Szybio
LIFE ORIGIN BIOTECH

SARS-CoV-2

IgM/IgG Antibody Assay Kit

(Immunochromatography)

Wuhan Life Origin Biotech Joint Stock Co., Ltd.

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Part one
Company qualification

Wuhan Life Origin Biotech Joint Stock Co., Ltd.

1. About Life Origin Biotech

Life Origin Biotech is a National High-Tech Enterprise with research, production and sales in one. It is located in the National High-tech Development Zone-Wuhan Optics Valley of China. After 10 years of effort, Life Origin Biotech has become a good partner of domestic clinicians and global researchers.

The company currently employs over 300 peoples, among them more than 30 are Masters or PhDs. It has built 1,000 square meters purification plant in accordance with the standards of pharmaceutical GMP and 5,600 square meters "Clinical In Vitro Diagnostic Reagents R&D Center". Life Origin Biotech has the national top four technology platforms: "IVD raw materials development and related product & technical service platform" and "Latex enhanced product R&D platform" and "R&D platform of chemiluminescent immunoassay reagents and related instruments " and "R&D platform of POCT diagnostic reagents and equipment" to form a complete industrial chain from IVD raw materials R&D to the IVD reagent sales. Life Origin Biotech has become one of the very few IVD reagents companies that have a complete IVD reagents industrial chain in China.

2. What We Do

As a manufacturer of In vitro diagnostic reagents and Scientific reagents, our only mission is to provide the best products and related custom service to clinicians or researchers to satisfy customer's needs.

2.1 In vitro diagnostic reagents

At present, more than 80 in vitro diagnostic reagent products have been certified by CFDA registration and CE compliance certification.

The main clinical applications of the products include: Renal function, Glucose metabolism, Pancreas, Liver function, Electrolytes, Blood lipid, Cardiovascular, Special proteins and Inorganic ions.

At present, our in vitro diagnostic reagent products take Wuhan as the center and radiate globally. Our products have covered 5 188 customers and established in-depth cooperation with 1 556 customers.

2.2 Scientific reagents

In 2011 Life Origin Biotech wholly acquired Wuhan Huamei Biotech Co., Ltd., (CUSABIO) the global well-known scientific research reagents and IVD raw material manufacturer. CUSABIO is a high-tech enterprise specialized in research reagents and IVD raw materials. Its products are sold in more than 90 countries worldwide. CUSABIO dedicated to providing 60,000+ validated antibodies, 6000+ recombinant proteins, 580+ cytokines and thousands of ELISA kits to global customers in the research fields of cancer, cell biology, immunology, neuroscience, epigenetics, etc. All kinds of our products can meet customers' different demands in various scientific research fields.

CUSABIO's high quality has been guaranteed by many published literatures in all kinds of famous journals, such as Science, Nature, Cell, Developmental Biology, Molecular Cell, Genes & Development, and so on. Now, the publications citing our products has reached more than 4,800, and hundreds of publications are updating every year.

3. Our Promise

Life Origin Biotech's goal is to provide the highest quality In vitro diagnostic reagents and Scientific reagents to satisfy customer's needs in different application scenarios. Here, we illuminate our promise from the following aspects.

3.1 Technical Support

For in vitro diagnostic products, we provide resident engineers, covering all provinces and municipalities in the country, to ensure that within 24 hours to respond to customer needs, timely solutions to customer problems.

For scientific reagents, we have a technical team consists of scientists with Doctorate and Master Degrees, which can solve customer problems within 24 hours by email, phone, live chat. And we have more than 200 online technical resources.

3.2 Global Presence

For in vitro diagnostic products, the team of sales engineers covers all provinces, municipalities, autonomous regions and municipalities directly under the Central Government.

For scientific reagents, our products have entered more than 90 companies in the world and established long-term cooperative relations with 115 distributors worldwide.

3.3 Product Quality Assurance

We have strict factory inspection process, and actively participate in the third-party evaluation organized by the Ministry of Health to strictly control production and product quality.

4. How to Keep Benign Development

In 2015, the company was approved by the Ministry of Human Resources and Social Affairs to set up postdoctoral research workstation, and relying on the postdoctoral workstation to cultivate outstanding talents and incubate new technology platform.

From 2016 to now, we have established Nobel laureate workstations with Nobel laureates Professor Hartmut Michel and Professor Randy Wayne Schekman. Each year, several professional technicians from their labs come to guide us in developing high-quality transmembrane proteins and exosome related products.

With good cooperation with excellent teams and the absorption of high-end technical personnel, the company constantly improves its own technology platform in its technical field, optimizes product performance, in order to better meet the various needs of customers.

Address: Wuhan Hi-Tech Medical Device Park B11, No.818 Gaoxin Avenue, Donghu Hi-Tech Development Zone 430206.
TEL: 027-87196336/81363255 **FAX:** 027-87196320
Website: http://www.szybio.com/

统一社会信用代码
91420100698327549A

营业执照

（副本）

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。

名　　称　武汉生之源生物科技股份有限公司

类　　型　股份有限公司(非上市、自然人投资或控股)

法定代表人　华权高

经营范围　生物工程与生物医学工程技术新产品的开发；科学研究用试剂、抗体的研发、生产及销售；一类、二类和三类医疗器械的开发、生产、销售、租赁、维修及技术服务；一类及二类医疗器械的批发兼零售；纳米材料（不含危险化学品）的开发、生产与销售；实验室认可咨询；货物进出口、技术进出口、代理进出口(不含国家禁止进出口的货物及技术)；普通货物道路运输、货运代理（凭许可证在核定期限内经营）；普通机械设备租赁。（涉及许可经营项目，应取得相关部门许可后方可经营）

注册资本　叁仟贰佰肆拾陆万叁仟伍佰圆整

成立日期　2009年12月25日

营业期限　长期

住　　所　武汉东湖新技术开发区高新大道818号高科医疗器械园B11号1楼、2楼、3楼

登记机关

2020 年 01 月 06 日

国家企业信用信息公示系统网址：http://www.gsxt.gov.cn

市场主体应当于每年1月1日至6月30日通过国家企业信用信息公示系统报送公示

国家市场监督管理总局监制

医疗器械生产许可证

许可证编号：鄂食药监械生产许20100488号

企业名称：武汉生之源生物科技股份有限公司

生产地址：武汉东湖开发区高新大道818号高科医疗器械园B11号1楼

法定代表人：华权高

生产范围：三类：6840体外诊断试剂；二类：6840体外诊断试剂、22-04免疫分析设备。***

企业负责人：华权高

住　　所：武汉东湖开发区高新大道818号高科医疗器械园B11号1楼、2楼

发证部门：湖北省药品监督管理局

有效期限：至　2025　年　4　月　11　日

发证日期：　2020　年　4　月　12　日

查询网址：http://www.hubfda.gov.cn

国家药品监督管理局制

REGISTRATION NO. 04717Q10000269

CERTIFICATE OF QUALITY MANAGEMENT SYSTEM FOR MEDICAL DEVICES

This is to certify that the quality management system of

Wuhan Life Origin Biotech Joint Stock Co., Ltd.

Registered Address: 1F&2F, Building B11, Wuhan Hi-tech Medical Devices Park, #818 Gaoxin Avenue, Donghu Hi-Tech Development Area, Wuhan Postcode: 430206

Manufacturing Address: 1F, Building B11, Wuhan Hi-tech Medical Devices Park, #818 Gaoxin Avenue, Donghu Hi-Tech Development Area, Wuhan

Has been assessed and conformed to the following standard(s)

YY/T 0287-2017 idt ISO 13485:2016

The certificate is valid for the following scope:

The Design, Development, Production and Service of In Vitro Diagnostic Reagent (See the Attached).

Date of issue: July 14, 2017

Date of expiry: July 13, 2020

General Manager:

BEIJING HUA GUANG CERTIFICATION OF MEDICAL DEVICES CO., LTD.

Note: This certificate will not be valid until the organization has been approved in the annual audits. The certificate information are available on the website of the certification and accreditation administration of the People's Republic of China (www.cnca.gov.cn) or the website of CMD (www.cmdc.com.cn). Address: 5th floor of Zhong Lian building, No.jia88, An Ding Men Wai street, Dongcheng district, Beijing,100011, P.R. China Telephone: 010-62351993

REGISTRATION NO. 04717Q10000269

Attachment:

1.5′-Nucleotidase Assay Kit By Enzymatic Colorimetric Method

2.Adenosine Deaminase Assay Kit By Enzymatic Method

3.Apolipoprotein A1 Assay Kit By Immunoturbidimetric Method

4.Apolipoprotein B Assay Kit By Immunoturbidimetric Method

5.Apolipoprotein E Assay Kit By Immunoturbidimetric Method

6.Anti-Streptolysin O Assay Kit By Latex Enhanced Immunoturbidimetric Method

7.Aspartate Aminotransferase Isoenzymes Assay Kit By Immunoinhibition Method

8.Complement 3 Assay Kit By Immunoturbidimetric Method

9.Complement 4 Assay Kit By Immunoturbidimetric Method

10.Cholinesterase Assay Kit By Continuous Monitoring Method

11.Creatine Kinase Isoenzyme MB Assay Kit By Selective Inhibition Method

12.Creatine Kinase Assay Kit By IFCC Method

13.C-reactive Protein Assay Kit By Immunoturbidimetric Method

14.Troponin I Assay Kit By Latex Enhanced Immunoturbidimetric Method

15.Cystatin C Assay Kit By Latex Enhanced Immunoturbidimetric Method

16.Fructosamine Assay Kit By NBT Method

17.Glucose Assay Kit By GOD-PAP Method

18.Homocysteine Assay Kit By Enzymatic Cycling Method

19.High Density Lipoprotein Cholesterol Assay Kit By Direct Method

20.Haptoglobin Assay Kit By Immunoturbidimetric Method

21.Full-range C-reactive Protein Assay Kit By Latex Enhanced Immunoturbidimetric Method

22.Immunoglobulin A Assay Kit By Immunoturbidimetric Method

23.Immunoglobulin G Assay Kit By Immunoturbidimetric Method

24.Immunoglobulin M Assay Kit By Immunoturbidimetric Method

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REGISTRATION NO. 04717Q10000269

Attachment:

25.Ischemia-modified Albumin Assay Kit By Albumin Cobalt Binding Test

26.Low Density Lipoprotein Cholesterol Assay Kit By Direct Method

27.Lipoprotein a Assay Kit By Latex Enhanced Immunoturbidimetric Method

28.Urinary Microalbumin Assay Kit By Immunoturbidimetric Method

29.Myoglobin Assay Kit By Latex Enhanced Immunoturbidimetric Method

30.Prealbumin Assay Kit By Immunoturbidimetric Method

31.Retinol Binding Protein Assay Kit By Latex Enhanced Immunoturbidimetric Method

32.Rheumatoid Factor Assay Kit By Latex Enhanced Immunoturbidimetric Method

33.Total Cholesterol Single Assay Kit By COD-CE-PAP Method

34.Total Cholesterol Dual Assay Kit By COD-CE-PAP Method

35.Transferrin Assay Kit By Immunoturbidimetric Method

36.Triglycerides Single Assay Kit By GPO-PAP Method

37.Triglycerides Dual Assay Kit By GPO-PAP Method

38.α1-Microglobulin Assay Kit By Latex Enhanced Immunoturbidimetric Method

39.β2-Microglobulin Assay Kit By Latex Enhanced Immunoturbidimetric Method

40.Alkaline Phosphatase Assay Kit By IFCC Method

41.Alanine Aminotransferase Assay Kit By IFCC Recommended Method

42.α-Amylase Assay Kit By Enzymatic Method

43.Aspartate Aminotransferase Assay Kit By IFCC Method

44.Carbon Dioxide Assay Kit By Enzymatic Method

45.Direct Bilirubin Assay Kit By Oxidizing Method

46.γ-Glutamyltransferase Assay Kit By IFCC Recommended Method

47.Inorganic Phosphorus Assay Kit By UV Method

48.Lactate Dehydrogenase Assay Kit By IFCC Method

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49.Magnesium Assay Kit By XB Method

50.Neutrophil Gelatinase-associated Lipocalin Assay Kit By Latex Enhanced Immunoturbidimetric Method

51.Total Bile Acids Assay Kit By Enzyme Cycling Method

52.Total Bilirubin Assay Kit By Oxidizing Method

53.Total Protein Assay Kit By Doumas Method

54.Uric Acid Assay Kit By URO-PAP Method

55.α-Hydroxybutyrate Dehydrogenase Assay Kit By DGKC Recommended Method

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Manufacturing Address: 1F, Building B11, Wuhan Hi-tech Medical Devices Park, #818 Gaoxin Avenue, Donghu Hi-Tech Development Area, Wuhan

Has been assessed and conformed to the following standard(s)

GB/T 19001-2016 idt ISO 9001:2015

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Date of issue: July 14, 2017

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General Manager:

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MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT IAF

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MANAGEMENT SYSTEM
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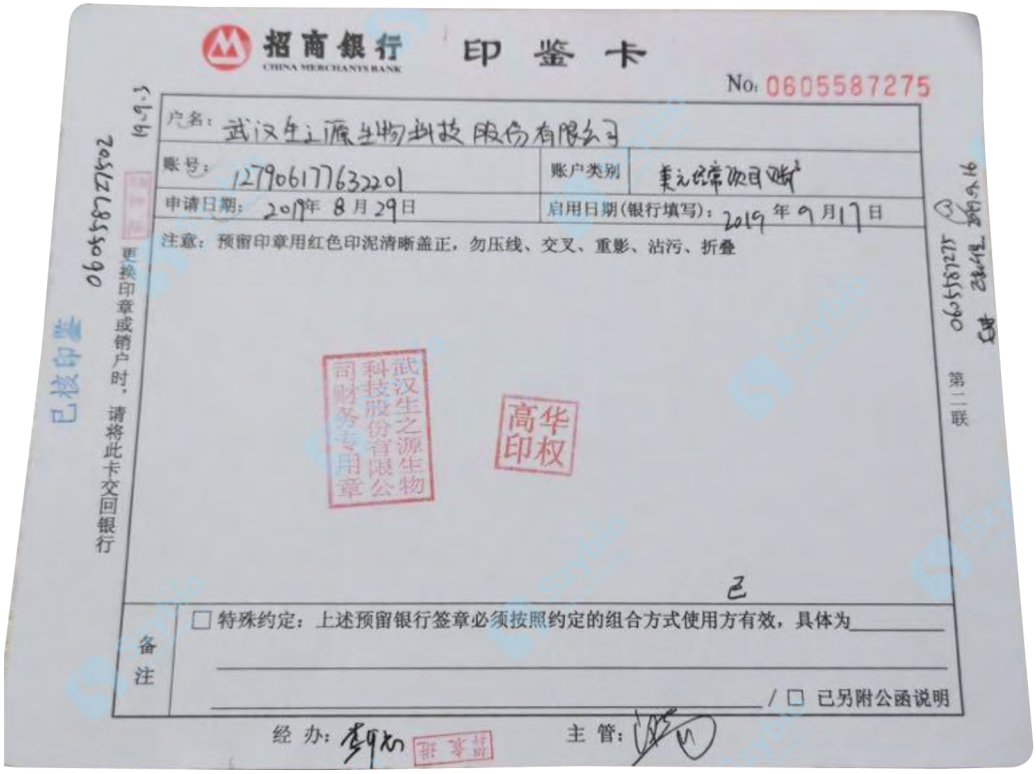
招商银行 CHINA MERCHANTS BANK

印鉴卡

No: 0605587275

户名：武汉生之源生物科技股份有限公司

账号：127906177632201　　账户类别：集团综合日账

申请日期：2019年8月29日　　启用日期(银行填写)：2019年9月17日

注意：预留印章用红色印泥清晰盖正，勿压线、交叉、重影、沾污、折叠

武汉生之源生物科技股份有限公司财务专用章

高华印权

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第二联

招商银行

单位结算产品服务申请书

编号：

单位基本信息

单位名称：

单位经办人：☐法定代表人（单位负责人） ☐被授权代理人　代理人姓名：　联系电话：　身份证件类型：☐身份证 ☐其他：　证件号码：

单位账号信息（选择确请打"√"）

账号 1	账号 2	账号 3
申请服务项目	申请服务项目	申请服务项目
☐电话银行服务 ☐新增 ☐取消 ☐密码重置	☐电话银行服务 ☐新增 ☐取消 ☐密码重置	☐电话银行服务 ☐新增 ☐取消 ☐密码重置
☐自助打印服务（回单、交易对账单） ☐新增 ☐取消 ☐密码重置	☐自助打印服务（回单、交易对账单） ☐新增 ☐取消 ☐密码重置	☐自助打印服务（回单、交易对账单） ☐新增 ☐取消 ☐密码重置
☐回单保管服务 ☐新增 ☐取消	☐回单保管服务 ☐新增 ☐取消	☐回单保管服务 ☐新增 ☐取消
☐支付密码功能 ☐需申请支付密码器	☐支付密码功能 ☐需申请支付密码器	☐支付密码功能 ☐需申请支付密码器
☐网上企业银行服务 （已有网银编号：　　） 网银功能选项： 基础功能（自动开通，含账务查询、信用查询、网上银企对账、网上自助申请（限登录方式为凭数字证书登录）等功能） ☐N02030 支付　☐N02020 内部转账 ☐N08010 定活互转　☐N08020 通知存款 ☐N24010 受托理财　☐N40010 移动支票 ☐N19010 银证转账　☐N03010 代发工资 ☐N03020 其他代发，代发类型及代码（请在第 3 联背面查找）：　　 其他（请在第 3 联背面查找）：	☐网上企业银行服务 网银功能选项： 基础功能（自动开通，含账务查询、信用查询、网上银企对账、网上自助申请（限登录方式为凭数字证书登录）等功能） ☐N02030 支付　☐N02020 内部转账 ☐N08010 定活互转　☐N08020 通知存款 ☐N24010 受托理财　☐N40010 移动支票 ☐N19010 银证转账　☐N03010 代发工资 ☐N03020 其他代发，代发类型及代码（请在第 3 联背面查找）：　　 其他（请在第 3 联背面查找）：	☐网上企业银行服务 网银功能选项： 基础功能（自动开通，含账务查询、信用查询、网上银企对账、网上自助申请（限登录方式为凭数字证书登录）等功能） ☐N02030 支付　☐N02020 内部转账 ☐N08010 定活互转　☐N08020 通知存款 ☐N24010 受托理财　☐N40010 移动支票 ☐N19010 银证转账　☐N03010 代发工资 ☐N03020 其他代发，代发类型及代码（请在第 3 联背面查找）：　　 其他（请在第 3 联背面查找）：

新申请网上企业银行（客户无网银编号的）需填写以下内容

组织机构代码		管理类型（业务审批模式）	☐需要审批 ☐不需要审批（仅限支付及黄金交易业务）	银企直联	☐是（需另签协议） ☐否
系统管理员	系统管理员姓名（1）		身份证件类型	☐身份证 ☐其他：	证件号码
	登录用户号及验证码获取	☐短信获取，移动电话（推荐采用）			
		☐电子邮件获取，邮箱地址			
	系统管理员姓名（2）		身份证件类型	☐身份证 ☐其他：	证件号码
	登录用户号及验证码获取	☐短信获取，移动电话（推荐采用）			
		☐电子邮件获取，邮箱地址			
系统管理员登录方式		☐凭数字证书登录　☐凭用户密码登录（客户只能开通并办理账务查询、信用查询和网上银企对账）			
数字证书	系统管理员（1）	☐申请证书：☐系统管理员领取 ☐指定代领人_____ ☐不约定领取人（非系统管理员本人领取证书的需另出具授权书）			
		☐不申请证书			
	系统管理员（2）	☐申请证书：☐系统管理员领取 ☐指定代领人_____ ☐不约定领取人（非系统管理员本人领取证书的需另出具授权书）			
		☐不申请证书			

客户盖章及银行审核栏

本单位已知悉并认可《招商银行单位结算产品服务协议》和《招商银行单位结算产品服务章程》，开户银行已应要求做出解释。

本申请书是《招商银行单位结算产品服务协议》的组成部分，本单位保证本申请书填写准确、真实、有效，所填内容经单位已确认无误。

申请单位（公章）：

法定代表人（单位负责人）/授权代理人：
（授权代理人签署的须出具授权书）

年　月　日

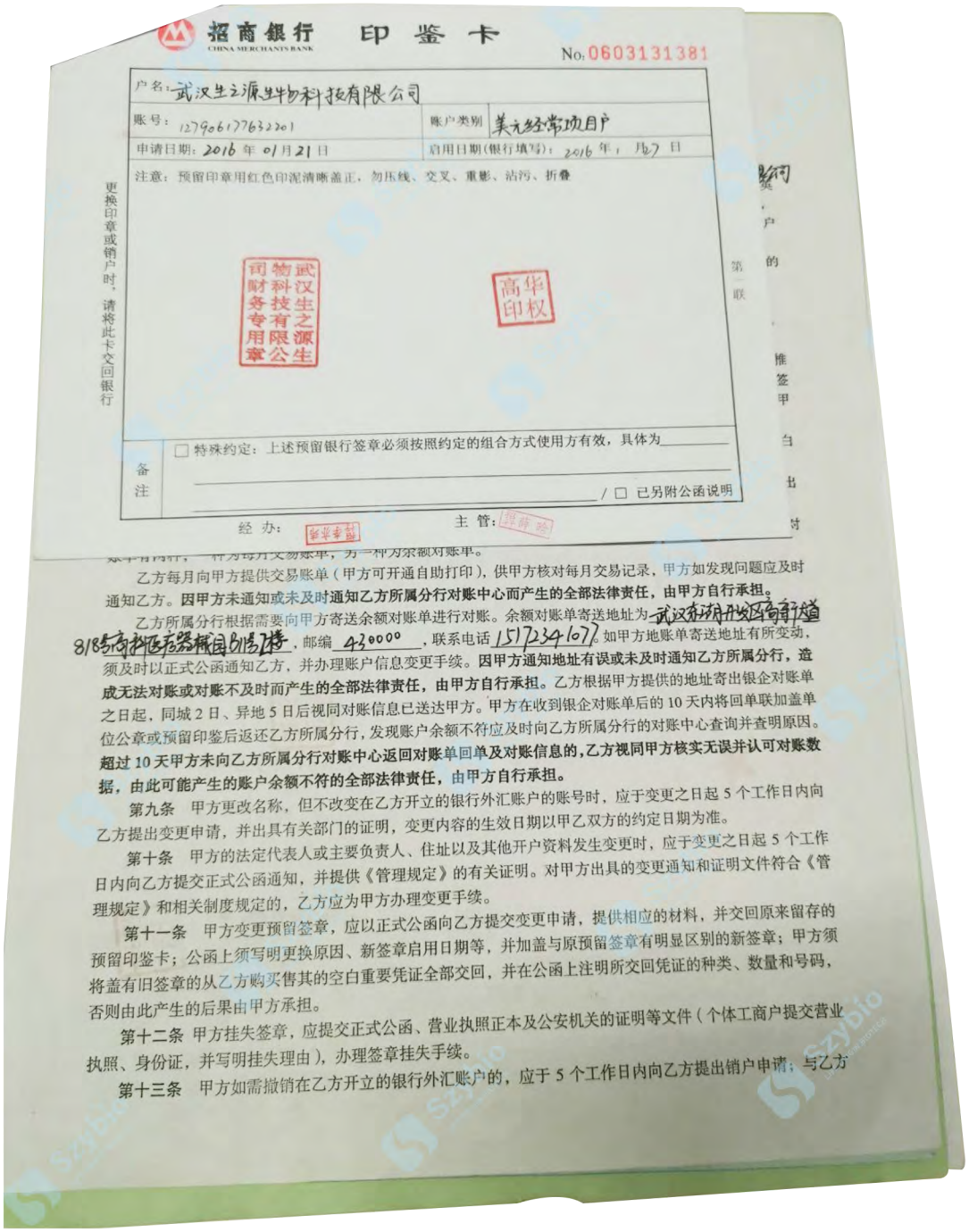
客户号：

经办：　复核：

银行（盖章）

年　月　日

第二联　客户留存



招商银行 CHINA MERCHANTS BANK 印鉴卡

No: 0603131381

户名：武汉生之源生物科技有限公司

账号：127906177632201　　账户类别：美元经常项目户

申请日期：2016 年 01 月 21 日　　启用日期(银行填写)：2016 年，月27 日

注意：预留印章用红色印泥清晰盖正，勿压线、交叉、重影、沾污、折叠

更换印章或销户时，请将此卡交回银行

第一联

武汉生之源生物科技有限公司财务专用章

高华印权

□ 特殊约定：上述预留银行签章必须按照约定的组合方式使用方有效，具体为_____

备注　_____ / □ 已另附公函说明

经办：　　主管：

乙方每月向甲方提供交易账单（甲方可开通自助打印），供甲方核对每月交易记录，甲方如发现问题应及时通知乙方。**因甲方未通知或未及时通知乙方所属分行对账中心而产生的全部法律责任，由甲方自行承担。**

乙方所属分行根据需要向甲方寄送余额对账单进行对账。余额对账单寄送地址为武汉东湖开发区高新大道8/18号光谷总部国际B栋7楼，邮编 430000，联系电话 15172341077。如甲方地账单寄送地址有所变动，须及时以正式公函通知乙方，并办理账户信息变更手续。**因甲方通知地址有误或未及时通知乙方所属分行，造成无法对账或对账不及时而产生的全部法律责任，由甲方自行承担。**乙方根据甲方提供的地址寄出银企对账单之日起，同城 2 日、异地 5 日后视同对账信息已送达甲方。甲方在收到银企对账单后的 10 天内将回单联加盖单位公章或预留印鉴后返还乙方所属分行，发现账户余额不符应及时向乙方所属分行的对账中心查询并查明原因。**超过 10 天甲方未向乙方所属分行对账中心返回对账单回单及对账信息的，乙方视同甲方核实无误并认可对账数据，由此可能产生的账户余额不符的全部法律责任，由甲方自行承担。**

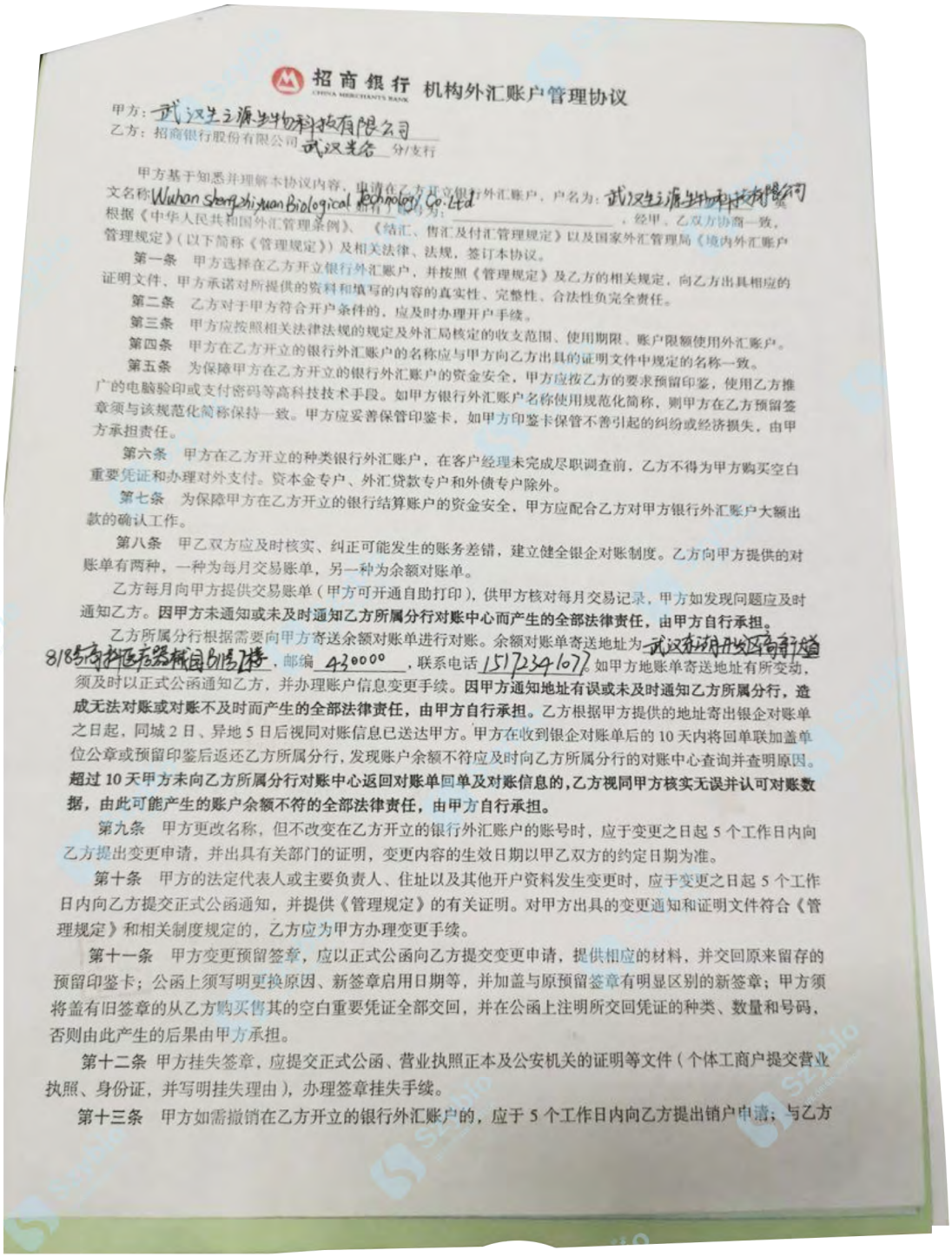
第九条 甲方更改名称，但不改变在乙方开立的银行外汇账户的账号时，应于变更之日起 5 个工作日内向乙方提出变更申请，并出具有关部门的证明，变更内容的生效日期以甲乙双方的约定日期为准。

第十条 甲方的法定代表人或主要负责人、住址以及其他开户资料发生变更时，应于变更之日起 5 个工作日内向乙方提交正式公函通知，并提供《管理规定》的有关证明。对甲方出具的变更通知和证明文件符合《管理规定》和相关制度规定的，乙方应为甲方办理变更手续。

第十一条 甲方变更预留签章，应以正式公函向乙方提交变更申请，提供相应的材料，并交回原来留存的预留印鉴卡；公函上须写明更换原因、新签章启用日期等，并加盖与原预留签章有明显区别的新签章；甲方须将盖有旧签章的从乙方购买售其的空白重要凭证全部交回，并在公函上注明所交回凭证的种类、数量和号码，否则由此产生的后果由甲方承担。

第十二条 甲方挂失签章，应提交正式公函、营业执照正本及公安机关的证明等文件（个体工商户提交营业执照、身份证，并写明挂失理由），办理签章挂失手续。

第十三条 甲方如需撤销在乙方开立的银行外汇账户的，应于 5 个工作日内向乙方提出销户申请；与乙方



招商银行 机构外汇账户管理协议

甲方：武汉生之源生物科技有限公司

乙方：招商银行股份有限公司 武汉光谷 分/支行

甲方基于知悉并理解本协议内容，申请在乙方开立银行外汇账户，户名为：武汉生之源生物科技有限公司 文名称：Wuhan Shengzhiyuan Biological Technology Co.Ltd 所有人证件号为：_____，经甲、乙双方协商一致，根据《中华人民共和国外汇管理条例》、《结汇、售汇及付汇管理规定》以及国家外汇管理局《境内外汇账户管理规定》（以下简称《管理规定》）及相关法律、法规，签订本协议。

第一条 甲方选择在乙方开立银行外汇账户，并按照《管理规定》及乙方的相关规定，向乙方出具相应的证明文件，甲方承诺对所提供的资料和填写的内容的真实性、完整性、合法性负完全责任。

第二条 乙方对于甲方符合开户条件的，应及时办理开户手续。

第三条 甲方应按照相关法律法规的规定及外汇局核定的收支范围、使用期限、账户限额使用外汇账户。

第四条 甲方在乙方开立的银行外汇账户的名称应与甲方向乙方出具的证明文件中规定的名称一致。

第五条 为保障甲方在乙方开立的银行外汇账户的资金安全，甲方应按乙方的要求预留印鉴，使用乙方推广的电脑验印或支付密码等高科技技术手段。如甲方银行外汇账户名称使用规范化简称，则甲方在乙方预留签章须与该规范化简称保持一致。甲方应妥善保管印鉴卡，如甲方印鉴卡保管不善引起的纠纷或经济损失，由甲方承担责任。

第六条 甲方在乙方开立的种类银行外汇账户，在客户经理未完成尽职调查前，乙方不得为甲方购买空白重要凭证和办理对外支付。资本金专户、外汇贷款专户和外债专户除外。

第七条 为保障甲方在乙方开立的银行结算账户的资金安全，甲方应配合乙方对甲方银行外汇账户大额出款的确认工作。

第八条 甲乙双方应及时核实、纠正可能发生的账务差错，建立健全银企对账制度。乙方向甲方提供的对账单有两种，一种为每月交易账单，另一种为余额对账单。

乙方每月向甲方提供交易账单（甲方可开通自助打印），供甲方核对每月交易记录，甲方如发现问题应及时通知乙方。**因甲方未通知或未及时通知乙方所属分行对账中心而产生的全部法律责任，由甲方自行承担。**

乙方所属分行根据需要向甲方寄送余额对账单进行对账。余额对账单寄送地址为武汉东湖开发区高新大道8/8号高科医疗器械园B栋2楼，邮编 430000，联系电话 15172341677。如甲方地账单寄送地址有所变动，须及时以正式公函通知乙方，并办理账户信息变更手续。**因甲方通知地址有误或未及时通知乙方所属分行，造成无法对账或对账不及时而产生的全部法律责任，由甲方自行承担。**乙方根据甲方提供的地址寄出银企对账单之日起，同城 2 日、异地 5 日后视同对账信息已送达甲方。甲方在收到银企对账单后的 10 天内将回单联加盖单位公章或预留印鉴后返还乙方所属分行，发现账户余额不符应及时向乙方所属分行的对账中心查询并查明原因。**超过 10 天甲方未向乙方所属分行对账中心返回对账单回单及对账信息的，乙方视同甲方核实无误并认可对账数据，由此可能产生的账户余额不符的全部法律责任，由甲方自行承担。**

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第十条 甲方的法定代表人或主要负责人、住址以及其他开户资料发生变更时，应于变更之日起 5 个工作日内向乙方提交正式公函通知，并提供《管理规定》的有关证明。对甲方出具的变更通知和证明文件符合《管理规定》和相关制度规定的，乙方应为甲方办理变更手续。

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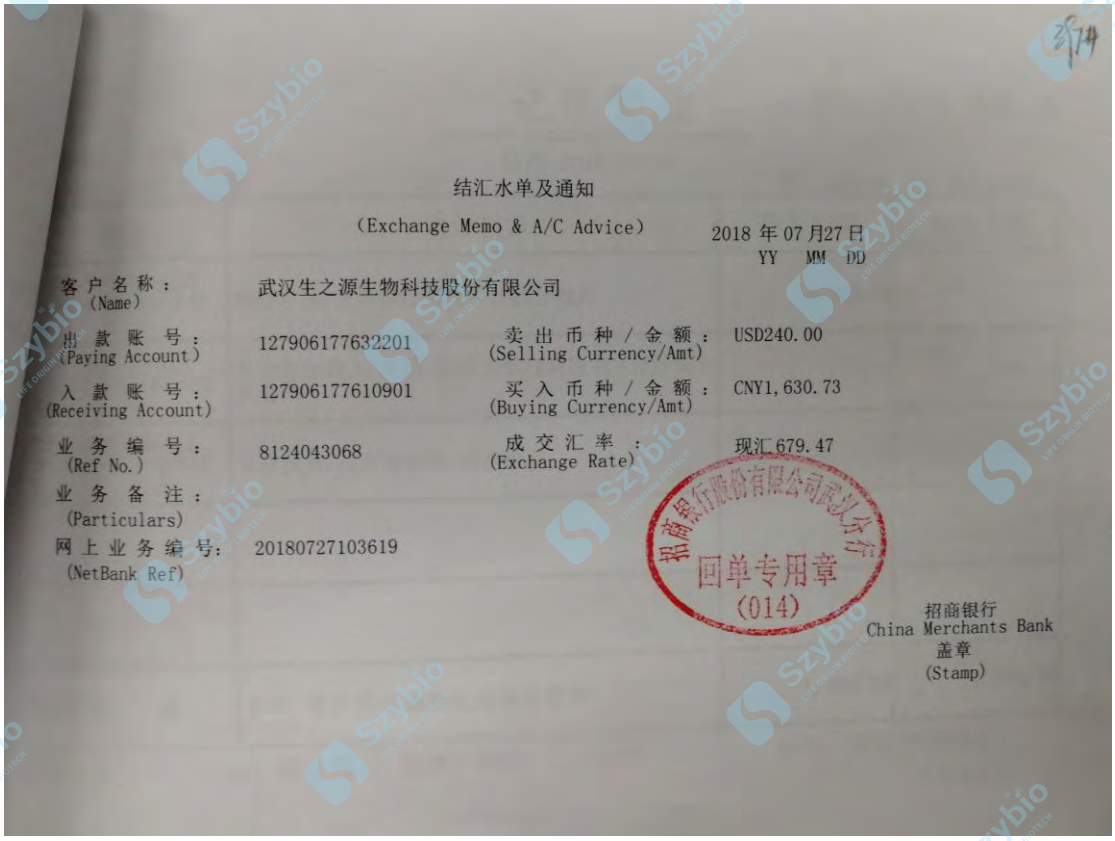
第十三条 甲方如需撤销在乙方开立的银行外汇账户的，应于 5 个工作日内向乙方提出销户申请；与乙方



结汇水单及通知

(Exchange Memo & A/C Advice)

2018 年 07 月27 日
YY MM DD

客户名称：(Name) 武汉生之源生物科技股份有限公司

出款账号：(Paying Account) 127906177632201

卖出币种/金额：(Selling Currency/Amt) USD240.00

入款账号：(Receiving Account) 127906177610901

买入币种/金额：(Buying Currency/Amt) CNY1,630.73

业务编号：(Ref No.) 8124043068

成交汇率：(Exchange Rate) 现汇679.47

业务备注：(Particulars)

网上业务编号：(NetBank Ref) 20180727103619

招商银行股份有限公司武汉分行 回单专用章 (014)

招商银行
China Merchants Bank
盖章
(Stamp)

结汇水单及通知

(Exchange Memo & A/C Advice)

2019 年 03 月07 日
YY MM DD

招商银行 CHINA MERCHANTS BANK

客户名称：(Name) 武汉生之源生物科技股份有限公司

出款账号：(Paying Account) 127906177632201

卖出币种/金额：(Selling Currency/Amt) USD80.04

入款账号：(Receiving Account) 127906177610901

买入币种/金额：(Buying Currency/Amt) CNY540.92

业务编号：(Ref No.) 3824329883

成交汇率：(Exchange Rate) 现汇675.81

业务备注：(Particulars)

网上业务编号：(NetBank Ref) 20190430090443

招商银行
China Merchants Bank
盖章
(Stamp)

招商银行股份有限公司 电子回单专用章

回单编号：1100005074369 回单验证码：9CE70C7D20AACD0E

提示：1.电子回单验证码相同表示同一笔业务回单，请勿重复记账使用。
2.已在银行柜台领用业务回单的单位，请注意核对，请勿重复记账使用。

打印时间：2020-03-30 18:54:07

Part two
Entry qualifications

Szybio

EC Declaration of Conformity

Regarding In Vitro Diagnostic Directive (98/79/EC)

Manufacturer:

Name: Wuhan Life Origin Biotech Joint Stock Co., Ltd

Address: Floor 1st, 2nd and 3nd , Wuhan Hi-Tech Medical Device Park B11, No.818 Gaoxin Avenue, Donghu Hi-Tech Development Zone

EC Representative

Name: SUNGO Europe B.V.

Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

Product

Name: Common name:

SARS-CoV-2 IgM/IgG Antibody Assay Kit (Immunochromatography)

Type: 10 tests/pack 、25 tests/pack 、50 tests/pack 、100 tests/pack

Classification: IVDD Other

We confirm our product can meet the requirement of In Vitro Diagnostic Medical Devices Directive (98/79EC) and the following harmonized standards.

EN ISO 13485:2016
EN ISO 14971:2012
EN ISO 18113-1:2011
EN 13612:2002
EN ISO 23640:2015
EN 13975:2003
EN ISO 15223-1:2016
EN 13975:2003
EN ISO 18113-2:2011
EN ISO 17511:2003
EN 13641:2002
EN 62366:2008

Signature: Qiangdo Hua.

Date: 26 Mar. 2020

CIBG
Ministerie van Volksgezondheid, Welzijn en Sport

> Retouradres Postbus 16114 2500 BC Den Haag

SUNGO Europe B.V.
T.a.v. de heer Luo
Olympisch Stadion 24
1076 DE Amsterdam

Farmatec

Bezoekadres:
Hoftoren
Rijnstraat 50
2515 XP Den Haag

T 070 340 6161

http://hulpmiddelen.farmatec.nl

Inlichtingen bij:
T.I. van Langeveld - Baas

medische_hulpmiddelen@minvws.nl

Ons kenmerk:
CIBG-20201001

Bijlagen
-

Uw aanvraag
27 maart 2020

Correspondentie uitsluitend richten aan het retouradres met vermelding van de datum en het kenmerk van deze brief.

Datum: 7 april 2020
Betreft: aanmelding In-vitro diagnostica

Geachte heer Luo,

Op 27 maart 2020 ontving ik uw notificatie krachtens artikel 4, eerste lid van het Nederlandse Besluit in-vitro diagnostica (BIVD) om onder de bedrijfsnaam Wuhan Life Origin Biotech Joint Stock Co., Ltd met Europees gemachtigde SUNGO Europe B.V. onderstaande producten als in-vitro diagnostica op de Europese markt te brengen.

De producten staan geregistreerd als in-vitro diagnostica onder nummer:

SARS-CoV-2 IgM/IgG Antibody Assay Kit (Immunochromatography)
(geen merknaam) (NL-CA002-2020-50066)
SARS-CoV-2 Nucleic Acid Dual-Detection Kit(Real-Time PCR Method)
(geen merknaam) (NL-CA002-2020-50067)

Hiermee heeft u voldaan aan uw verplichting op grond van artikel 4, BIVD.

In alle verdere correspondentie betreffende bovenvermelde producten verzoek ik u deze nummers te vermelden. Aan deze nummers kunnen geen verdere rechten ontleend worden, ze dienen alleen om de notificatie administratief te vergemakkelijken.

De registratie van in-vitro diagnostica als medisch hulpmiddel op grond van de Classificatiecriteria (Bijlage II) bij Richtlijn 98/79/EG betreffende medische hulpmiddelen voor in-vitro diagnostiek is onderhevig aan mogelijke revisies van Europese regelgeving inzake de classificatie van medische hulpmiddelen en aan voortschrijdend wetenschappelijk inzicht (zie artikel artikel 10, eerste lid van Richtlijn 98/79/EG).

Notificatie van in-vitro diagnostische medische hulpmiddelen impliceert dat de fabrikant, Wuhan Life Origin Biotech Joint Stock Co., Ltd de CE-conformiteitsmarkering heeft aangebracht op de desbetreffende producten alvorens deze in een EU-lidstaat in de handel te brengen. Zodoende garandeert SUNGO Europe B.V. dat de in-vitro diagnostica voldoen aan de essentiële eisen zoals opgenomen in bijlage I bij Richtlijn 98/79/EG (en in het daarmee corresponderende onderdeel 1 bij het besluit)

Volledigheidshalve wijzen wij u erop dat een in-vitro diagnosticum moet voldoen aan de eisen uit het BIVD. Het BIVD is gebaseerd op Richtlijn voor in-vitro diagnostiek, 98/79/EG. Met name wijzen wij u op de Nederlandse-taaleis zoals deze in Nederland geldt, de eisen voor het ter beschikking houden van de technische documentatie en de plicht tot het hebben van een Post Marketing Surveillance- en vigilantiesysteem.

Tot slot merk ik op dat met uw notificatie - de administratieve notificatie als fabrikant - en deze brief geen sprake is van een oordeel over de status of kwalificatie van uw product: notificering betekent niet dat daadwerkelijk sprake is van een in-vitro diagnosticum in de zin van de onderhavige wet- en regelgeving. In voorkomende gevallen kan de Inspectie Gezondheidszorg en Jeugd (IGJ), belast met het toezicht op de naleving van het bij of krachtens de wet bepaalde, een standpunt innemen over de status van een product, waarbij het volgens vaste jurisprudentie uiteindelijk aan de nationale rechter is om te bepalen of een product onder de definitie van in-vitro diagnosticum valt.

De Minister voor Medische Zorg en Sport,
namens deze,

Afdelingshoofd
Farmatec

Dr. M.J. van de Velde

Dhr. M.J. van de Velde

EC Declaration of Conformity

Regarding In Vitro Diagnostic Directive (98/79/EC)

Manufacturer:

Name: Wuhan Life Origin Biotech Joint Stock Co., Ltd

Address: Floor 1st. 2nd and 3nd , Wuhan Hi-Tech Medical Device Park B11, No.818 Gaoxin Avenue, Donghu Hi-Tech Development Zone

EC Representative

Name: SUNGO Europe B.V.

Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

Product

Name: Common name:

SARS-CoV-2 IgM/IgG Antibody Assay Kit (Immunochromatography)

Type: 10 tests/pack 、25 tests/pack 、50 tests/pack 、100 tests/pack

Classification: IVDD Other

We confirm our product can meet the requirement of In Vitro Diagnostic Medical Devices Directive (98/79EC) and the following harmonized standards.

EN ISO 13485:2016
EN ISO 14971:2012
EN ISO 18113-1:2011
EN 13612:2002
EN ISO 23640:2015
EN 13975:2003
EN ISO 15223-1:2016
EN 13975:2003
EN ISO 18113-2:2011
EN ISO 17511:2003
EN 13641:2002
EN 62366:2008

Signature: Quangao Hua

Date: 26. Mar. 2020

On behalf of SUNGO Europe office, I confirmed we are EU REP of the company who issue this document.

Sungo global service

Authorized Signature (S)

商务部 海关总署 国家市场监督管理总局公告2020年第12号 关于进一步加强防疫物资出口质量监管的公告

文章来源：商务部对外贸易司 2020-04-25 19:23 文章类型：原创 内容分类：政策

在全球疫情持续蔓延的特殊时期，为更有效支持国际社会共同应对全球公共卫生危机，现就进一步加强防疫物资质量监管、规范出口秩序有关措施公告如下：

一、加强非医用口罩出口质量监管。自4月26日起，出口的非医用口罩应当符合中国质量标准或国外质量标准。

商务部确认取得国外标准认证或注册的非医用口罩生产企业清单（中国医药保健品进出口商会网站www.cccmhpie.org.cn动态更新），市场监管总局提供国内市场查处的非医用口罩质量不合格产品和企业清单（市场监管总局网站www.samr.gov.cn动态更新），非医用口罩出口企业报关时须提交电子或书面的出口方和进口方共同声明（参考附件1），确认产品符合中国质量标准或国外质量标准，进口方接受所购产品质量标准且不用于医用用途，海关凭商务部提供的企业清单验放，对不在市场监管总局提供的企业清单内的，海关接受申报，予以验放。

对4月26日之前已签订的采购合同，出口报关时须提交电子或书面的出口方和进口方共同声明（参考附件1）。

二、进一步规范医疗物资出口秩序。自4月26日起，产品取得国外标准认证或注册的新型冠状病毒检测试剂、医用口罩、医用防护服、呼吸机、红外体温计的出口企业，报关时须提交电子或书面声明（参考附件2），承诺产品符合进口国（地区）质量标准和安全要求，海关凭商务部提供的取得国外标准认证或注册的生产企业清单（中国医药保健品进出口商会网站www.cccmhpie.org.cn动态更新）验放。

取得国外标准认证或注册的医疗物资生产企业清单

Name List of Medical Devices and Supplies Companies with Certification/Authorization from other Countries

序号	生产企业	统一社会信用代码	国外注册认证情况
No.	**Company**	**Uniform Social Credit Code**	**Status of Certification / Authorization in Other Countires**
五、	新型冠状病毒检测试剂 Coronavirus Reagent Test kits		
1	北京万泰生物药业股份有限公司 Beijing Wantai Biological Pharmacy Enterprise Co., Ltd.	91110114600067778R	欧盟 CE 认证
2	深圳市锦瑞生物科技有限公司 Genrui Biotech Inc.	91440300766350741W	欧盟 CE 认证
3	安徽福贸生物科技有限公司 Anhui Formaster Biosci Co., Ltd.	91340225MA2TENM49Y	欧盟 CE 认证
4	安徽深蓝医疗科技股份有限公司 Anhui Deepblue Medical Technology Co., Ltd.	913401005501903714	欧盟 CE 认证
5	必欧瀚生物技术（合肥）有限公司 BIOHIT HealthCare(Hefei) Co., Ltd.	913401000822055000	欧盟 CE 认证
6	北京金沃夫生物工程科技有限公司 Beijing Jinwofu Bioengineering Technology Co. Ltd.	911101067861530162	欧盟 CE 认证
7	北京科卫临床诊断试剂有限公司 Beijing Kewei Clinical Diagnostic Reagent INC.	911101161022068352	欧盟 CE 认证
8	北京库尔科技有限公司 Core Technology Co., Ltd.	91110114785541383H	欧盟 CE 认证

9	北京乐普医疗科技有限责任公司 Beijing Lepu Medical Technology Co., Ltd.	911101146705533929	欧盟 CE 认证
10	北京热景生物技术股份有限公司 Beijing Hotgen biotech Co., Ltd.	91110115777090586H	欧盟 CE 认证
11	厦门艾德生物医药科技股份有限公司 Amoy Diagnostics Co., Ltd.	9135020066474298XL	欧盟 CE 认证
12	厦门宝太生物科技有限公司 Xiamen Biotime Biotechnology Co., Ltd.	91350205671268681J	欧盟 CE 认证
13	厦门为正生物科技股份有限公司 Xiamen Wiz Biotech CO., LTD.	91350200072804016N	欧盟 CE 认证
14	海格德生物科技（深圳）有限公司 H-Guard(China) Co., Ltd.	91440300077516830Q	欧盟 CE 认证
15	珠海市银科医学工程股份有限公司 Zhuhai Encode Medical Engineering Co., Ltd.	91440400789435684P	欧盟 CE 认证
16	武汉明德生物科技股份有限公司 Wuhan EasyDiagnosis Biomedicine Co., Ltd.	9142010066953862X0	欧盟 CE 认证
17	武汉生之源生物科技股份有限公司 Wuhan Life Origin Biotech Joint Stock Co., Ltd.	91420100698327549A	欧盟 CE 认证
18	光景生物科技（苏州）有限公司 Lumigenex(Suzhou) Co., Ltd.	91320594551169670K	欧盟 CE 认证
19	江苏硕世生物科技有限公司 Jiangsu Bioperfectus Technologies Co., Ltd.	91321291553790049X	欧盟 CE 认证
20	苏州新波生物技术有限公司 Suzhou Sym-Bio Lifescience Co., Ltd.	913205857287201588	欧盟 CE 认证
21	苏州海苗生物科技有限公司 HymonBio Co., Ltd.	91320585354528566E	欧盟 CE 认证
22	山东欣莱生物科技有限公司 Shandong ThinkLab Biotechnology Co., Ltd.	91370800MA3DCF8E6W	欧盟 CE 认证
23	青岛汉唐生物科技有限公司 Qingdao Hightop Biotech Co., Ltd.	91370700266827355D	欧盟 CE 认证

24	上海科华生物工程股份有限公司 Shanghai Kehua Bio-engineering Co., Ltd.	91310000132660318J	欧盟 CE 认证
25	丹娜（天津）生物科技有限公司 Dynamiker Biotechnology(Tianjin) Co., Ltd.	911201160931130117	欧盟 CE 认证
26	杭州博拓生物科技股份有限公司 Hangzhou Biotest Biotech Co., Ltd	9133010079969193XF	欧盟 CE 认证
27	杭州创新生物检控技术有限公司 Hangzhou Genesis Biodetection & Biocontrol Ltd	913301007441160062	欧盟 CE 认证
28	杭州德安奇生物工程有限公司 Hangzhou Deangel Biological Engineering Co., Ltd	91330110589868581E	欧盟 CE 认证
29	杭州迪安生物技术有限公司 Dian Diagnostics	9133011009204064XN	欧盟 CE 认证
30	杭州莱和生物技术有限公司 Hangzhou Laihe Biotech Co., Ltd	91330108589866519M	欧盟 CE 认证
31	杭州隆基生物技术有限公司 Hangzhou Clongene Biotech Co.,Ltd	913301107620252127	欧盟 CE 认证
32	杭州泰熙生物技术有限公司 Hangzhou Testsea biotechnology Co., Ltd.	91330110MA27W8H87B	欧盟 CE 认证
33	杭州微策生物技术有限公司 Vivachek Biotech (Hangzhou) Co., Ltd.	913301000743141922	欧盟 CE 认证
34	杭州协合医疗用品有限公司 Hangzhou Singclean Medical Products Co., Ltd	91330101747181911R	欧盟 CE 认证
35	康永生物技术有限公司 Prometheus Bio Inc.	91330101MA2CFB2J1T	欧盟 CE 认证
36	美康生物科技股份有限公司 Medicalsystem Biotechnology Co., Ltd	913302007503871799	欧盟 CE 认证
37	浙江东方基因生物制品股份有限公司 Zhejiang Orient Gene Biotech Co.,Ltd	913305007804719612	欧盟 CE 认证
38	中翰盛泰生物技术股份有限公司 Joinstar Biomedical Technology Co.,Ltd	913301005660614000	欧盟 CE 认证

39	重庆中元汇吉生物技术有限公司 Chongiqng Zhongyuan Huiji Biotechnology Co.,Ltd	915001043278176610	欧盟 CE 认证
40	艾维可生物科技有限公司 Avioq Bio-tech Co.,Ltd.	91370613MA3C5MUG2H	欧盟 CE 认证
41	杭州安旭生物科技股份有限公司 Assure Tech (Hangzhou) Co., Ltd.	913301066767726252	欧盟 CE 认证
42	基蛋生物科技股份有限公司 Getein Biotech, Inc.	913201007360621166	欧盟 CE 认证
43	江苏美克医学技术有限公司 Jiangsu Medomics Medical Technology Co.,Ltd.	91320191MA1RA46X7Q	欧盟 CE 认证
44	三诺生物传感股份有限公司 Sinocare Inc.	91430100740620301T	欧盟 CE 认证
45	上海思路迪生物医学科技有限公司 3D Biomedicine Science & Technology Co., Limited	91310112MA1GBGBP12	欧盟 CE 认证
46	杭州睿丽科技有限公司 Hang Zhou Realy Technology Limited Company	913301013219351652	欧盟 CE 认证
47	南京黎明生物制品有限公司 Nanjing Liming Biological Products Co., Ltd.	9132010272837745XD	欧盟 CE 认证
48	北京健乃喜生物技术有限公司 Beijing Genesee Biotech ,inc. （持证公司：CTK Biotech, Inc.）	91110116679618092L	欧盟 CE 认证
49	苏州新波生物技术有限公司 Suzhou SYM-BIO Life Science Co., Ltd. （持证公司：珀金埃尔默公司 PerkinElmer, Inc.）	913205857287201588	美国 EUA
50	赛莱克斯生物科技（苏州） 有限公司 Cellex Biotech (Suzhou) Co., Ltd. （持证公司：Cellex INC）	91320505321623444A	美国 EUA
51	赛莱克斯生物科技（苏州） 有限公司 Cellex Biotech (Suzhou) Co., Ltd. （持证公司：Cellex INC）	91320505321623444A	澳大利亚 TGA

Part three
Export qualification

对外贸易经营者备案登记表

备案登记表编号：02092307　　统一社会信用代码：91420100698327549A
进出口企业代码：

经营者中文名称	武汉生之源生物科技股份有限公司		
经营者英文名称	Wuhan Life Origin Biotech Joint Stock Co.,Ltd.		
组织机构代码		经营者类型（由备案登记机关填写）	私营股份有限公司
住　所	武汉东湖开发区高新大道818号高科医疗器械园B11号1楼、2楼		
经营场所（中文）	武汉东湖开发区高新大道818号高科医疗器械园B11号1楼、2楼		
经营场所（英文）	Floor 1st and 2nd,Building B11,Wuhan Hi-tech Medical Devices Park,No.818 Gaoxin Avenue,Wuhan East Lake High-tech Development Zone, Wuhan		
联系电话	027-87196336	联系传真	027-87196320
邮政编码	430206	电子邮箱	admin@szybio.com
工商登记注册日期	2009-12-25	工商登记注册号	

依法办理工商登记的企业还须填写以下内容

企业法定代表人姓名	华权高	有效证件号	340304197107160832
注册资金	壹仟叁佰万元		（折美元）

依法办理工商登记的外国（地区）企业或个体工商户（独资经营者）还须填写以下内容

企业法定代表人／个体工商负责人姓名		有效证件号	
企业资产／个人财产			（折美元）

备注	

填表前请认真阅读背面的条款，并由企业法定代表人或个体工商负责人签字、盖章。

备案登记机关

签　章

2016　年05　月24　日

出入境检验检疫报检企业备案表

编号：16070817135000000668
备案类别：自理企业　　　　　　　　　　　　备案号码：4200607847

企业名称	中文	武汉生之源生物科技股份有限公司
	英文	Wuhan Life Origin Biotech Joint Stock Co., Ltd
住　　所	武汉东湖开发区高新大道818号高科医疗器械园B11号1楼、2楼	
经营场所		

企业性质	其他	企业类别	
营业执照号		统一社会信用代码（组织机构代码）	91420100098327549A
开户银行		银行账号	
法定代表人/负责人	华权高	有效证件号	
联 系 人		联系电话	
传　　真		电子邮箱	

快件运营企业备案还须填写以下内容

快递业务经营许可证号		经营范围	

报检专用章印模：（使用报检专用章的需提供，另附页）
填表前请认真阅读背面的条款，并由企业法定代表人（负责人）签字、盖章

中华人民共和国湖北出入境检验检疫局 报检企业管理专用章 001

备案机构（签章）

2016 年 7 月 29 日

中国(湖北)国际贸易单一窗口 China International Trade Single Window | 企业资质

智能在线客服 | 欢迎您，武汉生之源生物科技股份有限公司 szysw01 |

企业资质
商务部资质
海关企业通用资质
企业注册登记
报关企业行政许可
查询
申请单查询
基本信息查询
公示异议

首页 基本信息查询

注册信息 出资者信息 报关人员信息 认证企业证书 行政处罚信息

企业基本信息

统一社会信用代码	91420100698327549A	海关注册编码	4201361332	状态	已注册
企业经营类别	进出口货物收发货人	注册海关	武昌海关	营业执照注册号	91420100698327549A
企业类别		属地检验检疫机关	湖北出入境检验检疫局	检验检疫备案号	4200607847
海关注册日期	2014-11-24	海关首次注册日期	2014-11-24	工商注册日期	2009-12-25
企业中文名称	武汉生之源生物科技股份有限公司				
企业英文名称	WUHAN LIFE ORIGIN BIOTECH JOINT STOCK CO.,LTD				
工商注册地址	武汉东湖开发区高新大道818号高科医疗器械园B11号1楼、2楼			邮政编码	430206
企业英文地址	FLOOR 1ST AND 2ND,BUILDING B11,WUHAN HI-TECH MEDICAL DEVICES PARK,NO.818 GAOXIN AVENUE,WUHAN EAST LAKE HIGH-TECH DEVELOM				
其他经营地址					
企业信用等级	一般信用企业	信用等级调整时间	2014-11-24	报关有效期	2068-07-31
注销标识	正常	企业类型	生产型	市场主体类型	
行政区划	湖北省武汉市洪山区	经济区划	高新技术产业开发区	特殊贸易区域	
组织机构类型	公司	经济类型	股份有限（公司）	行业种类	
跨境电子商务企业类型	电子商务企业 电子商务交易平台 物流企业 支付企业 监管场所经营人				
报关权批准机关	地市级商务部门	批准文号	02092307	企业资信标识	00000000
开户银行	农业银行武汉江夏支行	开户账号	1708****3624		
注册资本(万)	1300	注册资本币制	人民币	注册资本(万元)	1300
企业传真		企业电子邮箱		企业网址	
法定代表人/负责人	华权高	法定代表人/负责人移动电话		法定代表人/负责人身份证件	身份证

空 运
By Air

NO.2020048493

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： 新型冠状病毒(SARS-CoV-2)IgM/IgG抗体测定试剂盒(免疫层析法)

Sample Name: SARS-CoV-2 IgM/IgG Antibody Assay Kit (Immunochromatomatography)

委托单位： 武汉生之源生物科技股份有限公司

生产单位： 武汉生之源生物科技股份有限公司

上海化工院检测有限公司 检验检测专用章

上化院 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

声　　明
Statement

1. 鉴定书无上海化工院检测有限公司检验检测专用章、二维码无效。
   The certification is invalid if it is not affixed the dedicated inspection and testing seal of Shanghai Research Institute of Chemical Industry Testing Co., Ltd.and QR Code on it.
2. 鉴定书复印件无效。
   Copies of the certification are invalid.
3. 鉴定书无主检、审核、批准签字无效。
   The certification is invalid without the signatures of appraiser, checker and approver.
4. 鉴定书涂改无效。
   The certification is invalid if it is forged or altered.
5. 委托单位必须保证送至本公司的样品及资料与真实的出运货物相一致，如有不符，所涉及的法律责任及其他后果均由委托单位自行承担。
   The client must guarantee that samples and documents provided for appraisal are consistent with the goods to be transported. Otherwise, the client shall bear all legal responsibilities and other consequences due to it.
6. 本鉴定书的鉴定结论仅适用于最终收到的样品。
   The conclusion of this certification only applies to the final sample as received.
7. 本鉴定书当年有效，铁路运输方式除外。特殊情况参见鉴定书备注。
   The certification is valid in the year subscribed on it except when transported by rail. Please refer to the comment of certification on special occasion.
8. 本鉴定书不考虑国家及经营人差异。
   The certification takes no account of the State and Operator Variations.
9. 货物的运输方式应与鉴定结论中的运输方式相一致。不同的运输方式，鉴定结果可能会有差异。
   The transportation mode of the goods shall be consistent with that in the appraisal conclusion. Different transportation modes may lead to different appraisal results.
10. 鉴定书真伪性可登入本公司网站 www.ghs.cn 或扫描鉴定书中二维码进行查询。
    The authenticity of the certification can be verified by our website(www.ghs.cn)or the QR code in the certification.
11. 送检申请可登入本公司网站 www.ghs.cn 进行网上委托。
    The application of the certification can be done via our website: www.ghs.cn.

地址：上海市光复西路2779号接待大厅
Address: Reception Hall, Shanghai Research Institute of Chemical Industry Co., Ltd, No.2779 West Guangfu Road, Shanghai, China.
邮编(Post code): 200062
电话(Tel):(008621)31765555
邮箱(Email): center@ghs.cn
网址(Website): www.ghs.cn

货物运输条件鉴定书

Certification for Safe Transport of Chemical Goods　　NO. 2020048493

样品名称 Sample Name	中文 Chinese	新型冠状病毒(SARS-CoV-2)IgM/IgG抗体测定试剂盒(免疫层析法)
	英文 English	SARS-CoV-2 IgM/IgG Antibody Assay Kit (Immunochromatomatography)
委托单位 Consignor		武汉生之源生物科技股份有限公司
生产单位 Manufacturer		武汉生之源生物科技股份有限公司
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		多色纸盒(内含无色透明液体和白色塑料测试板)，稍有气味 Multicolor Paper box(containing colorless transparent liquid and white plastic test board),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: 2020-04-22　　签发日期: Issue Date: 2020-04-22　　生效日期: Effective Date: 2020-04-22

备注 Comment	无。 None.

批准 Approver:　　审核 Checker:　　主检 Appraiser:

货物运输条件鉴定书

Certification for Safe Transport of Chemical Goods NO. 2020048493

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	该货物不属易燃危险品。 The product is not classified in flammable substance.
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:181504-

报告结束

QG07

中华人民共和国海关
报关单位注册登记证书

海关注册编码：4201361332

组织机构代码：698327549

企业名称：武汉生之源生物科技股份有限公司

企业住所：武汉东湖开发区高新大道818号高科医疗器械园B11号1楼,2楼

企业经营类别：进出口货物收发货人

注册登记日期：2014年11月24日

法定代表人：华权高

有效期：长期

注册海关：武汉东湖新技术开发区海关

核发日期：2016年6月17日

Wuhan Life Origin Biotech Joint Stock Co., Ltd.
No. 818 Gaoxin Avenue, Wuhan Hi-tech Medical Devices Park, Building B11,
East-Lake Development Zone 430206, Hongshan District, Wuhan, Hubei, P.R. China.
Tel: +86 27 87196282 | Fax: +86 27 87196150 | URL: http://en.szybio.com

Material Safety Data Sheet

1. IDENTIFICATION OF PRODUCT AND SUPPLIER

Product name: SARS-CoV-2 IgM/IgG Antibody Assay Kit (Immunochromatography)
Supplier: Wuhan Life Origin Biotech Joint Stock Co., Ltd.
No. 818 Gaoxin Avenue, Wuhan Hi-tech Medical Devices Park, Building B11,
East-Lake Development Zone 430206, Hongshan District, Wuhan, Hubei, P.R. China.
Tel: +86 27 87196282 | Fax: +86 27 87196150 | URL: http://en.szybio.com
Email: szybio@szybio.com

2. CHEMICAL CHARACTERISATION / INFORMATION ON INGREDIENTS

1.Test card: the test card consists of a plastic card and a test strip. The test strip consists of a nitrocellulose membrane (the detection area is coated with mouse anti-human IgM antibody and mouse anti-human IgG antibody, and the quality control area is coated with rabbit anti-chicken IgY antibody), gold pad (sprayed with colloidal gold-labeled SARS-CoV-2 recombinant antigen and chicken IgY antibody), sample pad, absorbent paper , and PVC board.
2.Buffer solution: containing phosphate buffer solution (pH6.5-8.0)

3. HAZARDS IDENTIFICATION

ROUTE OF ENTRY/EXPOSURE
SKIN CONTACT: [x] EYE CONTACT: [x] INHALATION: [x] INGESTION: [x] SKIN ABSORPTION [x]
Effects of acute exposure:
SKIN CONTACT: May cause irritation.
EYE CONTACT: May cause irritation.
INGESTION: May be harmful if ingested.
INHALATION: May cause irritation to mucous membranes and upper respiratory tract.

Effects of chronic exposure: No data available.
SENSITIZATION TO PRODUCT: Not Available
SYNERGISTIC PRODUCTS: Not Available
LD50: MOPSO: Not Available

4. FIRST AID MEASURES

SKIN: In case of contact, immediately flush area with plenty of water.
EYES: Immediately flush eyes with plenty of water for at least 15 minutes and get medical attention.
ORAL: If ingested drink plenty of fluids and contact a physician.
INHALATION: If inhaled move victim to fresh air. If not breathing give artificial respiration. If breathing is difficult give oxygen, and call physician.

5. FIRE-FIGHTING MEASURES

Flammable: NO
Extinguishing media: As appropriate for fire in surrounding materials.
Flash point: Not Applicable
Upper flammable limit: Not Applicable
Lower flammable limit: Not Applicable
Auto-ignition temperature: Not Applicable
Hazardous combustion products: No data

Explosion data
Sensitivity to mechanical impact: Not Applicable
Sensitivity to static discharge: Not Applicable
Unusual fire and explosion hazards: No Data

6. ACCIDENTAL RELEASE MEASURES

Local exhaust: Not Required
Protective clothing: Lab Coat
Protective gloves: Rubber/Latex
Eye protection: Safety glasses
Other precautions: Avoid contact and inhalation, do not get in eyes, on skin or clothing. Do not pipet by mouth. Wash contaminated clothing before reuse.
Respiratory protection: None normally required.
Leak and spill procedure: Absorb small leaks or spills with sponge, mop up large spills with plenty of soap and water.

7. HANDLING AND STORAGE

Handling: Normal precautions for handling chemicals must be observed.
Storage: Store the test kit at 2°C-30°C, with a valid period of 6 months. Test strip should be used within 20 minutes once the foil pouch is opened. The date of manufacture and expiry date are shown on the label.
Shipping regulations: Not regulated

8. EXPOSURE CONTROLS / PERSONNEL PROTECTION

Refer to point No. 6.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state:Divided into two parts: detection card (solid) and buffer (liquid).
Appearance and odor: Buffer is clear or light yellow liquid reagent.
Odor threshold: NO odor.
Vapor pressure: Not Available
Vapor density: Not Available
Specific gravity: Not Available
Evaporation rate: Not Available
Melting point: Not Available
Boiling point: Not Available
Solubility in water: Not Applicable
Coefficient of oil/water distribution: Not Available

10. STABILITY AND REACTIVITY

Stable: Yes
Hazardous polymerization: Will not occur.
Incompatibility with other substances: Not Available
Hazardous decomposition products: Not Available

11. TOXICOLOGICAL INFORMATION

Refer to point No. 3.

12. ECOLOGICAL INFORMATION

Water Hazard Class: Data not yet available.

13. DISPOSAL CONSIDERATIONS

Waste disposal: Liquid waste dilute with large volumes of water and dispose of into sewer system, in accordance with local regulations. Solid waste is disposed of in accordance with applicable federal, state, provincial, and local regulations.

14. TRANSPORT INFORMATION

Shipping information: Not regulated

15. REGULATORY INFORMATION

Not applicable.

16. OTHER INFORMATION

The information herein is believed to be correct as of the date hereof but is provided without warranty of any kind. The recipient of our products is responsible for observing any laws and guidelines applicable.

Wuhan Life Origin Biotech Joint Stock Co., Ltd.

Part four
Product information

Instruction of the SARS-CoV-2 IgM/IgG Antibody Assay Kit (Immunochromatography)

【Product Name】

SARS-CoV-2 IgM/IgG Antibody Assay Kit (Immunochromatography)

【Package Specification】

10 tests/pack

25 tests/pack

50 tests/pack

100 tests/pack

【Intended Use】

This product is used for the qualitative detection of IgM and IgG antibodies of SARS-CoV-2 in human serum, plasma or whole blood in vitro.

This product is only used as a supplementary detection indicator for suspected cases with negative detection of SARS-CoV-2 nucleic acid or used in conjunction with nucleic acid detection in the diagnosis of suspected cases. It cannot be used as a basis for diagnosis and exclusion of SARS-CoV-2 pneumonia, and is not suitable for general population screening.

For medical institutions only. A positive test result needs further confirmation. A negative test result cannot rule out the possibility of infection.

In the process of pathogenic microorganism infection, IgG and IgM are the most commonly used antibody markers of infectious diseases. IgM, as the first antibody in the process of infection, is usually used as a marker of acute infection. With the development of infection, IgM concentration gradually decreased and disappeared after the appearance of IgG. IgG usually exists in the body for a long time, even if the virus has been completely eliminated. Positive blood can be used as an indicator of infection and previous infection. Therefore, detecting SARS-CoV-2 IgM antibody and IgG antibody is of great clinical significance and is of great significance for effective control of the large-scale transmission of the SARS-CoV-2.

【Test Principle】

This product adopts colloidal gold immune technology, spraying SARS-CoV-2 recombinant antigen labeled with colloidal gold and chicken IgY on the gold pad; two detection lines (G-line and M-line) and a control line (C-line) are coated on the nitrocellulose membrane. The M-line is coated with mouse anti-human IgM monoclonal antibody, which is used to detect the SARS-CoV-2 IgM antibody. The G-line is coated with mouse anti-human IgG monoclonal antibody for detecting the SARS-CoV-2 IgG antibody. The C-line is coated with rabbit anti-chicken IgY. When testing, an appropriate amount of sample to be tested is added to the sample well of the test card, and the sample will move forward along the test card under capillary action. If the sample contains the SARS-CoV-2 IgM antibody, the antibody binds to the colloidal gold-labeled SARS-CoV-2 recombinant antigen, the immune complex will form a complex with the coated mouse anti-human IgM monoclonal antibody at the M-line, showing a purple-red M-line, suggesting that the SARS-CoV-2 IgM antibody is positive. If the sample contains the SARS-CoV-2 IgG antibody, the antibody binds to the colloidal gold-labeled SARS-CoV-2 recombinant antigen, and the immune complex will form a complex with the coated mouse anti-human IgG monoclonal antibody at the G-line, showing a purple-red G-line, suggesting that the SARS-CoV-2 IgG antibody is positive. If the test G-line and M-line are not colored, a negative result is displayed. The test card also contains a control C-line. The purple-red control C-line should appear regardless of whether a test line appears. If the control C-line does not appear, the test result is invalid, and the sample needs to be tested again.

【Main Components】

(1) Test card: The test card is consists of a plastic card and a test strip. The test strip is consists of a nitrocellulose membrane (the detection area is coated with mouse anti-human IgM antibody and mouse anti-human IgG antibody, and the quality control area is coated with rabbit anti-chicken IgY antibody), gold pad (sprayed with colloidal gold-labeled SARS-CoV-2 recombinant antigen and chicken IgY antibody), sample pad, absorbent paper, and PVC board.

(2) Sample diluent: Buffer solution (pH 6.5-8.0) that contains phosphate, corresponding to the specifications of the kit.

(3) Pasteur pipette: corresponded to the specifications of the kit.

Packing specification	10 tests/pack	25 tests/pack	50 tests/pack	100 tests/pack
Sample diluent	450μL/pc* 10 pcs or 2mL/bottle * 1 bottle	450μL/pc* 25 pcs or 4mL/bottle * 1 bottle	450μL/pc* 50 pcs or 4mL/bottle * 2 bottles	450μL/pc* 100 pcs or 4mL/bottle * 4 bottles
Pasteur pipette	10 pcs * 1 bag	25 pcs * 1 bag	25 pcs * 2 bags	25 pcs * 4 bags
/	See packaging for details	See packaging for details	See packaging for details	See packaging for details

Note: The components in different batches of kits can't be used interchangeably.

【Storage And Validity】

Store the test kit at 2℃-30°C, with a valid period of 6 months. Test strip should be used within 20 minutes once the foil pouch is opened. The date of manufacture and expiry date are shown on the label.

【Sample Requirement】

1. Apply to serum, heparin and sodium citrate anticoagulated plasma, EDTA anticoagulated whole blood samples.

2. The samples should be shaken up and down 5-10 times immediately after collection, and should not be shaken with force.

3. Serum, plasma and whole blood samples can be stored at 2-8 ℃ for 7 days; serum and plasma samples can be stored frozen at -20 ℃ for 25 days. It should be returned to room temperature before the test, and the test should be conducted as soon as possible within 8 hours after the sample is collected. The samples should be detected immediately after collection. If the samples cannot be detected timely, they should be stored at 2-8 ℃, and avoid repeated freezing and thawing.

4. Samples with severe lipemia, hemolysis, and microbial contamination cannot be used for the detection of this product; Turbid samples affect the determination results of this product. The use of heat-inactivated samples is not recommended.

【Detection Procedures】

1. If the reagent is removed from the refrigerator, it needs to be restored to room temperature before testing. The test should be performed at room temperature.

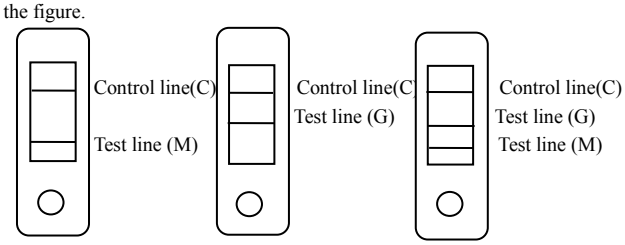
2. Open the aluminum foil bag of the test card, take out the test card and place it on the table horizontally.

3. Pipette 10μL (1 drop with Pasteur pipette) of serum, plasma , or 20μL(2 drops with a Pasteur pipette) of the whole blood into the sample hole, then pipette 60μL buffer (2 drops with a dropper) into the sample hole of the test card too.

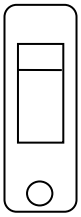
4. Read the result within 15 minutes, and the results read after 18min are invalid.

【Interpretation Of Result】

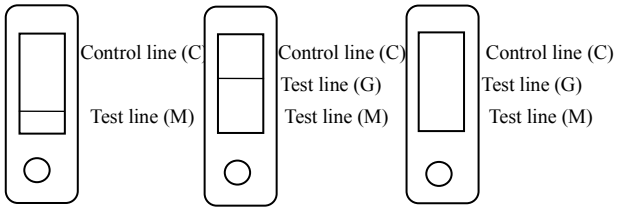
1) Positive results: Both the test line (G) and the control line (C) show color bands, indicating that IgG antibody of the SARS-CoV-2 is positive; Both the test line (M) and the control line (C) show color bands, indicating that the SARS-CoV-2 IgM antibody is positive. The test line (M), (G) and control line (C) all show color bands, indicating that the SARS-CoV-2 IgM and IgG antibodies are positive. As shown in the figure.



2) Negative result: If only the control line C develops color, and neither the G nor M detection lines develop color, no IgM/IgG antibody of SARS-CoV-2 is detected, and the result is negative. As shown in the figure.



3) Invalid result: No band appears on the control line (C), and it is judged as an invalid result regardless of whether the detection line (G) (M) shows a band. As shown in the figure.



【Performance】

1. Coincidence rate of negative reference: Test negative reference materials of enterprises, the results should be all negative.

2. Coincidence rate of positive reference: Test positive IgM antibody reference materials (including strong, medium and borderline positive) of enterprise, the results should be positive, and the results of IgG antibody should be all negative; Test positive IgG antibody reference materials (including strong, medium and borderline positive) of enterprise, the results should be positive, and the results of IgM antibodies should be all negative.

3. Minimum detection limit: Enterprise reference products for the minimum detection limit of IgM antibody, S1, S2 test results should be positive, S3 test results should be positive or negative, IgG antibody results should be negative; Enterprise reference products for the minimum detection limit of IgG antibodies, S4, S5 test results should be positive, S6 test results should be positive or negative, IgM antibody results should be negative.

4. Repeatability: Test IgM antibody precision reference materials of enterprises, the results should be positive, and the results of IgG antibody should be all negative; Test IgG antibody precision reference materials of enterprises, the results should be positive, and the results of IgM antibody should be all negative.

5. Batch to batch: Test IgM antibody precision reference materials of enterprises, the results should be positive, and the results of IgG antibody should be all negative; Test IgG antibody precision reference materials of enterprises, the results should be positive, and the results of IgM antibody should be all negative.

【Limitation】

1. The kit is only for the detection of human serum, plasma and whole blood samples.

2. The test results may be wrong due to technical reasons, operational errors and other sample factors.

3. In the early stage of infection, if the virus-specific IgM antibody is not produced or the titer is very low, it will lead to negative results. If a virus infection is suspected, the patient should be reminded to check again within 7-14 days. During re-examination, the second sample was taken and tested at the same time with the first sample under the same conditions to determine whether there was a serum transformation of the first infection or the titer of virus-specific IgM or IgG antibody increased significantly.

4. The test results of this product are only for clinical reference, and should not be used as the sole basis for clinical diagnosis and treatment. The clinical management of patients should be considered in combination with their symptoms/signs, medical history, other laboratory tests, treatment response, epidemiology and other information.

5. Patients with impaired immune function or receiving immunosuppressive therapy, such as those infected with human immunodeficiency virus (HIV) or receiving immunosuppressive therapy after organ transplantation, have limited reference value for serological IgM antibody detection, which may lead to wrong medical interpretation.

6. Those who have accepted blood transfusions or have been treated with other blood products in recent months should be cautious in analyzing their positive test results.

【Precautions】

1. Equilibrate the sample diluent and test card to room temperature (more than 30min) before testing.

2. The test should be performed strictly in accordance with the instructions.

3. The result must be interpreted at 15min, and the result read after 18min is invalid.

4. Do not use repeated freeze-thaw, highly hemolyzed and lipemia samples.

5. The test samples should be regarded as infectious agents, and they must be operated in accordance with the infectious disease laboratory operation rules, and pay attention to biological safety.

6. This product contains animal-derived substances. Although it is not contagious, it should be treated with care as a potential source of infection when handling it. Users should take precautions to ensure their safety and that of others. After the test is completed, the used test cards, sample diluents, and straws, etc. are treated as biomedical waste.

7. This product is a single-use in vitro diagnostic reagent. Do not reuse it. It is only used for in vitro diagnostics. Do not use expired products.

8. Do not use a kit with obvious damage and damaged test card in the package.

9. There is desiccant in the aluminum foil bag, not to be taken orally.

【Interpretation Of Logo】

CE mark; LOT Batch number; Expiry date;

Date of manufacture; Manufacturer name;

EC REP Name and address of the EC representative;

No direct sunlight; Users need to refer to the instructions;

Medical equipment should avoid dampness and keep dry;

Medical devices intended for one-time use or used in a single procedure for a single patient;

IVD Logo of in vitro diagnostic reagents.

【References】

Guidelines for the preparation of in vitro diagnostic reagent instructions.

【Bsaic Information】

Wuhan Life Origin Biotech Joint Stock Co., Ltd.
Wuhan Hi-tech Medical Devices Park, Building B11, #818 Gaoxin Road, Donghu Hi-Tech Development Area, Wuhan, Hubei Province 430206, P.R. China
Tel:+86-027-87926888 Fax:+86-027-87196320

EC REP
SUNGO Europe B.V
Olympisch Stadion 24, 1076DE Amsterdam, Netherlands
Tel/Fax: +31(0)2021 11106
E-mail: ec.rep@sungogroup.com

【Modification Date】

Modification date: 04/03/2020

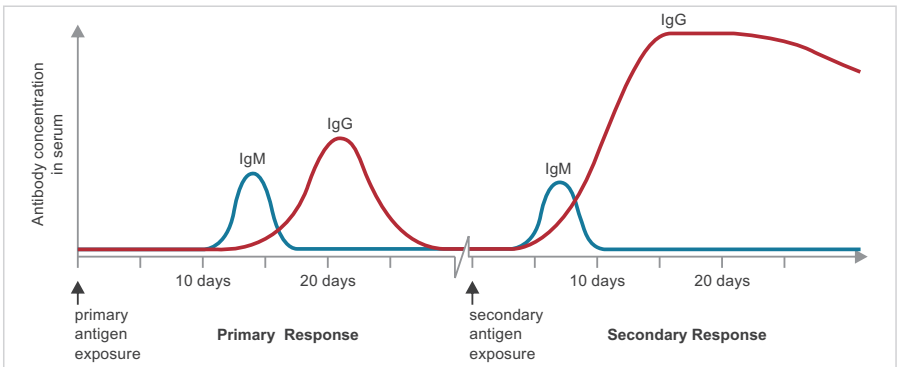
SARS-CoV-2

The SARS-CoV-2 IgM/IgG Antibody Assay Kit
(Immunochromatography)

With the spread of the COVID-19, there has been a global outbreak trend. Now, how to quickly and accurately screen and identify patients with COVID-19 has become a critical question in the battle against the SARS-CoV-2.

Relying on its own production of core raw materials, Wuhan Life Origin Biotech Joint Stock Company has developed a SARS-CoV-2 antibody rapid detection kit, which has been granted access to the EU.

The tendency of antibodies to appear after infection with SARS-CoV-2.



The body will produce specific antibodies against the SARS-CoV-2 about 7 days after the virus infection. Therefore, the detection of specific antibodies in blood samples can also reflect the presence of viral infections.

Product Property

• We collected 200 serum samples from confirmed patients with COVID-19. Through statistical analysis of the test results, we found that the positive rate of IgM was 87.5% (82.10%-91.75%), and the positive rate of IgG was 90.0% (84.98%-93.78%) in the confirmed samples.

Table1 : Summary of positive rate results for confirmed patients with COVID-19

Detected Antibody	Positive	Negative	Total	Positive Rate	95%CI
IgM	175	25	200	87.5%	82.10%-91.75%
IgG	180	20	200	90.0%	84.98%-93.78%

• We collected 100 healthy human serum samples. Through statistical analysis of the test results, we found that the negative rate of IgM was 98.0% (92.96% -99.76%), and the negative rate of IgG was 99.0% (94.55% -99.98%) found in healthy human serum samples.

Table 2: The negative rate results of the healthy people

Detected Antibody	Positive	Negative	Total	Negative Rate	95%CI
IgM	2	98	100	98%	92.96%-99.76%
IgG	1	99	100	99%	94.55%-99.98%

Advantages of the Kit

• Short detection time (3-15 minutes) and rapid screening of the suspected patients;

• Simple operation and do not need professional equipment;

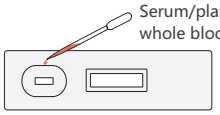
• The results are intuitive and can be judged with the naked eye;

• The transportation of the kit is convenient and can be transported at room temperature;

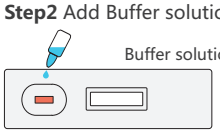
•Suitable for multiple specimen types to better meet the needs of clinical testing.

Detection Process and Result Judgment

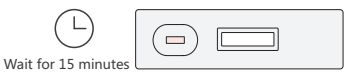
Step1 Add blood sample



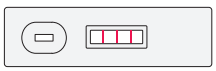
Step2 Add Buffer solution

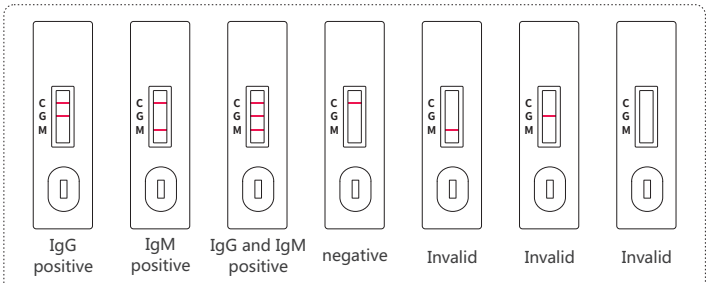


Step3 Incubation reaction



Step4 Read the result





Wuhan Life Origin Biotech Joint Stock Co., Ltd.

Address: Wuhan Hi-Tech Medical Device Park B11, No.818 Gaoxin Avenue, Donghu Hi-Tech Development Zone 430206.
TEL: 027-87196336/81363255 FAX: 027-87196320
Website: http://www.szybio.com/


25 tests/pack
PASS
25 tests/pack
QUALIFIED CERTIFICATE
CHECKER:
PASS 01
Szybio
Instruction of the SARS-CoV-2 IgM/IgG Antibody Assay Kit (Immunochromatography)

Szybio

Wuhan Life Origin Biotech Joint Stock Co., Ltd.

Certificate of Analysis

SZY-ZK-JL-037 S.N：2003-01

Product Name	SARS-CoV-2 IgM/IgG Antibody Assay Kit（Immunochromatography）	**Sampling QTY**	2 packs
Product Size	10 tests/pack、25 tests/pack 50 tests/pack、100 tests/pack	**Batch No.**	Lot C200318001
Inspection Date	Mar. 18th, 2020 – Mar. 20th, 2020	**Expiry Date**	6 Months
Inspection Standard	Technical Requirements of SARS-CoV-2 IgM/IgG Antibody Assay Kit（Immunochromatography）		

Inspection Item	Standard Code	Inspection Data	Result
Appearance	Packing Box tidy and clean, all components complete; Test Card tidy and clean, burr-free, without breakage, well fixed card; Buffer Solution without leakage; Tag clear, complete and correct.	Meet Requirement	Qualified
Film Strip Width	2.8mm±0.4mm	2.9	Qualified
Fluid Migration Velocity	≥10mm/min	23.6	Qualified
Net Content	≥tagged value	Meet Requirement	Qualified
Coincidence rate of negative reference	Test negative reference materials of enterprises, the results should be all negative.	IgM/IgG N1-N10 10/10	Qualified
Coincidence rate of positive reference	Test positive IgM antibody reference materials (including strong, medium and borderline positive) of enterprise, the results should be positive, and the results of IgG antibody should be all negative； Test positive IgG antibody reference materials (including strong, medium and borderline positive) of enterprise, the results should be positive, and the results of IgM antibodies should be all negative.	IgM P1-P10 10/10 IgG P11-P20 10/10	Qualified

Minimum detection limit	Enterprise reference products for the minimum detection limit of IgM antibody, S1, S2 test results should be positive, S3 test results should be positive or negative, IgG antibody results should be negative; Enterprise reference products for the minimum detection limit of IgG antibodies, S4, S5 test results should be positive, S6 test results should be positive or negative, IgM antibody results should be negative.	IgM S1-S3 3/3 IgG S4-S6 3/3	Qualified
Repeatability	Test IgM antibody precision reference materials of enterprises, the results should be positive, and the results of IgG antibody should be all negative; Test IgG antibody precision reference materials of enterprises, the results should be positive, and the results of IgM antibody should be all negative.	P3 10/10 P4 10/10 P8 10/10 P13 10/10 P14 10/10 P18 10/10	Qualified
Batch to batch	Test IgM antibody precision reference materials of enterprises, the results should be positive, and the results of IgG antibody should be all negative; Test IgG antibody precision reference materials of enterprises, the results should be positive, and the results of IgM antibody should be all negative.	P3 10/10 P4 10/10 P8 10/10 P13 10/10 P14 10/10 P18 10/10	Qualified
Package	Product box adopts double-sided coated print; Reagent bottle uses stipulated plastic bottle; reagent and manual inside the box.	Meet Requirement	Qualified

Conclusion： According to《Technical Requirements of SARS-CoV-2 IgM/IgG Antibody Assay Kit (Immunochromatography)》, Product **Meet** Requirements.

（Inspection Items end here）

Inspector: 程江林 Checker: 张阳明 Principal: 段旭

包装尺寸	规格/容量	尺寸和体积	含箱重量（kg）	体积重量（kg）
			国内快递	国际快递
试剂盒	25 人份/盒	180*130*80mm	0.22-0.26	/
包装箱（小号）	4 盒/箱 （共计 100 人份）	300*259*232mm （体积 0.018m³）	1.22-1.38	4
包装箱（中号）	15 盒/箱 （共计 375 人份）	430*307*252mm （体积 0.034m³）	3.78-4.38	7
包装箱（大号）	25 盒/箱 （共计 625 人份）	430*307*437mm （体积 0.058m³）	6.14-7.14	12
试剂人份数	箱数	总体积（m³）	含箱重量（kg）	体积重量（kg）
			国内快递	国际快递
100	1	0.018	1.2-3.8	4
1000	2	0.092	9.9-11.5	19
5000	8	0.091	49.1-57.1	96
1 万	16	0.923	98.2-571.2	192
5 万	80	4.614	491.2-571.2	960
10 万	160	9.229	982.4-1142.4	1920
存储条件及有效期		2-30℃储存，有效期 6 个月。		

packing size	specification	size and volume	Gross weight（kg）	volume weight（kg）
			China Express	International express
Independent packaging	25tests/pack	180*130*80mm	0.22-0.26	/
Small carton	4 packs/box （100tests）	300*259*232mm （volume 0.01803m³）	1.22-1.38	4
Medium carton	15 packs/box （375tests）	430*307*252mm （volume 0.03327m³）	3.78-4.38	7
Large carton	25 packs/box （625tests）	430*307*437mm （volume 0.05768m³）	6.14-7.14	12
Tests	Cartons	Volume（m³）	Gross weight（kg）	volume weight（kg）
			China Express	International express
100	1	0.018	1.2-3.8	4
1000	2	0.092	9.9-11.5	19
5000	8	0.091	49.1-57.1	96
10000	16	0.923	98.2-571.2	192
50000	80	4.614	491.2-571.2	960
100000	160	9.229	982.4-1142.4	1920
Storage And Validity		Store the test kit at 2℃-30℃, with a valid period of 6 months.		