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

新型冠状病毒抗原检测试剂盒

SARS-CoV-2 Antigen Rapid Test Kit

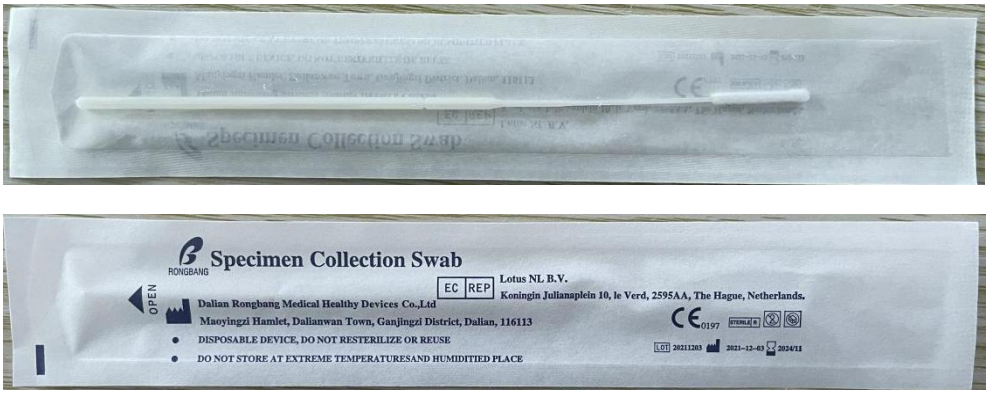
深圳市绿诗源生物技术有限公司
Green Spring Shenzhen Lvshiyuan Biotechnology Co.,ltd.

目 录

产品明细 Product details

产品名称	规格	盒子尺寸（长*宽*高/cm）	箱子尺寸（长*宽*高/cm）	重量（KG）
新冠病毒抗原检测试剂盒 SARS-CoV-2 Antigen Rapid Test Kit	25 人份/盒 25tests/box	21*13.5*8.5	57.5*43.5*46	18
	10 人份/盒 10tests/box	21.5*13.5*7.5 小内盒 21*7*1.3	70.3*44.9*32.4	15.5
	5 人份/盒 5tests/box	21*7*4.5	43.5*43.3*47.5	11

鼻咽拭子

序号	品牌	图片
1	大连荣邦	

稀释液

序号	名称	图片
1	铝箔封稀释液	

公司简介 Company Profile

深圳市绿诗源生物技术有限公司成立于 2003 年，是由留学美国多年的著名学者创办的一家高新技术企业，公司以研发最先进的体外诊断试剂（IVD）、食品安全检测试剂、动物疾病诊断试剂、小分子抗原抗体等产品为主，致力于生物制剂在全球的产业化。

Shenzhen Lvshiyuan Biotechnology Co., Ltd, was founded in 2003 by a senior scholar who had studied in America for many years. It is a high-tech enterprise specializing in the development and production of the most advanced In vitro diagnostic reagents(IVD),food safety test reagent,animal disease diagnostic reagent, small molecule antigen & antibody,committed to the industrialization of biological reagent around the world.

公司通过了 ISO9001、ISO13485 质量管理体系认证，先后取得国家级高新技术企业、深圳市高新技术企业、博士后创新实践基地、3A 信用企业等级、医疗器械生产许可证等资质证书，同时获得了多项专利证书。

LSY get the ISO9001 certificate of quality management system, The review of ISO13485 has been passed, we can get this certificate soon.we has achieved many qualification certificates, such as National HI-TECH enterprise certificate，Shenzhen HI-TECH enterprise certificate , Postdoctoral innovation practice base，AAA-grade credit enterprise, Medical Equipment Production License etc. LSY also get a number of patent certificate.

二十一世纪是生物高科技时代，我们以“关爱健康、造福社会；专注产品、引领行业；创造效益、回报股东；完善机制、成就员工。”为企业使命，秉承“品质铸就品牌，品牌成就生命”的品质理念，为客户提供领先的生物技术产品和完善的技术服务。

In the 21st biological high-tech era,LSY takes the “Health care,benefit to society;Focus on products,lead the industry;Create benefits,repay shareholders; perfect mechanism,succeed employees. “as our Enterprise mission and adheres to the Quality philosophy of “Quality makes brand,brand is life.”,providing the advanced biological technology products and the perfect technical service for the customers.

营业执照 Business license

营 业 执 照（副本）

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

ISO9001 认证证书 **ISO9001 certification**

GUARDIAN INDEPENDENT CERTIFICATION

CERTIFICATE OF REGISTRATION

认证证书

深圳市绿诗源生物技术有限公司

统一社会信用代码：914403007576264357

注册地址：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
生产地址：深圳市大鹏新区滨海二路国家海洋生物产业园 D 栋

质量管理体系已完成评审并符合

GB/T19001-2016/ISO9001:2015

以下之认证范围

食品安全检测试剂盒、动物疫病诊断试剂盒、检测卡的研发、生产及服务

颁证日期：**2022** 年 **02** 月 **14** 日　　有效日期：**2025** 年 **02** 月 **11** 日

首次签发证书日：**2019** 年 **02** 月 **13** 日

证书编号： J22Q2GZ8012523R1M

获得本认证证书并不意味着证书持有者可以免除其应尽的其他法律义务，当本认证范围中的产品或活动有行政许可要求时，本证书仅在证书持有者的行政许可范围内有效。获证组织须定期接受 GIC 年度监督，并经审核合格方继续有效。请扫描左侧二维码查询证书信息。本证书信息可在国家认证认可监督管理委员会官方网站（www.cnca.gov.cn）或 GIC 网站（www.gicg.com.cn）查询

扫码查询证书有效性

GIC 微信公众号

证书签发：

证书专用章

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. S3510506UL, www.jas-anz.org/register

MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT IAF

JAS-ANZ

ISO 13485 认证证书 ISO 13485 certification

SGS

Certificate CN20/42084

The management system of

Shenzhen Lvshiyuan Biotechnology Co., Ltd.

101, 201, 301, Building D, No. 2, Industrial Avenue, Buxin Village, Buxin Community, Dapeng Subdistrict Office, Dapeng New District, Shenzhen, Guangdong, 518120, P.R. China

has been assessed and certified as meeting the requirements of

ISO 13485:2016
EN ISO 13485:2016

For the following activities

Design, Manufacture and Distribution of Dry Fluorescent Immunoassay Instrument and In Vitro Diagnostic Test Kits (ELISA, Colloidal Gold) for SARS-CoV-2, Influenza A and Influenza B.

This certificate is valid from 2 March 2021 until 13 June 2023
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 26 May 2023
Issue 2. Certified since 14 June 2020

Authorised by

SYSTEM CERTIFICATION ISO 13485 SGS

UKAS MANAGEMENT SYSTEMS 0005

SGS United Kingdom Ltd
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

HC SGS 13485 2016 0118

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对外贸易经营者备案登记表 Foreign trade operator registration form

对外贸易经营者备案登记表

备案登记表编号：01637671　　进出口企业代码：4403757626435

经营者中文名称	深圳市绿诗源生物技术有限公司		
经营者英文名称	Shenzhen Lvshiyuan Biotechnology Co.,Ltd		
组织机构代码	757626435	经营者类型（由备案登记机关填写）	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		
经营场所（中文）	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		
经营场所（英文）	Floor 101, 201, 301, D Building, No. 2, Industrial Road, Buxin Village, Buxin Community, Dapeng Office, Dapeng New District, Shenzhen, China		
联系电话		联系传真	
邮政编码	518120	电子邮箱	
工商登记注册日期	2003-12-29	工商登记注册号	440307102858446

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	王晓丽	有效证件号	220104196411280326
注册资金	壹仟万元		（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	

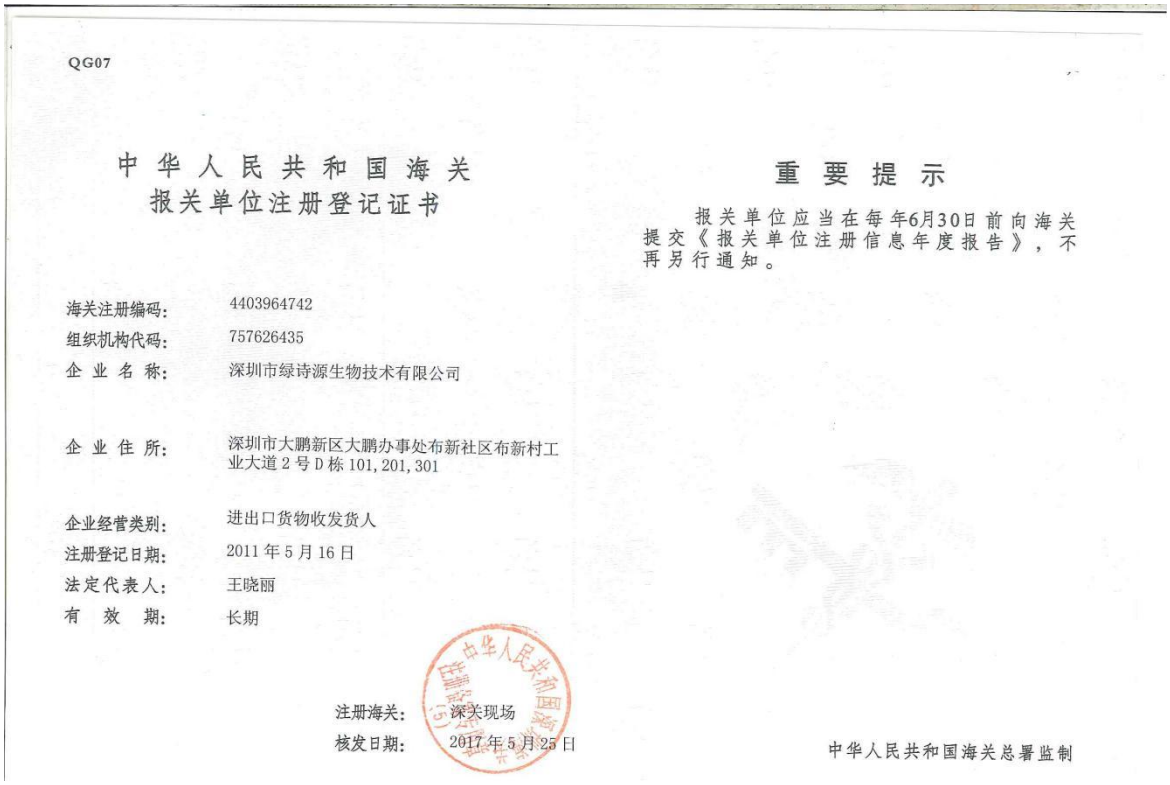
填表前请认真阅读背面的条款，并由企业法定代表人或个体工商负责人签字、盖章。

备案登记机关

签　章

2013 年 11 月 15 日

报关注册登记证书 Customs registration certificate



QG07

中华人民共和国海关
报关单位注册登记证书

重要提示

报关单位应当在每年6月30日前向海关提交《报关单位注册信息年度报告》，不再另行通知。

海关注册编码：4403964742
组织机构代码：757626435
企业名称：深圳市绿诗源生物技术有限公司
企业住所：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
企业经营类别：进出口货物收发货人
注册登记日期：2011年5月16日
法定代表人：王晓丽
有效期：长期

注册海关：深关现场
核发日期：2017年5月25日

中华人民共和国海关总署监制

医疗器械生产许可证 Medical device production license

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：见医疗器械生产产品登记表
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：广东省药品监督管理局
有效期限：至 2025 年 06 月 14 日
发证日期：2020 年 06 月 15 日

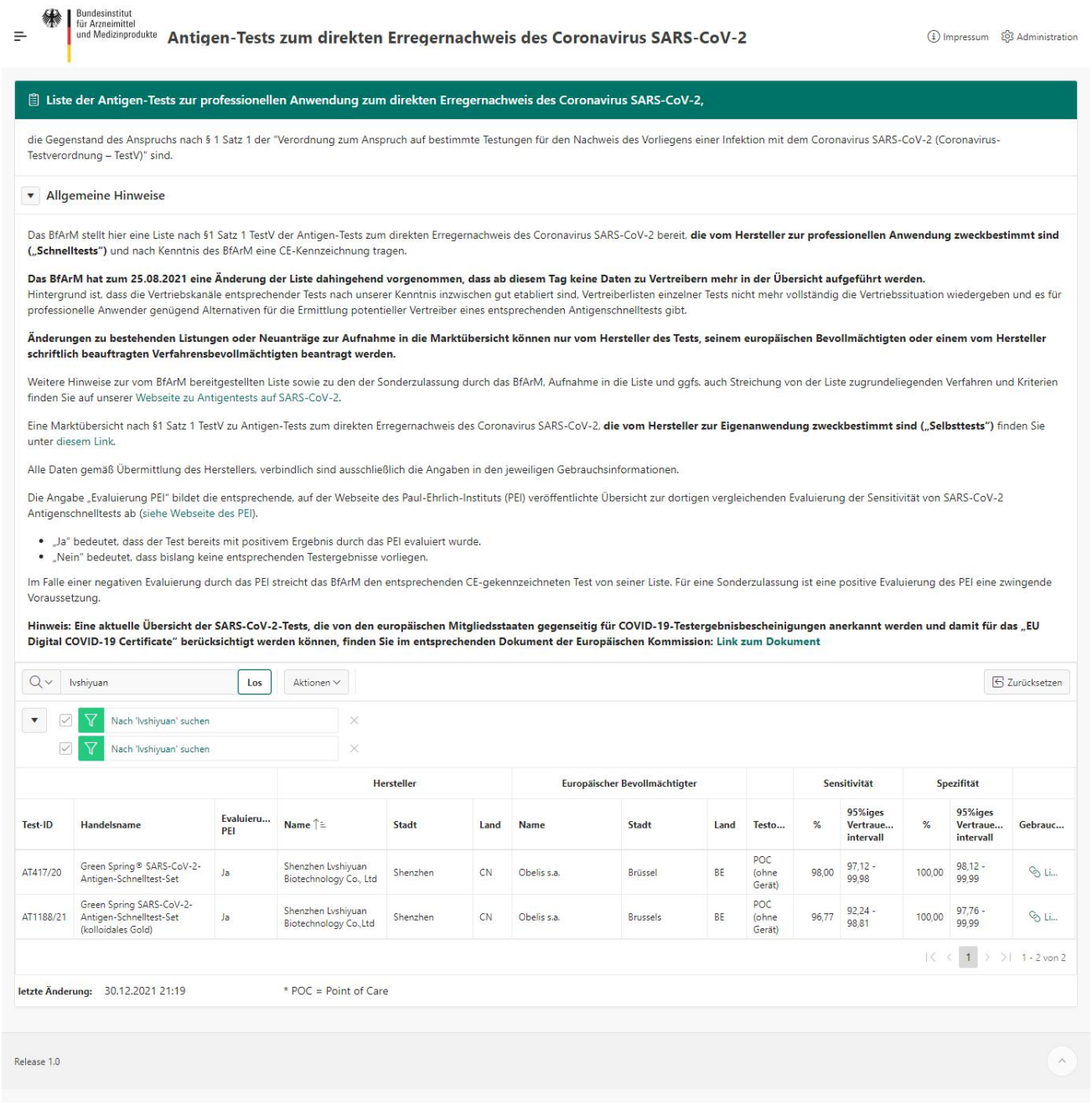
国家食品药品监督管理总局制

取得国外标准认证截图

Obtained screenshots of foreign standard certification

德国 BfArM 批准抗原检测用于专业检测

Germany BfArM Approval of antigen tests for professional testing



Bundesinstitut für Arzneimittel und Medizinprodukte

Antigen-Tests zum direkten Erregernachweis des Coronavirus SARS-CoV-2

Impressum Administration

Liste der Antigen-Tests zur professionellen Anwendung zum direkten Erregernachweis des Coronavirus SARS-CoV-2,

die Gegenstand des Anspruchs nach § 1 Satz 1 der "Verordnung zum Anspruch auf bestimmte Testungen für den Nachweis des Vorliegens einer Infektion mit dem Coronavirus SARS-CoV-2 (Coronavirus-Testverordnung – TestV)" sind.

Allgemeine Hinweise

Das BfArM stellt hier eine Liste nach §1 Satz 1 TestV der Antigen-Tests zum direkten Erregernachweis des Coronavirus SARS-CoV-2 bereit, **die vom Hersteller zur professionellen Anwendung zweckbestimmt sind („Schnelltests")** und nach Kenntnis des BfArM eine CE-Kennzeichnung tragen.

Das BfArM hat zum 25.08.2021 eine Änderung der Liste dahingehend vorgenommen, dass ab diesem Tag keine Daten zu Vertreibern mehr in der Übersicht aufgeführt werden.
Hintergrund ist, dass die Vertriebskanäle entsprechender Tests nach unserer Kenntnis inzwischen gut etabliert sind, Vertreiberlisten einzelner Tests nicht mehr vollständig die Vertriebssituation wiedergeben und es für professionelle Anwender genügend Alternativen für die Ermittlung potentieller Vertreiber eines entsprechenden Antigenschnelltests gibt.

Änderungen zu bestehenden Listungen oder Neuanträge zur Aufnahme in die Marktübersicht können nur vom Hersteller des Tests, seinem europäischen Bevollmächtigten oder einem vom Hersteller schriftlich beauftragten Verfahrensbevollmächtigten beantragt werden.

Weitere Hinweise zur vom BfArM bereitgestellten Liste sowie zu den der Sonderzulassung durch das BfArM, Aufnahme in die Liste und ggfs. auch Streichung von der Liste zugrundeliegenden Verfahren und Kriterien finden Sie auf unserer Webseite zu Antigentests auf SARS-CoV-2.

Eine Marktübersicht nach §1 Satz 1 TestV zu Antigen-Tests zum direkten Erregernachweis des Coronavirus SARS-CoV-2, **die vom Hersteller zur Eigenanwendung zweckbestimmt sind („Selbsttests")** finden Sie unter diesem Link.

Alle Daten gemäß Übermittlung des Herstellers, verbindlich sind ausschließlich die Angaben in den jeweiligen Gebrauchsinformationen.

Die Angabe „Evaluierung PEI" bildet die entsprechende, auf der Webseite des Paul-Ehrlich-Instituts (PEI) veröffentlichte Übersicht zur dortigen vergleichenden Evaluierung der Sensitivität von SARS-CoV-2 Antigenschnelltests ab (siehe Webseite des PEI).

- „Ja" bedeutet, dass der Test bereits mit positivem Ergebnis durch das PEI evaluiert wurde.
- „Nein" bedeutet, dass bislang keine entsprechenden Testergebnisse vorliegen.

Im Falle einer negativen Evaluierung durch das PEI streicht das BfArM den entsprechenden CE-gekennzeichneten Test von seiner Liste. Für eine Sonderzulassung ist eine positive Evaluierung des PEI eine zwingende Voraussetzung.

Hinweis: Eine aktuelle Übersicht der SARS-CoV-2-Tests, die von den europäischen Mitgliedsstaaten gegenseitig für COVID-19-Testergebnisbescheinigungen anerkannt werden und damit für das „EU Digital COVID-19 Certificate" berücksichtigt werden können, finden Sie im entsprechenden Dokument der Europäischen Kommission: Link zum Dokument

lvshiyuan | Los | Aktionen | Zurücksetzen

Nach 'lvshiyuan' suchen

Nach 'lvshiyuan' suchen

			Hersteller			Europäischer Bevollmächtigter				Sensitivität		Spezifität		
Test-ID	Handelsname	Evaluieru... PEI	Name	Stadt	Land	Name	Stadt	Land	Testo...	%	95%iges Vertraue... intervall	%	95%iges Vertraue... intervall	Gebrauc...
AT417/20	Green Spring® SARS-CoV-2-Antigen-Schnelltest-Set	Ja	Shenzhen Lvshiyuan Biotechnology Co., Ltd	Shenzhen	CN	Obelis s.a.	Brüssel	BE	POC (ohne Gerät)	98,00	97,12 - 99,98	100,00	98,12 - 99,99	Li...
AT1188/21	Green Spring SARS-CoV-2-Antigen-Schnelltest-Set (kolloidales Gold)	Ja	Shenzhen Lvshiyuan Biotechnology Co.,Ltd	Shenzhen	CN	Obelis s.a.	Brussels	BE	POC (ohne Gerät)	96,77	92,24 - 98,81	100,00	97,76 - 99,99	Li...

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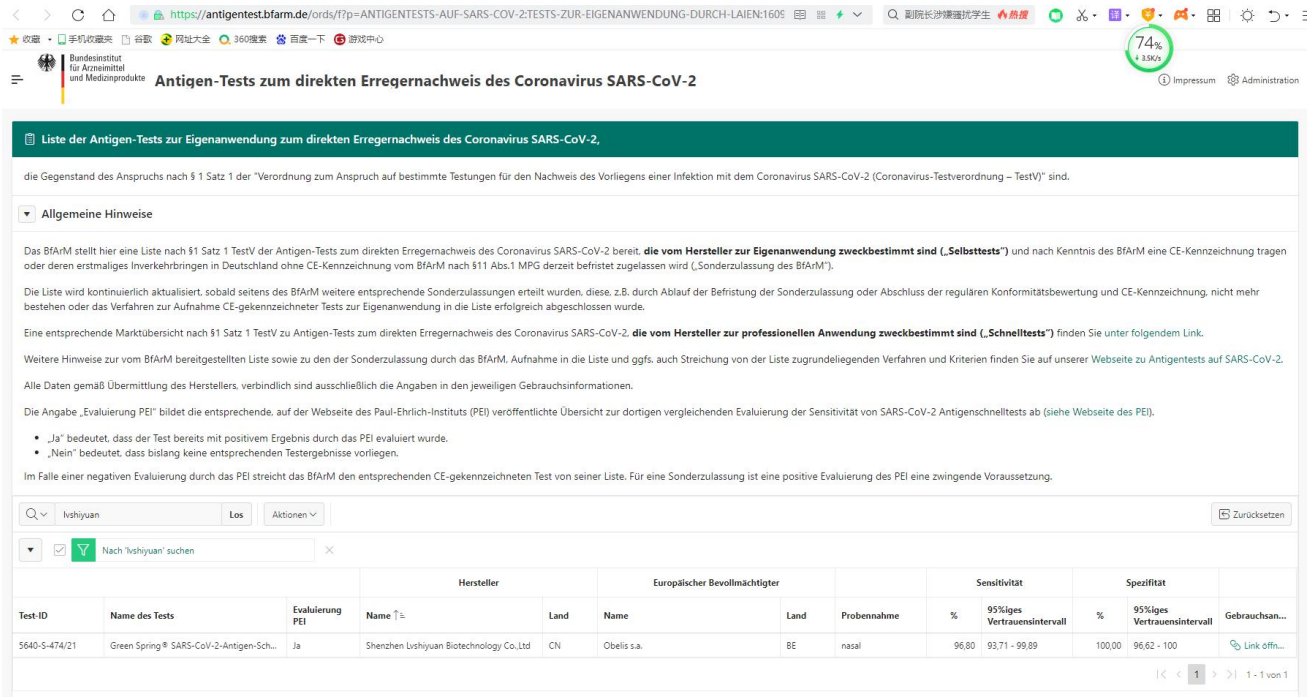
letzte Änderung: 30.12.2021 21:19 * POC = Point of Care

Release 1.0

德国 BfArM 批准用于自检的抗原检测

Germany BfArM Approval of antigen tests for self-testing



https://antigentest.bfarm.de/ords/f?p=ANTIGENTESTS-AUF-SARS-COV-2:TESTS-ZUR-EIGENANWENDUNG-DURCH-LAIEN:1609

Bundesinstitut für Arzneimittel und Medizinprodukte

Antigen-Tests zum direkten Erregernachweis des Coronavirus SARS-CoV-2

Impressum | Administration

Liste der Antigen-Tests zur Eigenanwendung zum direkten Erregernachweis des Coronavirus SARS-CoV-2,

die Gegenstand des Anspruchs nach § 1 Satz 1 der "Verordnung zum Anspruch auf bestimmte Testungen für den Nachweis des Vorliegens einer Infektion mit dem Coronavirus SARS-CoV-2 (Coronavirus-Testverordnung – TestV)" sind.

Allgemeine Hinweise

Das BfArM stellt hier eine Liste nach §1 Satz 1 TestV der Antigen-Tests zum direkten Erregernachweis des Coronavirus SARS-CoV-2 bereit, **die vom Hersteller zur Eigenanwendung zweckbestimmt sind („Selbsttests")** und nach Kenntnis des BfArM eine CE-Kennzeichnung tragen oder deren erstmaliges Inverkehrbringen in Deutschland ohne CE-Kennzeichnung vom BfArM nach §11 Abs.1 MPG derzeit befristet zugelassen wird („Sonderzulassung des BfArM").

Die Liste wird kontinuierlich aktualisiert, sobald seitens des BfArM weitere entsprechende Sonderzulassungen erteilt wurden, diese, z.B. durch Ablauf der Befristung der Sonderzulassung oder Abschluss der regulären Konformitätsbewertung und CE-Kennzeichnung, nicht mehr bestehen oder das Verfahren zur Aufnahme CE-gekennzeichneter Tests zur Eigenanwendung in die Liste erfolgreich abgeschlossen wurde.

Eine entsprechende Marktübersicht nach §1 Satz 1 TestV zu Antigen-Tests zum direkten Erregernachweis des Coronavirus SARS-CoV-2, **die vom Hersteller zur professionellen Anwendung zweckbestimmt sind („Schnelltests")** finden Sie unter folgendem Link.

Weitere Hinweise zur vom BfArM bereitgestellten Liste sowie zu den der Sonderzulassung durch das BfArM, Aufnahme in die Liste und ggfs. auch Streichung von der Liste zugrundeliegenden Verfahren und Kriterien finden Sie auf unserer Webseite zu Antigentests auf SARS-CoV-2.

Alle Daten gemäß Übermittlung des Herstellers, verbindlich sind ausschließlich die Angaben in den jeweiligen Gebrauchsinformationen.

Die Angabe „Evaluierung PEI" bildet die entsprechende, auf der Webseite des Paul-Ehrlich-Instituts (PEI) veröffentlichte Übersicht zur dortigen vergleichenden Evaluierung der Sensitivität von SARS-CoV-2 Antigenschnelltests ab (siehe Webseite des PEI).

- „Ja" bedeutet, dass der Test bereits mit positivem Ergebnis durch das PEI evaluiert wurde.
- „Nein" bedeutet, dass bislang keine entsprechenden Testergebnisse vorliegen.

Im Falle einer negativen Evaluierung durch das PEI streicht das BfArM den entsprechenden CE-gekennzeichneten Test von seiner Liste. Für eine Sonderzulassung ist eine positive Evaluierung des PEI eine zwingende Voraussetzung.

Ivshiyuan | Los | Aktionen | Zurücksetzen

Nach 'Ivshiyuan' suchen

			Hersteller		Europäischer Bevollmächtigter			Sensitivität		Spezifität		
Test-ID	Name des Tests	Evaluierung PEI	Name	Land	Name	Land	Probennahme	%	95%iges Vertrauensintervall	%	95%iges Vertrauensintervall	Gebrauchsan...
5640-S-474/21	Green Spring® SARS-CoV-2-Antigen-Sch...	Ja	Shenzhen Ivshiyuan Biotechnology Co.,Ltd	CN	Obelis s.a.	BE	nasal	96,80	93,71 - 99,89	100,00	96,62 - 100	Link öffn...

1 - 1 von 1

PEI 认证证书 Paul-Ehrlich-Institut certification

Bundesinstitut für Impfstoffe und biomedizinische Arzneimittel
Federal Institute for Vaccines and Biomedicines

Paul-Ehrlich-Institut

12.02.2021

Comparative evaluation of the sensitivities of SARS-CoV-2 antigen rapid tests

Aim

Comparison of different antigen rapid tests with using identical sample material

Material

Pools from nasopharyngeal and oropharyngeal swabs.

Dry swabs were included in PBS; moist swabs were already included in the transport media of various compositions. Pools are random mixtures obtained from up to 10 samples of comparable CT values diluted 1:10 in negative samples in PBS. The CT values of a pool were determined by means of different PCR assays, and the putative number of RNA copies calculated with the aid of the INSTAND standards. In the case of the PCRs used, a CT value of 25 corresponds to around 10^6 RNA copies/mL. 18 samples each were analysed with CT<25, 23 samples with CT between 25 and 30, and 9 samples with CT>30. The replication of the virus in cell culture was determined as a possible correlate for infectiousness as another characteristic of the samples.

Method

The pools were aliquoted, frozen, shipped, and thawed for evaluation of the tests. For each test, 50 µL of the pool were analysed using the components of the test provided, e.g. swabs. Laboratories participating in the comparative evaluation included the Robert Koch-Institut, the Paul-Ehrlich-Institut, the reference laboratory for coronaviruses (Charité), and the Institute for Microbiology of the German Army (Bundeswehr).

Summary

This comparative evaluation of a large number of SARS-CoV-2 rapid antigen tests (point of care tests; POCT) of different designs and manufacturers with the same sample set allows an overview of the current state of art regarding sensitivity. The results do not allow any conclusions regarding specificity of the tests.

Those POCTs which have up to now been included in the evaluation and have been assessed as reflecting the current state of the art are listed in the table below. Other tests, which were assessed as not reflecting the state of the art were deleted from the list of the Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte, BfArM). This comparative evaluation is constantly continued, and the table is amended accordingly.

You should be aware that this comparative evaluation can only cover a random sample of the SARS-CoV-2 rapid antigen tests listed by the BfArM, thus eligible for refunding, and that many other products could not (yet) be taken into account, despite the interests on the part of the manufacturers/distributors.

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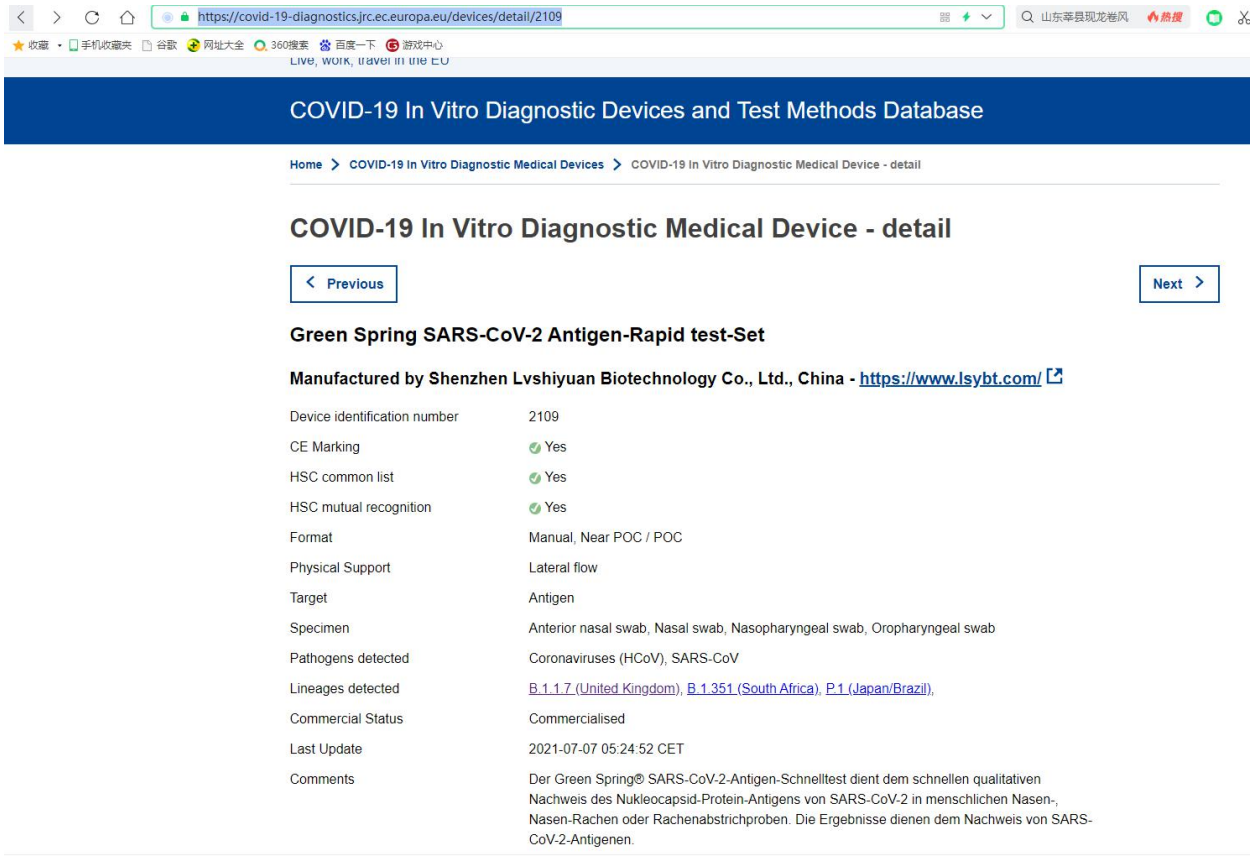
Last updated: 12.02.2021

Overview of SARS-CoV-2 Antigen Rapid Tests Assessed as Reflecting the Current State of the Art

Name of Test	Manufacturer (Distributor)
Panbio™COVID-19 Ag Rapid Test Device (NASOPHARYNGEAL)	Abbott Rapid Diagnostics Jena GmbH
RIDA®QUICK SARS-CoV-2 Antigen	R-Biopharm AG
SARS-CoV-2 Rapid Antigen Test	SD BIOSENSOR (Roche Diagnostics GmbH)
NADAL® COVID-19 Ag Schnelltest	nal von minden gmbh
STANDARD™ F COVID-19 Ag FIA	SD BIOSENSOR
STANDARD™ Q COVID-19 Ag Test	SD BIOSENSOR
BIOSYNEX COVID-19 Ag BSS	BIOSYNEX SWISS SA
MEDsan® SARS-CoV-2 Antigen Rapid Test	MEDsan GmbH
TestNOW® - COVID-19 Antigen	Affimedix
NowCheck® COVID-19 Ag Test	BIONOTE
Coronavirus Ag Rapid Test Cassette (Swab)	Zhejiang Orient Gene Biotech Co.,Ltd
Sofia SARS Antigen FIA	Quidel Corporation
COVID-19 Ag Test Kit	Guangdong Wesail Biotech Co., Ltd.
CLINITEST® Rapid COVID-19 Antigen Test	Siemens Healthineers
ESPLINE® SARS-CoV-2	Fujirebio Inc. (Mast Diagnostica GmbH)
BD Veritor™ System for Rapid Detection of SARS-CoV-2	Becton Dickinson
GenBody COVID-19 Ag	IVC Pragen Healthcare
LumiraDx SARS-CoV-2 Ag Test	LumiraDX
Exdia COVID-19-Ag-Test	Precision Biosensor Inc. (Axon Lab AG)
SARS-CoV-2 Ag Rapid Test (FIA)	Wantai (Beijing Wantai Biological Pharmacy Enterprise Co., Ltd.)
SARS-CoV-2 Antigen Schnelltest	Xiamen Boson Biotech Co., Ltd (Medicovid-AG; technomed GmbH; Löwe Medizintechnik)
COVID-19 Antigen Schnelltest (Colloidal Gold)	Joinstar Biomedical Technology Co., Ltd (CIV care impuls Vertrieb)
mö-screen Corona Antigen Test	Mölab GmbH
Rapid SARS-CoV-2 Antigen Test Card	MP Biomedicals Germany GmbH
Lyher Novel Coronavirus (COVID-19) Antigen Test Kit (Colloidal Gold)	Hangzhou Laihe Biotech Co., Ltd. (Lissner Qi GmbH)
AMP Rapid Test SARS-CoV-2 Ag	Ameda Labordiagnostik GmbH
Clungene COVID-19 Antigen Rapid Test	Hangzhou Clongene Biotech Co., Ltd.
GensureTM COVID-19 Antigen Rapid Test Kit	GenSure Biotech Inc.
SARS-CoV-2 Antigen Rapid Test Kit	Beijing Lepu Medical Technology Co., Ltd
Hightop SARS-CoV-2 (Covid-19) Antigen Rapid Test	Qingdao Hightop Biotech Co., Ltd.
Rapid Covid-19 Antigen Test (Colloidal Gold)	Anbio (Xiamen) Biotechnology Co., Ltd

Name of Test	Manufacturer (Distributor)
Safecare COVID-19 Ag Rapid Test Kit (Swab)	Safecare Biotech Hangzhou Co., Ltd.
QuickProfile Covid-19 Antigen Test Card	LumiQuick Diagnostics, Inc.
Covid 19 Antigen Schnelltest	BioRepair GmbH
Green Spring SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)	Shenzhen Lvshiyuan Biotechnology Co., Ltd.
CAT Antigen Covid Rapid Test	Oncosem Onkolojik Sistemler San. Ve Tic. A.S.
ScheBo SARS-CoV-2 Quick Antigen	ScheBo Biotech AG
Nova Test SARS-CoV-2 Antigen Rapid Test Kit	Atlas Link Technology Co., Ltd.
Toda Coronadiag Ag	Toda Pharma
Humasis COVID-19 Ag Test	Humasis Co., Ltd.
Beijing Hotgen Biotech Co., Ltd.	Neuartiges Coronavirus (2019-nCoV)-Antigentest (Kolloidales Gold); Novel Coronavirus 2019-nCoV Antigen Test (Colloidal gold)
Xiamen AmonMed Biotechnology Co.,Ltd.	COVID-19 Antigen Rapid Test Kit (Colloidal Gold)
Canea COVID-19 Antigen Schnelltest	Core Technology Co., Ltd.
fluorecare COVID-19 SARS-CoV-2 Spike Protein Test Kit (Colloidal Gold Chromatographic Immunoassay)	Shenzhen Microprofit Biotech Co., Ltd
Tetsealabs® Rapid Test Kit COVID-19 Antigen Test Cassette	Hangzhou Testsea Biotechnology Co., Ltd
Lysun COVID-19 Antigen Rapid Test Device (Colloidal Gold)	Hangzhou Lysun Biotechnology Co., Ltd.

欧盟通用和互认清单 On the EU common list & Mutual Recognition list



https://covid-19-diagnostics.jrc.ec.europa.eu/devices/detail/2109

COVID-19 In Vitro Diagnostic Devices and Test Methods Database

Home > COVID-19 In Vitro Diagnostic Medical Devices > COVID-19 In Vitro Diagnostic Medical Device - detail

COVID-19 In Vitro Diagnostic Medical Device - detail

Previous | Next

Green Spring SARS-CoV-2 Antigen-Rapid test-Set

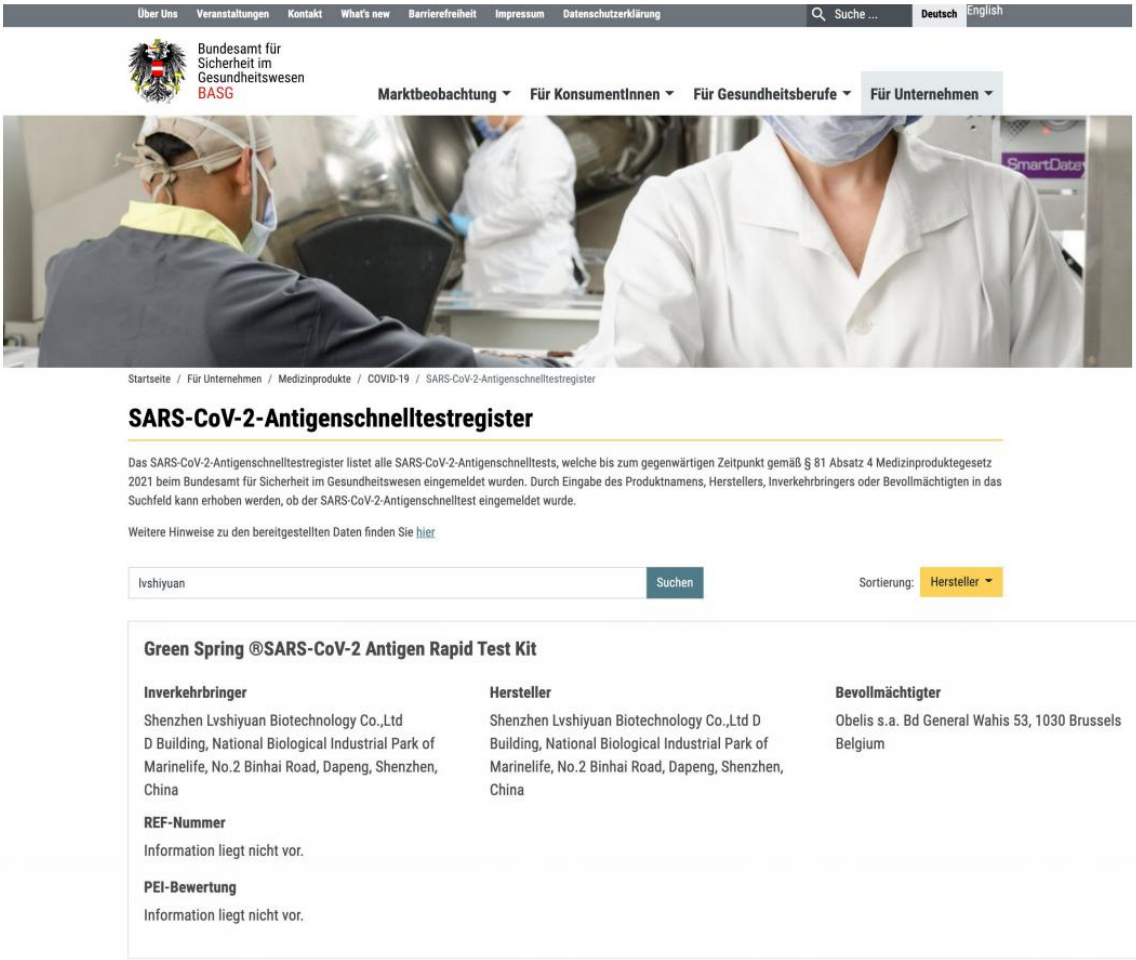
Manufactured by Shenzhen Lvshiyuan Biotechnology Co., Ltd., China - https://www.lsybt.com/

Device identification number	2109
CE Marking	Yes
HSC common list	Yes
HSC mutual recognition	Yes
Format	Manual, Near POC / POC
Physical Support	Lateral flow
Target	Antigen
Specimen	Anterior nasal swab, Nasal swab, Nasopharyngeal swab, Oropharyngeal swab
Pathogens detected	Coronaviruses (HCoV), SARS-CoV
Lineages detected	B.1.1.7 (United Kingdom), B.1.351 (South Africa), P.1 (Japan/Brazil),
Commercial Status	Commercialised
Last Update	2021-07-07 05:24:52 CET
Comments	Der Green Spring® SARS-CoV-2-Antigen-Schnelltest dient dem schnellen qualitativen Nachweis des Nukleocapsid-Protein-Antigens von SARS-CoV-2 in menschlichen Nasen-, Nasen-Rachen oder Rachenabstrichproben. Die Ergebnisse dienen dem Nachweis von SARS-CoV-2-Antigenen.

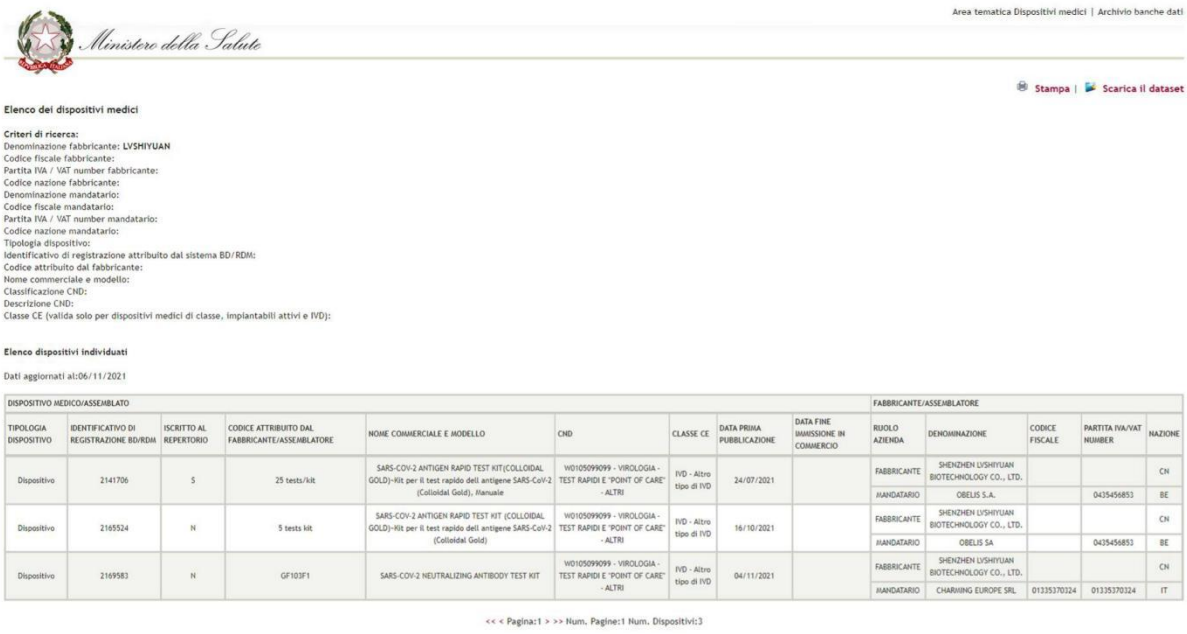
比利时白名单 Whitelist of Belgium

LiClear Biotech (Hangzhou)	SARS-CoV-2 Nucleocapsid (N) Antigen Rapid Test Cassette	95.1	99.3	NP swab	-	No
LumiQuick Diagnostics	QuickProfile COVID-19 Antigen Test Strip	94.0	99.0	NP swab	1267	Yes
MEDsan	SARS-CoV-2 Antigen Rapid Test	92.5	99.8	Nasal swab/OP swab	1180	Yes
MP Biomedicals	Rapid SARS-CoV-2 Antigen Test Card	96.4	99.0	NP swab/OP swab	1481	Yes
Multi-G	Covid19CHECK-GEN	92.5	99.2	NP swab/OP swab	-	No
	COVID19CHECK-NAS (COVID-19 antigen rapid test cassette)	98.1	99.2	Nasal swab	-	No
	COVID19CHECK-SAL (Sars-Cov-2 Antigen Rapid Test)	96.8 (Cts 33)	99.1	Saliva	-	No
Mylab Discovery Solutions Pvt	PathoCatch COVID-19 Antigen Lateral Flow Test Device	92.0	100.0	Nasal swab	-	No
nal von minden	NADAL COVID-19 Ag Rapid Test	97.6	99.9	NP swab/OP swab	1162	Yes
Nanjing Vazyme Medical Technology	Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Antigen Detection Kit (Colloidal Gold-Based)	97.6	99.3	Nasal swab/OP swab	1849	No
NanoEntek	FREND COVID-19 Ag	94.7	100.0	NP swab	1420	Yes
Nantong Diagnosis Biotechnology	Covid-19 Antigen Saliva Test Kit (Colloidal Gold) (Cassette)	98.1	99.3	Saliva	1617	No
	Covid-19 Antigen Test Kit (Colloidal Gold)	98.8/98.5	100.0	NP swab/OP swab	-	No
New Gene (Hangzhou) Bioengeneering	Covid-19 Antigen Detection Kit	97.3/95.7/95.1	99/99/99.1	Nasal swab/OP swab/Sputum	1501	Yes
ONCOSEM Onkolojik Sistemler San. ve Tic. A.S.	2019-nCoV Antigen Rapid Test Kit	97.6	99.3	NP swab	-	No
Ortho-Clinical Diagnostics	VITROS SARS-CoV-2 Antigen test	97.8	99.2	NP swab	1200	Lab test
PCL	PCL COVID19 Ag Gold	90.8 (Ct<30)/91.7	99.5/100	Saliva/NP swab	1758	No
Prestige Diagnostics	2019-nCoV Antigen Device	90.9	99.1	NP swab	1202	No
PRIMA Lab	PRIMACOVID COVID-19 Antigen Rapid Test	96.4/92.9	99.2/100	NP swab/Nasal swab	1797	No
Qingdao Hightop Biotech	SARS-CoV-2 Antigen Rapid Test (Immunochromatography)	92.7/95.0/95.0	99.8/99.8/99.8	Nasal swab/NP swab/OP swab	1341	Yes
Quidel	Sofia SARS Antigen FIA	96.7	100.0	NP swab/Nasal swab	1097	Yes
	Sofia 2 Flu + SARS Antigen FIA	95.2	100.0	NP swab/Nasal swab	-	No
Roche Diagnostics	Elecsys SARS-CoV-2 Antigen	94.5	99.9	NP swab/OP swab	2156	Lab test
SD Biosensor (distributed by Roche)	SARS-CoV-2 Rapid Antigen Test	96.5	99.7	NP swab	1604	Yes
Shenzhen Huian Biosci Technology	SARS-CoV-2 Antigen Test Kit (Colloidal Gold)	94.6	99.1	Nasal swab	-	No
Shenzhen Landwind Biotechnology	SARS-CoV-2 Antigen Test Kit (Colloidal Gold)	95.7	99.2	Nasal swab	-	No
Shenzhen Lvshiyuan Biotechnology	Green Spring SARS-CoV-2-Antigen-Rapid Test Kit (Colloidal Gold)	96.8/98	100.0	Nasal swab/NP swab	2109	Yes
Shenzhen Microprofit Biotech	Fluorecare SARS-CoV-2 Test Kit	98.6/100	100.0	NP swab/Nasal swab	-	No
	Fluorecare SARS-CoV-2 Spike Protein Test Kit	98.6	100.0	NP swab	1228	No
Shenzhen Ultra Diagnostics Biotech	SARS-CoV-2 Antigen Test kit (SC0201 + SC0202)	92/100/96	100.0	NP swab/OP swab/Saliva	-	No
	SARS-CoV-2 Antigen Test kit (SC0203 + SC0204)	92/95.7/97.3	100/99/99	NP swab/OP swab/Sputum	-	No
Shenzhen YHLO Biotech Co	GLINE-2019-nCoV Ag	96.5/97.4	99.3/99.3	NP swab/Nasal swab	1347	No
Surescreen	COVID-19 Coronavirus Rapid Antigen Test Cassette	93.3	100.0	NP swab/OP swab	1275	No
Todapharma	TODA Coronadiag Ag	96.6	100.0	NP swab/OP swab	1466	Yes
Ulti med Products	COVID-19 Antigen Test (Nasopharyngeal Swab)	96.4	99.2	NP swab	1455	No
	COVID-19 and Influenza A+B Antigen Combo Rapid Test (Nasopharyngeal Swab)	96.4	99.2	NP swab	1391	No
Van Oostveen Medical	Coronavirus Ag Rapid Test Cassette (Swab)	96.7	99.2	NP swab	1831	No
VivaChek Biotech	VivaDiag Pro SARS-CoV-2 Ag Rapid Test	96.1/96.1/97.0	100.0	NP swab/OP swab/Nasal swab	2103	Yes
	VivaDiag SARS-CoV-2 Ag Rapid Test	95.0	100.0	NP swab/OP swab/Nasal swab	2102	No
	VivaDiag SARS-CoV-2 Ag Saliva Rapid Test	98.3	100.0	Saliva	1980	No

奥地利白名单 Whitelist of Austria



意大利白名单 Whitelist of Italy



瑞士白名单 Whitelist of Switzerland

Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

Eidgenössisches Departement des Innern EDI
Bundesamt für Gesundheit BAG
Taskforce BAG Covid-19 AG Testung

Listen der validierten SARS-CoV-2-Schnelltests zur Fachanwendung[1]
Listes des tests rapides validés pour le SARS-CoV-2 pour usage professionnel
Liste dei test rapidi validati per il SARS-CoV-2 per uso professionale

25.10.2021

Die Schnelltests sind ausschliesslich für **bestimmte Probematerialien** validiert und nur dementsprechend anzuwenden. In der Schweiz dürfen **keine** Antigen-Schnelltests mit **Speichel** als Probematerial ausserhalb von Laboratorien eingesetzt werden. Informationen bezüglich des Einsatzes der Schnelltests finden Sie auf der BAG-Webseite Covid-19-Testung.

Webseite Covid-19 Testung

Les tests rapides sont validés exclusivement pour **certains types de prélèvements** et ne doivent ainsi être utilisés que pour ceux-ci. En Suisse, **aucun** test antigénique rapide utilisant la **salive** comme matériel de prélèvement ne peut être utilisé en dehors des laboratoires. Des informations sur l'emploi prévu des tests rapides sont disponibles sur le site web de l'OFSP Tests COVID-19.

Site internet Tests COVID-19

I testi rapidi sono validati solo per **certi tipi di campioni** e possono essere utilizzati solo per questo scopo. In Svizzera, **nessun** test antigenico rapido che utilizza la **saliva** come materiale di campionamento può essere utilizzato al di fuori dei laboratori. Le informazioni su come utilizzare i test rapidi sono disponibili sul sito internet dell'UFSP «Test COVID-19».

Sito web Test COVID-19

Validierte SARS-CoV-2-Schnelltests
Tests rapides SARS-CoV-2 validés
Test rapidi SARS-CoV-2 validati

Hersteller, Antigen Schnelltest Fabricant, Tests rapides antigéniques Azienda, Test antigenici rapidi	Test/Kitcode for submission declaration [2]	Combi-test [3]	JRC ID	Grace period until [4]
AAZ-LMB, COVID-VIRO	26		1833	
Abbott Rapid Diagnostics, Panbio Covid-19 Ag Rapid Test	2		1232	
Abioteq GmbH, Cora Gentest-19			2374	
AccuBioTech Co.,Ltd, Accu-Tell SARS-CoV-2 Ag Cassette			2579	
Acon Biotech (Hangzhou) Co., Ltd, Flowflex SARS-CoV-2 Antigen Rapid Test			1457	
ACON Laboratories, Inc, Flowflex SARS-CoV-2 Antigen rapid test			1468	
AESKU.DIAGNOSTICS GmbH & Co. KG, AESKU.RAPID SARS-CoV-2			2108	
Affimedix, Inc., TestNOW® - COVID-19 Antigen Test			2130	
AMEDA Labordiagnostik GmbH, AMP Rapid Test SARS-CoV-2 Ag	19		1304	
Anbio (Xiamen) Biotechnology Co., Ltd, Rapid COVID-19 Antigen Test(Colloidal Gold)			1822	
Anhui Deep Blue Medical Technology Co., Ltd, COVID-19 (SARS-CoV-2) Antigen Test Kit (Colloidal Gold) - Nasal Swab			1815	
Anhui Deep Blue Medical Technology Co., Ltd, COVID-19 (SARS-CoV-2) Antigen Test Kit(Colloidal Gold)			1736	
Anhui Formaster Biosci Co., Ltd., New Coronavirus (COVID-19) Antigen Rapid Test			2089	
ArcDia International Ltd, mariPOC SARS-CoV-2			768	
ArcDia International Oy Ltd, mariPOC Quick Flu+		X	2079	
ArcDia International Oy Ltd, mariPOC Respi+		X	2078	
Artron Laboratories Inc, Artron COVID-19 Antigen Test			1618	
Asan Pharmaceutical CO., LTD, Asan Easy Test COVID-19 Ag			1654	
Assure Tech. (Hangzhou) Co., Ltd, ECOTEST COVID-19 Antigen Rapid Test Device			770	
Assure Tech. (Hangzhou) Co., Ltd., ECOTEST COVID-19 Antigen Rapid Test Device			2350	
Atlas Link Technology Co., Ltd., NOVA Test® SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold Immunochromatography)	22		2010	
AVALUN SAS, Ksmart® SARS-COV2 Antigen Rapid Test			1800	
AXIOM Gesellschaft für Diagnostica und Biochemica mbH, COVID-19 Antigen Rapid Test			2101	
Azure Biotech Inc, COVID-19 Antigen Rapid Test Device			1906	
Becton Dickinson, BD Veritor™ System for Rapid Detection of SARS CoV 2			1065	
Beijing Hotgen Biotech Co., Ltd, Novel Coronavirus 2019-nCoV Antigen Test (Colloidal Gold)			1870	
Beijing Jinwofu Bioengineering Technology Co.,Ltd., Novel Coronavirus (SARS-CoV-2) Antigen Rapid Test Kit			2072	
Beijing Lepu Medical Technology Co., Ltd, SARS-CoV-2 Antigen Rapid Test Kit			1331	
Beijing O&D Biotech Co., Ltd., COVID-19 Antigen Rapid Test			2494	
Beijing Wantai Biological Pharmacy Enterprise Co., Ltd, WANTAI SARS-CoV-2 Ag Rapid Test (Colloidal Gold)			1485	
Beijing Wantai Biological Pharmacy Enterprise Co., Ltd, Wantai SARS-CoV-2 Ag Rapid Test (FIA)			1484	15.12.2021
BioGnost Ltd, CoviGnost AG Test Device 1x20			2031	
BIOHIT HealthCare (Hefei) Co., Ltd, SARS-CoV-2 Antigen Rapid Test Kit (Fluorescence Immunochromatography)			2247	
BioMaxima SA, SARS-CoV-2 Ag Rapid Test			1286	
Biomerica, Inc., Biomerica COVID-19 Antigen Rapid Test (nasopharyngeal swab)			2035	
Bionote, Inc, NowCheck COVID-19 Ag Test			1599	
Bio-Rad Laboratories / Zhejiang Orient Gene Biotech, Coronavirus Ag Rapid Test Cassette (Swab)	11		1242	
BIOSYNEX S.A., BIOSYNEX COVID-19 Ag BSS	17		1223	
BIOSYNEX S.A., BIOSYNEX COVID-19 Ag+ BSS	18		1494	
BIOTEKE CORPORATION (WUXI) CO., LTD, SARS-CoV-2 Antigen Test Kit (colloidal gold method)			2067	
Biotical Health S.L.U., biotical SARS-CoV-2 Ag Card			2013	
Boditech Med Inc, AFIAS COVID-19 Ag			1989	
BTNX Inc, Rapid Response COVID-19 Antigen Rapid Test			1236	
CerTest Biotec, CerTest SARS-CoV-2 Card test			1173	
Chil Tibbi Malzeme Sanayi ve Ticaret Limited Şirketi, CHIL COVID-19 Antigen Rapid Test (Nasopharyngeal / Oropharyngeal Swab-Casette)			1691	
Chongqing M&D Biotechnology Co. Ltd. 2019-nCoV Antigen Test Kit			2150	
Core Technology Co., Ltd, Coretests COVID-19 Ag Test			1919	
CTK Biotech, Inc, OnSite COVID-19 Ag Rapid Test			1581	
DDS DIAGNOSTIC, Test Rapid Covid-19 Antigen (tampon nazofaringian)			1225	
DIALAB GmbH, DIAQUICK COVID-19 Ag Cassette			1375	
DiaSorin S.p.A, LIAISON® SARS-CoV-2 Ag			1960	
DNA Diagnostic, COVID-19 Antigen Detection Kit			2242	
Dräger Safety AG & Co. KGaA, Dräger Antigen Test SARS-CoV-2			2273	
Dynamiker Biotechnology (Tianjin) Co., Ltd., Dynamiker SARS-CoV-2 Ag Rapid Test			2533	
Edinburgh Genetics Limited, ActivXpress+ COVID-19 Antigen Complete Testing Kit			1243	
Eurobio Scientific, EBS SARS-CoV-2 Ag Rapid Test	25		1739	
Fujirebio, ESPLINE SARS-CoV-2			2147	
GA Generic Assays GmbH, GA CoV-2 Antigen Rapid Test			1855	
GenBody, Inc, Genbody COVID-19 Ag Test			1244	15.12.2021
Genrui Biotech Inc, SARS-CoV-2 Antigen Test Kit (Colloidal Gold)			2012	
GenSure Biotech Inc, GenSure COVID-19 Antigen Rapid Kit			1253	
Getein Biotech, Inc, SARS-CoV-2 Antigen (Colloidal Gold)			1820	
Getein Biotech, Inc., One Step Test for SARS-CoV-2 Antigen (Colloidal Gold)			2183	
Goldsite Diagnostics Inc, SARS-CoV-2 Antigen Kit (Colloidal Gold)			1197	
Green Cross Medical Science Corp., GENEDIA W COVID-19 Ag			1144	
Guangdong Hecin Scientific, Inc., 2019-nCoV Antigen Test Kit (colloidal gold method)			1747	
Guangdong Longsee Biomedical Co., Ltd, COVID-19 Ag Rapid Test Kit (Immuno-Chromatography)			1216	
Guangdong Wesail Biotech Co., Ltd, COVID-19 Ag Test Kit			1360	
Guangzhou Dechens Biotechnology Co., LTD, V-CHEK, 2019-nCoV Ag Rapid Test Kit (Immunochromatography)			1324	
Guangzhou Wondfo Biotech Co., Ltd, Wondfo 2019-nCoV Antigen Test (Lateral Flow Method)	23		1437	
Hangzhou AllTest Biotech Co., Ltd, COVID-19 Antigen Rapid Test	10		1257	
Hangzhou Clongene Biotech Co., Ltd, COVID-19 Antigen Rapid Test Cassette			1610	
Hangzhou Clongene Biotech Co., Ltd, Covid-19 Antigen Rapid Test Kit	20		1363	
Hangzhou Clongene Biotech Co., Ltd, COVID-19/Influenza A+B Antigen Combo Rapid Test		X	1365	
Hangzhou Immuno Biotech Co.,Ltd, Immunobio SARS-CoV-2 Antigen ANTERIOR NASAL Rapid Test Kit (minimal invasive)			1844	
Hangzhou Immuno Biotech Co.,Ltd, SARS-CoV-2 Antigen Rapid Test			2317	
Hangzhou Laihe Biotech Co., Ltd, LYHER Novel Coronavirus (COVID-19) Antigen Test Kit(Colloidal Gold)			1215	
HANGZHOU LYSUN BIOTECHNOLOGY CO., LTD, COVID-19 Antigen Rapid Test Device（Colloidal Gold)	7		2139	
Hangzhou Testsea Biotechnology Co., Ltd, COVID-19 Antigen Test Cassette			1392	
Healgen Scientific, Coronavirus Ag Rapid Test Cassette			1767	
Hoyotek Biomedical Co.,Ltd, Corona Virus (COVID-19) Antigen Rapid Test (Colloidal Gold)			1929	
Hubei Jinjian Biology Co., Ltd, SARS-CoV-2 Antigen Test Kit			1759	
Humasis, Humasis COVID-19 Ag Test			1263	
Innova Medical Group, Inc., Innova SARS CoV-2 Antigen Rapid Qualitative Test			1801	
Innovation Biotech (Beijing) Co.,ltd, Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (swab)			2278	
InTec PRODUCTS, INC., Rapid SARS-CoV-2 Antigen Test (nasopharyngeal specimen)			2419	
Jiangsu Biogerlecdus Technologies Co., Ltd., Novel Corona Virus (SARS-CoV-2) Ag Rapid Test Kit			2107	
Jiangsu Diagnostics Biotechnology Co.,Ltd., COVID-19 Antigen Rapid Test Cassette (Colloidal Gold)			1920	
Jiangsu Medomics medical technology Co.,Ltd., SARS-CoV-2 antigen Test Kit (LFIA)			2006	
Jiangsu Well Biotech Co., Ltd., COVID-19 Ag Rapid Test Device			2144	
Joinstar Biomedical Technology Co., Ltd, COVID-19 Rapid Antigen Test (Colloidal Gold)			1333	
JOYSBIO (Tianjin) Biotechnology Co., Ltd, SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)			1764	
Labnovation Technologies Inc, SARS-CoV-2 Antigen Rapid Test Kit			1266	
Lumigenex (Suzhou) Co., Ltd, PocRoc®SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)			2128	
LumiQuick Diagnostics Inc, QuickProfile COVID-19 Antigen Test			1267	
LumiraDX, LumiraDx SARS-CoV-2 Ag Test	9		1268	
MEDsan GmbH, MEDsan SARS-CoV-2 Antigen Rapid Test	6		1180	
Merlin Biomedical (Xiamen) Co., Ltd., SARS-CoV-2 Antigen Rapid Test Cassette			2029	
MEXACARE GmbH, MEXACARE COVID-19 Antigen Rapid Test			1775	
mOLab, m0-screen Corona Antigen Test			1190	
MP Biomedicals, Rapid SARS-CoV-2 Antigen Test Card	15		1481	
Nal von minden GmbH, NADAL COVID-19 Ag +Influenza A/B Test		X	2104	
Nal von minden GmbH, NADAL COVID-19 Ag Test	33		1162	
NanoEntek, FREND COVID-19 Ag	34		1420	
NanoRepro AG, NanoRepro SARS-CoV-2 Antigen Rapid Test			2200	
NESAPOR EUROPA SL, MARESKIT			2241	
New Gene (Hangzhou) Bioengineering Co., Ltd, COVID-19 Antigen Detection Kit	30		1501	
Novatech, SARS CoV-2 Antigen Rapid Test			1762	
Oncosem Onkolojik Sistemler San. ve Tic. A.S., CAT			1199	
PCL Inc, PCL COVID19 Ag Rapid FIA			308	
PCL Inc., PCL COVID19 Ag Gold			2243	
PerGrande BioTech Development Co., Ltd., SARS-CoV-2 Antigen Detection Kit (Colloidal Gold Immunochromatographic Assay)			2116	
Precision Biosensor, Inc, Exdia COVID-19 Ag	13		1271	
Prognosis Biotech, Rapid Test Ag 2019-nCov			1495	
Qingdao Hightop Biotech Co., Ltd, SARS-CoV-2 Antigen Rapid Test (Immunochromatography)			1341	
Quidel Corporation, Sofia SARS Antigen FIA	21		1097	
Rapid Pathogen Screening, Inc., LIAISON® Quick Detect Covid Ag Assay			2290	
Roche (SD BIOSENSOR), SARS-CoV-2 Rapid Antigen Test	1		1604	
Roche (SD BIOSENSOR), SARS-CoV-2 Rapid Antigen Test Nasal			2228	
ROCHE Diagnostics, Elecsys® SARS-CoV-2 Antigen			2156	
Safecare Biotech (Hangzhou) Co.,Ltd, COVID-19 Antigen Rapid Test Kit (Swab)			1489	
Safecare Biotech (Hangzhou) Co.,Ltd, Multi-Respiratory Virus Antigen Test Kit(Swab) (Influenza A+B/ COVID-19)		X	1490	
ScheBo Biotech AG, ScheBo SARS CoV-2 Quick Antigen			1201	
SD BIOSENSOR Inc, STANDARD F COVID-19 Ag FIA	24		344	
SD BIOSENSOR Inc, STANDARD Q COVID-19 Ag Test			345	
SD BIOSENSOR Inc, STANDARD Q COVID-19 Ag Test Nasal			2052	
SGA Medikal, V-Chek SARS-CoV-2 Ag Rapid Test Kit (Colloidal Gold)			1319	
SGA Medikal, V-Chek SARS-CoV-2 Rapid Ag Test (colloidal gold)			1357	
Shenzhen Dymind Biotechnology Co., Ltd, Sars-CoV-2 antigen test kit (colloidal gold)			2415	
Shenzhen Huian Biosci Technology Co., Ltd., SARS-CoV-2 Antigen Test Kit (Colloidal Gold)			2414	
Shenzhen Kisshealth Biotechnology Co., Ltd, SARS-CoV-2 Antigen Test Kit (GICA)			1813	
Shenzhen Lvshiyuan Biotechnology Co., Ltd., Green Spring SARS-CoV-2 Antigen-Rapid test-Set			2109	
Shenzhen Microprofit Biotech Co., Ltd, SARS-CoV-2 Antigen Test Kit (Colloidal Gold Chromatographic Immunoassay)			1967	
Shenzhen Microprofit Biotech Co., Ltd, SARS-CoV-2 Spike Protein Test Kit (Colloidal Gold Chromatographic Immunoassay)			1178	

英国注册证书 Registration Certificate of UK

Medicines & Healthcare products Regulatory Agency

MHRA

Medicines & Healthcare products Regulatory Agency

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

+44 (0) 20 3080 6000
gov.uk/mhra

PureUKCA Ltd
59
St. Martin's Lane
Middlesex
London
WC2N 4JS
England, United Kingdom

09 September 2021

Dear **Avril Huang**

We are pleased to confirm that the application to register or update an existing registration for the following manufacturer, which you submitted on **09 September 2021** has been reviewed:

Application reference: **2021090901215399**

Manufacturer organisation: **Shenzhen Lvshiyuan Biotechnology Co.,Ltd.**
Address:
D Building, No.2 Industrial Avenue, Buxin Village, Buxin Community, Dapeng Subdistrict Office, Dapeng New District, Shenzhen, 518120 China
Shenzhen
518120
China

Manufacturer registration status: **Registered**

Device(s):

GMDN term	Status	Comment
SARS-CoV-2 antigen IVD, kit, immunochromatographic test (ICT), rapid	Registered	

Please note this letter does not represent any form of accreditation, certification or approval by the UK Competent Authority.

If you stop placing devices on the market or if you are not complying with the Regulations, you should inform us so that we can amend our records. You should be aware that it is an offence to place on the market UKCA or CE marked devices that do not comply with the regulations.

Please inform us of the following chargeable changes:

1. **company/organisation information e.g. name and address**
2. **additional devices (GMDN code or term)**

Please also use the Devices Online Registration Database (DORS) to tell us of the following changes e.g. removal/ discontinuation of a device (GMDN) or product from your registration record, change of contact person, telephone number and/or email address, for which payment of our statutory fee does not apply.

Please note that the name and address of manufacturer, UK Responsible Person or Authorised Representative (Northern Ireland only) and devices that have been registered will be published on our Public Access Registration Database (PARD).

The account number for your company/organisation is **0000018481.**

Yours sincerely,

Ngozi Onyeukwu
Device registrations service
Devices division
MHRA

柬埔寨注册证书 Cambodia Registration certificate

ព្រះរាជាណាចក្រកម្ពុជា
KINGDOM OF CAMBODIA
ជាតិ សាសនា ព្រះមហាក្សត្រ
NATION RELIGION KING

ក្រសួងសុខាភិបាល
MINISTRY OF HEALTH

ថ្ងៃ[illegible] ខែ[illegible] ឆ្នាំ[illegible] ព.ស ២៥៦៥
រាជធានីភ្នំពេញ, ថ្ងៃទី 04 ខែ 11 ឆ្នាំ ២0 21

ទិញ្ញាបនបត្របញ្ជិការប្រតិករ
REAGENT REGISTRATION LICENSE

ក្រសួងសុខាភិបាលអនុញ្ញាតផ្តល់ជូនវិញ្ញាបនបត្របញ្ជិកា លេខ **CAM N0286IR-21** ចំពោះប្រតិករដែលមានចរិតលក្ខណៈដូចខាងក្រោម:

The reagent described below is authorized to be granted the Registration License No **CAM N0286IR-21**

១- ឈ្មោះប្រតិករ (Reagent Name) : **SARS - Cov-2 Antigen Rapid Test Kit (Colloidal Gold) 25tests/kit**

- រូបមន្ត (Composition) :

២-ឈ្មោះ និង អាសយដ្ឋានរោងចក្រផលិតប្រតិករ

Name And Address of Manufacturer:
Shenzhen Lvshiyuan Biotechnology Co.,Ltd
101,201,301,D Building,No.2 Industrial Avenue, Buxin Village, Buxin Community, Dapeng Subdistrict Office,Daper New District,Shenzhen. China

ឈ្មោះ និង អាសយដ្ឋានម្ចាស់កម្មសិទ្ធិបញ្ជិកាប្រតិករ

Name And Address of the License Holder:
OPEN SUORCES TECHNOLOGY CO.,LTD
#128D6-7 (2nd floor),Samdech Sothearos Blvd(3),Sangkat Tonle Bassac, Khan Chamkarmon,Phnom Penh,Cambodia

៣-ក្រសួងសុខាភិបាល រក្សាសិទ្ធិក្នុងការព្យួរទុក ឬ លុបចោលនូវវិញ្ញាបនបត្របញ្ជិកាប្រតិករក្នុងករណី ដែលសាមីជនមិនគោរព តាមច្បាប់ដែលនៅជាធរមាន

The Ministry of Health will cancel or suspend the Reagent Registration License if the License Holder fails to comply with the regulation in force

៤-វិញ្ញាបនបត្របញ្ជិកាប្រតិករនេះ មានសុពលភាពសម្រាប់រយៈពេល ៣ ឆ្នាំ គិតពីថ្ងៃ **២៨-១០-២០២១** ដល់ **២៨-១០-២០២៤**

This reagent License is valid for three years from **28-10-2021** to **28-10-2024**

៥-៦ខែ មុនផុតកំណត់ត្រូវបំពេញសំណុំបែបបទសុំវិញ្ញាបនបត្របញ្ជិកាប្រតិករសារជាថ្មី។

Reagent Registration License shall renew six months prior to its expired date.

Dr. OR VANDINE
SECRETARY OF STATE

肯尼亚 EUA　**EUA of Kenya**

MINISTRY OF HEALTH

PHARMACY AND POISONS BOARD

(Section 3B(2)(e) of the Pharmacy and Poisons Act, Cap 244 Laws of Kenya)

IN-VITRO DIAGNOSTIC EMERGENCY USE AUTHORIZATION

This Emergency Use Authorization is issued to **Shenzhen Lvshiyuan Biotechnology Co., Ltd,** for distribution and sale of ***SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)***

Emergency use Authorization (EUA) No.	**MD/2021/10326**
EUA valid until	End of COVID -19 Pandemic or EUA revocation
Device category	Medical Device class C/D
GMDN	N/A
GMDN Term	N/A
Intended purpose	Qualitative detection of SARS-CoV-2 nucleocapsid antigen (Ag) in human nasal swab specimens from individuals who are suspected of COVID-19 by use of immunochromatographic technique
Conditional Approval	For Screening Purposes Only

PPB · LICENSE · MD/2021/10326 · APPROVED

EUA No.: MD/2021/10326

Date of Authorization: September 15th 2021

SR No. 018930/21

FORM 7

MINISTRY OF HEALTH

THE PHARMACY AND POISONS ACT
(*Cap.244, Sub. Leg.*)
(*The Pharmacy and Poisons Rules*)

WHOLESALE DEALER'S LICENCE

Messrs. BELLWAY PHARMACEUTICALS LIMITED -RIARA RD of JAIKULPHARM2020@YAHOO.COM

carrying on business at 330/192, are hereby authorized to sell poisons by way of wholesale dealing.

23-02-2021
Date

Note. (i) This licence expires on 31st day of December 2021

Fee: KShs. 30000

Licence No. BU202108744

MINISTRY OF HEALTH
PHARMACY AND POISONS BOARD

Telegram: "MINHEALTH" Nairobi
Telephone: 020-2716905/6, 020-3562107
Cellphone: 0733-884411/0720 608811
Fax: 2713409
Email: admin@pharmacyboardkenya.org
Website: www.pharmacyboardkenya.org

Pharmacy & Poisons Board Hse
Along Lenana Road
P. O. Box 27663-00506
NAIROBI

When replying please quote our ref No:

PPB/PER/GEN/VOL.I/21/35 Date: September, 15th 2021

MAH (MANUFACTURER/SUPPLIER)

Shenzhen Lvshiyuan Biotechnology Co., Ltd,
101,201,301 Building, No.2
Industrial Avenue, Buxin Village,
Buxin Communitym Dapeng Subdistrict Office,
Dapang New District Shenzhen,
Guangdongm P.R China.

Through'

Local Technical Representative

Bellway Pharmaceutical Limited,
330/192 Riara Road, Kilimani,
P.O. Box 25443-00603,
Nairobi

Dear Sir/Madam,

RE: APPLICATION FOR IN-VITRO DIAGNOSTIC MEDICAL DEVICE EMERGENCY USE AUTHORIZATION OF *SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)*

Reference is made to the above subject.

The Pharmacy and Poisons Act (Cap 244) provides for the regulatory oversight of Medical Devices including In-Vitro Diagnostics (IVDs) in Kenya by the Pharmacy and Poisons Board "the Board". Please note that the Expert committee on medicals devices & IVDs of the Board is tasked with reviewing applications for Covid-19) test kits. The Board's policy requires that all IVDs meet certain conditions prior to approval; including submission of product dossier and validation protocols and reports that evidence threshold of key performance parameters. The validating laboratory must be an accredited laboratory, such as, Kenya Medical Research Institute that is recognized by the Board.

荷兰注册证 Registration Certificate in Netherlands

CIBG
Ministerie van Volksgezondheid, Welzijn en Sport

> Retouradres Postbus 16114 2500 BC Den Haag

Kingsmead Service B.V.
T.a.v. de heer Jeff
Zonnehof 36
2632 BE Nootdorp

Farmatec

Bezoekadres:
Hoftoren
Rijnstraat 50
2515 XP Den Haag

T 070 340 6161

http://hulpmiddelen.farmatec.nl

Inlichtingen via:
medische_hulpmiddelen@minvws.nl

Ons kenmerk:
CIBG-20216547

Bijlagen
-

Uw aanvraag
1 november 2021

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

Datum: 18 november 2021
Betreft: aanmelding In-vitro diagnostica

Geachte heer Jeff,

Op 1 november 2021 ontving ik uw notificatie krachtens artikel 4, eerste lid van het Nederlandse Besluit in-vitro diagnostica (BIVD) om onder de bedrijfsnaam Shenzhen Lvshiyuan Biotechnology Co.,Ltd met Europees gemachtigde Kingsmead Service B.V. onderstaand product als in-vitro diagnosticum op de Europese markt te brengen.

Het product staat geregistreerd als in-vitro diagnosticum onder nummer:

SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)
(geen merknaam) (NL-CA002-2021-62947)

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

In alle verdere correspondentie betreffende bovenvermeld product verzoek ik u dit nummer te vermelden. Aan dit nummer kunnen geen verdere rechten ontleend worden, het dient 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, Shenzhen Lvshiyuan Biotechnology Co.,Ltd de CE-conformiteitsmarkering heeft aangebracht op het desbetreffende product alvorens het in een EU-lidstaat in de handel te brengen. Zodoende garandeert Kingsmead Service B.V. dat het in-vitro diagnosticum voldoet aan de essentiële eisen zoals opgenomen in bijlage I bij Richtlijn 98/79/EG (en in het daarmee corresponderende onderdeel 1 bij het besluit)

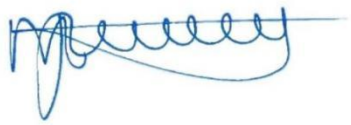
Volledigheidshalve wijzen wij u erop dat een in-vitro diagnosticum moet voldoen aan de eisen uit het BIVD. Het BIVD is gebaseerd op Richtlijn voor in-vitro diagnostiek, 98/79/EG. Met name wijzen wij u op de Nederlandse-taaleis zoals deze in Nederland geldt, de eisen voor het ter beschikking houden van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

Let op:
de notificatie van uw 'IVD Algemeen' product vervalt per 26 mei 2022.
Valt uw IVD product onder een hogere risicoklasse (lijst A, B of zelftesten)? Dan mag uw product tot en met uiterlijk 25 mei 2025 op de markt blijven als IVD product.

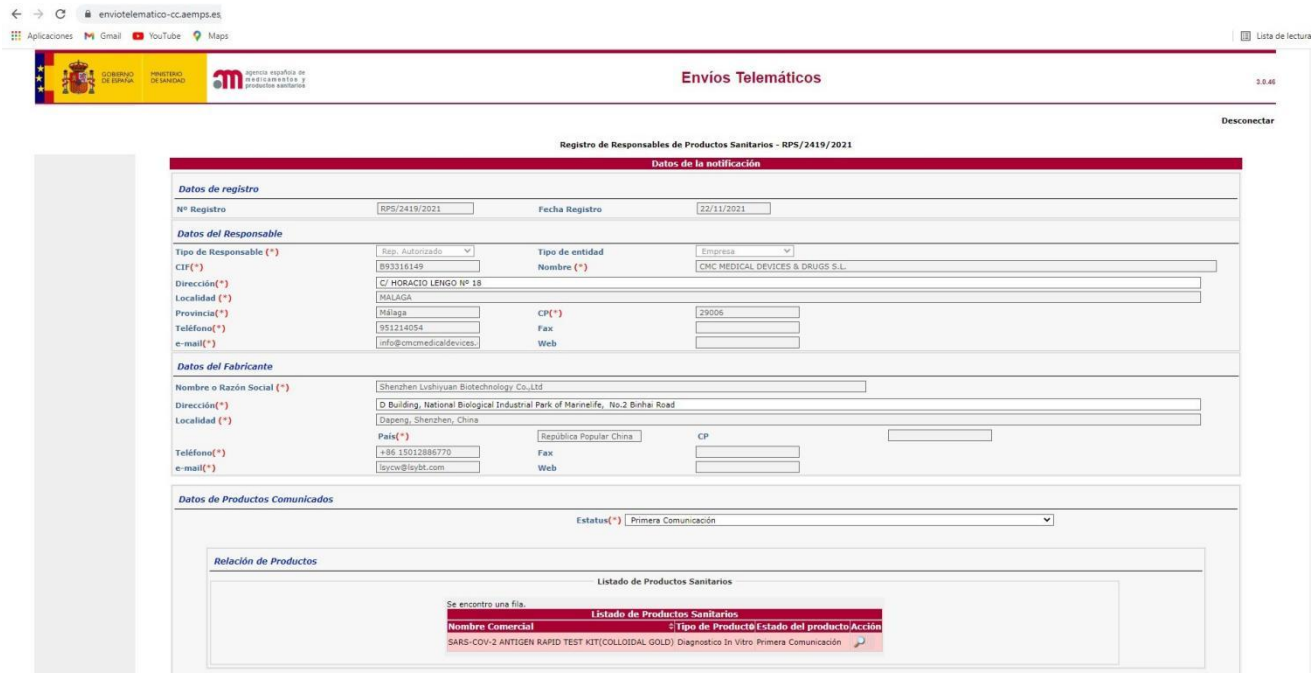
De Staatssecretaris van Volksgezondheid, Welzijn en Sport,
namens deze,

Afdelingshoofd
Farmatec



Dr. M.J. van de Velde

西班牙注册证 Spanish Registration Certificate



Envíos Telemáticos

Desconectar

Registro de Responsables de Productos Sanitarios - RPS/2419/2021

Datos de la notificación

Datos de registro

Nº Registro	RPS/2419/2021	Fecha Registro	22/11/2021

Datos del Responsable

Tipo de Responsable (*)	Rep. Autorizado	Tipo de entidad	Empresa
CIF(*)	B93316149	Nombre (*)	CMC MEDICAL DEVICES & DRUGS S.L.
Dirección(*)	C/ HORACIO LENGO Nº 18		
Localidad (*)	MALAGA		
Provincia(*)	Málaga	CP(*)	29006
Teléfono(*)	951214054	Fax	
e-mail(*)	info@cmcmedicaldevices.	Web	

Datos del Fabricante

Nombre o Razón Social (*)	Shenzhen Lvshiyuan Biotechnology Co.,Ltd		
Dirección(*)	D Building, National Biological Industrial Park of Marinelife, No.2 Binhai Road		
Localidad (*)	Dapeng, Shenzhen, China		
País(*)	República Popular China	CP	
Teléfono(*)	+86 15012886770	Fax	
e-mail(*)	lsycw@lsybt.com	Web	

Datos de Productos Comunicados

Estatus(*) Primera Comunicación

Relación de Productos

Listado de Productos Sanitarios

Se encontro una fila.

Listado de Productos Sanitarios			
Nombre Comercial	Tipo de Producto	Estado del producto	Acción
SARS-COV-2 ANTIGEN RAPID TEST KIT(COLLOIDAL GOLD)	Diagnostico In Vitro	Primera Comunicación	

泰国白名单 Whitelist of Thailand

รายชื่อชุดตรวจสำหรับ COVID-19 ประเภท Rapid Test แบบตรวจหา Antigen
รูปแบบการใช้โดยบุคลากรทางการแพทย์เท่านั้น (Professional Use Only)
ที่ได้รับการอนุญาตให้ผลิต/นำเข้า จากสำนักงานคณะกรรมการอาหารและยา
ข้อมูล ณ วันที่ 16 ธันวาคม 2564

ลำดับที่	ชื่อผลิตภัณฑ์	ชื่อผู้นำเข้า	ชื่อผู้ผลิต	วันที่ได้รับอนุญาต (วัน/เดือน/ปี)	เลขที่ใบรับรองประเมินเทคโนโลยี
130	Virusee ® SARS-CoV-2 Antigen Rapid Test (Colloidal Gold) รหัสสินค้า VSLFA-01, VSLFA-20	บริษัท สรรพศิริ เทรดดิ้ง จำกัด	[illegible]	9/12/2564	T 6400558
131	Servere Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Antigen Detection Kit (Colloidal Gold-Based) รหัสสินค้า C8602CA	บริษัท ซาจุน จำกัด	[illegible]	9/12/2564	T 6400559
132	BD Kit for Rapid Detection of SARS-CoV-2 รหัสสินค้า 256091, 256113, 256114	บริษัท ซิลลิค ฟาร์มา จำกัด	[illegible]	9/12/2564	T 6400561
133	SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)	บริษัท แฮปปี้ วิชั่นส์ จำกัด	Shenzhen Lvshiyuan Biotechnology Co., Ltd. China	13/12/2564	T 6400562

阿拉伯联合酋长国和沙特阿拉伯的自由销售证明
Free sales certificate in UNITED ARAB EMIRAT and SAUDI ARABIA

CIBG
Ministerie van Volksgezondheid, Welzijn en Sport

> Retouradres Postbus 16114 2500 BC Den Haag

Kingsmead Service B.V.
T.a.v. de heer Jeff
Zonnehof 36
2632 BE Nootdorp

Farmatec

Bezoekadres:
Hoftoren
Rijnstraat 50
2515 XP Den Haag

T 070 340 6161

http://hulpmiddelen.farmatec.nl

Inlichtingen via:
medische_hulpmiddelen@
minvws.nl

Ons kenmerk:
CIBG-20217418

Bijlagen
2

Uw aanvraag
21 december 2021

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

Datum: 10 januari 2022
Betreft: exportverklaring(en) medische hulpmiddelen/IVD

Geachte heer Jeff,

Hierbij ontvangt u de door u aangevraagde exportverklaring(en) voor:

SAUDI ARABIA (34659)
UNITED ARAB EMIRATES (34660)

Afgegeven exportverklaringen IVD Klasse other producten of gecombineerde exportverklaringen van IVD Klasse other producten met hogere risicoklasse producten vervallen per 26 mei 2022.
Valt uw IVD product onder een hogere risicoklasse (lijst A, B of zelftesten)? Dan mag uw product tot en met uiterlijk 25 mei 2025 op de markt blijven als IVD product.

Met vriendelijke groet,
Farmatec

Medewerker Medische Hulpmiddelen

Ministry of Health, Welfare and Sport
CIBG
P.O. Box 16114
2500 BC The Hague
THE NETHERLANDS

STATEMENT

The undersigned herewith declares that according to the Decree on In-Vitro Diagnostics, which is based on the European Directive 98/79/EC concerning in-vitro diagnostic medical devices,

Kingsmead Service B.V.
Zonnehof 36
2632 BE Nootdorp
THE NETHERLANDS

acts as authorised representative of the manufacturer.

The manufacturer:

Shenzhen Lvshiyuan Biotechnology Co.,Ltd
D Building, National Biological Industrial Park of Marinelife, No.2 Binhai Road, Dapeng
Shenzhen 518120
CHINA

is authorised to manufacture and/or supply the medical device/devices mentioned below:

SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)

This device/these devices may be placed on the Dutch market and on the markets of the other Member States of the European Union, and be exported to States and territories outside the European Union. This free sale certificate may only be used for export outside the European Union.

The present statement is drawn up at the request of the interested party in order to be submitted to the Health Authorities of SAUDI ARABIA .

This statement is valid until May 26, 2022.

The Hague, January 10, 2022

On behalf of State Secretary for Health, Welfare and Sport
Farmatec | CIBG

Dr. M.J. van de Velde

Mr. M.J. van de Velde
Head of Department

Our reference: 20217418
Certificate number: 34659

Ministry of Health, Welfare and Sport
CIBG
P.O. Box 16114
2500 BC The Hague
THE NETHERLANDS

STATEMENT

The undersigned herewith declares that according to the Decree on In-Vitro Diagnostics, which is based on the European Directive 98/79/EC concerning in-vitro diagnostic medical devices,

Kingsmead Service B.V.
Zonnehof 36
2632 BE Nootdorp
THE NETHERLANDS

acts as authorised representative of the manufacturer.

The manufacturer:

Shenzhen Lvshiyuan Biotechnology Co.,Ltd
D Building, National Biological Industrial Park of Marinelife, No.2 Binhai Road, Dapeng
Shenzhen 518120
CHINA

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This statement is valid until May 26, 2022.

The Hague, January 10, 2022

On behalf of State Secretary for Health, Welfare and Sport
Farmatec | CIBG

Dr. M.J. van de Velde

Mr. M.J. van de Velde
Head of Department

Our reference: 20217418
Certificate number: 34660

马来西亚自测证 Self-test approval of MDA Malaysia

PIHAK BERKUASA PERANTI PERUBATAN
Medical Device Authority
KEMENTERIAN KESIHATAN MALAYSIA
Ministry of Health Malaysia
Aras 6, Prima 9, Prima Avenue II,
Blok 3547, Persiaran Apec,
63000 Cyberjaya, Selangor
Malaysia.

Ref : (76) MDA.600-1/6/27
Date : 19 November 2021

SPD Scientific (M) Sdn Bhd
F-G-45, Block F, Jalan PJU 1A/3
Taipan 2 Damansara, Ara Damansara
47301 Petaling Jaya, Selangor Darul Ehsan
(Attention to: Hor Zian Khang)

Dear Sir/Madam,

CONDITIONAL APPROVAL FOR IMPORTATION AND DISTRIBUTION OF MEDICAL DEVICE (COVID-19 SELF TEST KIT)

With reference to the above, I wish to inform that the Authority grants your establishment a conditional approval for the importation and distribution of medical device as listed in **Appendix 1**.

2. Please be informed that the validity of this conditional approval is from **19/11/2021** to **19/11/2022** and is subject to the following:

i) Your establishment shall ensure that the medical device under this conditional approval complies with safety and performance requirements as stipulated in Medical Device Act 2012 (Act 737);
ii) Your establishment shall adhere to the conditions as stipulated in **Appendix 2**.
iii) The use of COVID-19 self test kit shall be limited for screening purpose only and all test results need further confirmation using RT-PCR.

3. This conditional approval for importation and distribution of this medical device is an interim measure in response to the current public health need during COVID-19 pandemic. This letter shall not be used for the purpose of promoting or advertising of the product and it does not exempt you from abiding to any laws or requirements by any other authorities of Malaysia.

Thank you,

(AHMAD SHARIFF BIN HAMBALI)
Chief Executive
Medical Device Authority
Ministry of Health Malaysia

Ref : (76) MDA.600-1/6/27
Date : 19 November 2021

Appendix 1

Medical Device Details

Name of Medical Device	:	Green Spring SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)
Brand/Model	:	Green Spring
Identifier	:	GF102B1S
Sample type	:	Nasal swab
Intended Use	:	It is used to qualitatively detect SARS-CoV-2 nucleocapsid protein antigen in human nasal swab specimen. It is meant for self-testing in home
Brief Description	:	The Green Spring® SARS-CoV-2 Antigen Rapid Test is a qualitative, membrane based immunoassay for the detection of SARS-CoV-2 nucleocapsid protein antigens. The test line region is coated with SARS-CoV-2 antibody. The sample reacts with the SARS-CoV-2 antibody in the test line region. If the specimen contains SARS-CoV-2 antigens, a colored line appears in the test line region as a relevant result. As a procedural control, a colored line appears in the control line area indicating that the correct volume of sample has been added and membrane wetting has occurred correctly. Result can be read in 15-20 minutes.
Lot Number	:	20210401
Manufacturer's name	:	Shenzhen Lvshiyuan Biotechnology Co., Ltd.P.R.China

MEDICAL DEVICE AUTHORITY
MINISTRY OF HEALTH

Appendix 2

Conditions:

1) The conditional approval for importation and distribution of the medical device listed in Appendix 1 is valid for one year.

2) An establishment given the conditional approval shall—

   i) collect data related to safety and performance of the medical device and shall submit the report to the Authority on a regular basis or when it is required by the Authority;

   ii) submit any information requested by the Authority within the prescribed period;

   iii) comply with any directions issued by the Authority from time to time;

   iv) comply with labelling requirements stipulated in Sixth Schedule of the Medical Device Regulations 2012, in particular instruction for use and disposal method, including using infographic, to make it easily understood by lay persons;

   v) provide suitable and adequate storage to ensure proper conservation of the medical device in accordance with the manufacturer's instruction;

   vi) perform inspection on the primary packages of the medical device and any breached packages shall be disposed off appropriately;

   vii) distribute the medical device only to licensed community pharmacies and healthcare institutions and they may sell the medical device online subject to appropriate distribution method specified by the manufacturer;

   viii) establish adequate precautions and control to prevent deterioration or damage of the medical devices up until the point of use;

   ix) ensure the delivery of medical devices adhere to the conditions specified by the manufacturer;

   x) provide documentation of all medical devices supplied to customers, the quantity supplied, the batch or lot number and/or model and serial number;

   xi) establish and maintain an appropriate distribution records up to retail distribution of the medical device to the end-user;

   xii) keep the record of delivery transactions as the proof of supply of the medical device to customers;

   xiii) dispose off medical device in accordance with regulatory requirements and any other applicable statutory requirements; and

   xiv) not carry out any secondary assembly activities on the medical device unless the manufacturers instruction states otherwise;

3) All information pertaining to this medical device including all supporting documents shall be kept at the premises and shall be made available upon request by the Authority.

4) An establishment shall establish and maintain a post-market surveillance system to monitor the traceability of the medical device throughout the supply chain.

5) The Authority reserves the right to make a visit or inspection to the establishment at any time without prior notice.

6) The Authority may revoke the conditional approval or may take legal action should the establishment fails to comply with any conditions imposed by the Authority.

7) An establismhent shall inform MDA on the new lot number of the same batch, in order to issue a new evaluation letter.

MEDICAL DEVICE AUTHORITY
MINISTRY OF HEALTH

海关备案 Customs record

中华人民共和国海关

出/入境特殊物品卫生检疫审批单

审批单号：深准202200003

申请单位			
单位性质	生产,销售		
单位名称	深圳市绿诗源生物技术有限公司	组织机构代码	757626435
单位地址	深圳市大鹏新区滨海二路国家海洋生物 产业园D栋	联系人	
E-mail		联系电话	
特殊物品信息			
出/入境方式	出境	发货人	深圳市绿诗源生物技术有限公司
运输存储条件	常温	运输方式	货运
特殊物品监管级别	D级	是否后续监管	否
查验拆检注意事项			
审批意见及检疫要求			
审批意见：	符合特殊物品卫生检疫行政许可要求		
检疫要求：	（一）检查出入境特殊物品名称、成分、批号、规格、数量、有效期、运输存储条件、输出/输入 国和生产厂家等项目是否与《特殊物品审批单》的内容相符。 （二）检查出入境特殊物品包装是否安全无破损、不渗、 不漏，存在生物安全风险的是否具有符合相关要求的生物危险品标识。		
审批有效期：	2022年01月05日-2023年01月05日		
签发时间：2022年01月05日		审批机构(盖章)：中国海关	
备注：			

审批单流水号：260200002022000051

审批单号：深准202200003

出/入境特殊物品卫生检疫审批单（附表）													
中文名称	英文名称	使用单位/生产商	使用地址	物品类别	物品种类	数量	重量	生产厂家	原产国	规格	成份列表	用途	是否分批核销
新型冠状病毒抗原检测试剂盒	SARS-CoV-2 Antigen Rapid Test Kit	深圳市绿诗源生物技术有限公司	深圳市大鹏新区滨海二路国家海洋生物 产业园D栋	生物制品	诊断试剂	无限量	无限量	深圳市绿诗源生物技术有限公司	中国	1人份/盒、5人份/盒、10人份/盒、15人份/盒、20人份/盒、25人份/盒、30人份/盒、40人份/盒、50人份/盒	抗原检测卡、干燥剂、采样拭子、滴管（内含缓冲液）、说明书	采用胶体金法，本产品适用于体外定性检测人鼻腔拭子样本中新型冠状病毒，用于辅助新型冠状病毒的诊断。	是

CE 认证 CE certification

Obelis SA
EUROPEAN AUTHORIZED REPRESENTATIVE CENTER

EUROPEAN RESPONSIBLE PERSON CENTER
Obelis
SINCE 1988

CERTIFICATE OF IVD NOTIFICATION

Ref. No.: BS 0171-2020
Order No.: OG 0117-2020

BELGIUM

Date: 19/11/2020

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 18/11/2020 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 19/11/2020, 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 Authorities or upon termination of the EAR agreement.

CE

Order No.: OG 0117-2020
Ref No.: BS 0171-2020

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	GF102B1	SARS-CoV-2 Antigen Rapid Test Kit	SARS-CoV-2 (COVID-19) Antigen Rapid Test Kit (Colloidal Gold)	SARS-CoV-2 (Covid-19) Antigen Rapid Test Kit is used to quanlitatively detect antigen of the novel coronavirus in nasal swab.	15.04.80.19	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

航空运输条件鉴定报告 Air transport conditions appraisal report

中国认可
检验
INSPECTION
CNAS IB0078

非限制性货物
NOT RESTRICTED

航 空 运 输 条 件 鉴 别 报 告 书

Identification and Classification Report for Air Transport of Goods

此报告本年度有效
有效期至2022年12月31日

报告编号：
Issued No.: PEKSZ2021123076 84ZP170002

生效日期：
Effective Date: 2022.01.01

委托单位：深圳市绿诗源生物技术有限公司
Applicant: Shenzhen Lvshiyuan Biotechnology Co.,Ltd.

物品名称：新型冠状病毒抗原检测试剂盒（胶体金法）
Name of Goods: SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)

北京迪捷姆空运技术开发有限公司
Beijing DGM Air Transport Technology Development Co.,Ltd.

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中科检测 ZHONGKE TESTING

深圳市绿诗源生物技术有限公司

Shenzhen Lvshiyuan Biotechnology Co., Ltd

依据联合国 GHS 制度第八修订版编/According to UN GHS (the 8th revised edition)

材料安全数据表

Material Safety Data Sheet

产品名称：	新型冠状病毒抗原检测试剂盒（胶体金法）
Product Name：	SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)

编制/Written by：Linda (Linda)　审核/Inspected by：Jose (Jose)　批准/Approved by：(Greally)

中科检测认证服务（深圳）有限公司 检测专用章 ZHONGKE SERVICES OF TESTING (SHENZHEN) CO., LTD. TESTING SERVICES NO.L1979

发布：中科检测认证服务（深圳）有限公司

ISSUED BY: ZHONGKE SERVICES OF TESTING (SHENZHEN) CO., LTD.

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