become one of the few companies with standard GMP workshops, with an annual output value of more than 80 million yuan.
14. In October 2013, the company successfully obtained the national high-tech enterprise certificate and Shenzhen high-tech enterprise certificate.
15. In January 2014, the company successfully obtained a medical device production license.
16. In March 2015, it was successfully awarded the Shenzhen Postdoctoral Innovation Practice Base.

17. November 2015 The ELISA test kit for swine O-foot-and-mouth disease virus antibody passed the examination by the State Intellectual Property Office and issued a patent certificate.
18. In December 2015, the "Aflatoxin Detection Kit Industrialization Application Demonstration Project" applied by our company won the 2015 "National Torch Project Industrialization Demonstration Project Certificate" by the Torch Center of the Ministry of Science and Technology.
19. January 2016 The company won the highest corporate credit AAA certificate issued by the National Association of Small and Medium Enterprises.
20. July 2016 The company's in vitro diagnostic products were successfully launched.
21. In 2017, successfully obtained medical device registration certificates for multiple products.
22. In 2018, the company's GMP standard production workshop and R & D center were newly upgraded, and a number of software copyrights were obtained.

# Product packaging and size

Instructions for use

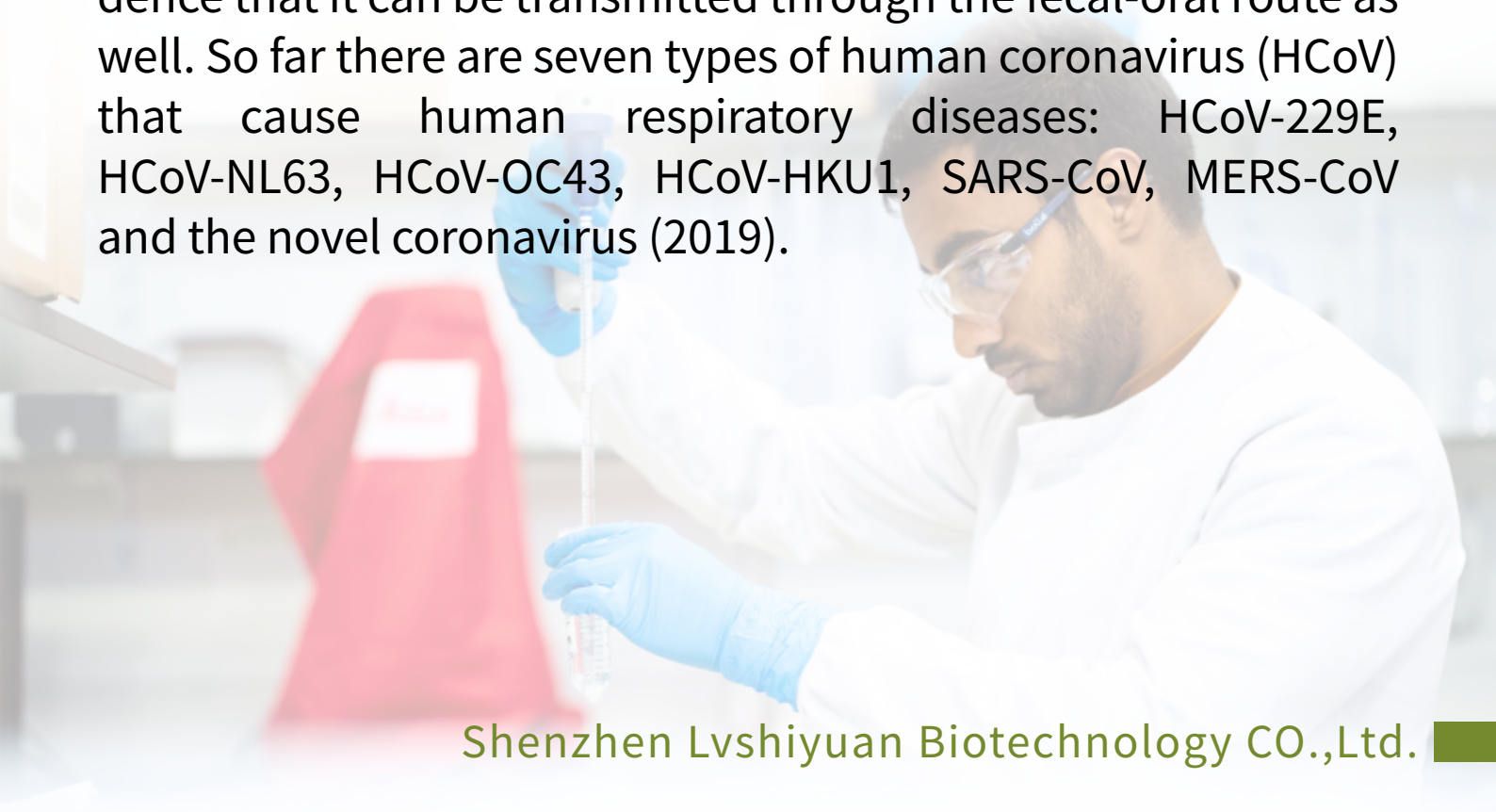
# COVID-19(2019-nCoV) Coronavirus IgG/IgM Rapid Test Kit Instructions for use

## Intended Use

Green Spring® COVID-19 (2019-nCoV) Coronavirus IgG/IgM Rapid Test Kit for COVID-19 is used to qualitatively detect total IgG and IgM antibodies of the novel coronavirus in human serum, plasma or whole blood in vitro.

## Summary

Coronavirus (CoV) belongs to the Cronoaviridae family and is divided into three types: α, β and γ. Alpha and beta are only pathogenic to mammals and 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 as well. So far there are seven types of human coronavirus (HCoV) that cause human respiratory diseases: HCoV-229E, HCoV-NL63, HCoV-OC43, HCoV-HKU1, SARS-CoV, MERS-CoV and the novel coronavirus (2019).

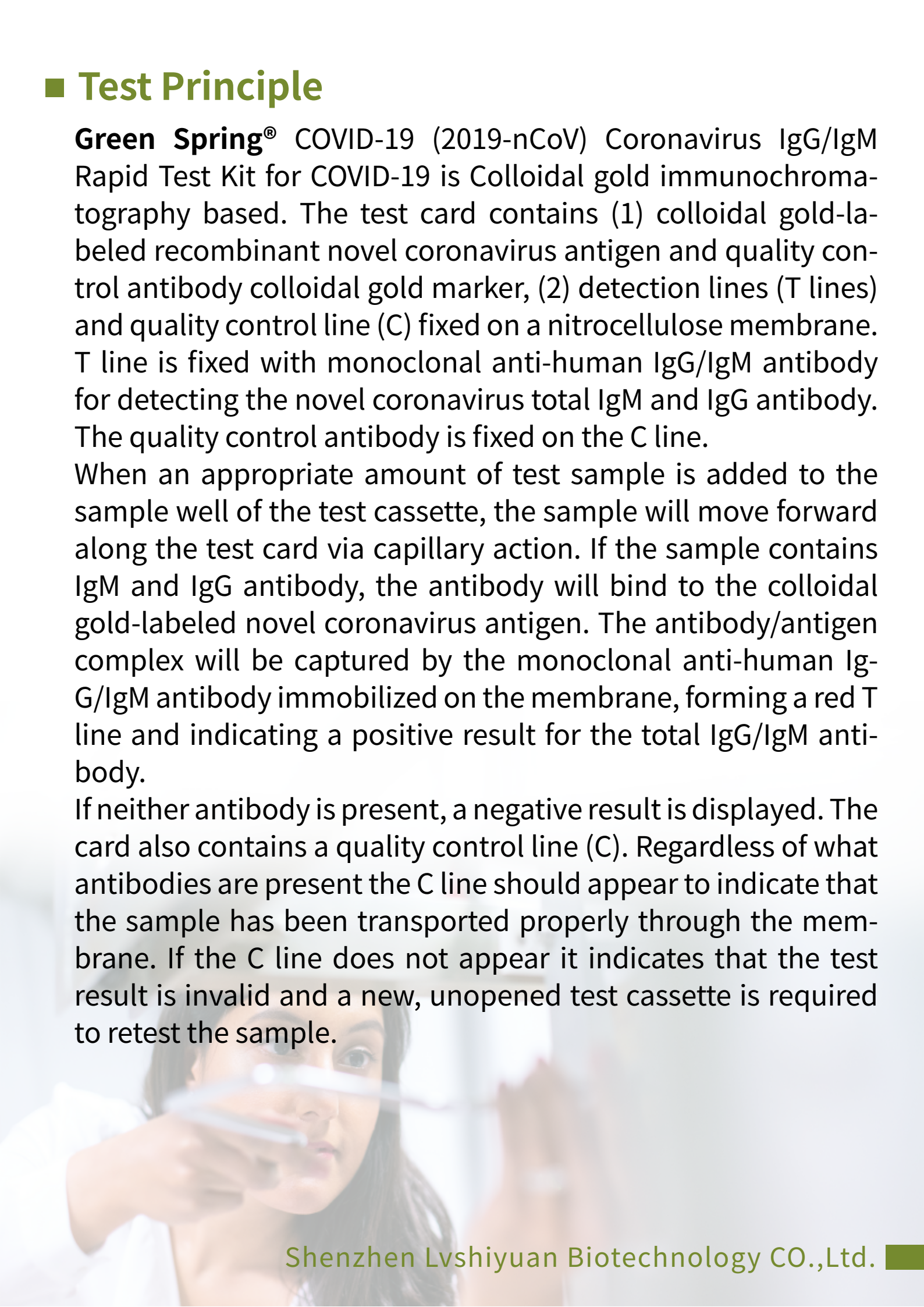


## Test Principle

**Green Spring®** COVID-19 (2019-nCoV) Coronavirus IgG/IgM Rapid Test Kit for COVID-19 is Colloidal gold immunochromatography based. The test card contains (1) colloidal gold-labeled recombinant novel coronavirus antigen and quality control antibody colloidal gold marker, (2) detection lines (T lines) and quality control line (C) fixed on a nitrocellulose membrane. T line is fixed with monoclonal anti-human IgG/IgM antibody for detecting the novel coronavirus total IgM and IgG antibody. The quality control antibody is fixed on the C line.

When an appropriate amount of test sample is added to the sample well of the test cassette, the sample will move forward along the test card via capillary action. If the sample contains IgM and IgG antibody, the antibody will bind to the colloidal gold-labeled novel coronavirus antigen. The antibody/antigen complex will be captured by the monoclonal anti-human IgG/IgM antibody immobilized on the membrane, forming a red T line and indicating a positive result for the total IgG/IgM antibody.

If neither antibody is present, a negative result is displayed. The card also contains a quality control line (C). Regardless of what antibodies are present the C line should appear to indicate that the sample has been transported properly through the membrane. If the C line does not appear it indicates that the test result is invalid and a new, unopened test cassette is required to retest the sample.



## Contents of the Kit

### One test kit contains:

- 25 Test Cassettes
- 25 Dropper
- 25 Lancet
- 25 Alcohol wipes
- 1 Buffer Solution Bottles
- 1 Package Insert


### One test cassette contains:

- Dried reagents with stabilizers
- Colloidal gold-labeled novel coronoavirus antigen
- Mouse anti-human IgG monoclonal antibody
- Mouse anti-human IgM monoclonal antibody
- Colloidal gold-labeled rabbit IgG
- Goat anti-rabbit IgG polyclonal antibody

### Materials not provided but required:

- Capillary Sampler
- Gloves
- Timer

## Warnings and Precautions

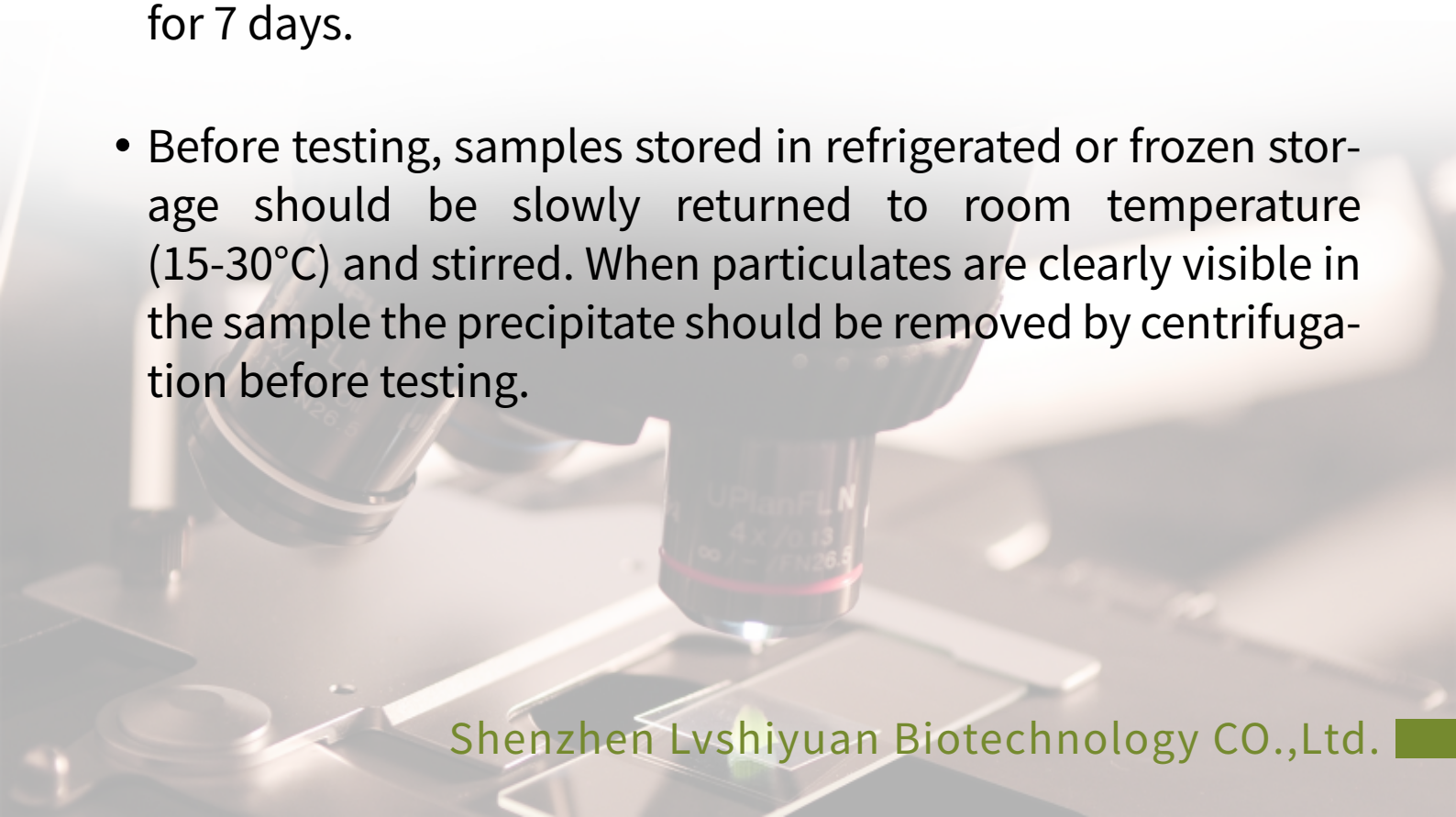
- Only for human in vitro clinical diagnostics only.
- The product should only be used by trained clinical professionals.
- After opening the sealed cassette pouch the test should be used within one hour.
- Do not immerse test cassette in water.
- Do not freeze test cassette or buffer solution.
- Handle specimens in accordance to the OSHA Standard on Bloodborne Pathogens.
- Wear protective gloves, clothing, and eyewear.
- Wash hands thoroughly after handling specimens.
- Do not use test cassette, buffer solution, or any kit component beyond the indicated expiration date.
- Dispose of all used or damaged test cassettes, capillary samplers, or other kit component as biohazardous materials.
- Do not use test cassette, buffer solution, or any other kit components if the pouch is damaged or the seal is broken.
- Do not use samples containing lipids, hemolysis, or turbidity which can affect results.
- Do not use water, Buffer Solution or other fluid as negative control.

## Storage Instructions

The reagent should be stored in the dark at room temperature (2°C to 30°C) and has a tentative shelf-life of 12 months. The container should be protected from light after being opened. Do not freeze.

## Sample Requirements

- Suitable for human serum, plasma, or whole blood samples including samples prepared by commonly-used anticoagulants (EDTA, heparin, sodium citrate).
- Fresh samples should be collected and tested immediately.
- Serum and plasma samples can be stored at 2-8°C for 5 days. If long-term storage of serum or plasma samples is required, store at -20°C and avoid repeated freeze/thaw cycles.
- Anticoagulated whole blood samples can be stored at 2-8°C for 7 days.
- Before testing, samples stored in refrigerated or frozen storage should be slowly returned to room temperature (15-30°C) and stirred. When particulates are clearly visible in the sample the precipitate should be removed by centrifugation before testing.



## ■ Test Procedure

**Do not open pouch until ready to use. Prep necessary materials:**

- **Test Cassettes**
- **Buffer solution**
- **Capillary Sampler Label Test cassette with patient ID**

### 1 Obtain a specimen using standard laboratory protocols.

Using capillary sampler, obtain 20μL of fingerstick or venous whole blood specimen or 10μL of serum or plasma.

• For intravenous sampling follow standard laboratory protocols.

### 2 Dispense the specimen into the Test Cassette sample well.

• Ensure that the entire sample is dispensed into the sample well

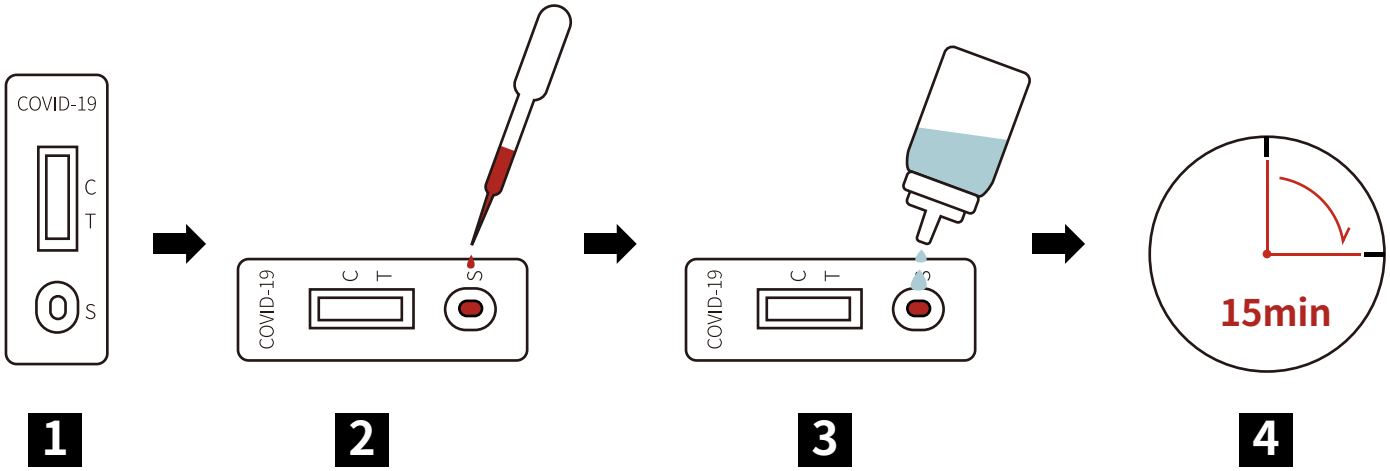
### 3 Remove cap of the Buffer Solution bottle and dispense 2-3 drops into the Test Cassette buffer well.

• Remove any air bubbles in the dropper.

• Test on a level surface at room temperature.

### 4 Allow test to run for 15 minutes. Read the results by viewing the detection window.

• Test results that have run over 20 minutes are invalid.




## Test Method Limitations

- **This product can only be used to detect the IgG/IgM antibodies of the novel coronavirus in human blood, serum, or plasma. It cannot be used with other body fluids or secretions.**
- **This product is only for qualitative testing and the specific content of each indicator must be measured using other quantitative methodologies.**
- **Negative results may be caused by low concentrations of the novel coronavirus IgG/IgM antibody in the sample and therefore cannot completely rule out the possibility of infection.**
- **The results of this test are for clinical reference only and should not be the only basis for diagnosis. Results should be used in combination with clinical observations and other testing methods.**
- **Test results can be affected by temperature and humidity.**

## Display of Results/Expected Values

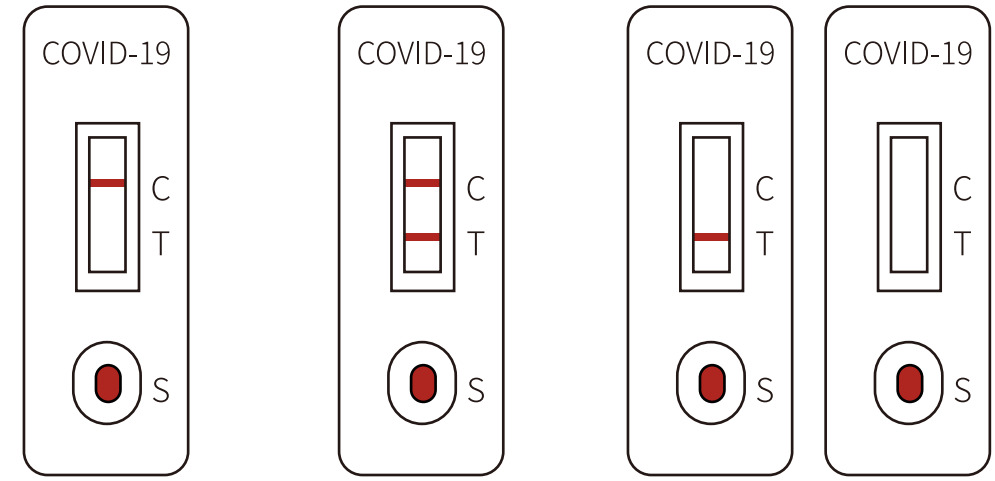
**A total of two detection lines are possible, with the control (C) line appearing when sample has been flowed through the cassette.**

### 1 Negative Result

If only the quality control line (C) appears and the detection T line is not visible, then no novel coronavirus antibody has been detected and the result is negative.

### 1 Positive Result, G and M

If the quality control line (C) and the detection T lines appear, then the novel coronavirus IgG/IgM antibodies have been detected and the result is positive for coronavirus antibodies.




**Negative** **Positive** **Invalid**

## Internal Quality Control Procedure

Each Test Cassette device has a built-in control. A red colored line in the detection window at the Control line can be considered an internal positive procedural control. The Control line will appear if the test procedure has been correctly performed. If the Control line does not appear, the test is invalid and a new test must be performed. If the problem persists, please contact your local vendor or **Green Spring®** for technical support.

## Shenzhen Lvshiyuan Biotechnology Co., Ltd

101,201,301, D Building, No.2 Industrial Avenue, Buxin Village, Buxin Community, Dapeng Subdistrict Office, Dapeng New District, Shenzhen, 518120 China
Tel: +86-755-2843-8788
Fax: +86-755-2893-8800
Email: info@lsybt.com
www.lsybt.com

# Office environment

# Certificate

# 营业执照

统一社会信用代码 91440300757626435 7

名　　称　深圳市绿诗源生物技术有限公司

主体类型　有限责任公司

住　　所　深圳市大鹏新区大鹏办事处布新社区布新村工业大道2号D栋101.201.301

法定代表人　王晓丽

成立日期　2003年12月29日

重要提示

1、商事主体的经营范围由章程确定。经营范围中属于法律、法规规定应当经批准的项目，取得许可审批文件后方可开展相关经营活动。

2、商事主体经营范围和许可审批项目等有关事项及年报信息和其他信用信息，请登录深圳市市场和质量监督管理委员会商事主体信用信息公示平台（网址http://www.szcredit.org.cn）或扫描执照的二维码查询。

3、商事主体须于每年1月1日-6月30日向商事登记机关提交上一年度的年度报告。商事主体应当按照《企业信息公示暂行条例》等规定向社会公示商事主体信息。

登记机关　深圳市市场监督管理局

2017 年04 月19 日

中华人民共和国国家工商行政管理总局监制

# CERTIFICATE OF REGISTRATION

The Quality Management Systems of

## Shenzhen Lvshiyuan Biotechnology Co., Ltd

**Unified Social Credit Code:914403007576264357**

*Registration address:101, 201, 301, D Building, No.2 Industrial Avenue, Buxin Village, Buxin Community, Dapeng Subdistrict Office, Dapeng New District, Shenzhen*
*Production address:D Building, National Biological Industrial Park Of Marinelife, Binhai No.2 Road, Dapeng, Shenzhen*

has been assessed by GIC and complying with

**GB/T19001-2016/ISO9001:2015**

For the following activities

**Research and development, production and service of food safety testing kits, animal disease diagnostic kits and test cards**

Date of Issue: **13 February 2019** Date of Expiry: **12 February 2022**

Date of Initial Certification: **13 February 2019**

**Certificate No.: J19Q2GZ8012523R0M**

Scan for certificate status

The granting of this certificate does not mean that the certificate holder can avoid any legal obligation. If the products or activities covered in the scope of certification require administrative license, the certificate shall be only valid within the scope of administrative licensing. The registered organization shall be subject to regular annual supervision by GIC, and the continual validity of the certificate is base upon conformity of audit. Please scan two-dimension code at lift to find the certificate information. This certificate can be queried at Certification and Accreditation Administration of the People's Republic of China official website (www. cnca.gov.cn) & GIC website (www. gicg.com.cn)

GIC WeChat public number

Signature: Helen

**Guardian Independent Certification Ltd**
*Registered in England*
*Sovereign House 212-224 Shaftesbury Avenue London England WC2H 8HQ*
*Accredited by Member of IAF MLA*
*JAS-ANZ registration no. 535105GUL, www.jas-anz.org/register*

Obelis EUROPEAN AUTHORIZED REPRESENTATIVE CENTER

EUROPEAN RESPONSIBLE PERSON CENTER — Obelis — SINCE 1988

# CERTIFICATE OF IVD NOTIFICATION

Ref. No.: BS 8841-2020

Order No.: BS 8825-2020

**BELGIUM**

Date: 20/03/2020

THIS IS TO CERTIFY THAT, ACCORDING TO THE COUNCIL DIRECTIVE 98/79/EC, OBELIS S.A. (O.E.A.R.C.) PERFORMED ALL NOTIFICATION DUTIES AND RESPONSIBILITIES AS THE EUROPEAN AUTHORIZED REPRESENTATIVE (EC REP) OF:

NAME: SHENZHEN LVSHIYUAN BIOTECHNOLOGY CO., LTD.

ADDRESS: 101, 201, 301, D BUILDING, NO. 2 INDUSTRIAL AVENUE, BUXIN VILLAGE, BUXIN COMMUNITY, DAPENG SUBDISTRICT OFFICE, DAPENG NEW DISTRICT, SHENZHEN, 518120, CHINA

AS STIPULATED AND DEMANDED BY THE AFOREMENTIONED DIRECTIVE.

The Manufacturer declares that the IVD devices comply with the Directive including all essential requirements.

The Manufacturer has provided Obelis s.a. (O.E.A.R.C.) with all the appropriate declarations according to the 98/79/EC Directive – article 10 requirements including the EC Declaration of Conformity confirming that his In-Vitro Diagnostics medical devices, as stipulated here above, are fulfilling the applicable requirements of the European Council Directive 98/79/EC

The notification of the following In-Vitro Diagnostic medical devices has been completed by Obelis s.a. (O.E.A.R.C.) on the 19/03/2020 in compliance with the European Council Directive 98/79/EC - article 10 requirements.

IN-VITRO DIAGNOSTIC MEDICAL DEVICES: PLEASE SEE ANNEX A - LIST OF DEVICES ( 1 PAGE, 1 DEVICE)

As of the 20/03/2020, and as long as the manufacturer will continue complying with the hereabove mentioned requirements* he therefore:

- Is required to affix the CE marking on these devices;

- Place these devices in the Territory of Belgium and/or the other EEA Member States (excluding territories not in alignment with Decision 2010/227/EU).

Obelis s.a. - O.E.A.R.C.

*Mr. G. Elkayam CEO*

*Obelis sa*

Obelis European Authorized Representative Center is a member of the European Association of Authorized Representatives (E.A.A.R.), ISO 9001 : 2015 and ISO 13485 : 2016 certified in accordance to the profession of a European Authorized Representative.

* This is not a CE mark and is only provided as a template for informational purposes.

** This Certificate will be automatically void if the notification is rejected by the EU Authcrities or upon termination of the EAR agreement.

Registered Address: Bd. Général Wahis 53 - 1030 Brussels I Registered Office Address: Bd Brand Whitlock 30, B-1200 Brussels - Belgium
T: + 32 (0) 2 732 5954 I F: + 32 (0) 2 732 6003 I Email: mail@obelis.net I Website: www.obelis.net

V3 – ID: 00454716 – 22/02/2019

Order No.: BS 8825-2020
Ref No.: BS 8841-2020

## Annex A - List of Devices

(Recital 29 of the Directive 98/79/EC on In Vitro Diagnostic Medical Devices)

| # | Catalogue reference number | Commercial Name | Generic Device Term | Short description and intended use | GMDN/ EDMS Code | Class |
|---|---|---|---|---|---|---|
| 1. | GF101A1 | COVID-19(2019-nCoV) Coronavirus IgG/IgM Rapid Test Kit | COVID-19(2019-nCoV) Coronavirus IgG/IgM Rapid Test Kit (Colloidal Gold) | COVID-19(2019-nCoV) Coronavirus IgG/IgM Rapid Test Kit is used to qualitatively detect IgG and IgM antibodies of the novel coronavirus in human serum, plasma or whole blood in vitro. | 15.70.90.90 | Others |



*Obelis s.a.*

G.ELKAYAM C.E.O

Obelis s.a. - O.E.A.R.C.
Registered Address
Bld Général Wahis 53
1030 Bruxelles
Tél. +32 2 732 59 54 - Fax +32 2 732 60 03

# 企业信用等级证书

CERTIFICATE OF ENTERPRISE CREDIT GRADE

深圳市绿诗源生物技术有限公司：

中大信依据《GB/T 23794-2015》对深圳市绿诗源生物技术有限公司从守信意愿、能力和表现三个维度进行了综合信用评价，结果为AAA。评价时间：2019年1月23日。特发此证。

证书说明：

1、中大信是经中国人民银行企业征信（编号10029）备案的征信机构，是社会信用体系建设部际联席会《全国社会信用标准化技术委员会》唯一第三方信用服务机构专家委员单位，是国家发改委确定的全国首批综合信用服务机构试点单位及各省(区市)政府双公示工作评估单位，是商务部、国资委、工信部、银监会、保监会、国务院机关事务管理局行业信用评价推荐机构，保留对其信用状况的动态跟踪观察并根据实际情况及时调整与公布信用级别变化之权力。

2、企业信用等级自评定之日起有效期为三年，每年进行复评。

3、有效期内企业改变名称的，必须持证到发证单位办理变更手续。

4、本证书只证明企业在有效期内的信用状况，不作他用。

证书编号：914403007576264357
颁发日期：2019年1月23日
有效期至：2022年1月22日
查询网址：大信网 www.zdxcredit.com

中大信信用管理有限公司
2019年1月23日

# 医疗器械生产许可证

许可证编号：粤食药监械生产许20142513号

企业名称：深圳市绿诗源生物技术有限公司

生产地址：深圳市大鹏新区大鹏办事处布新社区布新村工业大道2号D栋101.201.301

法定代表人：王晓丽

生产范围：Ⅱ类6840体外诊断试剂，Ⅱ类6840临床检验分析仪器。

企业负责人：宁波

住　　所：深圳市大鹏新区大鹏办事处布新社区布新村工业大道2号D栋101.201.301

发证部门：广东省食品药品监督管理局

有效期限：至 2020 年 08 月 30 日

发证日期：2017 年 02 月 22 日

国家食品药品监督管理总局制

证书号第3369776号

# 发明专利证书

发明名称：克拉霉素半抗原、人工抗原和抗体及其制备方法应用

发　明　人：宁波;李隆军;刘明如;赖启隆;朱永利;蒋永青;吴育春

专　利　号：ZL 2016 1 1125939.6

专利申请日：2016年12月09日

专利权人：深圳市绿诗源生物技术有限公司

地　　址：518000 广东省深圳市大鹏新区大鹏办事处布新社区布新村工业大道2号D栋101.201.301

授权公告日：2019年05月10日　　授权公告号：CN 106589024 B

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专利证书记载专利权登记时的法律状况。专利权的转移、质押、无效、终止、恢复和专利权人的姓名或名称、国籍、地址变更等事项记载在专利登记簿上。

局长
申长雨

国家知识产权局
2019年05月10日



其他事项参见背面

中华人民共和国国家知识产权局
STATE INTELLECTUAL PROPERTY OFFICE
OF THE PEOPLE'S REPUBLIC OF CHINA

# 专利登记簿副本

专利号:ZL201210540608.4　　证书号:1578458

## I 著录项目

| | | |
|---|---|---|
| 发明名称: | 以多聚赖氨酸为载体的双酚A包被抗原制备方法及其应用 |
| 申请日: | 2012年12月14日 |
| 公开日: | 2013年04月17日 |
| 授权日: | 2015年02月04日 |
| 主分类号: | G01N 33/531(2006.01) |
| 发明人: | 刘晶、宁波、蒋永青 |

专利权人:深圳市绿诗源生物技术有限公司
专利权人地址:深圳市大鹏新区大鹏办事处布新社区布新村工业大道2号D栋101、201、301
专利权人邮政编码:518120
国籍或注册的国家或地区:中国

## II法律状态

截止至办理本专利登记簿副本之日,该专利权有效。
年费缴纳至2016年12月13日

## III 其他登记事项

专利权授予
授权公告日:2015年02月04日

中华人民共和国国家知识产权局
2016年02月22日
专利登记簿用章
(20)

证书号第6702397号

# 实用新型专利证书

实用新型名称：一种基于量子点的苯乙醇胺A检测试纸

发　明　人：赵肃清;王防修;梁雨昕;陈莹珊

专　利　号：ZL 2017 2 0276807.7

专利申请日：2017年03月21日

专 利 权 人：深圳市绿诗源生物技术有限公司

授权公告日：2017年12月08日

本实用新型经过本局依照中华人民共和国专利法进行初步审查，决定授予专利权，颁发本证书并在专利登记簿上予以登记。专利权自授权公告之日起生效。

本专利的专利权期限为十年，自申请日起算。专利权人应当依照专利法及其实施细则规定缴纳年费。本专利的年费应当在每年03月21日前缴纳。未按照规定缴纳年费的，专利权自应当缴纳年费期满之日起终止。

专利证书记载专利权登记时的法律状况。专利权的转移、质押、无效、终止、恢复和专利权人的姓名或名称、国籍、地址变更等事项记载在专利登记簿上。

局长
申长雨

中华人民共和国国家知识产权局

2017年12月08日

证书号第6854199号

# 实用新型专利证书

实用新型名称：一种基于抗体和量子点的双酚A检测试纸

发　明　人：赵肃清；王防修；梁雨昕；张磊；周剑青；陈莹珊；黄丕浓
刘洁

专　利　号：ZL 2017 2 0286229.5

专利申请日：2017年03月23日

专 利 权 人：深圳市绿诗源生物技术有限公司；广东工业大学

授权公告日：2018年01月12日

本实用新型经过本局依照中华人民共和国专利法进行初步审查，决定授予专利权，颁发本证书并在专利登记簿上予以登记。专利权自授权公告之日起生效。

本专利的专利权期限为十年，自申请日起算。专利权人应当依照专利法及其实施细则规定缴纳年费。本专利的年费应当在每年03月23日前缴纳。未按照规定缴纳年费的，专利权自应当缴纳年费期满之日起终止。

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局长
申长雨

中华人民共和国国家知识产权局

2018年01月12日

中山大學 附属第三医院
THE THIRD AFFILIATED HOSPITAL OF SUN YAT-SEN UNIVERSITY

# 新型冠状病毒肺炎 IgG/IgM 抗体检测实验总结

1. 实验目的：
采用深圳市绿诗源生物技术有限公司的 COVID-19（2019-nCoV）冠状病毒 IgM/IgG 抗体试剂（免疫层析法）与核酸检测及 CT 确诊的临床血清标本，考察本试剂的等效性。

2. 实验时间：2020 年 3 月 23 日

3. 实验地点：中山大学附属第三医院检验科

4. 产品的预期用途，原理，检测方法
预期用途：用于体外定性检测人血清或血浆、全血中 COVID-19（2019-nCoV）冠状病毒 IgM/IgG 抗体，主要用于新型冠状病毒肺炎的初筛。
原理：本试剂盒采用免疫层析法，检测卡含有：1)胶体金标记的重组新型冠状病毒抗原和质控抗体金标记物；2)固定有一条检测线（ T 线）和一条质控线（ C 线）的硝酸纤维素膜。T 线固定有重组新型冠状病毒抗原，用于检测新型冠状病毒 IgM 抗体；G 线固定有试剂，用于检测新型冠状病毒总 IgM 和 IgG 抗体；C 线固定有质控抗体。当适量的待测样本加入到检测卡的样本孔中，该样本将在毛细作用下沿着检测卡向前移动，如果样本中含有 IgM 和 IgG 抗体，则该抗体会与胶体金标记新型冠状病毒抗原结合，该免疫复合物会被膜上固定的新型冠状病毒抗原捕获，形成紫红色的 M 线，显示新型冠状病毒 IgM 抗体阳性。如果检测线 G 和 M 都不显色，显示阴性结果。该检测卡还包含一条质控线 C，不管是否有检测线出现，紫红色的质控线 C 都应出现。

中山大学附属第三医院 检验科

5. 实验设计：

5.1 实验材料

评价试剂：深圳市绿诗源生物技术有限公司的 COVID-19(2019-nCoV)冠状病毒 IgM/IgG 抗体试剂（免疫层析法）；样本类型：血浆

5.2 实验方法

实验操作流程如下：

1. 测试前仔细阅读使用说明书，待测标本，检测试剂及其他检测用材料均需要平衡至室温状态。
2. 沿铝箔袋撕口大开将试剂卡取出平放。
3. 向检测卡的加样孔（小孔）中加入 10 微升血清/血浆/全血样本，再向测试卡的稀释液加样孔（大孔）中滴加 2-3 滴约 60-80 微升样本稀释液。
4. 15 分钟观察显示结果，20 分钟以后观察结果无临床指导意义。
5. 数据统计及分析。

6. 临床样本的选择、数量及收集方法

（1）临床样本的选择

入选标准：

根据新冠肺炎诊疗方案（试行第六版）确诊病人的血清/血浆/全血标本，性别、年龄不限。

临床研究随机选取符合入选标准的血液样本进行检测。

（2）样本数量

实验的总样本数为 60 例，采用待评价试剂和进行单次测定的方式。

（3）样本的收集方法

样本采集原则上由临床单位专业人员按临床采血技术规范操作采集（检测项目有特殊要求除外），血浆样本可用于测试。

7. 数据处理与记录保存

实验人员应按要求准确，完整地记录与实验相关的信息及实验结果。

| 编号 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
|---|---|---|---|---|---|---|---|---|---|---|
| | 阴性 | 阴性 | 阴性 | 阴性 | 阴性 | 阴性 | 阴性 | 阴性 | 阴性 | 阴性 |
| 编号 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 |
| | 阴性 | 阴性 | 阴性 | 阴性 | 阴性 | 阴性 | 阴性 | 阴性 | 阴性 | 阴性 |
| 编号 | 21 | 22 | 23 | 24 | 25 | 26 | 27 | 28 | 29 | 30 |
| | 阴性 | 阴性 | 阳性 | 阳性 | 阴性 | 阴性 | 阳性 | 阴性 | 阴性 | 阴性 |
| 编号 | 31 | 32 | 33 | 34 | 35 | 36 | 37 | 38 | 39 | 40 |
| | 阴性 | 阴性 | 阴性 | 阴性 | 阴性 | 阴性 | 阴性 | 阴性 | 阴性 | 阴性 |
| 编号 | 41 | 42 | 43 | 44 | 45 | 46 | 47 | 48 | 49 | 50 |
| | 阴性 | 阴性 | 阴性 | 阴性 | 阴性 | 阴性 | 阴性 | 阳性 | 阴性 | 阴性 |
| 编号 | 51 | 52 | 53 | 54 | 55 | 56 | 57 | 58 | 59 | 60 |
| | 阴性 | 阴性 | 阴性 | 阴性 | 阴性 | 阴性 | 阴性 | 阴性 | 阴性 | 阴性 |
| 编号 | 61 | 62 | 63 | 64 | 65 | | | | | |
| | 阴性 | 阴性 | 阳性 | 阴性 | 阳性 | | | | | |

其中，23、24、65 号样本均为确诊新冠已治愈出院患者，其余为未确诊新冠患者。

结论

编号 1-20 例（排除新冠患者）阴性标本 100%符合。

编号 21-22 号样本源自非确诊新冠患者，但某品牌胶体金检测试剂测定阳性且另一品牌化学发光检测试剂 IgM 抗体阳性，绿诗源结果为阴性。

编号 23、24、65 号样本（确诊新冠已治愈出院患者），100%符合。

编号 25-64 号为未确诊新冠患者，且某品牌胶体金检测试剂测定阳性，绿诗源结果 3 例弱阳，37 例阴性。

（以下空白）

操作人

审核人

Test Report

# 深圳市疾病预防控制中心

# 卫生检测报告

编号 B2020004　　第 1 页　共 4 页

| | |
|---|---|
| 受检（委托）单位：深圳市疾病预防控制中心<br>Shenz hen Center for Diseases Control and Prevention | 地址：南山区龙苑路 8 号<br>Nanshan District, No.8 Longyuan Road |
| 样品类别：血清(serum) | 采（送）检单号：/ |
| 样品状态：液态 Liquid | 采样方式：/ |
| 样品来源：送样 Sample | 检测日期：2020 年 3 月 21 日 |
| 检测项目：SARS-CoV-2 抗体检测(IgG，IgM);<br>SARS-CoV-2 IgG and IgM antibody Combined Test Kit,Colloidal Gold Chromatographic Immunoassay | 检测环境条件：温度：24℃　湿度：48% |
| 检测方法：深圳市绿诗源生物技术有限公司（IgM/IgG 胶体金免疫层析法试剂盒说明书）<br>**Shenzhen Lvshiyuan Biotechnology Co. Ltd(IgM/IgG Colloidal Gold Chromatographic Immunoassay)** | |

检测结果：

**Detection results**

与核酸荧光 PCR 对比阳性符合检出率为 77%；阴性样本检出阳性率为百分子 3%

The positive coincidence rate **of** IgM/IgG **Colloidal Gold Chromatographic Immunoassay** with PCR was 77%.The positive rate of negative samples was 3%.

见下面附件，

**See the attachment below**

检测者：　　复核者：　　签发者：

深圳市疾病预防控制中心 急性传染病检测专用章

签发日期：　2020 年 3 月 21 日（盖章）

附件：

Attachment:

| 样本信息 Information of samples | | | | | 品牌：绿诗源 Brand: Green Spring<br>名称 Name: COVID-19 (2019-nCoV) Coronavirus IgG/IgM Rapid Test Kit （20200303） |
|---|---|---|---|---|---|
| 实验室编号Number | 样本类型 Sample type | 采样日期 Sample collection date | 临床诊断信息 Clinical diagnosis | 确诊日期 Date of diagnosis | 总抗体检测结果 Test results of total antibodies |
| 1 | 血清 serum | / | 新冠肺炎 COVID-19 | 1.25 | - |
| 2 | 血清 serum | / | 新冠肺炎 COVID-19 | 1.22 | - |
| 3 | 血清 serum | / | 新冠肺炎 COVID-19 | 1.25 | + |
| 4 | 血清 serum | 1.22 | 新冠肺炎 COVID-19 | 1.22 | - |
| 5 | 血清 serum | / | 新冠肺炎 COVID-19 | 1.22 | + |
| 6 | 血清 serum | 1.22 | 新冠肺炎 COVID-19 | 1.23 | - |
| 7 | 血清 serum | / | 新冠肺炎 COVID-19 | 1.16 | - |
| 8 | 血清 serum | / | 新冠肺炎 COVID-19 | 1.23 | - |
| 9 | 血清 serum | 1.22 | 新冠肺炎 COVID-19 | 1.23 | - |
| 10 | 血清 serum | / | 新冠肺炎 COVID-19 | 1.22 | - |
| 11 | 血清 serum | 2.7 | 新冠肺炎 COVID-19 | 2.7 | + |
| 12 | 血清 serum | 2.19 | 新冠肺炎 COVID-19 | 2.3 | + |
| 13 | 血清 serum | 2.9 | 新冠肺炎 COVID-19 | 1.20 | + |
| 14 | 血清 serum | 2.11 | 新冠肺炎 COVID-19 | 1.20 | + |
| 15 | 血清 serum | 2.7 | 新冠肺炎 COVID-19 | 1.20 | + |
| 16 | 血清 serum | 2.10 | 新冠肺炎 COVID-19 | 1.28 | + |
| 17 | 血清 serum | 2.3 | 新冠肺炎 COVID-19 | 1.28 | + |
| 18 | 血清 serum | 2.16 | 新冠肺炎 COVID-19 | 1.27 | + |
| 19 | 血清 serum | 2.10 | 新冠肺炎 COVID-19 | 1.27 | + |
| 20 | 血清 serum | 2.3 | 新冠肺炎 COVID-19 | 1.25 | + |
| 21 | 血清 serum | 2.19 | 新冠肺炎 COVID-19 | 2.5 | + |
| 22 | 血清 serum | 2.11 | 新冠肺炎 COVID-19 | 1.26 | + |
| 23 | 血清 serum | 2.16 | 新冠肺炎 COVID-19 | 1.25 | + |
| 24 | 血清 serum | 2.15 | 新冠肺炎 COVID-19 | 1.24 | + |
| 25 | 血清 serum | 2.9 | 新冠肺炎 COVID-19 | 1.26 | + |
| 26 | 血清 serum | 2.7 | 新冠肺炎 COVID-19 | 1.26 | + |
| 27 | 血清 serum | 2.16 | 新冠肺炎 COVID-19 | 2.2 | + |
| 28 | 血清 serum | 2.8 | 新冠肺炎 COVID-19 | 1.28 | + |
| 29 | 血清 serum | 2.4 | 新冠肺炎 COVID-19 | 2.4 | ± |
| 30 | 血清 serum | 2.9 | 新冠肺炎 COVID-19 | 2.3 | + |
| 31 | 血清 serum | / | 健康人 Healthy person | / | - |
| 32 | 血清 serum | / | 健康人 Healthy person | / | - |
| 33 | 血清 serum | / | 健康人 Healthy person | / | - |
| 34 | 血清 serum | / | 健康人 Healthy person | / | - |
| 35 | 血清 serum | / | 健康人 Healthy person | / | - |
| 36 | 血清 serum | / | 健康人 Healthy person | / | - |
| 37 | 血清 serum | / | 健康人 Healthy person | / | - |
| 38 | 血清 serum | / | 健康人 Healthy person | / | - |
| 39 | 血清 serum | / | 健康人 Healthy person | / | - |
| 40 | 血清 serum | / | 健康人 Healthy person | / | - |

| | | | | | |
|---|---|---|---|---|---|
| 41 | 血清 serum | / | 健康人 Healthy person | / | - |
| 42 | 血清 serum | / | 健康人 Healthy person | / | - |
| 43 | 血清 serum | / | 健康人 Healthy person | / | - |
| 44 | 血清 serum | / | 健康人 Healthy person | / | - |
| 45 | 血清 serum | / | 健康人 Healthy person | / | - |
| 46 | 血清 serum | / | 健康人 Healthy person | / | - |
| 47 | 血清 serum | / | 健康人 Healthy person | / | - |
| 48 | 血清 serum | / | 健康人 Healthy person | / | - |
| 49 | 血清 serum | / | 健康人 Healthy person | / | - |
| 50 | 血清 serum | / | 健康人 Healthy person | / | - |
| 51 | 血清 serum | / | 健康人 Healthy person | / | - |
| 52 | 血清 serum | / | 健康人 Healthy person | / | - |
| 53 | 血清 serum | / | 健康人 Healthy person | / | - |
| 54 | 血清 serum | / | 健康人 Healthy person | / | - |
| 55 | 血清 serum | / | 健康人 Healthy person | / | - |
| 56 | 血清 serum | / | 健康人 Healthy person | / | - |
| 57 | 血清 serum | / | 健康人 Healthy person | / | - |
| 58 | 血清 serum | / | 健康人 Healthy person | / | ± |
| 59 | 血清 serum | / | 健康人 Healthy person | / | - |
| 60 | 血清 serum | / | 健康人 Healthy person | / | - |

以下空白 Blank below