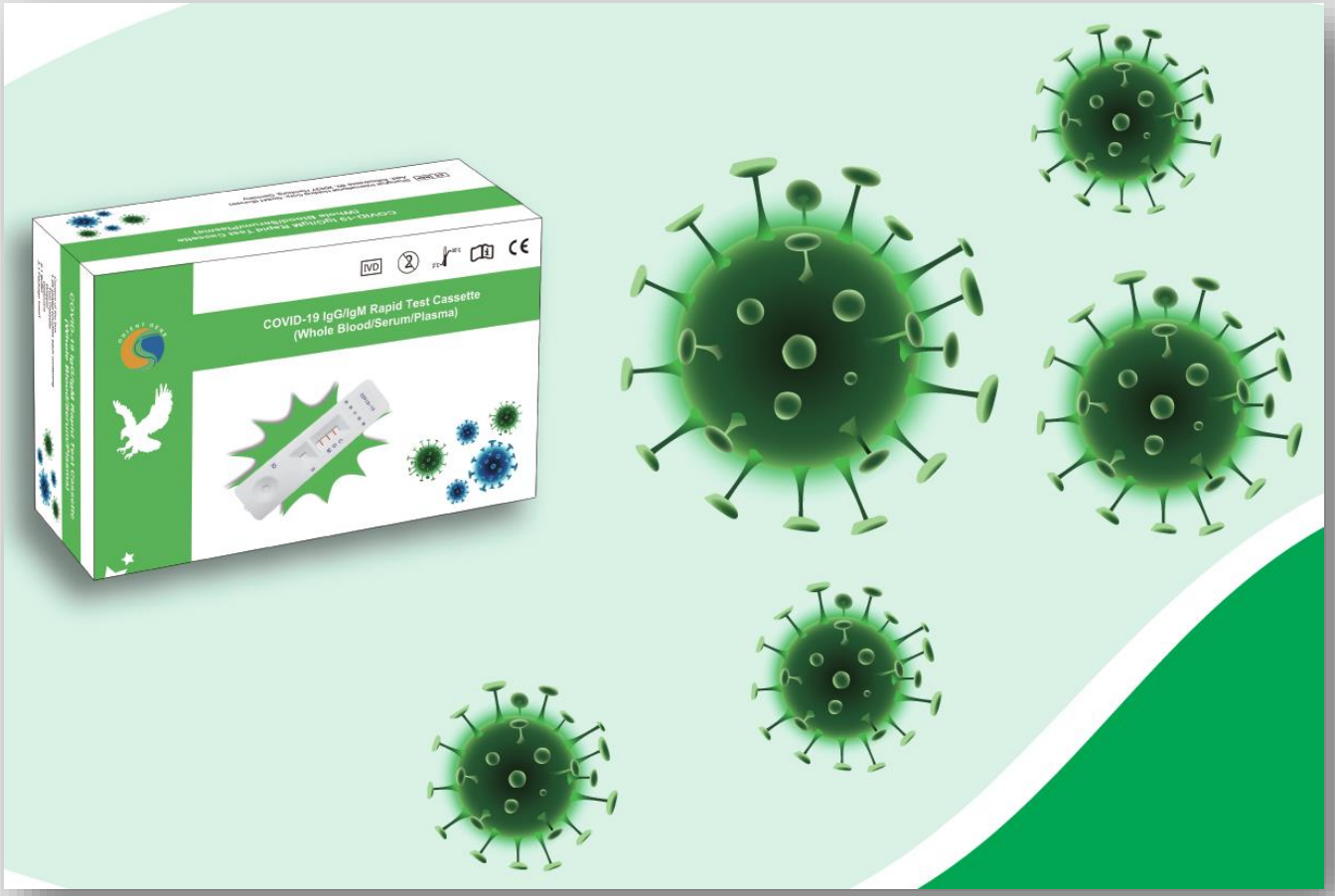
PRODUCT PROFILE

COVID-19 IgG/IgM Rapid Test Cassette

Brief Introduction



Product Description:
COVID-19 IgG/IgM Rapid Test

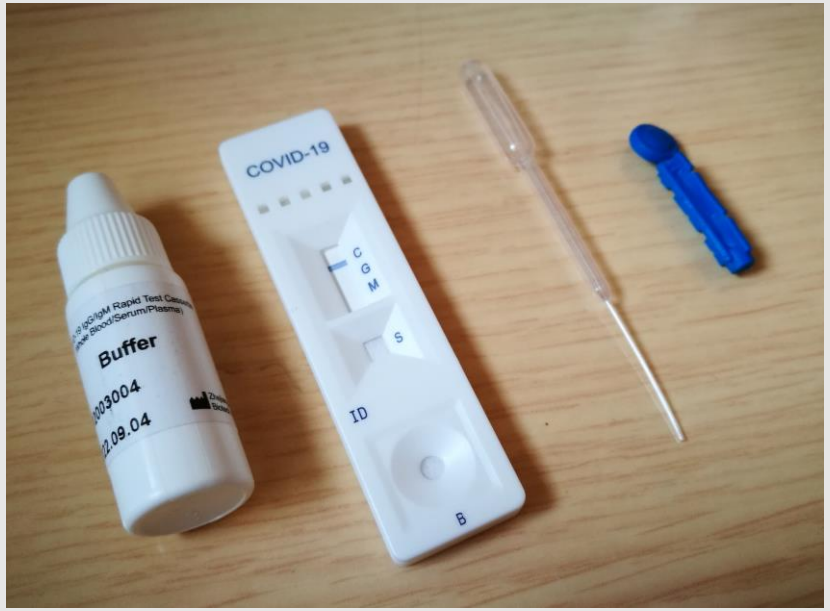
Specimen:
Whole Blood/Serum/Plasma

Format:
Cassette

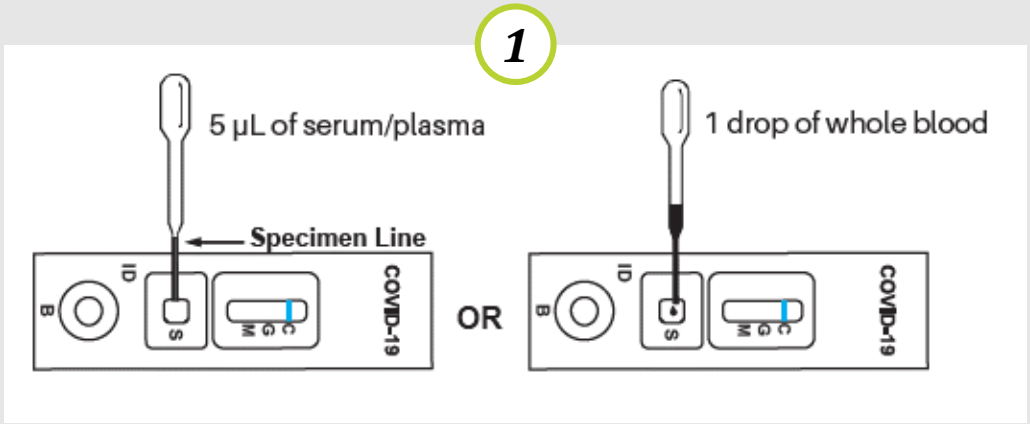
This is a solid phase immunochromatographic assay for the rapid, qualitative and differential detection of IgG and IgM antibodies to COVID-19 in human whole blood, serum or plasma.

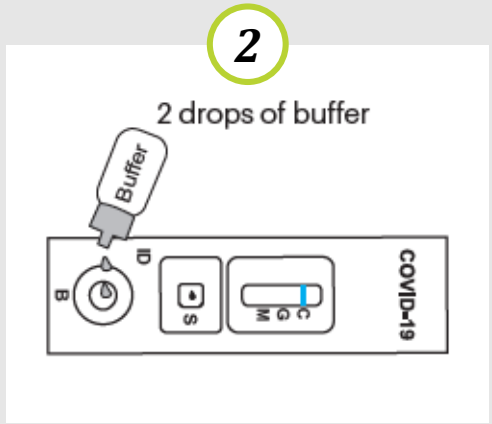
COVID-19 IgG/IgM Rapid Test Cassette
(Whole Blood/Serum/Plasma)
Buffer
202003004
2022.09.04

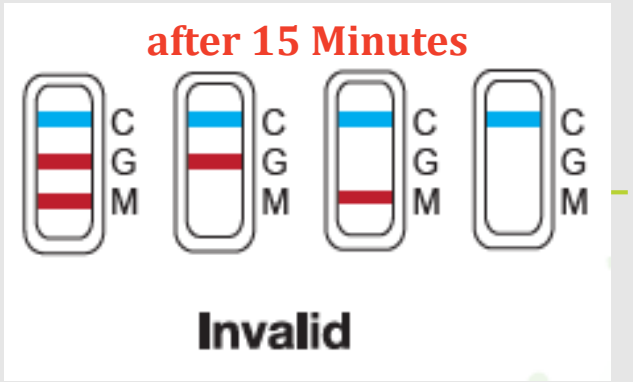
Buffer
COVID-19
One Step Rapid Test
For in vitro diagnostic use only

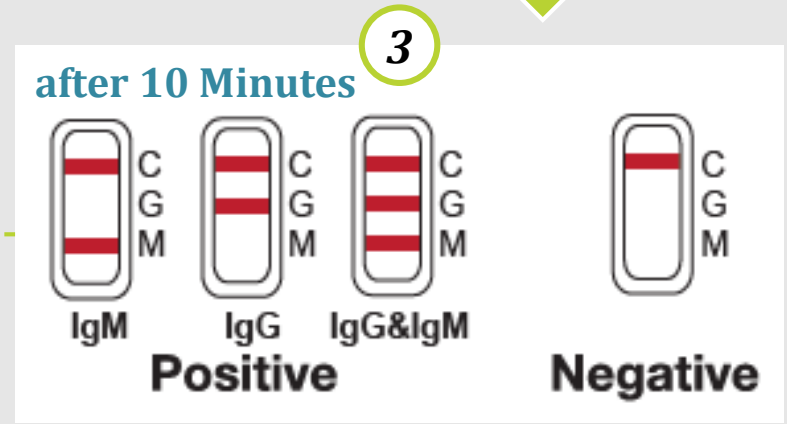

COVID-19
Buffer
C
G
M
S
ID
B

Test Procedure & Interpretation









USP OF THE PRODUCT

Outstanding Research Team

Easy, Convenient, Fast

Accurate ≥ 97%

Low Risk of Infection

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

INTENDED USE

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

INTRODUCTION

Coronaviruses are enveloped RNA viruses that are distributed broadly among humans, other mammals, and birds and that cause respiratory, enteric, hepatic, and neurologic diseases. Seven coronavirus species are known to cause human disease. Four viruses - 229E, OC43, NL63, and HKU1 - are prevalent and typically cause common cold symptoms in immunocompetent individuals.4 The three other strains - severe acute respiratory syndrome coronavirus (SARS-CoV), Middle East respiratory syndrome coronavirus (MERS-CoV) and 2019 Novel Coronavirus (COVID-19) - are zoonotic in origin and have been linked to sometimes fatal illness. IgG and IgM antibodies to 2019 Novel Coronavirus can be detected with 2-3 weeks after exposure, IgG remains positive, but the antibody level drops overtime.

PRINCIPLE

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

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

MATERIALS SUPPLIED

1,Cassette 2,Dropper 3, Desiccant 4, Buffer 5,Package insert

MATERIAL REQUIRED BUT NOT PROVIDED

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

STORAGE AND STABILITY

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

WARNINGS AND PRECAUTIONS

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

SPECIMEN COLLECTION

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

TEST PROCEDURE

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

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

For Serum or Plasma Specimens:

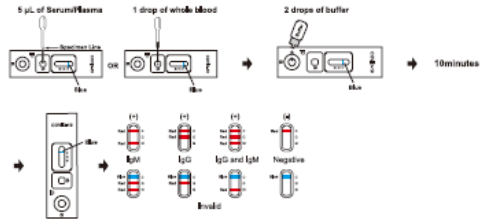
With a 5 µL mini plastic dropper provided, draw serum/plasma specimen to exceed the specimen line as showed in the following image and then transfer drawn serum/plasma specimen into the sample well (S). Then add 2 drops (about 80µL) of sample buffer to the buffer well (B) immediately. Avoid air bubbles.

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

For Whole Blood Specimen:

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

Wait for the colored line(s) to appear. The result should be read in 10 minutes. Positive results may be visible as soon as 2 minutes. Do not interpret the result after 15 minutes.



INTERPRETATION OF RESULTS

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

IgM POSITIVE:

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

IgG POSITIVE:

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

IgG and IgM POSITIVE:

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

INVALID:

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

QUALITY CONTROL

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

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

LIMITATIONS

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

PERFORMANCE CHARACTERISTICS

Clinical Performance

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

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

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

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

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

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

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

REFERRENCE

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

MDST

检 验 报 告

Test Report

报告编号：G20200222

产 品 名 称：新型冠状病毒抗原快速检测试纸（胶体金法）

规 格 型 号：卡型单人份包装：20人份/盒

受 检 单 位：浙江东方基因生物制品股份有限公司

检 验 类 别：委托检验

国家食品药品监督管理局

杭州医疗器械质量监督检验中心

国家食品药品监督管理局杭州医疗器械质量监督检验中心

检 验 报 告

报告编号：G20200222　　共 5 页 第 1 页

样品名称	新型冠状病毒抗原快速检测试纸（胶体金法）		
规格型号	卡型单人份包装：20人份/盒	检验类别	委托检验
委托人/单位	浙江东方基因生物制品股份有限公司		
受检单位名称	浙江东方基因生物制品股份有限公司		
制造单位名称	浙江东方基因生物制品股份有限公司		
取样方式	送样	抽样地点	/
抽样日期	/	抽样基数	/
抽样人	/	样品接受日期	2020-02-06
样品数量	27盒（另有参考品51支）	样品生产日期	2020-01-25 2020-01-27 2020-01-29
样品批号/编号	20200125 20200127 20200129		
检验依据	《新型冠状病毒抗原快速检测试纸（胶体金法）》产品技术要求		
检验项目	全性能检验		
检验日期	2020年02月07日～2020年02月25日		
检验结论	被检样品符合浙江东方基因生物制品股份有限公司的《新型冠状病毒抗原快速检测试纸（胶体金法）》产品技术要求中性能要求的规定。		

检验报告专用章

批准：张莉　　审核：　　主检：

职务：授权签字人

日期：2020.02.26　　日期：2020.02.26　　日期：2020.02.25

临床性能比对评价报告

产品名称：新型冠状病毒 IgM/IgG 抗体检测试纸（胶体金法）

生产厂家：浙江东方基因生物制品股份有限公司

评价单位：中国科学院大学宁波华美医院

评价时间：2020 年 2 月

附件

ATTACHMENT

证书编号：浙湖食药监械出 20200067 号 （共 页）

Certificate NO.：浙湖食药监械出 20200067 号 （Page）

序号 SN	产品名称 Product(s)	规格型号 Model	注册或备案 Registration certificate(s)
1	新型冠状病毒 IgG/IgM 抗体检测试纸 COVID-19 IgG/IgM Rapid Test	Device 卡式 GCCOV-302/GCCOV-402	/
2	新型冠状病毒抗原检测试纸 COVID-19 Ag Rapid Test	Device 卡式 GCCOV-502	/
3	单核细胞增多症 IgG/IgM 抗体检测试纸 Mononucleosis IgG/IgM Rapid Test	Device 卡式 GCMON-402	/
4	轮状病毒/腺病毒检测试纸 Rotavirus/Adenovirus Combo Rapid Test	Device 卡式 GCROA/ADE-602	/
空白 Blank	空白 Blank	空白 Blank	空白 Blank

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

CE-DOC-OG127
version 1.0

EC Declaration of Conformity

In accordance with Directive 98/79/EC

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

Legal Manufacturer Addres..: *3787#, East Yangguang Avenue, Dipu Street, An.. 313300, Huzhou, Zhejiang,China*

Declares, that the produc..
Product Name and Mod..(s)

COVID-19 IgG/I.. Ra..id T.. Cassette (Whole Blood/Serum/Plasma)	GCCOV-402a

Classification: *Oth..r*
Conformity assessment route: *..nex II..EC DE..LARATION OF CONFORMITY)*

We, the Manufacturer, herewith declare with sole ..sp..nsibility that our product/s mentioned above meet/s the provisions of the Dire..ive ../..EC of the European Parliament and of the Council on In-Vitro Diagnostic Medical Devices.

We hereby explicitly appoint

EC Representative's Name: Shanghai Internatio..al H..ld..g Corp. GmbH (Europe)

EC Representative's Address: Eiffestrasse 8.. 20..37 H..mburg, Germany

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

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

Date Signed: February 12, 2020

Joyce Pang

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

ZHEJIANG ORIENT GENE BIOTECH CO., LTD

www.sh..
REPRESE..
YOU
SHINE IN EU

Confirmation

of EU product notifications submitting

Herewith we confirm that

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

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

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

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

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

14 February 2020

Shanghai International Holding Corporation Germany GmbH Eiffestrasse 80 20537 Hamburg

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

空运 By Air

NO.2020130256

CNAS 中国认可检验 INSPECTION CNAS IB0071

货物运输条件鉴定书

Certification for Safe Transport of Chemical Goods

非限制性货物

样品名称： 单克隆抗体检测试纸（有缓冲液）

Sample Name: DIAGNOSTIC TEST (COMPONENT INCLUDING BUFFER)

委托单位： 浙江东方基因生物制品股份有限公司

生产单位： 浙江东方基因生物制品股份有限公司

上海化工院检测有限公司 检验检测专用章

上海化工院检测有限公司

Shanghai Research Institute of Chemical Industry Testing Co., Ltd

空运 By Air

空运 By Air

货物运输条件鉴定书

Certification for Safe Transport of Chemical Goods NO. 2020130256

Page 1 / 2

样品名称 Sample Name	中文 Chinese	单克隆抗体检测试纸（有缓冲液）
	英文 English	DIAGNOSTIC TEST (COMPONENT INCLUDING BUFFER)
委托单位 Consignor		浙江东方基因生物制品股份有限公司
生产单位 Manufacturer		浙江东方基因生物制品股份有限公司
检验方法、程序 Inspection Methods and Procedures		国际航空运输协会《危险品规则》61版 IATA Dangerous Goods Regulations (DGR) 61st Edition
样品外观与气味 Appearance & Odor		白色塑料测试板和液体，稍有气味 White Plastic test board and liquid, Weak odor

IDENTIFICATION CONCLUSION 鉴定结论

1. 危险性识别(Hazards identification)

无。
None.

2. 空运按照IATA DGR办理的类项(Suggestion according to IATA DGR)

可按非限制性货物条件办理。
The substance is not subject to IATA DGR.

3. 包装要求(Packaging requirements)

无。
None.

检验日期: Inspection Date: 2019-12-07 签发日期: Issue Date: 2019-12-07 生效日期: Effective Date: 2020-01-01

备注 Comment: 无。 None.

批准 Approver: 张小[illegible] 审核 Checker: 董学性 主检 Appraiser: 刘[illegible]

上海化工院检测 检验检测 (2

货物运输条件鉴定书

Certification for Safe Transport of Chemical Goods NO. 2020130256

Page 2 / 2

鉴定项目 Identification Items	鉴定结果 Identification Conclusion Results
爆炸危险性鉴定 Identification of Explosive Hazard	该货物不属于爆炸品。 The product is not classified in Explosives.
易燃危险性鉴定 Identification of Flammable Hazards	经闭杯闪点测试，在70度下没有发生闪燃，表明该货物不属于第3类易燃液体。 In the closed-cup flash point test, no flash was detected below 70℃, so the product is not classified in Class 3 (Flammable Liquids).
氧化危险性鉴定 Identification of Oxidative Hazards	该货物不属于氧化剂和有机过氧化物。 The product is not classified in oxidizing substances and organic peroxides.
毒害及传染危险性鉴定 Identification of Toxic & Infectious Hazards	该货物不属于有毒和感染性物质。 The product is not classified in toxic and infectious substances.
放射危险性鉴定 Identification of Radioactive Hazard	该货物无放射危险性。 The product is not classified in radioactive material.
腐蚀危险性鉴定 Identification of Corrosive Hazard	该货物不属于腐蚀品。 The product is not classified in corrosives.
其他危险性鉴定 Identification of other Hazards	该货物无其它危险性。 The product presents no other dangerous properties.

-验证码: 032624-

报告结束

ABOUT THE MANUFACTURER

Zhejiang Orient Gene Biotech Co., Ltd. is a high-tech manufacturing facility in China which integrated R&D, Production and Sales. The company was founded in 2005 covers 144 area and built 92,000 m2 of GMP workshops, office buildings and auxiliary houses. Products include: Genetic diagnosis, Colloidal gold rapid diagnostic tests, Dry chemical strips (urinalysis), Bio-liquid diagnostic kits, Clinical test instruments, POCT time-resolved Fluor immunoassay Test kit (TRFI), Raw materials etc. Most of their products are CE certificated and more than 32 items have FDA certificate. The products are exported to more than 120 countries and regions, such as North and South America, Europe, South Asia, Southeast Asia, Middle East, Africa, Russia and Australia.

天眼查 TianYanCha.com
国家中小企业发展基金旗下
官方备案企业征信机构
查公司 查老板 查关系
浙江东方基因生物制品股份有限公司
天眼一下
VIP会

企业简介

天眼查

公司全称	浙江东方基因生物制品股份有限公司		
英文名称	Zhejiang Orient Gene Biotech Co., Ltd		
上市曾用名	浙江东方基因生物制品有限公司	工商登记	913305007804719612
注册资本	9000万人民币	所属行业	-
董事长	方效良	董秘	王晓波
法定代表人	方效良	总经理	方效良
员工人数	1028	管理人员人数	16
控股股东	方效良、方剑秋、方炳良(持有浙江东方基因生物制品股份有限公司股份比例：17.38、16.41、13.13%)	实际控制人	方效良、方剑秋、方炳良(持有浙江东方基因生物制品股份有限公司股份比例：17.38、16.41、13.13%)
最终控制人	方效良、方剑秋、方炳良(持有浙江东方基因生物制品股份有限公司股份比例：17.38、16.41、13.13%)		
主营业务	从事体外诊断产品研发、生产与销售		

下载 APP

TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

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

has established and applies a quality management system for medical devices for the following scope:

(see attachment for scope)

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date:	2018-03-17
Certificate Registration No.:	SX 60126352 0001
An audit was performed. Report No.:	15077992 008
This Certificate is valid until:	2021-03-16

Certification Body

DAkkS Deutsche Akkreditierungsstelle D-ZM-14169-01-02

Date 2018-01-30

X. Ren

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail:cert-validity@de.tuv.com http://www.tuv.com/safety

10/020 d 04.08 ® TÜV, TUEV and TUV are registered trademarks. Utilisation and application requires prior approval.

TÜVRheinland®

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60126352 0001
Report No.: 15077992 008

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

Scope:
Design and Development, Manufacture and Distribution of In Vitro Diagnostic Reagents for Cardiac Diseases, Infectious Diseases Oncology and for Biochemistry as well as Rapid Tests for Fertility, Rapid Tests for Drugs of Abuse, Chlamydia Trachomatis Antigen, Toxoplasma gondii(Toxo) IgG/IgM, Toxoplasma gondii(Toxo) IgG, Toxoplasma gondii(Toxo) IgM, Digital Pregnancy Tests for Self-testing, and Distribution of Urine Analyzer as well

Certification Body

DAkkS Deutsche Akkreditierungsstelle D-ZM-14169-01-02

Date: 2018-01-30

X. Ren

10/020 d 04.08 ® TÜV, TUEV and TUV are registered trademarks. Utilisation and application requires prior approval.

HEALGEN®
D★S
DIAGNOSTAR
ACCURATE
我们的产品
OUR PRODUCTS
Genetic & Molecular Diagnosis 基因诊断试剂
Liquid Biochip 液态生物芯片
POCT Reagent 体外即时诊断试剂
Biochemistry Reagent 生化诊断试剂
Dry Chemistry Strip 干式生化试纸
POCT Analyzer 体外即时诊断仪器
Raw Materials 生物原料
专业 专心 专注
FDA
CE
TÜVRheinland
CFDA

HEALGEN®
WHO
Malaria Rapid Test
疟疾即时诊断试剂盒
List A CE
HIV 1/2 Rapid Test
艾滋病毒即时诊断试剂盒
HCV Rapid Test
丙肝即时诊断试剂盒
Digital Pregnancy Test
早孕电子笔
Drugs of Abuse Test Series
毒品检测系列
Urine Multi-Drug Screen Test
尿液毒品多合一即时检测试剂
Oral Fluid Drug Test
唾液毒品即时检测试剂
Cardiac Marker Fluorescence Quantitative Test Kits
心肌系列荧光定量即时诊断试剂
One Step Marijuana Test Kit
大麻即时检测试剂盒
Urine Drug Test Cup
毒品即时检测杯型试剂
Raw Materials
生物原料
FDA
CE
TÜVRheinland
CFDA