Care for love Focus on health

新冠试剂资质目录

SARS-CoV-2 diagnostic kits qualification catalogue

序号 Serial number	证书 Certificate
Part Ⅰ：公司资质 Company Certificate	
1	营业执照 Business license
2	医疗器械经营许可证 Medical device business license
3	医疗器械生产许可证 Medical device production license
4	海关报关单位注册登记证书 Registration certificate of customs declaration unit
5	一类医疗器械生产备案凭证 Medical device production license of class Ⅰ
6	核酸提取纯化试剂盒出口销售证明 CERTIFICATE FOR EXPORTATION OF DNA/RNA Extraction Kit
7	核酸提取纯化试剂盒出口销售证明 CERTIFICATE FOR EXPORTATION OF Nucleic acid extraction kit(magnetic beads method)
8	对外贸易经营备案登记表 Registration Form for Foreign Trade Management Record
9	ISO13485 体系证书 ISO13485 Certificate
10	一次性使用病毒采样管备案信息表（胍盐灭活） Record information form of disposable virus sampling tube (guanidine salt inactivation)
11	一次性使用病毒采样管备案信息表（表面活性剂灭活） Record information form of disposable virus sampling tube (surfactant inactivation)
Part Ⅱ：EC 符合性声明及 CE 证书 EC Declaration of Conformity and CE Certificate	
1	新冠抗原检测卡自我声明（自测版） EC Declaration of Conformity of SARS-CoV-2 Antigen Rapid Test (Self-test)

2	新冠抗原检测卡自我声明（专业版） EC Declaration of Conformity of SARS-CoV-2 Antigen Rapid Test (Professional use)
3	新冠抗原检测系统自我声明 EC Declaration of Conformity of System Device for SARS-CoV-2 Antigen Rapid Test
4	新冠 PCR 自我声明 EC Declaration of Conformity of SARS-CoV-2 PCR Test
5	新冠/流感 A/流感 B 三联抗原检测系统自我声明 EC Declaration of Conformity of System Device for SARS-CoV-2/Influenza A/ Influenza B Combo antigen Rapid Test
6	新冠抗体自我声明 EC Declaration of Conformity of SARS-CoV-2 IgM/IgG Antibody Rapid Test
7	新冠/流感 A/流感 B 三联核酸检测系统自我声明 EC Declaration of Conformity of SARS-CoV-2/Influenza A/ Influenza B PCR test
8	CE 证书 CE Certificate
9	CE 证书(新冠抗原笔、新冠/流感 A/流感 B 抗原三联检测卡、新冠/流感 A/流感 B 核酸三联检测试剂) CE Certificate (System Device for SARS-CoV-2 Antigen Rapid Test, System Device for SARS-CoV-2/Influenza A/ Influenza B Combo antigen Rapid Test, SARS-CoV-2/Influenza A/ Influenza B PCR test)
Part Ⅲ：新冠抗原试剂在各个国家所获证书汇总 List of SARS-CoV-2 Antigen Rapid Test Certificate in other countries	
1	新冠抗原自测版意大利白名单 Italian white list of SARS-CoV-2 antigen (Self-test)
2	新冠抗原专业版意大利白名单 Italian white list of SARS-CoV-2 antigen (Professional use)
3	新冠、消化道及生殖道产品意大利卫生部注册备案 SARS-CoV-2, digestive tract and reproductive tract tests are registered by the Italian Ministry of Health

4	新冠抗原检测笔获新加坡 HSA 认证 System Device for SARS-CoV-2 antigen test was certified by Singapore HSA
5	新冠抗原检测卡获马来西亚 MDA 认证 SARS-CoV-2 antigen test was certified by Malaysia MDA
6	新冠抗原取得印尼 FDA 注册证 SARS-CoV-2 antigen was certified by Indonesian FDA
7	新冠抗原荣获危地马拉注册证 SARS-CoV-2 antigen test was certified by Guatemalan FDA
8	新冠抗原获阿根廷 ANMAT 认证 SARS-CoV-2 antigen test was certified by Argentine ANMAT
9	新冠抗原菲律宾 FDA 认证 SARS-CoV-2 antigen test was certified by Philippine FDA
10	新冠抗原检测笔荣获印尼 FDA 注册证 System Device for SARS-CoV-2 antigen test was certified by Indonesian FDA
11	新冠/流感 A/流感 B 抗原三联检测笔获德国 FDA 注册备案 System Device for SARS-CoV-2/Influenza A/ Influenza B Combo antigen Rapid Test was registered by German FDA
12	新冠/流感 A/流感 B 抗原三联检测笔获意大利卫生部注册备案 System Device for SARS-CoV-2/Influenza A/ Influenza B Combo antigen Rapid Test was registered by the Italian Ministry of Health
13	新冠抗原笔巴西 ANVISA 认证 System Device for SARS-CoV-2 antigen test was registered by Brazil ANVISA
14	新冠抗原试剂通过英国 DHSC 认证 SARS-CoV-2 antigen test got DHSC certification in UK
15	新冠抗原试剂通过新加坡 HSA 认证 SARS-CoV-2 antigen test was certified by Singapore HSA

16	新冠抗原试剂获孟加拉国进口许可证 SARS-CoV-2 antigen test has obtained import license from Bangladesh
17	新冠抗原试剂获南非注册证 SARS-CoV-2 antigen test obtained South Africa registration certificate
18	新冠抗原试剂获马来西亚自测证 SARS-CoV-2 antigen test self-test certificate from Malaysia MDA
19	新冠抗原笔获泰国 FDA 自测证（鼻拭子） SARS-CoV-2 antigen test pen obtained the self-test certificate of Thailand FDA (nasal swab)
20	新冠抗原笔获泰国 FDA 自测证（唾液） SARS-CoV-2 antigen test pen obtained the self-test certificate of Thailand FDA (saliva)
21	新冠抗原卡获泰国 FDA 自测证（鼻拭子） SARS-CoV-2 antigen test obtained the self-test certificate of Thailand FDA (nasal swab)
22	新冠抗原笔获泰国 FDA 自测证（唾液） SARS-CoV-2 antigen test obtained the self-test certificate of Thailand FDA (saliva)
23	新冠抗原试剂获文莱卫生部认证 SARS-CoV-2 antigen test has been certified by Ministry of Health, Brunei Darussalam.
24	新冠抗原试剂进入 FIND 评估清单 SARS-CoV-2 antigen test enters the FIND evaluation list
25	新冠抗原试剂进入欧盟卫生和食品安全总局通用清单 SARS-CoV-2 antigen test enters the common list of EUROPEAN COMMISSION DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Part Ⅳ：新冠 PCR 试剂在各个国家所获证书汇总 List of SARS-CoV-2 PCR Test Certificate in other countries	
1	新冠 PCR 获新加坡 HSA 认证 SARS-CoV-2 PCR was certified by Singapore HSA
2	新冠 PCR 取得印尼 FDA 注册证 SARS-CoV-2 PCR was certified by Indonesian FDA
3	新冠 PCR 荣获厄瓜多尔认证 SARS-CoV-2 PCR was certified by Ecuadorian FDA
4	新冠抗体、PCR 获巴西 ANVISA 认证 SARS-CoV-2 IgM/IgG antibody test and PCR were registered by Brazil ANVISA
5	核酸提取试剂获印尼 FDA 注册 The nucleic acid extraction reagent was registered by Indonesia FDA
6	新冠 PCR 巴西 ANVISA 认证 SARS-CoV-2 PCR was registered by Brazil ANVISA
Part Ⅴ：新冠抗体试剂在各个国家所获证书汇总 List of SARS-CoV-2 IgM/IgG Antibody Rapid Test Certificate in other countries	
1	新冠抗体取得巴西 ANVISA 认证 SARS-CoV-2 IgM/IgG antibody test was registered by Brazil ANVISA
2	新冠抗体试剂获马来西亚 MDA 认证 SARS-CoV-2 IgM/IgG antibody test was registered by Malaysia MDA
Part Ⅵ：新冠试剂已取得的权威检测报告 Test Report for SARS-CoV-2 diagnostic kits from different lab	
1	新冠**抗原**试剂中检院报告 Test Report for SARS-CoV-2 antigen test from National Institute for Food and Drug Control
2	新冠**抗原**试剂英国卫生部三期临床报告 Validation outcome for SARS-CoV-2 antigen test in phase 3A conduct by DHSC in UK

3	新冠**抗原**试剂印尼 CDC 检测报告 Test Report for SARS-CoV-2 antigen test from Indonesian CDC
4	Consuleote Scientifico Futura Diagnostica 评估黎明 SARS-CoV-2 **抗原**试剂非常适合对疑似 SARS-CoV-2 感染进行初步筛选 Consuleote Scientifico Futura Diagnostica Assessment Strongstep® Sars-COV-2 antigen reagent is ideal for preliminary screening of suspected SARS-COV-2 infection
5	新冠**抗原**试剂（卡和笔）经泰国 FDA 指定研究机构评估，性能优异，特异性 100%，敏感性 95%以上 Sars-CoV-2 antigen reagent has been evaluated by the research institution designated by the FDA of Thailand, with excellent performance, 100% specificity and more than 95% sensitivity
6	新冠**抗原**自测试剂经马来西亚大学评估，性能优异 Sars-CoV-2 antigen self-test reagent has been evaluated by the University of Malaysia and has excellent performance
7	新冠**抗原**卡通过德国联邦疫苗和生物医学研究所评估验收 Sars-CoV-2 antigen self-test reagent has been evaluated and accepted by Paul-Ehrlich-Institut
8	新冠**抗原**卡通过意大利实验室评估，特异性 100%，敏感度 90% Sars-CoV-2 antigen self-test reagent was evaluated by Italian laboratory, with specificity of 100% and sensitivity of 90%

9	新冠 PCR 中检院报告 Test Report for SARS-CoV-2 PCR from National Institute for Food and Drug Control
10	巴西圣埃斯皮里托联邦大学对黎明新冠 PCR 性能评估报告 Evaluation report on performance of Strongstep® SARS-CoV-2 PCR by Espirito Santo State University
11	马德里赫塔菲大学医院对黎明新冠 PCR 评估灵敏度 98.77%，特异性 98.13 The sensitivity and specificity of evaluation of Strongstep® SARS-CoV-2 PCR in Servicio de Microbiologia. Hospital Universitario de Getafe,Madrid.Marzo were 98.77% and 98.13%, respectively
12	黎明新冠 PCR 试剂印尼 CDC 评估报告，**敏感性和特异性均为 100%** The sensitivity and specificity of Strongstep® SARS-CoV-2 PCR from Indonesia CDC evaluation report were 100%
13	黎明新冠**抗体**性能评估发表于欧洲临床微生物学与传染病杂志 Strongstep® SARS-CoV-2 antibody performance evaluation was published in European Journal of Clinical Microbiology & Infectious Diseases
14	黎明新冠**抗体**性能评估发表于国际传染病杂志 Strongstep® SARS-CoV-2 antibody performance evaluation was published in lnternational Journal of Infectious Diseases

编号 320102000201907180048
No. 320102000201907180048

统一社会信用代码

9132010272837745XD

Uniform Social Credit Code
9132010272837745XD

营业执照

Operation License

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　南京黎明生物制品有限公司
Company name Nanjing Liming Bio-products Co.,Ltd.

类　　型　有限责任公司
Type Limited liability company

法定代表人　张树文
Legal representative Zhang Shuwen

经营范围
Business scope

I类医疗器械、II类医疗器械（须取得许可或批准后方可经营）、III类临床检验分析仪器、体外诊断试剂、医用激光仪器设备、医用高频仪器设备、医用超声仪器及有关设备、医用冷疗、低温、冷藏设备及器具销售；三类6840体外诊断试剂生产；自营和代理各类商品和技术的进出口（但国家限定公司经营或禁止进出口商品和技术除外）；医药技术服务、技术转让；房地产经纪。（依法须经批准的项目，经相关部门批准后方可开展经营活动）

Medical device belonging to classification 1 and 2
Sales of clinical analysis equipment, IVD, medical lasers, medical high-frequency equipment, medical ultrasonic equipment, medical cold therapy ' low-temperature ' refrigerated devices belonging to classification 3
Manufacturing of 6840 IVDs belonging to classification 3
Sales and distribution of importing&exporting of commodities and techniques
Medical technique service, technqiue transfer
Real estate sales
Other business authorized by offical relative depts.

注册资本　1000万元整
Registered capital RMB10,000,000.00

成立日期　2001年06月27日
Establised dated on 27th, June 2001

营业期限　2001年06月27日至******
Business validity Unlimited duration starting from 27th,June 2001

住　　所　玄武区蒋王庙116-1号
Registered location No.116-1 Jiangwangmiao, Xuanwu District, Nanjing

登记机关
Registered office

南京市玄武区市场监督管理局

2019年07月18日
Date: 18th, July 2019

SEAL: MARKETING INSPECTION ADMINISTRATION OF XUANWU DISTRICT, NANJING

NMPA

医疗器械经营许可证

Medical device Business License

许可证编号：苏宁食药监械经营许20150433号
License No.: No. 20150433 Suning Food and Drug Supervision and Equipment Management Permit

企业名称：南京黎明生物制品有限公司
Company name:Nanjing Liming Bio-products Co., LTD

法定代表人：张树文
Legal representative:Zhang Shuwen

经营方式：批发
Business mode: Wholesale

企业负责人：张树文
Head of enterprise: Zhang Shuwen

住　　所：南京市玄武区蒋王庙街116-1号
Registered location: No.116-1, Jiangwangmiao Street, Xuanwu District, Nanjing

经营范围：2002 edition wholesale:6823, 6824, 6825, 6840 IVD(low-temperature transportation), 6857, 6858, 6870***
Business scope: 2002版批发：6823，6824，6825，6840（诊断试剂需低温冷藏运输贮存），6857，6858，6870***
2017 edition wholesale: 01, 06, 07, 08, 09, 11, 16 (Excluding instrument, No plastic contact lens), 17(Excluding instrument), 18(Excluding instrument), 21, 22, 6840 IVD(low-temperature transportation)
2017版批发：01，06，07，08，09，11，16（不含植入类非硬，不含整形角膜接触镜），17（不含植入类非械），18（不含植入类器械），21，22，6840体外诊断试剂需低温冷藏运输贮存***

经营场所：南京市玄武区花园路12号七楼
Business location:7/F, No.12 Huayuan Road, Xuanwu District, Nanjing

库房地址：南京市玄武区花园路12号四楼（400-407）
Warehouse address: Floor 4, No.12, Huayuan Road, Xuanwu District, Nanjing (400-407)

发证部门：南京市市场监督管理局
License issuing department: Provincial Administration of Nanjing Market

有效期限：至 2024 年 09 月 28 日
Term of validity:Unil September 28, 2024

发证日期：2021 年 07 月 21 日
Date of issue: July 21, 2021

国家药品监督管理局制

1903792

医疗器械生产许可证

Medical device Production License

许可证编号：苏食药监械生产许 20010489 号

License No. : Su Food Pharmaceutical Supervisory apparatus Production permit 20010489

企业名称：南京黎明生物制品有限公司

Company name: Nanjing Liming Bio-products Co., LTD

生产地址：南京市玄武区花园路 12 号

Production Address: No.12, Huayuan Road, Xuanwu District, Nanjing

法定代表人：张树文

Legal representative: Zhang Shuwen

企业负责人：张树文

Head of enterprise: Zhang Shuwen

住　　所：南京市玄武区蒋王庙街 116-1 号

Registered location: No. 116-1, Jiangwangmiao Street, Xuanwu District, Nanjing

生产范围：见产品登记表

Scope of production: see registration form of medical device production

发证部门：江苏省药品监督管理局

License issuing department: Jiangsu Drug Administration

有效期限：至　2025　年　09　月　13　日

Term of validity: until September 13, 2025

发证日期：2021　年　01　月　04　日

Date of issue: January 4, 2021

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：3201961424

组织机构代码：72837745X

企业名称：南京黎明生物制品有限公司

企业住所：南京玄武区蒋王庙 116-1 号

企业经营类别：进出口货物收发货人

注册登记日期：2012 年 9 月 19 日

法定代表人：张树文

有效期：长期

注册海关：金陵海关

核发日期：2015 年 9 月 17 日

中华人民共和国金陵海关 注册备案专用章（2）

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。

中华人民共和国海关总署监制

江苏省第一类医疗器械生产备案凭证

备案号：苏宁食药监械生产备20170006号

企业名称	南京黎明生物制品有限公司		
住 所	南京市玄武区蒋王庙116-1号		
生产场所	南京市玄武区花园路12号一楼一层		
法定代表人	张树文	企业负责人	张树文
邮编	210042	联系电话	025-85288526
生产范围	I类：6840 体外诊断试剂***		

生产产品列表	产品名称	产品备案号	是否受托生产	备注
	真菌荧光染色液（一步法）	苏宁械备20170041号	否	/
	寄生虫及真菌荧光染色液	苏宁械备20180007号	否	/
	毛囊虫荧光染色液（一步法）	苏宁械备20180011号	否	/
	Papilloma Virus L1检测试剂盒（免疫组织化学）	苏宁械备20190023号	否	/
	p16/Ki-67检测试剂盒（免疫细胞化学法）	苏宁械备20190046号	否	/
	真菌D-葡聚糖检测荧光染色液	苏宁械备20190135号	否	/
	运送培养基	苏宁械备20200123号	否	/
	核酸提取纯化试剂	苏宁械备20200168号	否	/
	核酸提取纯化试剂盒	苏宁械备20210039号	否	/
	汉重荧光染色液	苏宁械备20210041号	否	/

变更备案记录	2020年9月23日，增加生产产品：核酸提取纯化试剂（备案号：苏宁械备20200168号） 2021年5月7日，增加生产产品：核酸提取纯化试剂盒（备案号：苏

	宁械备20210039号）、双重荧光染色液（备案号：苏宁械备20210041号）

备案部门（公章）

2021年05月07日

中华人民共和国
PEOPLE'S REPUBLIC OF CHINA
医疗器械产品出口销售证明
CERTIFICATE FOR EXPORTATION OF MEDICAL PRODUCTS

证书编号： 苏宁药监械出 20212373 号
Certificate NO.: SNYJXC20212373

产品名称： 见附件；
Product(s): See Attachment

规格型号： 见附件；
Model: See Attachment;

产品注册或备案凭证号： 见附件；
Registration certificate(s): See Attachment;

生产企业： 南京黎明生物制品有限公司
Manufacturer: Nanjing Liming Bio-Products Co., Ltd.

生产企业住所： 南京市玄武区蒋王庙街 116-1 号
Address of manufacturer: 116-1 jiangwangmiao street, Xuanwu District, Nanjing

生产许可或备案凭证号： 苏宁食药监械生产备 20170006 号
Manufacturing License(s): NO.SNSYJXSCB20170006

兹证明上述产品已准许在中国生产和销售。
This is to certify that the above products have been registered to be manufactured and sold in China.

证明有效日期至： 2023 年 08 月 23 日
This certification valid until: 2023-08-23

备注： /
Remark: /

江苏省药品监督管理局
2021 年 08 月 23 日

附件：

证书编号：苏宁药监械出 20212373 号

Certificate NO.: SNYJXC20212373

序号 NO	产品名称（中文）Product(s)（chinese）	产品名称（英文）Product(s)	规格型号（中文）Specification/model（chinese）	规格型号（英文）Specification/mode	产品注册证或备案凭证号(中文) Registration certificate(s)	产品注册证或备案凭证号(英文) Registration certificate(s)
1	核酸提取纯化试剂盒	DNA/RNA Extraction Kit	见附件（苏宁械备 20210039 号）	See Attachment（NO.SNXB20210039）	苏宁械备 20210039 号	NO.SNXB20210039

中华人民共和国
PEOPLE'S REPUBLIC OF CHINA
医疗器械产品出口销售证明
CERTIFICATE FOR EXPORTATION OF MEDICAL PRODUCTS

证书编号： 苏宁药监械出 20212520 号
Certificate NO.: SNYJXC20212520

产品名称： 见附件;
Product(s): See Attachment

规格型号： 见附件;
Model: See Attachment;

产品注册或备案凭证号： 见附件;
Registration certificate(s): See Attachment;

生产企业： 南京黎明生物制品有限公司
Manufacturer: Nanjing Liming Bio-Products Co., Ltd.

生产企业住所： 南京市玄武区蒋王庙街 116-1 号
Address of manufacturer: 116-1 Jiangwangmiao street, Xuanwu District, Nanjing

生产许可或备案凭证号： 苏宁食药监械生产备 20170006 号
Manufacturing License(s): NO.SNSYJXSCB20170006

兹证明上述产品已准许在中国生产和销售。
This is to certify that the above products have been registered to be manufactured and sold in China.

证明有效日期至： 2023 年 09 月 02 日
This certification valid until: 2023-09-02

备注： /
Remark: /

江苏省药品监督管理局
2021 年 09 月 02 日

附件：

证书编号：苏宁药监械出 20212520 号

Certificate NO.: SNYJXC20212520

序号 NO	产品名称（中文）Product(s)（chinese）	产品名称（英文）Product(s)	规格型号（中文）Specification/model（chinese）	规格型号（英文）Specification/mode	产品注册证或备案凭证号(中文) Registration certificate(s)	产品注册证或备案凭证号(英文) Registration certificate(s)
1	核酸提取纯化试剂盒	Nucleic acid extraction kit(magnetic beads method)	见附件（苏宁械备 20210039 号）	See Attachment（NO.SNXB20210039）	苏宁械备 20210039 号	NO.SNXB20210039

对外贸易经营者备案登记表

备案登记表编号：02780352　　统一社会信用代码：91320102728377745XD
进出口企业代码：

经营者中文名称	南京黎明生物制品有限公司		
经营者英文名称	NANJING LIMING BIO-PRODUCTS CO.,LTD.		
组织机构代码		经营者类型（由备案登记机关填写）	私营企业
住　所	南京市玄武区蒋王庙街116-1号		
经营场所（中文）	南京市玄武区蒋王庙街116-1号		
经营场所（英文）	116-1 JIANGWANGMIAO STREET ,XUANWU DISTRICT NANJING		
联系电话	02585476723	联系传真	02585476387
邮政编码	210042	电子邮箱	INFO@LIMINGBIO.COM
工商登记注册日期	2001-6-27	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	张树文	有效证件号	510702196612229358
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

2017　年09　月04　日

ISO13485认证证书

TÜVRheinland

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

Nanjing Liming Bio-products Co., Ltd.
No12 Huayuan Road
210042 Nanjing, Jiangsu
China

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

Design and Development, Manufacture and Distribution of In Vitro Immunochromatographic Diagnostic Reagents Kits for Infectious Diseases and Fertility

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

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

Effective Date:	2019-08-02
Certificate Registration No.:	SX 60135624 0001
An audit was performed. Report No.:	15047001 008
This Certificate is valid until:	2022-02-01

Certification Body

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

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Date 2019-08-02

Fuxiu Sheng

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

第一类医疗器械备案信息表

备案号：苏宁械备20210164号

备案人名称	南京黎明生物制品有限公司
备案人组织机构代码	91320102728377 45XD
备案人注册地址	南京市玄武区蒋王庙116-1号
生产地址	南京市玄武区花园路12号一楼一层
产品名称	一次性使用病毒采样管
型号/规格	1mL/支：20支/盒（含20对拭子）、50支/盒（含50对拭子）、100支/盒（含100对拭子）；2mL/支：20支/盒（含20对拭子）、50支/盒（含50对拭子）、100支/盒（含100对拭子）；3mL/支：20支/盒（含20对拭子）、50支/盒（含50对拭子）、100支/盒（含100对拭子）；5mL/支：20支/盒（含200支拭子）；6mL/支：20支/盒（含200支拭子）。
产品描述	本产品由拭子、保存管（含保存液）组成，非无菌提供。保存液主要成分：Tris-HCL缓冲液，月桂酰肌氨酸钠、NP-40，EDTA-2Na，TritonX-100，酚红，纯化水；
预期用途	用于临床样本的采集、转运和保存。
备注	
备案单位和日期	南京市市场监督管理局 2021年11月7日
变更情况	

第一类医疗器械备案信息表

备案号：苏宁械备20210166号

备案人名称	南京黎明生物制品有限公司
备案人组织机构代码	9132010272837745XD
备案人注册地址	南京市玄武区蒋王庙116-1号
生产地址	南京市玄武区花园路12号一楼一层
产品名称	一次性使用病毒采样管
型号/规格	1mL/支：20支/盒（含20对拭子）、50支/盒（含50对拭子）、100支/盒（含100对拭子）；2mL/支：20支/盒（含20对拭子）、50支/盒（含50对拭子）、100支/盒（含100对拭子）；3mL/支：20支/盒（含20对拭子）、50支/盒（含50对拭子）、100支/盒（含100对拭子）；5mL/支：20支/盒（含200支拭子）；6mL/支：20支/盒（含200支拭子）。
产品描述	本产品由拭子、保存管（含保存液）组成，非无菌提供。保存液主要成分：Tris-HCL缓冲液，异硫氰酸胍，NaCl，EDTA-2Na，TritonX-100，酚红，纯化水；
预期用途	用于临床样本的采集、转运和保存。
备注	
备案单位和日期	南京市市场监督管理局 2021年11月23日
变更情况	

CE

EC Declaration of Conformity

according to the Directive 98/79/EC
(applicable to **self-testing** *IVD* Devices only)

新冠抗原检测卡自我声明（自测版）

Manufacturer: Nanjing Liming Bio-Products Co., Ltd.
Address: No. 12, Huayuan Road, Nanjing, Jiangshu, 210042. P.R. China
*Products:*Strongstep®SARS-CoV-2 Antigen Rapid Test(Cat.No.500200)
Model: 1Test/box、2Tests/box、3Tests/box、4Tests/box、5Tests/box、7Tests/box、10Tests/box、15Tests/box、20Tests/box、25 Tests/box

Category: **Self-testing**
Conformity assessment route: **Annex III(6), of Directive** (98/79/EC on IVDD)
Applicable Standards:

EN ISO 18113-1:2011	EN ISO 18113-2:2011	EN 13612:2002
EN ISO 23640:2015	EN 13641:2002	EN ISO 14971:2019
EN ISO 15223-1:2016	EN ISO 13485:2016	EN 13975:2003
EN 62366:2015		

We, the Manufacturer, herewith declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In-Vitro Diagnostic Medical Devices.

We hereby explicitly appoint Wellkang Ltd t/a Wellkang Tech Consulting located at Enterprise Hub,NW Business Comples,1 Beraghmore,Rd.Derry,BT48 8SE,N. Ireland,UK to act as our European Authorised Representative as defined in the aforementioned Directive.

Signed on 06 /(Day) 05 /(Month) of 2021. Place: Nanjing

Represented by: Zhang Shuwen

Signature (on behalf of the manufacturer): Zhang Shuwen

Full Name of authorized signatory: Zhang Shuwen
Position held in the company: President

Company Seal/Stamp:

CE

EC Declaration of Conformity

according to the Directive 98/79/EC
(applicable to **Others/General** *IVD* Devices only)

新冠抗原检测卡自我声明（专业版）

Manufacturer: Nanjing Liming Bio-Products Co., Ltd.
Address: No. 12, Huayuan Road, Nanjing, Jiangshu, 210042. P.R. China
*Products:*Strongstep®SARS-CoV-2 Antigen Rapid Test(Cat.No.500200)
Model: 1Test/box、2Tests/box、3Tests/box、4Tests/box、5Tests/box、7Tests/box、10Tests/box、15Tests/box、20Tests/box、25 Tests/box

Category: **Others/General**
Conformity assessment route: **Annex III, except point 6, of Directive (**Module **A)**
Applicable Standards:

EN ISO 18113-1:2011	EN ISO 18113-2:2011	EN 13612:2002
EN ISO 23640:2015	EN 13641:2002	EN ISO 14971:2019
EN ISO 15223-1:2016	EN ISO 13485:2016	EN 13975:2003

We, the Manufacturer, herewith declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In-Vitro Diagnostic Medical Devices.

We hereby explicitly appoint Wellkang Ltd t/a Wellkang Tech Consulting located at Enterprise Hub,NW Business Comples,1 Beraghmore,Rd.Derry,BT48 8SE,N. Ireland,UK to act as our European Authorised Representative as defined in the aforementioned Directive.

Signed on 06 /(Day) 05 /(Month) of 2021. Place: Nanjing

Represented by: Zhang Shuwen

Signature (on behalf of the manufacturer) Zhang Shuwen

Full Name of authorized signatory: Zhang Shuwen
Position held in the company: President

Company Seal/Stamp:

新冠抗原检测系统自我声明

CE

EC Declaration of Conformity

according to the Directive 98/79/EC
(applicable to **Others/General** *IVD* Devices only)

Manufacturer: Company Name: Nanjing Liming Bio-Products Co., Ltd.
Address: No. 12, Huayuan Road, Nanjing, Jiangsu, 210042. P.R. China

Product/s: StrongStep® System Device for SARS-CoV-2 Antigen Rapid Test (Cat. No. 500210)
Model: 20 Tests/Box

Category: **Others/General**
Conformity assessment route: **Annex III, except point 6, of Directive** (Module **A**)

Applicable Standards:

EN ISO 18113-1:2011	EN ISO18113-2:2011	EN 13612:2002
EN ISO 23640:2015	EN 13641:2002	EN ISO 14971:2012
EN ISO 15223-1:2016	EN ISO 13485:2016	EN 13975:2003

We, the Manufacturer, herewith declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In-Vitro Diagnostic Medical Devices.

We hereby explicitly appoint Wellkang Ltd t/a Wellkang Tech Consulting located at Enterprise Hub, NW Business Complex,1 Beraghmore Rd. Derry, BT48 8SE, N. Ireland,UK to act as our European Authorised Representative as defined in the aforementioned Directive.

Signed on 02/(Day) 11 /(Month) of 2020. Place: Nanjing

Represented by: Zhang Shuwen

Signature (on behalf of the manufacturer) Zhang shu wen

Full Name of authorized signatory: Zhang Shuwen
Position held in the company: President

Company Seal/Stamp:

新冠PCR自我声明

CE

EC Declaration of Conformity

according to the Directive 98/79/EC
(applicable to **Others/General** *IVD* Devices only)

Manufacturer: Company Name: Nanjing Liming Bio-Products Co., Ltd.
Address: No. 12, Huayuan Road, Nanjing, Jiangsu, 210042. P.R. China

Product's: StrongStep® Novel Coronavirus (SARS-CoV-2) Multiplex Real-Time PCR Kit）(detection for three genes) (Cat. No. 500190)
Model: 96 Tests/Box

Category: **Others/General**
Conformity assessment route: **Annex III, except point 6, of Directive** (Module **A**)

Applicable Standards:

EN ISO 18113-1:2011	EN ISO18113-2:2011	EN 13612:2002
EN ISO 23640:2015	EN 13641:2002	EN ISO 14971:2012
EN ISO 15223-1:2016	EN ISO 13485:2016	EN 13975:2003

We, the Manufacturer, herewith declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In-Vitro Diagnostic Medical Devices.

We hereby explicitly appoint Wellkang Ltd t/a Wellkang Tech Consulting located at Enterprise Hub, NW Business Complex,1 Beraghmore Rd. Derry, BT48 8SE, N. Ireland,UK to act as our European Authorised Representative as defined in the aforementioned Directive.

Signed on 07/(Day) 11 /(Month) of 2020. Place: Nanjing

Represented by: Zhang Shuwen

Signature (on behalf of the manufacturer) Zhang Shuwen

Full Name of authorized signatory: Zhang Shuwen
Position held in the company: President

Company Seal/Stamp:

新冠/流感A/流感B三联抗原检测系统自我声明

CE

EC Declaration of Conformity

according to the Directive 98/79/EC
(applicable to **Others/General** *IVD* Devices only)

Manufacturer: Company Name: Nanjing Liming Bio-Products Co., Ltd.
Address: No. 12, Huayuan Road, Nanjing, Jiangsu, 210042. P.R. China

Product's: StrongStep® System Device for SARS-CoV-2 & Influenza A/ B Combo Antigen Rapid Test (Cat. No. 500220)
Model: 20Tests/Box

Category: **Others/General**
Conformity assessment route: **Annex III, except point 6, of Directive** (Module **A**)

Applicable Standards:

EN ISO 18113-1:2011	EN ISO18113-2:2011	EN 13612:2002
EN ISO 23640:2015	EN 13641:2002	EN ISO 14971:2012
EN ISO 15223-1:2016	EN ISO 13485:2016	EN 13975:2003

We, the Manufacturer, herewith declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In-Vitro Diagnostic Medical Devices.

We hereby explicitly appoint Wellkang Ltd t/a Wellkang Tech Consulting located at Enterprise Hub, NW Business Complex,1 Beraghmore Rd. Derry, BT48 8SE, N. Ireland,UK to act as our European Authorised Representative as defined in the aforementioned Directive.

Signed on 07 /(Day) 11 /(Month) of 2020. Place: Nanjing

Represented by: Zhang Shuwen

Signature (on behalf of the manufacturer) Zhang Shuwen

Full Name of authorized signatory: Zhang Shuwen
Position held in the company: President

Company Seal/Stamp:

新冠抗体自我声明

CE

EC Declaration of Conformity

according to the Directive 98/79/EC
(applicable to **Others/General** *IVD* Devices only)

Manufacturer: Company Name: Nanjing Liming Bio-Products Co., Ltd.
Address: No. 12, Huayuan Road, Nanjing, Jiangsu, 210042. P.R. China

Product/s: StrongStep® SARS-CoV-2 IgM/IgG Antibody Rapid Test
(Cat. No. 502090)
Model: 20 Tests/Box

Category: **Others/General**
Conformity assessment route: **Annex III, except point 6, of Directive** (Module **A**)

Applicable Standards:

EN ISO 18113-1:2011	EN ISO18113-2:2011	EN 13612:2002
EN ISO 23640:2015	EN 13641:2002	EN ISO 14971:2012
EN ISO 15223-1:2016	EN ISO 13485:2016	EN 13975:2003

We, the Manufacturer, herewith declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In-Vitro Diagnostic Medical Devices.

We hereby explicitly appoint Wellkang Ltd t/a Wellkang Tech Consulting located at Enterprise Hub, NW Business Complex,1 Beraghmore Rd. Derry, BT48 8SE, N. Ireland,UK to act as our European Authorised Representative as defined in the aforementioned Directive.

Signed on 02 /(Day) 11 /(Month) of 2020. Place: Nanjing

Represented by: Zhang Shuwen

Signature (on behalf of the manufacturer) Zhang Shuwen

Full Name of authorized signatory: Zhang Shuwen
Position held in the company: President

Company Seal/Stamp:

新冠/流感A/流感B三联核酸检测系统自我声明

CE

EC Declaration of Conformity

according to the Directive 98/79/EC
(applicable to **Others/General** *IVD* Devices only)

Manufacturer: Company Name: Nanjing Liming Bio-Products Co., Ltd.
Address: No. 12, Huayuan Road, Nanjing, Jiangsu, 210042. P.R. China

Product/s: StrongStep® SARS-CoV-2 & Influenza A/B Multiplex Real-Time PCR Kit (Cat. No. 510010)
Model: 96 Tests/Box

Category: **Others/General**
Conformity assessment route: **Annex III, except point 6, of Directive** (Module **A**)

Applicable Standards:

EN ISO 18113-1:2011	EN ISO18113-2:2011	EN 13612:2002
EN ISO 23640:2015	EN 13641:2002	EN ISO 14971:2012
EN ISO 15223-1:2016	EN ISO 13485:2016	EN 13975:2003

We, the Manufacturer, herewith declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In-Vitro Diagnostic Medical Devices.

We hereby explicitly appoint Wellkang Ltd t/a Wellkang Tech Consulting located at Enterprise Hub, NW Business Complex,1 Beraghmore Rd. Derry, BT48 8SE, N. Ireland,UK to act as our European Authorised Representative as defined in the aforementioned Directive.

Signed on 07 /(Day) 11 /(Month) of 2020. Place: Nanjing

Represented by: Zhang Shuwen

Signature (on behalf of the manufacturer) Zhang shu wen

Full Name of authorized signatory: Zhang Shuwen
Position held in the company: President

Company Seal/Stamp:

Medicines & Healthcare products Regulatory Agency

MHRA

MHRA
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

Our Ref:IVD000560

Dr Edward Wang
Wellkang Ltd
16 Castle Street
Dover
Kent
CT16 1PW

20 March 2020

Dear Dr Wang

IN VITRO DIAGNOSTIC MEDICAL DEVICES REGULATIONS 2002: REGULATION 44
Registration of manufacturers of *In-Vitro Diagnostic* Medical Devices and devices for Performance Evaluation

Thank you for informing the Competent Authority of the change to the original notification dated (date the registration was registered); ***Manufacturers*** **Name:- Liming Bio-Products Co Ltd** located at **Manufacturers Address:- No.12 Huayuan Road Nanjing, Jiangsu, China 210042** for whom you are acting as the authorised representative and for supplying the medical device information.

The change(s) to your registration has been recorded based on your declaration that you have determined that the device(s) fall within the definition of "in vitro diagnostic medical device", and that you have classified it/them correctly taking into account the intended purpose(s) and mode(s) of action. In accepting your registration, I should make clear that the Competent Authority does not examine each individual notification and therefore cannot and does not necessarily endorse these determinations. Neither does this letter represent any form of accreditation or approval by the UK Competent Authority.

Your registration is based upon your declaration on the RG3 form and means that you should now be operating under the In Vitro Diagnostic Medical Devices Directive and the 2002 Regulations for the products you asked us to register, by fully complying with the essential requirements, CE marking those products or labelling them as such.

If you stop placing devices on the market or if you are not complying with the Regulations you should inform us as required by the Regulations. You should be aware that it is an offence to place on the market CE marked devices that do not comply with the Regulations.

The information you provided has been recorded against the reference number shown at the top of this letter, which we ask you to quote in all future correspondence and communications.

Please inform us of any changes to:

- the company information
- additional generic groups of devices or, for Annex II or Self-Test devices, additional devices
- discontinuation of a generic group of devices or, for Annex II or Self-Test devices, discontinuation of devices

Medicines & Healthcare products Regulatory Agency

MHRA

Please use RG3, the Registration form, to tell us about any of these changes. A ee of £70 is payable for each change or set of changes notified.

Thank you for registering the following generic groups of devices

1. ***Part 5: IVDs which are not Annex II and not self-test devices***
2.
3. ***For reagnets, reagent products, calibration and control materials:***
4. ***group by common technological characteristics and/or analytes***
5.
6. ***New products:***
7. ***None***
8.
9. ***For performance evaluation:***
10. ***None***
11.
12. ***Neither:***
13. ***HSV Antigen***
14. ***Gonococcal Antigen Detection***
15. ***Candida albicans***
16. ***Other Parasitology***
17. ***Other Bacteriology Rapid Tests***
18. ***Rotavirus***
19. ***Adenovirus***
20. ***Other Multiple Viruses***
21. ***H. Pylori Antibody Assays***
22. ***H. Pylori Antigen Detection***
23. ***Strep B - Rapid Test***
24. ***Human Papilloma Virus***
25. ***Strep A - Rapid Test***
26. ***Haemoglobin (Hb)***
27. ***Procalcitonin***
28. ***Salmonella Antigen Detection***
29. ***Salmonella Antibody Assays***
30. ***Legionella Antibody Assays***
31. ***Other Mycology Immunoassays***
32. ***Other Specific Proteins Rapid Tests***
33. ***Other Individual and Specified Hormones/Proteins RT & POC***
34. ***Coronavirus***
35. ***Coronavirus - NA Reagents***
36.
37.
38. ***For other IVDs, group by appropriate indications***
39.
40. ***New products:***
41. ***None***
42.
43. ***For performance evaluation:***
44. ***None***
45.
46. ***Neither:***
47. ***None***
48.
49.
50. ***Part 6: IVDs which are Annex II or self-test devices***
51.
52. ***For reagnets, reagent products, calibration and control materials:***

Medicines & Healthcare products Regulatory Agency

MHRA

53. group by common technological characteristics and/or analytes
54.
55. New products:
56. None
57.
58. For performance evaluation:
59. None
60.
61. Neither:
62. None
63.
64.
65. For other IVDs, group by appropriate indications
66.
67. New products:
68. None
69.
70. For performance evaluation:
71. None
72.
73. Neither:
74. None
75.

If you have any queries regarding your registration, please do not hesitate to contact us.

Yours sincerely

Malcolm Ridgway
Data Integrity Support Officer

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

Wellkang Ltd
Enterprise Hub, NW Business Complex
1 Beraghmore Road
Derry, Northern Ireland
BT48 8SE
United Kingdom

09 December 2020

Dear **Edward Wang**

We are pleased to confirm that the application to register or update an existing registration for the following manufacturer, which you submitted on **09 December 2020** has been reviewed:

Application reference: **2020120901188535**

Manufacturer organisation: **Nanjing Liming Bio-Products Co., Ltd.**
Address:
No.12, Huayuan Road,
Nanjing, Jiangsu
210042
China

Manufacturer registration status: **Registered**

Device(s):

CE 认证

GMDN term	Status	MHRA comment
64787 - SARS-CoV-2 antigen IVD, kit, immunochromatographic test (ICT), rapid	Registered	

(新冠抗原笔)

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 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 manufacturers and authorised representatives and their devices that have been registered will be published on our Public Access Registration Database (PARD). This applies to non-in vitro diagnostic devices only.

The account number for your company/organisation is **0000011119.**

Yours sincerely,

Ngozi Onyeukwu
Device registrations service
Devices division
MHRA

10/12/2020, 13:00

CE认证

(新冠/流感A/流感B核酸三联检测试剂)

Dear Edward Wang,

We are pleased to confirm that the application to register or update an existing registration for the following manufacturer, which you submitted on 10 December 2020 has been reviewed:

Application reference: 2020121001188589

Manufacturer organisation: Nanjing Liming Bio-Products Co., Ltd.
Address:
No.12, Huayuan Road,
Nanjing, Jiangsu
210042
China

Manufacturer registration status: Registered

Device(s):

GMDN term	Status	MHRA comment
47922 - Multiple respiratory virus nucleic acid IVD, kit, nucleic acid technique (NAT)	Registered	

Please note this email confirmation 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 CE marked devices that do not comply with the regulations.

Please inform us of the following chargeable changes:

- **company/organisation information e.g. name and address**
- **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 manufacturers and authorised representatives and their devices that have been registered will be published on our Public Access Registration Database (PARD). This applies to non-in vitro diagnostic devices only.

To see full details of this registration you will need to sign into your account.

The account number for your company/organisation is 0000011119. Keep a record of this.

Remember: do not share your account details and keep them safe.
MHRA won't accept responsibility for any unauthorised access to your account.

Please do not respond directly to this email address. The originating email account is not monitored.

Yours sincerely,
Device registrations service
Devices division
MHRA
10 South Colonnade, Canary Wharf, London, E14 4PU
020 30807272

10/12/2020, 12:50

CE认证

(新冠/流感A/流感B抗原三联检测卡)

Dear Edward Wang,

We are pleased to confirm that the application to register or update an existing registration for the following manufacturer, which you submitted on 10 December 2020 has been reviewed:

Application reference: 2020121001188588

Manufacturer organisation: Nanjing Liming Bio-Products Co., Ltd.
Address:
No.12, Huayuan Road,
Nanjing, Jiangsu
210042
China

Manufacturer registration status: Registered

Device(s):

GMDN term	Status	MHRA comment
64770 - Multiple respiratory virus antigen IVD, kit, immunochromatographic test (ICT), rapid	Registered	

Please note this email confirmation 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 CE marked devices that do not comply with the regulations.

Please inform us of the following chargeable changes:

- **company/organisation information e.g. name and address**
- **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 manufacturers and authorised representatives and their devices that have been registered will be published on our Public Access Registration Database (PARD). This applies to non-in vitro diagnostic devices only.

To see full details of this registration you will need to sign into your account.

The account number for your company/organisation is 0000011119. Keep a record of this.

Remember: do not share your account details and keep them safe.
MHRA won't accept responsibility for any unauthorised access to your account.

Please do not respond directly to this email address. The originating email account is not monitored.

Yours sincerely,
Device registrations service
Devices division
MHRA
10 South Colonnade, Canary Wharf, London, E14 4PU
020 30807272
device.registrations@mhra.gov.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

Wellkang Ltd
Enterprise Hub, NW Business Complex
1 Beraghmore Road
Derry, Northern Ireland
BT48 8SE
Northern Ireland, United Kingdom

05 November 2021

Dear **Edward Wang**

We are pleased to confirm that the application to register or update an existing registration for the following manufacturer, which you submitted on **28 October 2021** has been reviewed:

Application reference: **2021102801220197**

Manufacturer organisation: **Nanjing Liming Bio-Products Co., Ltd.**
Address:
No.12, Huayuan Road,
Nanjing, Jiangsu
210042
China

Manufacturer registration status: **Registered**

Device(s):

CE证书（新冠中和抗体）

GMDN term	Status	Comment
65441 - SARS-CoV-2 total/neutralizing antibody 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 **0000011119.**

Yours sincerely,

Ngozi Onyeukwu
Device registrations service
Devices division
MHRA

Ministero della Salute

新冠抗原自测版意大利白名单

Stampa | Scarica il dataset

Elenco dei dispositivi medici

Criteri di ricerca:
Denominazione fabbricante:
Codice fiscale fabbricante:
Partita IVA / VAT number fabbricante:
Codice nazione fabbricante:
Denominazione mandatario:
Codice fiscale mandatario:
Partita IVA / VAT number mandatario:
Codice nazione mandatario:
Tipologia dispositivo:
Identificativo di registrazione attribuito dal sistema BD/RDM: **2146749**
Codice attribuito dal fabbricante:
Nome commerciale e modello:
Classificazione CND:
Descrizione CND:
Classe CE (valida solo per dispositivi medici di classe, impiantabili attivi e IVD): **IVD - Altro tipo di IVD**

Elenco dispositivi individuati

Dati aggiornati al:21/08/2021

DISPOSITIVO MEDICO/ASSEMBLATO									FABBRICANTE/ASSEMBLATORE				
TIPOLOGIA DISPOSITIVO	IDENTIFICATIVO DI REGISTRAZIONE BD/RDM	ISCRITTO AL REPERTORIO	CODICE ATTRIBUITO DAL FABBRICANTE/ASSEMBLATORE	NOME COMMERCIALE E MODELLO	CND	CLASSE CE	DATA PRIMA PUBBLICAZIONE	DATA FINE IMMISSIONE IN COMMERCIO	RUOLO AZIENDA	DENOMINAZIONE	CODICE FISCALE	PARTITA IVA/VAT NUMBER	NAZIONE
Dispositivo	2146749	S	500200	STRONGSTEP SARS-COV-2 ANTOGEN TEST AUTODIAGNOSTICO NASO/FARINGEO/SALIVARE	W0105099099 - VIROLOGIA - TEST RAPIDI E "POINT OF CARE" - ALTRI	IVD - Altro tipo di IVD	19/08/2021		FABBRICANTE	LIMING BIO-PRODUCTS CO., LTD			CN
									MANDATARIO	LUME IMPORT S.R.L.	15457571006	15457571006	IT

<< < Pagina:1 > >> Num. Pagine:1 Num. Dispositivi:1

Ministero della Salute

新冠抗原专业版意大利白名单

DISPOSITIVO MEDICO/ASSEMBLATO									FABBRICANTE/ASSEMBLATORE				
TIPOLOGIA DISPOSITIVO	IDENTIFICATIVO DI REGISTRAZIONE BD/ROM	ISCRITTO AL REPERTORIO	CODICE ATTRIBUITO DAL FABBRICANTE/ASSEMBLATORE	NOME COMMERCIALE E MODELLO	CND	CLASSE CE	DATA PRIMA PUBBLICAZIONE	DATA FINE IMMISSIONE IN COMMERCIO	RUOLO AZIENDA	DENOMINAZIONE	CODICE FISCALE	PARTITA IVA/VAT NUMBER	NAZIONE
Dispositivo	2038726	S	500190	STRONGSTEP NOVEL CORONAVIRUS (SARS-COV-2) MULTIPLEX REAL-TIME PCR KIT (DETECTION FOR 3 GENES)	W0105040619 - CORONAVIRUS	IVD - Altro tipo di IVD	01/12/2020		FABBRICANTE	LIMING BIO-PRODUCTS CO., LTD			CN
									MANDATARIO	WELLKANG LTD		GB4740528	GB
Dispositivo	1989183	S	500200	STRONGSTEP SARS-COV-2 ANTIGEN RAPID TEST	W0105099099 - VIROLOGIA - TEST RAPIDI E "POINT OF CARE" - ALTRI	IVD - Altro tipo di IVD	31/08/2020		FABBRICANTE	LIMING BIO-PRODUCTS CO., LTD			CN
									MANDATARIO	WELLKANG LTD.		GB4740528	GB
Dispositivo	2030105	S	500200	STRONGSTEP SARS-COV-2 ANTIGEN RAPID TEST	W0105099099 - VIROLOGIA - TEST RAPIDI E "POINT OF CARE" - ALTRI	IVD - Altro tipo di IVD	24/11/2020		FABBRICANTE	LIMING BIO-PRODUCTS CO., LTD			CN
									MANDATARIO	MAYPO S.R.L.	05884370585	01352180796	IT
Dispositivo	1951220	S	502090	SARS-COV-2 IGG/IGM AB RAPID TEST	W0105040619 - CORONAVIRUS	IVD - Altro tipo di IVD	08/05/2020		FABBRICANTE	LIMING BIO-PRODUCTS CO., LTD			CN
									MANDATARIO	WELLKANG LTD		GB4740528	GB
Dispositivo	2064302	S	510010	SARS-COV-2 & INFLUENZA AB MULTIPLEX REAL-TIME PCR KIT	W0105040519 - CORONAVIRUS - REAGENTI NAS	IVD - Altro tipo di IVD	12/02/2021		FABBRICANTE	LIMING BIO-PRODUCTS CO., LTD			CN
									MANDATARIO	LUME IMPORT S.R.L.	15457571006	15457571006	IT

黎明新冠抗原及生殖道、消化道系列产品获意大利卫生部注册备案

Ministero della Salute

Stampa | Scarica il dataset

Elenco dei dispositivi medici

Criteri di ricerca:
Denominazione fabbricante: **liming bio**
Codice fiscale fabbricante:
Partita IVA / VAT number fabbricante:
Codice nazione fabbricante:
Denominazione mandatario:
Codice fiscale mandatario:
Partita IVA / VAT number mandatario:
Codice nazione mandatario:
Tipologia dispositivo:
Identificativo di registrazione attribuito dal sistema BD/RDM:
Codice attribuito dal fabbricante:
Nome commerciale e modello:
Classificazione CND:
Descrizione CND:
Classe CE (valida solo per dispositivi medici di classe, impiantabili attivi e IVD):

Elenco dispositivi individuati

Dati aggiornati al:31/10/2020

DISPOSITIVO MEDICO/ASSEMBLATO								FABBRICANTE/ASSEMBLATORE				
TIPOLOGIA DISPOSITIVO	IDENTIFICATIVO DI REGISTRAZIONE BD/RDM	ISCRITTO AL REPERTORIO	CODICE ATTRIBUITO DAL FABBRICANTE/ASSEMBLATORE	NOME COMMERCIALE E MODELLO	CND	CLASSE CE	DATA PRIMA PUBBLICAZIONE	DATA FINE IMMISSIONE IN COMMERCIO	RUOLO AZIENDA	DENOMINAZIONE	CODICE FISCALE	PARTITA IVA/VAT NUMBER	NAZIONE
Dispositivo	1766776	S	500020	STRONGSTEP¡ NEISSERIA GONORRHOEAE ANTIGEN RAPID	W0105010201 - GONOCOCCHI, RICERCA ANTIGENI	IVD - Altro tipo di IVD	24/11/2018		FABBRICANTE	LIMING BIO-PRODUCTS CO., LTD			CN
									MANDATARIO	WELLKANG LTD		047405287	GB
Dispositivo	1666608	S	500030	CANDIDA ALBICANS ANTIGENE RAPID TEST	W0105060302 - CANDIDA ALBICANS	IVD - Altro tipo di IVD	02/02/2018		FABBRICANTE	LIMING BIO-PRODUCTS CO., LTD			CN
									MANDATARIO	WELLKANG LTD		047405287	GB
Dispositivo	1666148	S	500040	TRICHOMONAS VAGINALIS ANTIGENE TEST RAPIDO	W0105090499 - TEST RAPIDI PER PARASSITOLOGIA - ALTRI	IVD - Altro tipo di	31/01/2018		FABBRICANTE	LIMING BIO-PRODUCTS CO., LTD			CN

DISPOSITIVO MEDICO/ASSEMBLATO									FABBRICANTE/ASSEMBLATORE				
TIPOLOGIA DISPOSITIVO	IDENTIFICATIVO DI REGISTRAZIONE BD/RDM	ISCRITTO AL REPERTORIO	CODICE ATTRIBUITO DAL FABBRICANTE/ASSEMBLATORE	NOME COMMERCIALE E MODELLO	CND	CLASSE CE	DATA PRIMA PUBBLICAZIONE	DATA FINE IMMISSIONE IN COMMERCIO	RUOLO AZIENDA	DENOMINAZIONE	CODICE FISCALE	PARTITA IVA/VAT NUMBER	NAZIONE
						IVD			MANDATARIO	WELLKANG LTD		047405287	GB
Dispositivo	1668227	S	500060	CANDIDA ALBICANS/TRICHOMONAS VAGINALIS ANTIGEN COMBO RAPID TEST	W010407 - MICROBIOLOGIA - TEST RAPIDI E "POINT OF CARE"	IVD - Altro tipo di IVD	08/02/2018		FABBRICANTE	LIMING BIO-PRODUCTS CO., LTD			CN
									MANDATARIO	WELLKANG LTD		047405287	GB
Dispositivo	1667186	S	500070	TEST RAPIDO HERPES SIMPLEX VIRUS 1 E 2-ANTIGENE	W0105040301 - HERPES SIMPLEX VIRUS (HSV), ANTIGENI	IVD - Altro tipo di IVD	03/02/2018		FABBRICANTE	LIMING BIO-PRODUCTS CO., LTD			CN
									MANDATARIO	WELLKANG LTD		047405287	GB
Dispositivo	1429801	N	500080	STRONG STEP BACTERIAL VAGINOSIS RAPID TEST-Quick PH Test	W01010699 - TEST RAPIDI CHIMICA CLINICA - ALTRI	IVD - Altro tipo di IVD	28/06/2016		FABBRICANTE	LIMING BIO-PRODUCTS CO., LTD			CN
									MANDATARIO	WELLKANG LTD.		GB7016633	GB
Dispositivo	1671317	S	500080	STRONGSTEP® BACTERIAL VAGINOSIS TEST RAPIDO	W0105090199 - BATTERIOLOGIA - TEST RAPIDI E "POINT OF CARE" - ALTRI	IVD - Altro tipo di IVD	14/02/2018		FABBRICANTE	LIMING BIO-PRODUCTS CO., LTD			CN
									MANDATARIO	WELLKANG LTD		GB4740528	GB
Dispositivo	1431688	S	500090	STRONGSTEP STREP B ANTIGEN RAPID TEST	W0105090104 - STREPTOCOCCUS AGALACTIAE (GRUPPO B) - TEST RAPIDO	IVD - Altro tipo di IVD	17/06/2016		FABBRICANTE	LIMING BIO-PRODUCTS CO., LTD			CN
									MANDATARIO	WELLKANG LTD		GB4740528	GB
Dispositivo	1429767	S	500150	STRONG STEP PROM RAPID TEST-Quick PROM Test	W01010699 - TEST RAPIDI CHIMICA CLINICA - ALTRI	IVD - Altro tipo di IVD	28/06/2016		FABBRICANTE	LIMING BIO-PRODUCTS CO., LTD			CN
									MANDATARIO	WELLKANG LTD.		GB7016633	GB
Dispositivo	1666680	S	500160	FIBRONECTINA FETALE TEST RAPIDO	W0102019005 - FIBRONECTINA	IVD - Altro tipo di IVD	21/02/2018		FABBRICANTE	LIMING BIO-PRODUCTS CO., LTD			CN
									MANDATARIO	WELLKANG LTD		047405287	GB
Dispositivo	1666693	S	500160	FIBRONECTINA FETALE TEST RAPIDO	W0102019005 - FIBRONECTINA	IVD - Altro tipo di IVD	02/02/2018		FABBRICANTE	LIMING BIO-PRODUCTS CO., LTD			CN
									MANDATARIO	WELLKANG LTD		047405287	GB
Dispositivo	1499682	S	500160	STRONGSTEP® FIBRONECTINA FETALE TEST RAPIDO	W0102160199 - PROTEINE SPECIFICHE - TEST RAPIDI E "POINT OF CARE" - ALTRI	IVD - Altro tipo di IVD	03/12/2016		FABBRICANTE	LIMING BIO-PRODUCTS CO., LTD			CN
									MANDATARIO	WELLKANG LTD		GB4740528	GB

黎明新冠抗原及生殖道、消化道系列产品获意大利卫生部注册备案

DISPOSITIVO MEDICO/ASSEMBLATO

TIPOLOGIA DISPOSITIVO	IDENTIFICATIVO DI REGISTRAZIONE BD/RDM	ISCRITTO AL REPERTORIO	CODICE ATTRIBUITO DAL FABBRICANTE/ASSEMBLATORE	NOME COMMERCIALE E MODELLO	CND	CLASSE CE	DATA PRIMA PUBBLICAZIONE	DATA FINE IMMISSIONE IN COMMERCIO
Dispositivo	1807085	S	500170	PROM RAPID TEST DEVICE	W0102160199 - PROTEINE SPECIFICHE - TEST RAPIDI E "POINT OF CARE" - ALTRI	IVD - Altro tipo di IVD	09/04/2019	
Dispositivo	1814112	S	500171	STRONGSTEP? PROM RAPID TEST DIPSTICK	W0102160199 - PROTEINE SPECIFICHE - TEST RAPIDI E "POINT OF CARE" - ALTRI	IVD - Altro tipo di IVD	03/05/2019	
Dispositivo	1989183	S	500200	STRONGSTEP SARS-COV-2 ANTIGEN RAPID TEST	W0105099099 - VIROLOGIA - TEST RAPIDI E "POINT OF CARE" - ALTRI	IVD - Altro tipo di IVD	31/08/2020	
Dispositivo	1499685	S	501030	STRONGSTEP® ROTAVIRUS/ADENOVIRUS ANTIGENE COMBO TEST RAPIDO	W0105099099 - VIROLOGIA - TEST RAPIDI E "POINT OF CARE" - ALTRI	IVD - Altro tipo di IVD	03/12/2016	
Dispositivo	1499587	S	501040	STRONGSTEP® H. PYLORI ANTIGENE TEST RAPIDO	W0105090102 - HELICOBACTER PYLORI - TEST RAPIDI E "POINT OF CARE"	IVD - Altro tipo di IVD	03/12/2016	
Dispositivo	1499638	S	502010	STRONGSTEP® H. PYLORI ANTICORPI TEST RAPIDO	W0105090102 - HELICOBACTER PYLORI - TEST RAPIDI E "POINT OF CARE"	IVD - Altro tipo di IVD	03/12/2016	
Dispositivo	1951220	S	502090	SARS-COV-2 IGG/IGM AB RAPID TEST	W0105040619 - CORONAVIRUS	IVD - Altro tipo di IVD	08/05/2020	

FABBRICANTE/ASSEMBLATORE

RUOLO AZIENDA	DENOMINAZIONE	CODICE FISCALE	PARTITA IVA/VAT NUMBER	NAZIONE
FABBRICANTE	LIMING BIO-PRODUCTS CO., LTD			CN
MANDATARIO	WELLKANG LTD		047405287	GB
FABBRICANTE	LIMING BIO-PRODUCTS CO., LTD			CN
MANDATARIO	WELLKANG LTD		047405287	GB
FABBRICANTE	LIMING BIO-PRODUCTS CO., LTD			CN
MANDATARIO	WELLKANG LTD.		GB4740528	GB
FABBRICANTE	LIMING BIO-PRODUCTS CO., LTD			CN
MANDATARIO	WELLKANG LTD		GB4740528	GB
FABBRICANTE	LIMING BIO-PRODUCTS CO., LTD			CN
MANDATARIO	WELLKANG LTD		GB4740528	GB
FABBRICANTE	LIMING BIO-PRODUCTS CO., LTD			CN
MANDATARIO	WELLKANG LTD		GB4740528	GB
FABBRICANTE	LIMING BIO-PRODUCTS CO., LTD			CN
MANDATARIO	WELLKANG LTD		GB4740528	GB

新冠抗原检测笔获新加坡HSA认证

Provisional Authorisation for COVID-19 Tests

Applicant	SK BIOTECH PTE. LTD.
Name of test	Liming Bio StrongStep® System Device for SARS-CoV-2 Antigen Rapid Test
Intended purpose (As per manufacturer's information for use)	*The StrongStep@System Device for SARS-CoV-2 Antigen Rapid Test is a rapid immunochromatographic assay for the detection of SARS-CoV-2 virus Nudeocapsid Protein antigen in human Nasal/Oropharyngeal swab collected from individuals who are suspected of COVID-19 by their healthcare provider within the first five days of the onset of symptoms. The assay is used as an aid in the diagnosis of COVID-19.*
Date of Provisional Authorisation	25 February 2021

新冠抗原检测卡获马来西亚MDA认证

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.

Tel: (+603)8230 0300
Faks: (+603)8230 0200
Portal Rasmi: www.mda.gov.my
Email: mdb@mda.gov.my

Ref. No. : (27) dlm. MDA.600-3/1/12 Jilid 83
Date : 1 September 2021

INTERSCIENCE SDN BHD
2, Jalan Sg Kayu Ara 32/38,
Berjaya Industial Park,
40460 Shah Alam, Selangor.
(attention to : Mr Tan Nam Kwang)

Dear Sir,

NOTIFICATION ON IMPORTATION/SUPPLY OF MEDICAL DEVICES FOR SPECIAL ACCESS UNDER THE MEDICAL DEVICE (EXEMPTION) ORDER 2016 :

- **Medical Device Name** : StrongStep SARS-CoV-2 Antigen Rapid Test – nasopharyngeal/oropharyngeal samples
- **Manufacturer** : Nanjing Liming Bio-products Co. Ltd.
  No 12 Huayuan Road 210042 Nanjing, Jiangsu China

With regards to your notification dated 30th November 2020, I wish to inform you on the decision made by the Expert IVD Evaluation Committee on 11th March 2021 to your application is as follows:
Recommended for Use.

2. Therefore, for the purpose of issuance of Special Access Letter, you are kindly requested to provide us with the required information as follows:

i. Completed Special Access Route B Form (with the information on Section B, Medical Practitioner Details);
ii. Customer Order Form (signed and stamped by the Public or Private Pathology Laboratory/Hospital) who is requesting the supply of COVID-19 Detection Kits during COVID-19 outbreak.

3. This letter DOES **NOT CONSTITUTE AN APPROVAL** for the product and shall not be used for the purpose of promoting or advertising the product.

Yours Sincerely,

Thank you,

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

KEMENTERIAN KESEHATAN REPUBLIK INDONESIA
DIREKTORAT JENDERAL KEFARMASIAN DAN ALAT KESEHATAN
Jalan H.R. Rasuna Said Blok X-5 Kavling 4 - 9 Jakarta 12950
Telepon : (021) 5201590 Pesawat 2029, 8011
Faksimile : (021) 52964838 Kotak Pos : 203

GERMAS

新冠抗原取得印尼FDA注册证

Berdasarkan Peraturan Menteri Kesehatan R.I Nomor 62 Tahun 2017 Tentang Izin Edar Alat Kesehatan, Alat Kesehatan Diagnostik In Vitro Dan Perbekalan Kesehatan Rumah Tangga dengan ini diberikan persetujuan untuk diedarkan dengan :

NOMOR IZIN EDAR

A L A T K E S E H A T A N

KEMENKES RI AKL 20303024804

Nama Dagang / Merek	:	**STRONGSTEP® SARS-CoV-2 Antigen Rapid Test**
Kelompok / Kelas Resiko	:	Diagnostik *In Vitro* / B
Kategori Produk	:	Peralatan Imunologi dan Mikrobiologi
Sub Kategori	:	Pereaksi Serologi
Jenis Produk	:	Respiratory viral panel multiplex nucleic acid assay
Tipe / Ukuran	:	Ref. No. 500200
Kemasan	:	Dus, kit, isi 20 tes cassette
Nama Produsen / Pabrikan	:	NANJING LIMING BIO-PRODUCTS CO., LTD., China
Nama Pendaftar	:	PT. SANSICO NATURA RESOURCES, DKI Jakarta
Atas dasar lisensi dari	:	-

Ketentuan

1. Persetujuan ini adalah Persetujuan Izin Edar Dimasa Darurat Covid-19, berlaku sampai dengan 25 Agustus 2021 (1 Tahun).
2. Wajib menyampaikan laporan berkala dan laporan jika ada kejadian yang tidak diinginkan akibat penggunaan Alat Kesehatan tersebut di atas sesuai ketentuan berlaku.
3. Persetujuan Izin Edar Dimasa Darurat dapat diperpanjang jika tidak ditemukan kejadian tidak diinginkan pada pemakaian.
4. Kementerian Kesehatan berhak meninjau atau mengevaluasi aspek keamanan, mutu, dan kemanfaatan apabila ditemukan bukti baru terkait Alat Kesehatan yang diterbitkan izin edarnya.
5. Apabila dikemudian hari ada pihak lain yang berhak atas merek dan/atau keagenan produk tersebut, pendaftar bersedia mengembalikan izin edar.
6. Penandaan dan informasi produk yang terlampir merupakan bagian yang tidak terpisahkan dari persetujuan izin edar ini.
7. Apabila di kemudian hari terdapat kekeliruan, maka persetujuan izin edar ini akan ditinjau kembali.

Jakarta, 25 Agustus 2020

KEMENTERIAN KESEHATAN REPUBLIK INDONESIA

Ditandatangani Secara Elektronik Oleh :
a.n Direktur Jenderal
Direktur Penilaian Alat Kesehatan dan PKRT

Dr. IGM. Wirabrata, Apt
NIP. 19751206 200312 1 001

Catatan:
- UU ITE No 11 Tahun 2007 Pasal 5 ayat 1
  Informasi Elektronik dan/atau Dokumen Elektronik dan/atau hasil cetaknya merupakan alat bukti hukum yang sah.
- Dokumen ini telah ditandatangani secara elektronik menggunakan sertifikat elektronik yang diterbitkan BSrE.

MINISTERIO DE SALUD PÚBLICA Y ASISTENCIA SOCIAL
DIRECCIÓN GENERAL DE REGULACIÓN, VIGILANCIA Y CONTROL DE LA SALUD
GUATEMALA, CENTRO AMERICA

新冠抗原采获危地马拉注册证

La infrascrita jefatura del Departamento de Regulación y control de Productos farmacéuticos y Afines, en vista del dictamen favorable emitido por la Unidad de Autorizaciones Sanitarias, y con fundamento al Reglamento para el Control Sanitario de los Medicamentos y Productos Afines , de fecha 20 de Octubre de 1,999

CERTIFICA

QUE HA QUEDADO INSCRITO EL PRODUCTO

DATOS DE LA INSCRIPCIÓN SANITARIA:

TIPO DE AFÍN:	EXPEDIENTE:	No INSCRIPCIÓN:	
REACTIVO DE LABORATORIO PARA DIAGNOSTICO	65Z98	RD-68701	
SERIE: 02/09/2020	**RESOLUCIÓN:** 02/09/2020	**VENCE:** 02/09/2025	**PROCESO:** OAP

DATOS DEL PRODUCTO:

NOMBRE:
STRONGSTEP® SARS COV-2 PRUEBA RAPIDA DE ANTIGENO / STRONGSTEP® SARS COV-2 ANTIGEN RAPID TEST

LABORATORIO FABRICANTE
NANJING LIMING BIO-PRODUCTS CO. LTD

PRODUCIDO PARA:
TECNOIMPLANTE

PAÍS DE ORIGEN:
CHINA

REPRESENTANTE EN EL PAÍS:
FRANCISCO JOSE ORELLANA ALEJOS

DISTRIBUIDO POR:
TECNOLOGIA IMPLANTABLE SOCIEDAD ANONIMA

DATOS TÉCNICOS DEL PRODUCTO:

PRESENTACION Y ENVASE

CAJA DE CARTON CONTENIENDO 20 PRUEBAS RAPIDAS DE ANTIGENO SARS-COV2 EN EMPAQUE DE ALUMINIO; DOS FRASCOS GOTERO VIAL CON TAMPON DE EXTRACCIÓN. 20 TUBOS DE EXTRACCIÓN, 20 HISOPOS EN EMPAQUE INDIVIDUAL E INSERTO. (REF: 500200)

FORMA COSMÉTICA: N/A		
VÍA DE ADMINISTRACIÓN:	**CONDICIÓN DE VENTA:**	**VIDA ÚTIL EN MESES:**
N/A	EXCLUSIVO LABORATORIO CLINICO	24

EXTENSIONES:

DISTRIBUIDORES ADICIONALES

DATOS DEL PROFESIONAL RESPONSABLE:

NOMBRE DEL PROFESIONAL:
CLAUDIA LORENA RODRIGUEZ RAMIREZ

NÚMERO DE COLEGIADO: 3,014

PERTENECIENTE AL COLEGIO DE:
COLEGIO DE FARMACEUTICOS Y QUIMICOS DE GUATEMALA

IMPORTANTE: La inscripción del producto autorizado, podrá en cualquier momento ser cancelado si el resultado de los análisis practicados en el Laboratorio Nacional de Salud, demuestre que no corresponde a la fórmula cuali-cuantitativa con que fue inscrito o que no llene las condiciones de calidad indispensables para este tipo de productos, y como consecuencia el propietario y/o representante legal y responsable del mismo quedan obligados a retirarlo del mercado en un tiempo de quince días.
Los interesados no podrán hacer uso del nombre de la Dirección General de Regulación, Vigilancia y Control de la Salud para propaganda comercial

Guatemala, 02 septiembre, 2020

Evaluación Profesional
Ventanilla de Servicios de Alimentos y Medicamentos

Código de Seguridad e Identificación Electronica: 395bb1c370e337b0e56391a965625cb8

USUARIO WSERRANO
2/09/2020 08:54:25

Ministerio de Salud
Secretaría de Calidad en Salud
A.N.M.A.T.

AUTORIZACIÓN PARA LA IMPORTACIÓN DE PRODUCTOS PARA DIAGNÓSTICO DE USO IN VITRO NO REGISTRADOS DE BAJA COMERCIALIZACIÓN DISP. 2675/99 ART. 6°

ANEXO

DATOS DEL SOLICITANTE

Razón Social: **ALCAT S.A.**

N° de Inscripción: **1680**

Dirección: **INGENIERO EIFFEL 4180 ,PARTIDO DE MALVINAS ARGENTINAS, EL TRIANGULO BUENOS AIRES**
Teléfono: 011-15-2461-2223

DATOS DEL PRODUCTO

Nombre del producto: **StrongStep® Sars-CoV-2 Antigen Rapid Test**

Indicación de uso: **El StrongStep® SARS-CoV-2 Antigen Rapid Test es un ensayo inmunocromatográfico rápido para la detección del antígeno COVID-19 del virus SARS-CoV-2 en en la nasofaringe humana**
El ensayo se utiliza como ayuda en el diagnóstico de COVID-19.

Descripción: **El StrongStep® SARS-CoV-2 Antigen Rapid Test emplea una prueba cromatográfica de flujo lateral. Los anticuerpos conjugados con látex (Latex-Ab) correspondientes a SARS-CoV-2 se inmovilizan en seco al final de tira de membrana de nitrocelulosa. Los anticuerpos del SARS-CoV-2 se unen en la zona de prueba (T) y la biotina-BSA se une en la zona de control (C). Cuando se agrega la muestra, migra por difusión capilar rehidratando el conjugado de látex. Si están presentes en la muestra, los antígenos del SARS-CoV-2 se unirán a las partículas formadoras de anticuerpos menos conjugados. Estas partículas continuarán migrando a lo largo de la tira hasta la Zona de Prueba (T) donde son capturadas por los anticuerpos del SARS-CoV-2 generando una línea roja visible. Si no hay antígenos del SARS-CoV-2 en la muestra, no se forma una línea roja en la zona de prueba (T). El conjugado de estreptavidina continuará migrando solo hasta que sea capturado en la Zona de Control (C) por la agregación de Biotina-BSA en**

Página 1 de 5

新冠抗原菲律宾FDA认证

25	[redacted]	[redacted]
26	[redacted]	[redacted]
27	[redacted]	[redacted]
28	[redacted]	[redacted]
29	[redacted]	[redacted]
30	[redacted]	[redacted]
31	[redacted]	[redacted]
32	[redacted]	[redacted]
33	[redacted]	[redacted]
34	STRONGSTEP® SARS-CoV-2 Antigen Rapid Test	Nanjing Liming Bio-Products Co., Ltd. – No.12 Huayuan Road, Nanjing, Jiangsu, 210042 P.R. China
35	[redacted]	[redacted]

KEMENTERIAN KESEHATAN REPUBLIK INDONESIA
DIREKTORAT JENDERAL KEFARMASIAN DAN ALAT KESEHATAN
Jalan H.R. Rasuna Said Blok X-5 Kavling 4 - 9 Jakarta 12950
Telepon : (021) 5201590 Pesawat 2029, 6011
Faksimile : (021) 52964836 Kotak Pos : 203

GERMAS

新冠抗原检测笔荣获印尼FDA注册证

Berdasarkan Peraturan Menteri Kesehatan R.I Nomor 62 Tahun 2017 Tentang Izin Edar Alat Kesehatan, Alat Kesehatan Diagnostik In Vitro Dan Perbekalan Kesehatan Rumah Tangga dengan ini diberikan persetujuan untuk diedarkan dengan :

NOMOR IZIN EDAR

ALAT KESEHATAN

KEMENKES RI AKL 20303120549

Nama Dagang / Merek	:	**STRONGSTEP® SARS-CoV-2 Antigen Rapid Test**
Kelompok / Kelas Resiko	:	Diagnostik *In Vitro* / B
Kategori Produk	:	Peralatan Imunologi dan Mikrobiologi
Sub Kategori	:	Pereaksi Serologi
Jenis Produk	:	Respiratory viral panel multiplex nucleic acid assay
Tipe / Ukuran	:	Ref. No. 500210
Kemasan	:	Dus, kit, isi 20 tes
Nama Produsen / Pabrikan	:	NANJING LIMING BIO-PRODUCTS CO., LTD., China
Nama Pendaftar	:	PT. SANSICO NATURA RESOURCES, DKI Jakarta
Atas dasar lisensi dari	:	-

Ketentuan

1. Persetujuan ini adalah Persetujuan Izin Edar Dimasa Darurat Covid-19, berlaku sampai dengan 22 Januari 2022 (1 Tahun).
2. Wajib menyampaikan laporan berkala dan laporan jika ada kejadian yang tidak diinginkan akibat penggunaan Alat Kesehatan tersebut di atas sesuai ketentuan berlaku.
3. Persetujuan Izin Edar Dimasa Darurat dapat diperpanjang jika tidak ditemukan kejadian tidak diinginkan pada pemakaian.
4. Kementerian Kesehatan berhak meninjau atau mengevaluasi aspek keamanan, mutu, dan kemanfaatan apabila ditemukan bukti baru terkait Alat Kesehatan yang diterbitkan izin edarnya.
5. Apabila dikemudian hari ada pihak lain yang berhak atas merek dan/atau keagenan produk tersebut, pendaftar bersedia mengembalikan izin edar.
6. Penandaan dan informasi produk yang terlampir merupakan bagian yang tidak terpisahkan dari persetujuan izin edar ini.
7. Apabila di kemudian hari terdapat kekeliruan, maka persetujuan izin edar ini akan ditinjau kembali.

Jakarta, 24 Januari 2021

KEMENTERIAN KESEHATAN REPUBLIK INDONESIA

Ditandatangani Secara Elektronik Oleh :
a.n. Direktur Jenderal
Direktur Penilaian Alat Kesehatan dan PKRT

Dr. IGM. Wiratama, Apt
NIP. 19751226 200512 1 001

Catatan:
- UU ITE No 11 Tahun 2007 Pasal 5 ayat 1
Informasi Elektronik dan/atau Dokumen Elektronik dan/atau hasil cetaknya merupakan alat bukti hukum yang sah.
- Dokumen ini telah ditandatangani secara elektronik menggunakan sertifikat elektronik yang diterbitkan BSrE.

Bundesinstitut für Arzneimittel und Medizinprodukte

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

Impressum

新冠/流感A/流感B抗原三联检测笔获德国FDA注册备案

Suchen: Alle Textspalten | Los | Aktionen | Zurücksetzen

	Hersteller			Deutscher Vertreiber	Europäischer Bevollmächtigter						Sensitivität		Spezifität		
Test-ID	Name	Stadt	L...	Name	Name	Stadt	L...	Handelsname des Tests	Testort *	Artikelnu...	%	95%ig... Vertra... intervall	%	95%ig... Vertra... intervall	Gebra... anwei...
AT1...	Nanjing Liming Bio-Products Co., Ltd	Nanjing	CN	Syn diagnostic, Dr. W. Gottstein	WellKang Ltd	Dover	GB	System Device for SARS-CoV-2 & Influenza A/B ComboAntigen Rapid Test	POC (ohne Gerät)	5002200	92,31	79,13 - 98,38	97,26	90,45 - 99,67	Link
AT2...	Nanjing Vazyme Medical Technology Co.,Ltd	Nanjing	CN	KL GmbH	Obelis S.A.	Brussels	BE	Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-COV-2) Antigen detection kit	POC (ohne Gerät)	C8602C	91,94	82,47 - 96,51	97,06	94,05 - 98,57	Link
AT0...	NanoEntek Inc	Guro-gu,Seoul	KR	MS Med-Tech Supplies GmbH	MT Promedt Consulting GmbH	St. Ingbert	DE	FREND COVID-19 Ag	POC (mit Gerät)	FRCOG020	94,12	78,94 - 98,97	100,00	93,93 - 100	Link
AT1...	Nantong Diagnos Biotechnology Co., Ltd.	Jiangsu Province	CN	NanoRepro AG	Lotus NL B.V.	The Hague	NL	DIAGNOS COVID-19 Antigen Test	POC (ohne Gerät)		92,59	85,60 - 99,57	98,59	95,85 - 100,00	Link
AT1...	Ningbo Beautiful Life Medical Biotechnology Development Co., Ltd.	Free Trade West Zone,Ningbo	CN	LINUS Handelshaus GmbH	Lotus NL B.V.	Den Haag	NL	Saliva SARS-Cov-2 (2019-nCoV) Antigen Combined Test Kit(Nanocarbon Assay)	POC (ohne Gerät)	0035	89,20	82,6 - 94	100,00	92,9 - 100	Link
AT1...	Oncosem Onkolojik Sistemler	Ankara	TR	Casada International GmbH	Ortho-Clinical Diagnostics	Illkirch-Graffenstaden	FR	CAT		CMA-031	93,75	85,36 - 99,99	98,04	96,14 - 99,94	Link
AT0...	Ortho-Clinical Diagnostics, Inc.	Pencoed	GB					VITROS Immunodiagnostic Products SARS-CoV-2 Antigen Reagent Pack	Labor	6199941	97,80	88,5 - 100,0	99,20	95,8 - 100,0	Link
AT0...	PCL, Inc.	Geumcheon-gu, Seoul	KR	Datametrex AI Limited				PCL COVID19 Ag Rapid FIA	POC (mit Gerät)		88,71	78,1 - 95,34	98,61	92,50 - 99,96	

Gesamt 213

Ministero della Salute

新冠/流感A/流感B抗原三联检测笔获意大利卫生部注册备案

Dispositivo	2052031	S	500190	TEST RAPIDO INFLUENZA & COVID -19	9602010690003 - ANALIZZATORI ALCOOL	ST - Test autodiagnostici (non inclusi nell'all. II)	20/01/2021	01/02/2022	FABBRICANTE	LIMING BIO-PRODUCTS CO., LTD			CN
									MANDATARIO	LUME IMPORT S.R.L.	15457571006	15457571006	IT

REPÚBLICA FEDERATIVA DO BRASIL
MINISTÉRIO DA SAÚDE
AGÊNCIA NACIONAL DE VIGILÂNCIA SANITÁRIA
GERÊNCIA GERAL DE TECNOLOGIA DE PRODUTOS PARA SAÚDE

CERTIFICADO DE PRODUTO

Agência Nacional de Vigilância Sanitária, vinculada ao Ministério da Saúde, CERTIFICA que o produto abaixo indicado, é fabricado de acordo com as leis vigentes no Brasil, com a sua venda autorizada em todo o Território Brasileiro.

RAZAO SOCIAL: **EQUILIBRIO COMÉRCIO DE PRODUTOS FARMACÊUTICOS EIRELI**

CNPJ: **05.215.461/0001-03**

ENDEREÇO: **SHCGN CR QUADRA 714/715, BLOCO D, LOJA 40, PARTE SUBSOLO CEP: 70761-640**

NOME TÉCNICO	CORONAVÍRUS
NOME COMERCIAL	StrongStep® System Device for SARS-CoV-2 Antigen Rapid Test
CLASSE DE RISCO	III - Classe III: produtos de alto risco ao indivíduo e ou médio risco à saúde pública
FABRICANTE LEGAL	NANJING LIMING BIO-PRODUCTS CO., LTD - CHINA, REPÚBLICA POPULAR - Fabricar
REGISTRO Nº	80589510016
DATA DO REGISTRO	08/03/2021
VÁLIDO ATÉ	08/03/2031

MODELO COMERCIAL:

20 dispositivos de teste embalados individualmente; 20 pacotes de swabs (2 swabs/pacote); 1 estação de trabalho; 1 instruções de uso

Documento emitido eletronicamente às: 17:00:07 do dia 26/03/2021 (Hora e data de Brasília - DF)

Código de controle do comprovante: 916C.AA67.EFB4.E87F.584F.F6D7.157A.8828.BBF1.0CC8

Conforme §2º, Art. 6º, RDC nº 27 de 15 de maio de 2013, qualquer alteração ou inclusão pós-registro ou pós-cadastro deferida que altere as informações do documento emitido, torná-lo-á inválido.

Verifique a autenticidade deste documento no endereço: http://www.anvisa.gov.br/validacertificadoggtps

Department of Health & Social Care

新冠抗原试剂通过英国DHSC认证

Guidance

Outcome of the evaluation of rapid diagnostic assays for specific SARS-CoV-2 antigens (lateral flow devices)

Updated 26 May 2021

Lateral flow device	Status	Date evaluation completed
[illegible]	Pass	13 November 2020
[illegible]	Pass	10 March 2021
[illegible]	Pass	21 May 2021
[illegible]	Pass	11 September 2020
Liming Bio StrongStep SARS-CoV-2 Antigen Rapid Test	Pass	2 March 2021
[illegible]	Pass	21 May 2021
[illegible]	Pass	5 February 2021
[illegible]	Pass	21 January 2021

新冠抗原试剂获新加坡HSA认证

Health Sciences Authority
11 Outram Road Singapore 169078
Tel: 65 6213 0838 Fax: 65 6213 0749
Website: www.hsa.gov.sg

HSA 600:36/01

01 March 2021

SK BIOTECH PTE. LTD.
COLEMAN STREET #10-06
THE ADELPHI
Singapore 179803

Dear Ms Too Wan Theng,

RE: STATUS OF SUPPLY OF MEDICAL DEVICES IN SINGAPORE

This letter serves to confirm that the following medical device product(s) have been issued Provisional Authorisation (MDPA2020-179) for supply in Singapore and may be exported from Singapore.

No.	Device Name	Intended Use
1	Liming Bio StrongStep® System Device for SARS-CoV-2 Antigen Rapid Test (500210)	The StrongStep@System Device for SARS-CoV-2 Antigen Rapid Test is a rapid immunochromatographic assay for the detection of SARS-CoV-2 virus Nudeocapsid Protein antigen in human Nasal/Oropharyngeal swab collected from individuals who are suspected of COVID-19 by their healthcare provider within the first five days of the onset of symptoms. The assay is used as an aid in the diagnosis of COVID-19.

Product Owner: Nanjing Liming Bio-Products Co., Ltd.
No. 12 Huayuan Road, Nanjing,
Jiangsu, 210042
P.R. China.

Manufacturing Site(s): Nanjing Liming Bio-Products Co., Ltd.
No. 12 Huayuan Road, Nanjing,
Jiangsu, 210042
P.R. China.

গণপ্রজাতন্ত্রী বাংলাদেশ সরকার
ঔষধ প্রশাসন অধিদপ্তর
ঔষধ ভবন, মহাখালী, ঢাকা-১২১২
www.dgda.gov.bd

স্মারক নং-ডিএ/২৭-১৪২/২০২০/ ১৯৭৭ তারিখ: ০১/০৯/২০২১খ্রি

বরাবর
G-Tech Solution Ltd.
Suite: B16, 16th Floor, Navana Tower
45, Gulshan South Avenue
Gulshan Circle-1, Dhaka

বিষয়ঃ অনাপত্তিসূচক সনদপত্র প্রদান প্রসঙ্গে।
সূত্রঃ জি-টেক/২০২১/১৯৮, তারিখ: ০৪.০৮.২০২১খ্রি।

উপর্যুক্ত বিষয় ও সূত্রের পরিপ্রেক্ষিতে নিম্নেবর্ণিত শুল্কে উল্লিখিত পণ্যটি শুল্ক বিভাগ হতে ছাড়করণের নিমিত্তে নিম্নলিখিত শর্তসাপেক্ষে অনাপত্তিসূচক সনদপত্র প্রদান করা হলো।

ইনভয়েস নং ও তারিখ	সরবরাহকারীর নাম ও দেশ	মেডিকেল ডিভাইসের নাম	পরিমাণ	উৎপাদনকারীর নাম ও দেশ
pz202108041 Date: 04.08.2021	LIMING BIO, China	SARS-CoV-2 Antigen Rapid Test (201)	500 Boxes	Nanjing Liming Bio-products Co., Ltd. China

শর্তসমূহ:

০১। আমদানিকৃত Antigen Test Kit সমূহ (১) এনাম মেডিকেল কলেজ ও হাসপাতাল, সাভার, ঢাকা-এ সরবরাহ করতে হবে।
০২। আমদানিকৃত Antigen Test Kit সমূহ 2^{0C} to 30^{0C} তাপমাত্রায় সংরক্ষণ ও সরবরাহ করতে হবে।
০৩। এ এনওসি ইস্যুর তারিখ হতে পরবর্তী ০৬ (ছয়) মাস বলবৎ থাকবে।
০৪। আমদানিকৃত পণ্যের গুনগত মান যে যে প্রতিষ্ঠানের (ক্রয়কারী প্রতিষ্ঠান) "মান যাচাই কমিটি" কর্তৃক যাচাই সাপেক্ষে গ্রহণ করতে হবে।
০৫। আমদানিকৃত Antigen Test Kit ব্যবহারের ফলে কোন অসুবিধা দেখা দিলে এ অধিদপ্তর দায়ী থাকবে না। আমদানিকারক সকল দায়-দায়িত্ব বহন করবেন।
০৬। আবেদনের সাথে সংযুক্ত কাগজপত্রাদি পরবর্তীতে যাচাই বাছাইকালে যদি নকল প্রমাণিত হয় তবে এ অনাপত্তিসূচক সনদপত্র বাতিল বলে গণ্য হবে এবং আইনানুগ ব্যবস্থা গ্রহণ করা হবে।
০৭। আমদানিকৃত পণ্য শুল্ক বিভাগ হতে ছাড়করণের ০৭ (সাত) দিনের মধ্যে এ অধিদপ্তরে Bill of Entry এর কপি দাখিলকরতঃ মূল্য সনদসহ Emergency Use Authorization (EUA) গ্রহণ করতে হবে।

মেজর জেনারেল মোঃ মাহবুবুর রহমান
মহাপরিচালক
01 SEP 2021
ঔষধ প্রশাসন অধিদপ্তর, ঢাকা
ফোনঃ ০২২২২২-৮০৮০৩
ই-মেইলঃ dgda.gov@gmail.com

Check by:

নং	নাম ও পদবি	অনুস্বাক্ষর
১.	আনিসুল হক, সিটিঘুন্ধকরিক	
২.	এ.টি.এম গোলাম কিবরিয়া খান, সহকারী পরিচালক	
৩.	মোঃ সালাহউদ্দিন, উপপরিচালক	

SAHPRA Head Office
Building A
Loftus Park
2nd Floor
Kirkness Road
Arcadia
0083

Enquiries: Medical Device Unit
Tel: N/A
Email: khanyisile.nkuku@sahpra.org.za
Ref. No. MDF V0058
Licence: 00001356MD_v1

V Care Medi Products Pty Ltd
373 Chief Albert Road
Pietermaritzburg
3200

Telephone number (033) 341 1922
E-mail address parma.naik@gmail.com / parma.naik@vcaremed.co.za

ATTENTION: Mr PS Naik

Dear Sir/ Madam,

RE: AUTHORISATION FOR THE SALE OF COVID-19 Antigen POINT-OF-CARE TEST KIT – SARS-Cov-2 Ag test Rapid

Authorisation is hereby granted by the South African Health Products Regulatory Authority (SAHPRA), in terms of Section 21 of the Medicines and Related Substances Act, 1965 (Act 101 of 1965), the Medicines Act, to **V Care Medi Products Pty Ltd** , the holder of a licence to manufacture and/or distribute medical devices and in-vitro diagnostics (IVDs), issued in terms of Section 22C(1)(b) of the Medicines Act, to sell **StrongStep® SARS-CoV-2 Antigen Rapid Test** subject to the conditions provided below.

PRODUCT NAME	**StrongStep® SARS-CoV-2 Antigen Rapid Test**
ORIGINAL MANUFACTURER	**Nanjing Liming Bio-Products Co., Ltd.**
HOLDER OF LICENCE ISSUED ITO SECTION 22C(1)(B)	**V Care Medi Products Pty Ltd**
LICENCE NUMBER	**00001356MD_v1**
AUTHORISED REPRESENTATIVE	**Mr PS Naik**
SECTION 21 REFERENCE NUMBER	**MD21.202109/02**

Section 21 of the Medicines Act enables SAHPRA to authorise any person to sell during a specified period to any specified person or institution a specified quantity of any medical device or IVD which is not registered. Any medical device or IVD sold in pursuance of authority granted under Section 21 may be used for such purposes and in such manner and during such period as the SAHPRA may in writing determine.

SELF-TEST COVID-19 TEST KIT FOR CONDITIONAL APPROVAL (APPROVED)

SELF-TEST COVID-19 TEST KIT FOR CONDITIONAL APPROVAL (APPROVED)

The list of Self-Test Covid-19 Test Kit that is approved for Conditional Approval based on the decision on the consensus of the Covid-19 Test Kit Expert committee is as follows.

All test submissions are scored according to: -
- the manufacturer reported clinical and analytical performance evidence.
- the evaluation test results from testing facilities are according to the committee evaluation criteria set by Clinical expert panels.
- Supporting Documents for COVID-19 IVD Test Kits Conditional Approval.

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.

This test kit can be supplied by registered pharmacists or private healthcare facilities.

Below is the list of all tests that have been selected to date and the status is Conditional Approval (**please note: list is updated on a routine basis**).

Notes:
***Sample type is based on testing facility evaluation report.**

** Self Test Kit COVID-19 IS FOR SALE/ PURCHASE AT LICENSED PHARMACIES AND CLINICS ONLY*

NO	COMPANY NAME	PRODUCT NAME	MANUFACTURER	IDENTIFIER	DETECTION	SAMPLE TYPE
31	[illegible]	[illegible]	[illegible]	[illegible]	RTK-Antigen (Self-test)	Saliva
23	[illegible]	[illegible]	[illegible]	[illegible]	RTK-Antigen (Self-test)	Saliva
33	[illegible]	[illegible]	[illegible]	[illegible]	RTK-Antigen (Self-test)	Saliva
24	Interscience Sdn Bhd	StrongStep® SARS-CoV-2 Antigen Rapid Test (Self-Test)	Nanjing Liming Bio-Products Co. Ltd., P.R. China.	500200	RTK-Antigen (Self-test)	Nasal swab

新冠抗原笔获泰国FDA自测证（鼻拭子）

แบบ ป.ท.

ใบรับรองการประเมินเทคโนโลยีเครื่องมือแพทย์

ใบรับรองการประเมิน ที่ T 6400429

ใบรับรองการประเมินฉบับนี้ให้ไว้แก่

บริษัท ยู.เอ็น.เอส. อินเตอร์เนชั่นแนล จำกัด

ผู้จดทะเบียนสถานประกอบการผลิตหรือนำเข้าเครื่องมือแพทย์ ใบจดทะเบียนที่ กท. สน. 294/2564
เพื่อแสดงว่าเป็นผู้ผลิตหรือนำเข้าเครื่องมือแพทย์ที่ได้รับการประเมินเทคโนโลยี ตามมาตรา ๖ (๘)
แห่งพระราชบัญญัติเครื่องมือแพทย์ พ.ศ. ๒๕๕๑ สำหรับเครื่องมือแพทย์
StrongStep x Crazydoctor Premium SARS-CoV-2 Antigen Rapid Test (Nasal Swab)

รายละเอียดเครื่องมือแพทย์ รหัสสินค้า 500210
ขนาดบรรจุ 1การทดสอบต่อกล่อง
ประเภทเพื่อการวินิจฉัยภายนอกร่างกาย ชนิดเพื่อการวินิจฉัยรายบุคคล แบบตรวจคัดกรอง
แบบตรวจหา แอนติเจนด้วยตนเอง (Home use/Self-test)
สิ่งส่งตรวจ Nasal swab
ชื่อและที่ตั้งของสถานที่ผลิตเครื่องมือแพทย์ในต่างประเทศ
Nanjing Liming Bio-Products Co., Ltd No. 12 Huayuan Road, Nanjing, Jiangsu, 210042 P.R. China

ณ สถานที่ผลิตหรือนำเข้าเครื่องมือแพทย์ชื่อ บริษัท ยู.เอ็น.เอส. อินเตอร์เนชั่นแนล จำกัด
ตั้งอยู่เลขที่ 450
ตรอก/ซอย จันทน์ 32 ถนน สาทร หมู่ที่ -
ตำบล/แขวง ทุ่งวัดดอน อำเภอ/เขต สาทร
จังหวัด กรุงเทพมหานคร รหัสไปรษณีย์ 10120 โทรศัพท์ 026758643 โทรสาร 026758643

ออกให้ไว้ ณ วันที่ 28 เดือน ตุลาคม พ.ศ. 2564

(นางสิรินมาส คัจฉมาศย์)
เภสัชกรชำนาญการพิเศษ
ผู้อนุญาต
ผู้ซึ่งเลขาธิการคณะกรรมการอาหารและยามอบหมาย

THAI FDA A4 1223569

新冠抗原笔获泰国FDA自测证（唾液）

แบบ ป.ท.

ใบรับรองการประเมินเทคโนโลยีเครื่องมือแพทย์

ใบรับรองการประเมิน ที่ T 6400430

ใบรับรองการประเมินฉบับนี้ให้ไว้แก่

บริษัท ยู.เอ็น.เอส. อินเตอร์เนชั่นแนล จำกัด

ผู้จดทะเบียนสถานประกอบการผลิตหรือนำเข้าเครื่องมือแพทย์ ใบจดทะเบียนที่ กท. สน. 294/2564 เพื่อแสดงว่าเป็นผู้ผลิตหรือนำเข้าเครื่องมือแพทย์ที่ได้รับการประเมินเทคโนโลยี ตามมาตรา ๖ (๘) แห่งพระราชบัญญัติเครื่องมือแพทย์ พ.ศ. ๒๕๕๑ สำหรับเครื่องมือแพทย์

StrongStep x Crazydoctor Premium SARS-CoV-2 Antigen Rapid Test (Saliva)

รายละเอียดเครื่องมือแพทย์ รหัสสินค้า 500210

ขนาดบรรจุ 1การทดสอบต่อกล่อง

ประเภทเพื่อการวินิจฉัยภายนอกร่างกาย ชนิดเพื่อการวินิจฉัยรายบุคคล แบบตรวจคัดกรอง

แบบตรวจหา แอนติเจนด้วยตนเอง (Home use/Self-test)

สิ่งส่งตรวจ Saliva

ชื่อและที่ตั้งของสถานที่ผลิตเครื่องมือแพทย์ในต่างประเทศ

Nanjing Liming Bio-Products Co., Ltd. No. 12 Huayuan Road, Nanjing, Jiangsu, 210042 P.R. China

ณ สถานที่ผลิตหรือนำเข้าเครื่องมือแพทย์ชื่อ บริษัท ยู.เอ็น.เอส. อินเตอร์เนชั่นแนล จำกัด

ตั้งอยู่เลขที่ 450

ตรอก/ซอย จันทน์ 32 ถนน สาทร หมู่ที่ -

ตำบล/แขวง ทุ่งวัดดอน อำเภอ/เขต สาทร

จังหวัด กรุงเทพมหานคร รหัสไปรษณีย์ 10120 โทรศัพท์ 026758643 โทรสาร 026758643

ออกให้ไว้ ณ วันที่ 28 เดือน ตุลาคม พ.ศ. 2564

([illegible])

เภสัชกรชำนาญการพิเศษ

ผู้อนุญาต

ผู้ซึ่งเลขาธิการคณะกรรมการอาหารและยามอบหมาย

新冠抗原卡获泰国FDA自测证（鼻拭子）

แบบ ป.ท.

ใบรับรองการประเมินเทคโนโลยีเครื่องมือแพทย์

ใบรับรองการประเมิน ที่ T 6400431

ใบรับรองการประเมินฉบับนี้ให้ไว้แก่

บริษัท ยู.เอ็น.เอส. อินเตอร์เนชั่นแนล จำกัด

ผู้จดทะเบียนสถานประกอบการผลิตหรือนำเข้าเครื่องมือแพทย์ ใบจดทะเบียนที่ กท. สน. 294/2564

เพื่อแสดงว่าเป็นผู้ผลิตหรือนำเข้าเครื่องมือแพทย์ที่ได้รับการประเมินเทคโนโลยี ตามมาตรา ๖ (๘)

แห่งพระราชบัญญัติเครื่องมือแพทย์ พ.ศ. ๒๕๕๑ สำหรับเครื่องมือแพทย์

StrongStep x Crazydoctor SARS-CoV-2 Antigen Rapid Test (Nasal Swab)

รายละเอียดเครื่องมือแพทย์ รหัสสินค้า 500200

ขนาดบรรจุ 1การทดสอบต่อกล่อง

ประเภทเพื่อการวินิจฉัยภายนอกร่างกาย ชนิดเพื่อการวินิจฉัยรายบุคคล แบบตรวจคัดกรอง

แบบตรวจหา แอนติเจนด้วยตนเอง (Home use/Self-test)

สิ่งส่งตรวจ Nasal swab

ชื่อและที่ตั้งของสถานที่ผลิตเครื่องมือแพทย์ในต่างประเทศ

Nanjing Liming Bio-Products Co., Ltd. No. 12 Huayuan Road, Nanjing, Jiangsu, 210042 P.R. China

ณ สถานที่ผลิตหรือนำเข้าเครื่องมือแพทย์ชื่อ บริษัท ยู.เอ็น.เอส. อินเตอร์เนชั่นแนล จำกัด

ตั้งอยู่เลขที่ 450

ตรอก/ซอย จันทน์ 32 ถนน สาทร หมู่ที่ -

ตำบล/แขวง ทุ่งวัดดอน อำเภอ/เขต สาทร

จังหวัด กรุงเทพมหานคร รหัสไปรษณีย์ 10120 โทรศัพท์ 026758643 โทรสาร 026758643

ออกให้ไว้ ณ วันที่ 28 เดือน ตุลาคม พ.ศ. 2564

(นางสิรินมาส คัชมาตย์)

เภสัชกรชำนาญการพิเศษ

ผู้อนุญาต

ผู้ซึ่งเลขาธิการคณะกรรมการอาหารและยามอบหมาย

แบบ ป.ท.

ใบรับรองการประเมินเทคโนโลยีเครื่องมือแพทย์

ใบรับรองการประเมิน ที่ T 6400432

ใบรับรองการประเมินฉบับนี้ให้ไว้แก่
บริษัท ยู.เอ็น.เอส. อินเตอร์เนชั่นแนล จำกัด
ผู้จดทะเบียนสถานประกอบการผลิตหรือนำเข้าเครื่องมือแพทย์ ใบจดทะเบียนที่ กท. สน. 294/2564
เพื่อแสดงว่าเป็นผู้ผลิตหรือนำเข้าเครื่องมือแพทย์ที่ได้รับการประเมินเทคโนโลยี ตามมาตรา ๖ (๘)
แห่งพระราชบัญญัติเครื่องมือแพทย์ พ.ศ. ๒๕๕๑ สำหรับเครื่องมือแพทย์
StrongStep x Crazydoctor SARS-CoV-2 Antigen Rapid Test (Saliva)

รายละเอียดเครื่องมือแพทย์ รหัสสินค้า 500200
ขนาดบรรจุ 1การทดสอบต่อกล่อง
ประเภทเพื่อการวินิจฉัยภายนอกร่างกาย ชนิดเพื่อการวินิจฉัยรายบุคคล แบบตรวจคัดกรอง
แบบตรวจหา แอนติเจนด้วยตนเอง (Home use/Self-test)
สิ่งส่งตรวจ Saliva
ชื่อและที่ตั้งของสถานที่ผลิตเครื่องมือแพทย์ในต่างประเทศ
Nanjing Liming Bio-Products Co., Ltd. No. 12 Huayuan Road, Nanjing, Jiangsu, 210042 P.R. China

ณ สถานที่ผลิตหรือนำเข้าเครื่องมือแพทย์ชื่อ บริษัท ยู.เอ็น.เอส. อินเตอร์เนชั่นแนล จำกัด
ตั้งอยู่เลขที่ 450
ตรอก/ซอย จันทน์ 32 ถนน สาทร หมู่ที่ -
ตำบล/แขวง ทุ่งวัดดอน อำเภอ/เขต สาทร
จังหวัด กรุงเทพมหานคร รหัสไปรษณีย์ 10120 โทรศัพท์ 026758643 โทรสาร 026758643
ออกให้ ณ วันที่ 28 เดือน ตุลาคม พ.ศ. 2564

ผู้ซึ่งเลขาธิการคณะกรรมการอาหารและยา มอบหมาย

新冠抗原试剂获文莱卫生部认证

Ministry of Health
Brunei Darussalam

COVID-19 RAPID TESTS KITS (ART)
AUTHORISED FOR USED IN BRUNEI DARUSSALAM.

The listed Covid-19 antigen rapid test kits that are recommended and authorized for use are based on the evaluation done by Ministry of Health, Brunei Darussalam. The results of the evaluations are determined according to the clinical and analytical performance of the test kits (sensitivity and specificity claimed by the manufacturers), safety standards, quality and efficacy of the test kits.

Ministry of Health, through the Department of Laboratory Services will continue to update the list of authorized Covid-19 rapid test kits in order to ensure the supplied antigen rapid tests kits are meeting the required standards.

This list is updated as at **22 November 2021**.

NO	PRODUCT NAME	MANUFACTURER	DETECTION	SAMPLE TYPE
32	StrongStep SARS-CoV-2 Rapid Antigen Test	Nanjing Liming Bio-product Co.Ltd, China	Antigen	Nasal/ Oropharyngeal

FIND EVALUATION OF SARS-COV-2 ANTIGEN (AG) DETECTING TESTS

新冠抗原试剂进入FIND评估清单

SARS-CoV-2 antigens are shed as the virus replicates during active infection, and thus their detection can be used to diagnose current infection.

FIND is conducting prospective diagnostic evaluation studies in collaboration with multiple, independent sites to determine the accuracy of COVID-19 antigen (Ag) detecting tests (RDTs). We are currently busy evaluating assays that have already been selected (Table 1) and the expression of interest (EOI) to participate in the Ag RDT evaluations is now closed.

Test submissions were selected through a scoring system taking into consideration:

- supplier-reported analytical performance
- supplier-reported clinical performance and size of the related study population/number of COVID-19 positive cases
- ease of use of the test (need for an instrument, sample type)
- manufacturing and distribution capacity (especially related to the ability of the company to access LMICs market)
- regulatory status – products with approval from stringent regulatory bodies such as FDA EUA or WHO EUL are scored higher than CE-IVD self-reported tests which are in turn scored higher than RUO tests.

Status of submission to WHO EUL or approval/failure of another COVID-19 test has also been considered for the final stage of selection.

ANTIGEN RDT EVALUATION PROTOCOL SUMMARY

Results for ongoing evaluations will continue to be updated on a routine basis (Table 1). Last update: **1 Dec 2021**

Note: *Lower test sensitivity has been observed repeatedly in the evaluations performed in the study sites in India. A root-cause analysis exercise, which included sampling and testing parameters, has been conducted and did not return a conclusive cause for this lower performance compared to results obtained at other study sites. It must be noted that all the referenced evaluations were conducted prior to the emergence of the newly detected variants in India, such as B.1.617. A remaining hypothesis, which has not been confirmed, is that the higher temperature and humidity conditions observed in India may be contributing to varied performance.*

Table 1. Antigen(Ag)-detection RDTs undergoing evaluation

Company	Assay	Country of manufacturer	Interpretation	Regulatory status	Evaluation status	Evaluation results
Nanjing Liming BioProducts Co.	StrongStep SARS Cov-2 Antigen Rapid Test	PR China	Visual	CE-IVD	To start	Not yet available

EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Public health, country knowledge, crisis management
Health Security

黎明新冠抗原试剂进入

欧盟卫生和食品安全总局通用清单

EU health preparedness:

A common list of COVID-19 rapid antigen tests; A common standardised set of data to be included in COVID-19 test result certificates; and A common list of COVID-19 laboratory based antigenic assays

Agreed by the Health Security Committee

Common list of COVID-19 rapid antigen tests (Annex I)

Agreed by the Health Security Committee on 17 February 2021.

First update: 10 May 2021; Second update: 16 June 2021; Third update: 7 July 2021; Fourth update: 14 July 2021; Fifth update: 23 July 2021; Sixth update: 20 October 2021; Seventh update: 10 November 2021; Eight update: 8 December 2021.

Common standardised data set to be included in COVID-19 test result certificates (Annex II)

Agreed by the Health Security Committee on 17 February 2021.

An update to Annex II was agreed by the HSC on 19 March 2021

Common list of COVID-19 laboratory based antigenic assays (Annex III)

Agreed by the Health Security Committee on 20 October 2021

Manufacturer	RAT commercial name	Device ID # [15]	Clinical performance *As reported by independent validation studies*	Clinical performance *Data by manufacturer* [16]	Completed validation studies	SARS-CoV-2 Target protein	Specimen [17]	Included in EU common list since:
			Retrospective in vitro study DE: Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of RPA at Ct ≤ 25; Manufacturer specificity: 99.9%					
Nanjing Liming Bio-Products Co., Ltd.	StrongStep® SARS-CoV-2 Antigen Rapid Test	2301	*Retrospective in vitro study* DE: Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99.26%	Sensitivity: 96.19 %, Specificity: 99.26 % Nasal swab	DE[2]	Nucleo-capsid protein	Nasal swab	8 December 2021

Health Sciences Authority
11 Outram Road Singapore 169078
Tel: 65 6213 0838 Fax: 65 6213 0749
Website: www.hsa.gov.sg

HSA 600:36/01

新冠PCR获新加坡HSA认证

28 July 2020

All Eights (Singapore) Pte Ltd
6 Harper Road #03-02 / #06-07,
Leong Huat Building,
Singapore 369674

Dear Jocelyn Koh,

RE: STATUS OF SUPPLY OF MEDICAL DEVICES IN SINGAPORE

This letter serves to confirm that the following medical device product(s) have been issued Provisional Authorisation (MDPA2020-101) for supply in Singapore and may be exported from Singapore.

No.	Device Name	Intended Use
1	StrongStep® Novel Coronavirus (SARS-CoV-2) Multiplex Real-Time PCR Kit (S00190)	This product is intended to be used to achieve qualitative detection of SARS-CoV-2 viral RNA extracted from nasopharyngeal swabs, oropharyngeal swabs, sputum and BALF from patients in association with an RNA extraction system and the designated PCR platforms listed above. The kit is intended for use by laboratory trained personnel.

Product Owner:	Nanjing Liming Bio-Products Co., Ltd. No. 12 Huayuan Road, Nanjing, Jiangsu, 210042 P.R. China.
Manufacturing Site:	Nanjing Liming Bio-Products Co., Ltd. No. 12 Huayuan Road, Nanjing, Jiangsu, 210042 P.R. China.

2. The medical device product(s) may be supplied to the healthcare institutions, private hospitals, medical clinics or clinical laboratories licensed under the PHMC Act (Cap. 248) for use on their patients.

3. The medical device product(s) may be exported out of Singapore subject to the duties and obligations as stipulated in the Health Products Act and the Health Products (Medical Devices) Regulation 2010.

4. The confirmation above is subject to the manufacturer's activities conforming to the ISO 13485 quality system.

Yours sincerely,

DR CHRISTOPHER LAM
SENIOR REGULATORY SPECIALIST
For GROUP DIRECTOR
HEALTH PRODUCTS REGULATION GROUP
HEALTH SCIENCES AUTHORITY

KEMENTERIAN KESEHATAN REPUBLIK INDONESIA
DIREKTORAT JENDERAL KEFARMASIAN DAN ALAT KESEHATAN
Jalan H.R. Rasuna Said Blok X-5 Kavling 4 - 9 Jakarta 12950
Telepon : (021) 5201590 Pesawat 2029, 8011
Faksimile : (021) 52964838 Kotak Pos : 203

新冠PCR取得印尼FDA注册证

Berdasarkan Peraturan Menteri Kesehatan R.I Nomor 62 Tahun 2017 Tentang Izin Edar Alat Kesehatan, Alat Kesehatan Diagnostik In Vitro Dan Perbekalan Kesehatan Rumah Tangga dengan ini diberikan persetujuan untuk diedarkan dengan :

NOMOR IZIN EDAR

ALAT KESEHATAN

KEMENKES RI AKL 20303024595

Nama Dagang / Merek	:	**StrongStep® Novel Coronavirus (SARS CoV- 2) Multiplex Real-Time PCR Kit (detection for three genes)**
Kelompok / Kelas Resiko	:	Diagnostik *In Vitro* / B
Kategori Produk	:	Peralatan Imunologi dan Mikrobiologi
Sub Kategori	:	Pereaksi Serologi
Jenis Produk	:	Respiratory viral panel multiplex nucleic acid assay
Tipe / Ukuran	:	Ref. No. 500190
Kemasan	:	Dus, kit, isi 96 tes
Nama Produsen / Pabrikan	:	NANJING LIMING BIO-PRODUCTS CO., LTD, China
Nama Pendaftar	:	PT. SANSICO NATURA RESOURCES, DKI Jakarta
Atas dasar lisensi dari	:	-

Ketentuan

1. Persetujuan ini adalah Persetujuan Izin Edar Dimasa Darurat Covid-19, berlaku sampai dengan 14 Agustus 2021 (1 Tahun).
2. Wajib menyampaikan laporan berkala dan laporan jika ada kejadian yang tidak diinginkan akibat penggunaan Alat Kesehatan tersebut di atas sesuai ketentuan berlaku.
3. Persetujuan Izin Edar Dimasa Darurat dapat diperpanjang jika tidak ditemukan kejadian tidak diinginkan pada pemakaian.
4. Kementerian Kesehatan berhak meninjau atau mengevaluasi aspek keamanan, mutu, dan kemanfaatan apabila ditemukan bukti baru terkait Alat Kesehatan yang diterbitkan izin edarnya.
5. Apabila dikemudian hari ada pihak lain yang berhak atas merek dan/atau keagenan produk tersebut, pendaftar bersedia mengembalikan izin edar.
6. Penandaan dan informasi produk yang terlampir merupakan bagian yang tidak terpisahkan dari persetujuan izin edar ini.
7. Apabila di kemudian hari terdapat kekeliruan, maka persetujuan izin edar ini akan ditinjau kembali.

Jakarta, 14 Agustus 2020

Ditandatangani Secara Elektronik Oleh :
a.n Direktur Jenderal
Direktur Penilaian Alat Kesehatan dan PKRT

KEMENTERIAN KESEHATAN REPUBLIK INDONESIA

Dr. IGAV. Wiradnyana, Apt
NIP. 19751126 200312 2 001

Catatan:
- UU ITE No 11 Tahun 2007 Pasal 5 ayat 1
  Informasi Elektronik dan/atau Dokumen Elektronik dan/atau hasil cetaknya merupakan alat bukti hukum yang sah.
- Dokumen ini telah ditandatangani secara elektronik menggunakan sertifikat elektronik yang diterbitkan BSrE.

Ministerio de Salud Pública

新冠PCR荣获厄瓜多尔认证

Agencia Nacional de Regulación, Control y Vigilancia Sanitaria - **ARCSA**

INFORME TÉCNICO PARA LA EMISIÓN DEL CERTIFICADO DE INSCRIPCIÓN EN EL REGISTRO SANITARIO DE DISPOSITIVOS MÉDICOS DE FABRICACIÓN EXTRANJERA

Fecha de elaboración: 08/09/2020

De conformidad con el (los) análisis técnico (s) y legal realizados para la Emisión del Certificado De Inscripción En El Registro Sanitario De Dispositivos Médicos De Fabricación Extranjera, correspondiente a la solicitud Nro. 16823616202000000005P, ingresada el 26/05/2020, se emite el siguiente informe:

Datos del producto analizado

Nombre de producto:	22-339 Reactivos/Kits para Ensayos de DIV, Ensayo Molecular, Infección, Virus, Coronavirus del Síndrome Respiratorio Agudo Severo, RNA
Clasificación:	DIV DIAG UU G6VIR RIII
Fabricante:	NANJING LIMING BIO-PRODUCTS CO., LTD.
Solicitante:	LEAL CHANTONG JOSE EDUARDO

Resultados

Análisis Documental Técnico

Fecha de elaboración de informe: 2020-09-08 14:02:25
Técnico responsable del análisis: RUTH ELISA ROLDÃ•N RÃ•OS
Líder responsable del análisis: FERNANDO FABIAN JIMENEZ SALAZAR

Resultados del análisis: Aceptado

Conclusión: Aceptado

新冠抗体、PCR获巴西ANVISA认证

RESOLUÇÃO-RE Nº 2.907, DE 6 DE AGOSTO DE 2020

O Gerente-Geral de Tecnologia de Produtos para Saúde, no uso das atribuições que lhe confere o art. 156, aliado ao art. 54, I, § 1º do Regimento Interno aprovado pela Resolução de Diretoria Colegiada - RDC nº 255, de 10 de dezembro de 2018, resolve:

Art. 1º Conceder a Transferência de Titularidade de Registro ou Cadastro e por consequente, cancelar o Registro ou Cadastro dos Produtos para Saúde, conforme anexo.

Art. 2º Esta Resolução entra em vigor no prazo de 90 (noventa) dias, após o sua publicação.

LEANDRO RODRIGUES PEREIRA

ANEXO

NOME DA EMPRESA / CNPJ
NOME COMERCIAL
NUMERO DO PROCESSO / REGISTRO
PETIÇÃO(ÕES) / EXPEDIENTE(S)

MANDALA BRASIL IMPORTAÇÃO E DISTRIBUIÇÃO DE PRODUTO MÉDICO HOSPITALAR LTDA / 09.117.476/0001-81
PLURYAL VOLUME
25351.666030/2020-86 / 80686360292
80061 - MATERIAL - Transferência de titularidade de registro de material de uso em saúde / 2274432201
PLURYAL VOLUME LIDOCAÍNA
25351.665973/2020-91 / 80686360291
80061 - MATERIAL - Transferência de titularidade de registro de material de uso em saúde / 2274344208
PLURYAL BOOSTER
25351.665964/2020-09 / 80686360288
80061 - MATERIAL - Transferência de titularidade de registro de material de uso em saúde / 2274229208
PLURYAL CLASSIC LIDOCAÍNA
25351.665965/2020-45 / 80686360289
80061 - MATERIAL - Transferência de titularidade de registro de material de uso em saúde / 2274233206
PLURYAL CLASSIC
25351.666001/2020-14 / 80686360290
80061 - MATERIAL - Transferência de titularidade de registro de material de uso em saúde / 2274329204

MEDSTAR IMPORTAÇÃO E EXPORTAÇÃO EIRELI / 03.580.620/0001-35
RECARGA PARA GRAMPEADOR LINEAR RLS
25351.306829/2019-06 / 80047300765
80084 - MATERIAL - Cancelamento de registro ou cadastro por transferência de titularidade / 2107748207
GRAMPEADOR LINEAR CORTANTE FLC/DLC COM RECARGA REACH
25351.367468/2019-41 / 80047300766
80084 - MATERIAL - Cancelamento de registro ou cadastro por transferência de titularidade / 2107848203

MEDSUPPLY COMÉRCIO DE MATERIAL HOSPITALAR LTDA - ME / 04.163.492/0001-97
Micro Fio Guia Liso Descartável Safe-Dura
25351.596158/2019-31 / 81021300025
80084 - MATERIAL - Cancelamento de registro ou cadastro por transferência de titularidade / 2275448202
Cânula Dirigível de Microressecção Óssea Safe-Dura
25351.596444/2019-05 / 81021300030
80084 - MATERIAL - Cancelamento de registro ou cadastro por transferência de titularidade / 2263119204
Cânula Cobbra
25351.787834/2014-09 / 81021300009
80084 - MATERIAL - Cancelamento de registro ou cadastro por transferência de titularidade / 2261015204
Empire Microincision
25351.119212/2015-90 / 81021300017
80084 - MATERIAL - Cancelamento de registro ou cadastro por transferência de titularidade / 2275231205

PASSROD IMPORTAÇÃO E EXPORTAÇÃO DE PRODUTOS PARA SAÚDE LTDA - ME / 26.185.222/0001-10
RECARGA PARA GRAMPEADOR LINEAR RLS
25351.666479/2020-44 / 81504790221
80061 - MATERIAL - Transferência de titularidade de registro de material de uso em saúde / 2275263203
GRAMPEADOR LINEAR CORTANTE FLC/DLC COM RECARGA REACH
25351.666584/2020-83 / 81504790222
80061 - MATERIAL - Transferência de titularidade de registro de material de uso em saúde / 2275599203

SÓLIDA HOSPITALAR - DISTRIBUIDORA DE MATERIAL HOSPITALAR EIRELI / 21.196.966/0001-56
Cânula Dirigível de Microressecção Óssea Safe-Dura
25351.677148/2020-30 / 81189660089
80049 - MATERIAL - Transferência de titularidade de cadastro de material de uso em saúde / 2306132204
Cânula de Microressecção Óssea Safe-Dura
25351.677309/2020-95 / 81189660090
80049 - MATERIAL - Transferência de titularidade de cadastro de material de uso em saúde / 2306591205
Cânula de Acesso Percutâneo N6
25351.677117/2020-89 / 81189660085
80049 - MATERIAL - Transferência de titularidade de cadastro de material de uso em saúde / 2306054209
Cânula Cobbra
25351.677191/2020-03 / 81189660087
80049 - MATERIAL - Transferência de titularidade de cadastro de material de uso em saúde / 2306239208
Micro Fio Guia Liso Descartável Safe-Dura
25351.677192/2020-40 / 81189660088
80049 - MATERIAL - Transferência de titularidade de cadastro de material de uso em saúde / 2306243206
Empire Microincision
25351.677146/2020-41 / 81189660086
80049 - MATERIAL - Transferência de titularidade de cadastro de material de uso em saúde / 2306127208

SUPORTE HOSPITALAR LTDA / 73.857.393/0001-28
Cânula de Acesso Percutâneo N6
25351.577685/2017-85 / 10275160054
80084 - MATERIAL - Cancelamento de registro ou cadastro por transferência de titularidade / 2277246204
Cânula de Microressecção Óssea Safe-Dura
25351.601210/2017-17 / 10275160055
80084 - MATERIAL - Cancelamento de registro ou cadastro por transferência de titularidade / 2277915209

VALENTINE CASSETTI DASSOUKI EPP / 19.666.443/0001-44
PLURYAL BOOSTER
25351.733333/2017-16 / 81085440012
80084 - MATERIAL - Cancelamento de registro ou cadastro por transferência de titularidade / 2181360204
PLURYAL CLASSIC LIDOCAÍNA
25351.033783/2018-96 / 81085440011
80084 - MATERIAL - Cancelamento de registro ou cadastro por transferência de titularidade / 2181471206
PLURYAL VOLUME
25351.733378/2017-91 / 81085440009
80084 - MATERIAL - Cancelamento de registro ou cadastro por transferência de titularidade / 2182416209
PLURYAL VOLUME LIDOCAÍNA
25351.033748/2018-77 / 81085440010
80084 - MATERIAL - Cancelamento de registro ou cadastro por transferência de titularidade / 2182577207
PLURYAL CLASSIC
25351.733332/2017-71 / 81085440014
80084 - MATERIAL - Cancelamento de registro ou cadastro por transferência de titularidade / 2181334205

Nº de Processos: 26

Total de Empresas: 7

RESOLUÇÃO-RE Nº 2.941, DE 7 DE AGOSTO DE 2020

O Gerente-Geral de Tecnologia de Produtos para Saúde, no uso das atribuições que lhe confere o art. 156, aliado ao art. 54, I, § 1º do Regimento Interno aprovado pela Resolução de Diretoria Colegiada - RDC nº 255, de 10 de dezembro de 2018, resolve:

Art. 1º Deferir as petições relacionadas à Gerência-Geral de Tecnologia de Produtos para a Saúde, com validade de 1(um) ano em atenção ao art. 12 da Resolução de Diretoria Colegiada - RDC nº 348, de 17 de março de 2020 e considerando o art. 8º e o art. 10 da Resolução de Diretoria Colegiada - RDC nº 349, de 19 de março de 2020, conforme anexo.

Art. 2º Esta Resolução entra em vigor na data de sua publicação.

LEANDRO RODRIGUES PEREIRA

ANEXO

NOME DA EMPRESA / CNPJ
NOME COMERCIAL
NUMERO DO PROCESSO / REGISTRO
PETIÇÃO(ÕES) / EXPEDIENTE(S)

ADVANCED MED IMPORTADORA E EXPORTADORA DE PRODUTOS FARMACÊUTICOS LTDA ME / 21.018.237/0001-70
Termômetro Infravermelho MDI907 - Testa e objetos
25351.747233/2020-72 / 81178709003
8024 - EQUIPAMENTO - Cadastro de Equipamento para Saúde / 2521500201

BASAL Comércio, Importação e Exportação Ltda / 17.002.220/0001-57
iThermo T5
25351.744405/2020-56 / 80988530020
80027 - EQUIPAMENTO - Cadastro de Família de Equipamentos para Saúde / 2514519203

DBI COMÉRCIO DE EQUIPAMENTOS MÉDICOS LTDA. / 18.552.189/0001-10
Monitor de Sinais Vitais Qube Mini 91389
25351.713952/2020-80 / 81178350028
8049 - EQUIPAMENTO - Registro de Equipamento para Saúde, de Médio e Pequeno Porte / 2419053205

ENDOBRAX COMÉRCIO, IMPORTAÇÃO E EXPORTAÇÃO DE EQUIPAMENTOS MÉDICOS LTDA / 07.427.470/0001-85
Respirador BIPAP Argus Série LA
25351.758081/2020-33 / 80393910037
80027 - EQUIPAMENTO - Cadastro de Família de Equipamentos para Saúde / 2555383206
MONITOR MULTIPARÂMETROS GENERAL MEDITECH - SERIE G3
25351.682850/2020-15 / 80393910036
8052 - EQUIPAMENTO - Registro de Família de Equipamentos para Saúde, de Médio e Pequeno Porte / 2322303202

EQUILÍBRIO COMÉRCIO DE PRODUTOS FARMACÊUTICOS EIRELI EPP / 05.215.461/0001-03
StrongStep® SARS-CoV-2 IgG/IgM Antibody Rapid Test
25351.603877/2020-50 / 80589510013
8433 - IVD - Registro de produto / 2079643209
StrongStep® Novel Coronavirus (SARS-CoV-2) Multiplex Real-Time PCR Kit
25351.747123/2020-19 / 80589510014
8433 - IVD - Registro de produto / 2488952201

MEDMAX COMÉRCIO DE EQUIPAMENTOS MÉDICOS E SIMILARES EIRELI- ME / 07.750.277/0001-61
BOMBA DE INFUSÃO
25351.730425/2020-28 / 80298970175
8049 - EQUIPAMENTO - Registro de Equipamento para Saúde, de Médio e Pequeno Porte / 2471453204

PASSROD IMPORTAÇÃO E EXPORTAÇÃO DE PRODUTOS PARA SAÚDE LTDA - ME / 26.185.222/0001-10
Videolaringoscópio Insight
25351.353456/2020-38 / 81504790183
80213 - EQUIPAMENTO - Alteração de cadastro - Aprovação requerida - Indicação e finalidade de uso; tipo de operador ou paciente ou ambiente de utilização; princípio de funcionamento; alteração de software (novas indicações e funcionalidades); acréscimo de equipamento; alteração técnica; alteração/inclusão de componentes em sistema; alteração/inclusão de partes e acessórios / 2454435203
Videolaringoscópio Flexível Insight
25351.351137/2020-22 / 81504790182
80213 - EQUIPAMENTO - Alteração de cadastro - Aprovação requerida - Indicação e finalidade de uso; tipo de operador ou paciente ou ambiente de utilização; princípio de funcionamento; alteração de software (novas indicações e funcionalidades); acréscimo de equipamento; alteração técnica; alteração/inclusão de componentes em sistema; alteração/inclusão de partes e acessórios / 2454447207
Videolaringoscópio Rígido Insight
25351.350892/2020-50 / 81504790185
80213 - EQUIPAMENTO - Alteração de cadastro - Aprovação requerida - Indicação e finalidade de uso; tipo de operador ou paciente ou ambiente de utilização; princípio de funcionamento; alteração de software (novas indicações e funcionalidades); acréscimo de equipamento; alteração técnica; alteração/inclusão de componentes em sistema; alteração/inclusão de partes e acessórios / 2456786208

KEMENTERIAN KESEHATAN REPUBLIK INDONESIA
DIREKTORAT JENDERAL KEFARMASIAN DAN ALAT KESEHATAN
Jalan H.R. Rasuna Said Blok X-5 Kavling 4 - 9 Jakarta 12950
Telepon : (021) 5201590 Pesawat 2029, 8011
Faksimile : (021) 52964838 Kotak Pos : 203

GERMAS

核酸提取试剂获印尼FDA注册

Berdasarkan Peraturan Menteri Kesehatan R.I Nomor 62 Tahun 2017 Tentang Izin Edar Alat Kesehatan, Alat Kesehatan Diagnostik In Vitro Dan Perbekalan Kesehatan Rumah Tangga dengan ini diberikan persetujuan untuk diedarkan dengan :

NOMOR IZIN EDAR

ALAT KESEHATAN

KEMENKES RI AKL 10204121343

Nama Dagang / Merek	:	**STRONGSTEP® DNA/RNA Extraction Kit**
Kelompok / Kelas Resiko	:	Diagnostik *In Vitro* / A
Kategori Produk	:	Peralatan Hematologi dan Patologi
Sub Kategori	:	Pereaksi dan Penyedia Specimen
Jenis Produk	:	General purpose reagent.
Tipe / Ukuran	:	REF: 504004
Kemasan	:	Box isi 100 dan 50 test
Nama Produsen / Pabrikan	:	NANJING LIMING BIO-PRODUCTS CO., LTD, China
Nama Pendaftar	:	PT. SANSICO NATURA RESOURCES, DKI Jakarta
Atas dasar lisensi dari	:	-

Ketentuan

1. Persetujuan izin edar berlaku sampai dengan 05 Februari 2023.
2. Wajib menyampaikan laporan berkala dan laporan jika ada kejadian yang tidak diinginkan akibat penggunaan Alat Kesehatan tersebut di atas sesuai ketentuan berlaku.
3. Apabila dikemudian hari ada pihak lain yang berhak atas merek dan/atau keagenan produk tersebut, pendaftar bersedia mengembalikan izin edar.
4. Penandaan dan informasi produk yang terlampir merupakan bagian yang tidak terpisahkan dari persetujuan izin edar ini.
5. Apabila di kemudian hari terdapat kekeliruan, maka persetujuan izin edar ini akan ditinjau kembali.

Jakarta, 13 Maret 2021

KEMENTERIAN KESEHATAN REPUBLIK INDONESIA

Ditandatangani Secara Elektronik Oleh :
a.n. Direktur Jenderal
Direktur Penilaian Alat Kesehatan dan PKRT

Dr. IGAV. Wiradnyana, Apt
NIP. 19751206 200912 1 001

Catatan:
- UU ITE No 11 Tahun 2007 Pasal 5 ayat 1
  Informasi Elektronik dan/atau Dokumen Elektronik dan/atau hasil cetaknya merupakan alat bukti hukum yang sah.
- Dokumen ini telah ditandatangani secara elektronik menggunakan sertifikat elektronik yang diterbitkan BSrE.

新冠PCR巴西ANVISA认证

REPÚBLICA FEDERATIVA DO BRASIL
MINISTÉRIO DA SAÚDE
AGÊNCIA NACIONAL DE VIGILÂNCIA SANITÁRIA
GERÊNCIA GERAL DE TECNOLOGIA DE PRODUTOS PARA SAÚDE

CERTIFICADO DE PRODUTO

Agência Nacional de Vigilância Sanitária, vinculada ao Ministério da Saúde, CERTIFICA que o produto abaixo indicado, é fabricado de acordo com as leis vigentes no Brasil, com a sua venda autorizada em todo o Território Brasileiro.

RAZAO SOCIAL: EQUILIBRIO COMÉRCIO DE PRODUTOS FARMACÊUTICOS EIRELI

CNPJ: 05.215.461/0001-03

ENDEREÇO: SHCGN CR QUADRA 714/715, BLOCO D, LOJA 40, PARTE SUBSOLO CEP: 70761-640

NOME TÉCNICO	CORONAVÍRUS
NOME COMERCIAL	StrongStep® Novel Coronavirus (SARS-CoV-2) Multiplex Real-Time PCR Kit
CLASSE DE RISCO	III - Classe III: produtos de alto risco ao indivíduo e ou médio risco à saúde pública
FABRICANTE LEGAL	NANJING LIMING BIO-PRODUCTS CO., LTD - CHINA, REPÚBLICA POPULAR - Fabricante Legal
REGISTRO Nº	80589510014
DATA DO REGISTRO	10/08/2020
VÁLIDO ATÉ	10/08/2030

MODELO COMERCIAL:

Reagente SARS-CoV-2 rt-qPCR - 12 x embalagens de vedação a vácuo/ Controle Positivo - 1 tubo de 2,0 mL/ Instruções de Uso - 1 unidade

Documento emitido eletronicamente às: 16:58:35 do dia 26/03/2021 (Hora e data de Brasília - DF)

Código de controle do comprovante: 1475.7572.06F7.E3A4.D0E4.A4B7.E014.4557.E5AA.BE93

Conforme §2º, Art. 6°, RDC n° 27 de 15 de maio de 2013, qualquer alteração ou inclusão pós-registro ou pós-cadastro deferida que altere as informações do documento emitido, torná-lo-á inválido.

Verifique a autenticidade deste documento no endereço: http://www.anvisa.gov.br/validacertificadoggtps

新冠抗体取得巴西ANVISA认证

MINISTÉRIO DA SAÚDE

AGÊNCIA NACIONAL DE VIGILÂNCIA SANITÁRIA

CERTIFICADO DE BOAS PRÁTICAS DE FABRICAÇÃO E CONTROLE DE PRODUTOS PARA SAÚDE

Considerando o disposto na Lei n.º 9.782, de 26 de janeiro de 1999, o Decreto nº 3.029, de 16 de abril de 1999 e a publicação no Diário Oficial da União por meio da Resolução RE n° 2.002 na data de ***19/06/2020*** *certifico que a empresa, a seguir descrita, cumpre com a legislação sanitária vigente, quanto às Boas Práticas de Fabricação de produtos para saúde exigidas pela autoridade sanitária brasileira, estando sujeita a inspeções periódicas.*

Fabricante: Nanjing Liming Bio-Products Co., Ltd.

Endereço: No 12 Huayuan Road 210042, Nanjing, Jiangsu, China.

Solicitante: DR Importação, Exportação e Distribuição Ltda. CNPJ: 17.634.786/0001-00

Autorização de Funcionamento: 8.09.913-8 Expediente: 1509338/20-9

Certificado de Boas Práticas de Fabricação de Produtos para Saúde:

Produtos para diagnóstico de uso in vitro da classe III - Emergência COVID-19

Validade até: A presente certificação terá validade durante a vigência da Resolução de Diretoria Colegiada - RDC 346/2020.

Documento assinado eletronicamente por **Ronaldo Lucio Ponciano Gomes**, **Gerente-Geral de Inspeção e Fiscalização Sanitária**, em 22/06/2020, às 15:13, conforme horário oficial de Brasília, com fundamento no art. 6º, § 1º, do Decreto nº 8.539, de 8 de outubro de 2015 http://www.planalto.gov.br/ccivil_03/_Ato2015-2018/2015/Decreto/D8539.htm.

A autenticidade deste documento pode ser conferida no site https://sei.anvisa.gov.br/autenticidade, informando o código verificador **1058051** e o código CRC **62746112**.

新冠抗体试剂获马来西亚MDA认证

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.

Tel: (+603)8230 0300
Faks: (+603)8230 0200
Portal Rasmi: www.mda.gov.my
Email: mdb@mda.gov.my

Ref. No. : (27) dlm. MDA.600-3/1/12 Jilid 85

Date : 1 September 2021

INTERSCIENCE SDN BHD
2, Jalan Sg Kayu Ara 32/38,
Berjaya Industial Park,
40460 Shah Alam, Selangor.
(attention to : Mr Tan Nam Kwang)

Dear Sir,

NOTIFICATION ON IMPORTATION/SUPPLY OF MEDICAL DEVICES FOR SPECIAL ACCESS UNDER THE MEDICAL DEVICE (EXEMPTION) ORDER 2016 :

- **Medical Device Name** : StrongStep® COVID-19 IgM/IgG Combo Rapid Test Device
- **Manufacturer** : Nanjing Liming Bio-products Co. Ltd.
  No 12 Huayuan Road 210042 Nanjing, Jiangsu China

With regards to your notification dated 30th November 2020, I wish to inform you on the decision made by the Expert IVD Evaluation Committee on 1st June 2021 to your application is as follows:
Recommended for Use.

2. Therefore, for the purpose of issuance of Special Access Letter, you are kindly requested to provide us with the required information as follows:

i. Completed Special Access Route B Form (with the information on Section B, Medical Practitioner Details);
ii. Customer Order Form (signed and stamped by the Public or Private Pathology Laboratory/Hospital) who is requesting the supply of COVID-19 Detection Kits during COVID-19 outbreak.

3. This letter DOES **NOT CONSTITUTE AN APPROVAL** for the product and shall not be used for the purpose of promoting or advertising the product.

Yours Sincerely,

Thank you,

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

CMA
180000100599

CNAS
中国认可
检测
TESTING
CNAS L0001

中国食品药品检定研究院

检验报告

报告编号：RZ202009282

检品名称：新型冠状病毒（SARS-CoV-2）抗原检测试剂盒（乳胶免疫层析法）

生产单位/产地：南京黎明生物制品有限公司

检验目的：注册检验(国产体外诊断试剂/首次注册/质量标准复核)

检验依据：产品技术要求

Department of Health and Social Care
39 Victoria Street Westminster
SW1H 0EU
TestingSuppliesTeam@dhsc.gov.uk

Department of Health & Social Care

新冠抗原试剂英国卫生部三期临床报告

COVID 19 TEST – VALIDATION OUTCOME

9 March 2021
Nina Wang
Nanjing Liming Bio-Products Co.Ltd

HF /HR/080321

Dear Nina Wang

COVID 19 TEST - VALIDATION OUTCOME

Thank you for your ongoing co-operation and for providing us with the samples of the LIMING StrongStep SARS-CoV-2 Antigen Rapid Detection Test (v2) test that we requested for validation.

Your product progressed through phase 3A validation and has been examined at a Design Authority Review (DAR). We would like to advise you that the LIMING StrongStep SARS-CoV-2 Antigen Rapid Detection Test (v2) was successful in the phase 3A validation and that the LIMING StrongStep SARS-CoV-2 Antigen Rapid Detection Test (v2) test showed no drop off in sensitivity when compared with the wild type with respect to the following variants - VOC1 Kent, UK, B.1.1.7 and VOC2 South Africa, B.1.351.

We will continue to evaluate the LIMING StrongStep SARS-CoV-2 Antigen Rapid Detection Test (v2) test against future variants as and when they arise, and we will report the results of any future validation to you.

CONFIDENTIALITY

We remind you of your ongoing obligations of confidentiality as set out in the non-disclosure agreement signed by you dated 20 August 2020.

We thank you for your continued interest in supporting our COVID-19 response

Yours sincerely,

NHS Test and Trace

Enc: Phase 3A validation result LIMING StrongStep SARS-CoV-2 Antigen Rapid Detection Test (v2)

KEMENTERIAN KESEHATAN RI
DIREKTORAT JENDERAL PELAYANAN KESEHATAN
BALAI BESAR LABORATORIUM KESEHATAN JAKARTA
Jalan Percetakan Negara No. 23 B Jakarta Pusat - 10560
Telp. (021) 4212524, 42804339, Fax. (021) 4245516
Website : www.bblkjakarta.com Email : bblkjakarta@yahoo.co.id

Balai Besar Labkes Jakarta

LAPORAN HASIL PEMERIKSAAN

新冠抗原试剂印尼CDC检测报告

No Seri : 942-1031/LK/III/2021

Nama Pengirim	:	Direktorat Jenderal Kefarmasian dan Alat Kesehatan Kemenkes RI	No. Lab	:	005875/BM/III/2021
Nama Bahan Uji	:	RDT Antigen Sars-Cov-2	No. Instalasi	:	3573 - 3662
Merek	:	StrongStep 500200 SARS-CoV-2 Antigen Rapid Test	Tanggal diterima di Lab	:	08 Maret 2021
NIE	:	AKL 20303024804			
No. Lot/Batch	:	2012027	Tanggal Pemeriksaan	:	15-18 Maret 2021
Tanggal Kedaluwarsa	:	31 Desember 2022	Penanggung Jawab	:	dr. Nita Nurhidayati, Sp.MK
Alamat	:	Jl. HR. Rasuna Said Blok X5 Kav. 4-9, Jakarta Selatan 12950	SIP	:	12/2.104/31.71.08/-1.779.3/e/2017

1. Seluruh sampel

Rapid Antigen	Qrt-Pcr		Sensitivitas	Spesifisitas	NPP	NPN	Akurasi
	Positif	Negatif	(%)	(%)	(%)	(%)	(%)
Positif	53	0	88,3	100	100	81,1	92,2
Negatif	7	30					
Jumlah	60	30					

2. Sampel Positif CT ≤ 25

Rapid Antigen	Qrt-Pcr		Sensitivitas	Spesifisitas	NPP	NPN	Akurasi
	Positif	Negatif	(%)	(%)	(%)	(%)	(%)
Positif	29	0	96,7	100	100	96,8	98,3
Negatif	1	30					
Jumlah	30	30					

KALK

KEMENTERIAN KESEHATAN RI
DIREKTORAT JENDERAL PELAYANAN KESEHATAN
BALAI BESAR LABORATORIUM KESEHATAN JAKARTA
Jalan Percetakan Negara No. 23 B Jakarta Pusat - 10560
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LAPORAN HASIL PEMERIKSAAN

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3. Sampel Positif CT > 25

Rapid Antigen	Qrt-Pcr		Sensitivitas	Spesifisitas	NPP	NPN	Akurasi
	Positif	Negatif	(%)	(%)	(%)	(%)	(%)
Positif	24	0	80,0	100	100	83,3	90,0
Negatif	6	30					
Jumlah	30	30					

Mengetahui
KEPALA BALAI BESAR LABKES JAKARTA

Dr. Nikan Westu Palupi, MKM
NIP. 196812312002122006

Jakarta, 19 Maret 2021
KEPALA INSTALASI LABKES KLNIK

Yusnabeti, SKM, MKM.
NIP. 197308051992032001

possibili frammenti di virus non infettanti o per follow-up di precedenti positività (infettività che va progressivamente diminuendo (Guarigione).

Consuleote Scientifico Futura Diagnostica评估黎明SARS-CoV-2抗原试剂

非常适合对疑似SARS-CoV-2感染进行初步筛选

L'analisi dei dati accorpati rivelano quindi :

Il campione 5 della serie ha dato valori di CLIA in ZONA GRIGIA, e valori di RT-PCR superiori a 32, per cui il risultato negativo del metodo CROM potrebbe essere allineato e considerato corrispondente agli altri due, e quindi riportato nella casella percentuale seguente come secondo valore.

Il campione 33 della serie ha dato valori di CLIA POSITIVI e valori di RT-PCR superiori a 32 per il gene N e per il gene RdRp, e valore del solo gene E rientranti nelle positività (da considerarsi quindi negativi in seconda istanza). Il risultato NEGATIVO del metodo CROM potrebbe quindi essere correlato con il metodo RT-PCR ed il valore del CLIA risultare quindi un falso positivo (secondi valori di % fra metodi).

IMMUNOCROM	PCR	PCR	CLIA	CLIA	
	POS	NEG	POS	NEG	TOTALI
	12	28	11	29	40
POSITIVO/NEGATIVO	9	31			40
% CORRELAZIONE	75%	90,3	81,8	96,5	
DATI CON MODIFICHE RT-PCR	11	29			
% CORRELAZIONE	81,8%	96,5 %			

I risultati preliminari di questa ricerca iniziale hanno posto in evidenza che il metodo Immunocromatografico StrongStep SARS-CoV-2 si presterebbe bene per una prima valutazione di screening da possibile infezione da SARS-CoV-2.

Il metodo si presenta molto semplice da eseguire e non presenta criticità di possibili effetti sull'operatore, per cui potrebbe tranquillamente essere utilizzato per scopi anche personali (Autodiagnosi).

I campioni sono stati testati in doppio, quindi anche su tampone salivare eseguito con la metodica SALIVETTE forniti dalla ditta Eurolab di Napoli ed hanno confermato i risultati ottenuti su campioni oro-faringei. Questa sembra una grande opportunità per poter utilizzare questo nuovo metodo nelle scuole, nei supermercati, negli aereoporti e quindi su grandi masse di persone ed in ambienti circoscritti.

In fede

Prof. Walter Taccone

Consuleote Scientifico Futura Diagnostica

Avellino, 7 Giugno 2021 alle ore 17:45

TECHNICAL REPORT

UNIVERSITI MALAYA
TIDREC@UM
LABORATORY ADDRESS:
Level 4, Block N & O, Faculty of Medicine, Universiti Malaya
50603 Kuala Lumpur.
Tel: +603-79676670 Email: tidrec@um.edu.my
Website: www.tidrec.com
HEAD OF LABORATORY: Sazaly Abu Bakar, Ph.D., FASc

REPORT TS4-0481-R

Evaluation of COVID-19 In Vitro Diagnostics Medical Devices

Product Details

Product:	StrongStep® SARS-CoV-2 Antigen Rapid Test (Self-Test)
Product code:	500200
Lot number:	2108001
Manufacturer:	Nanjing Liming Bio-Products Co. Ltd., P.R. China
Requested by:	Interscience Sdn. Bhd.
Address:	2, Jalan Sg. Kayu Ara 32/38, Berjaya Industrial Park, 40460 Shah Alam, Selangor
Contact number:	+60 12 219 8141
Email:	ggphang@its-interscience.com
Date of request:	19th August 2021
Type of sample tested:	Nasal swab (self-test); saliva (self-test)

Executive Summary

The evaluation study was performed to determine the performance of a self-test kit - the StrongStep® SARS-CoV-2 Antigen Rapid Test in detecting SARS-CoV-2 antigen from nasal swab samples as well as saliva samples. The testing was performed on 42 SARS-CoV-2 positive and 30 SARS-CoV-2 negative nasal swab samples as well as 30 SARS-CoV-2 positive and 30 SARS-CoV-2 negative saliva samples (by real-time RT-PCR). The positive nasal swab samples consisted of samples with Ct values 18.11–36.95 and the analysis was performed on two groups of samples displaying Ct value <30 and >30. The positive saliva samples, on the other hand, consisted of samples with Ct values 16.76–29.52. The evaluation showed that the tested device was able to detect SARS-CoV-2 antigen with 100% sensitivity and specificity from nasal swab samples with <30 Ct value, and with 83.3% sensitivity for nasal swab samples with >30 Ct value. When tested on saliva samples, it was able to detect SARS-CoV-2 antigen with 86.7% sensitivity and 100% specificity.

13.10.2021

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 few other products could not (yet) be taken into account, despite the interests on the part of the manufacturers/distributors.

Contact

Email: sarscov2ivd@pei

新冠抗原卡通过德国联邦疫苗和生物医学研究所评估验收

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StrongStep® SARS-COV2 Antigen Rapid Test	Nanjing Liming Bio-Products Co., Ltd. (Nanjing, China)
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[illegible]	[illegible]
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AZIENDA OSPEDALIERO - UNIVERSITARIA
Città della Salute e della Scienza di Torino

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- Centro Traumatologico Ortopedico, Istituto Chirurgico Ortopedico Regina Maria Adelaide - centr. tel. +39.0116933111
- Infantile Regina Margherita, Ostetrico Ginecologico S. Anna - centr. tel. +39.0113134444

新冠抗原卡通过意大利实验室评估，
特异性100%，敏感度90%

Dipartimento Medicina di Laboratorio
S.C. Microbiologia Virologia U.
Direttore: Prof.ssa Rossana CAVALLO
rossana.cavallo@unito.it
Segreteria: tel 011.633.5222 – fax 011.633.6384

Torino, 01/10/2021

Alla c.a. D.ssa Carla Rolle

Direttore Farmaceutica Territoriale A.S.L. Città di Torino
Coordinatore Ufficio Gestione D.P.I.
D.I.R.M.E.I. - A.S.L. Città di Torino

OGGETTO: relazione sulle prove effettuate presso l'AOU Città della Salute e della Scienza relative alla fornitura di test rapidi salivari per la rilevazione qualitativa dell'Antigene specifico del virus SARS-COV-2 "PROCEDURA D'URGENZA PER LA STIPULA DI UN ACCORDO QUADRO PER LA FORNITURA DI TEST RAPIDI SALIVARI PER LA RILEVAZIONE QUALITATIVA DELL'ANTIGENE SPECIFICO DEL VIRUS SARSCOV-2 (67-2021)".

Le prove sono state effettuate presso l'AOU Città della Salute e della Scienza di Torino.
Sono stati utilizzati 2 kit StrongStep® SARS-CoV-2 Antigen Rapid Test - Liming Bio (LUME IMPORT SRL) per un totale di 40 test (dispositivo di prelievo del campione salivare mediante imbutino di carta incluso nel kit); in parallelo sono stati effettuati altrettanti test molecolari su campioni di saliva (dispositivo di prelievo Lollisponge, processazione su strumentazione Panther Hologic) e su tamponi naso-faringei (processazione su strumentazione Panther Hologic).
I test sono stati effettuati su operatori sanitari del laboratorio della SC Microbiologia e Virologia U.
Prima sessione: sono stati effettuati 30 test su altrettanti soggetti; tutti i campioni sono risultati concordemente negativi sia al test antigenico sia al test molecolare (saliva e tampone naso-faringeo). La specificità è risultata quindi pari al 100%.
Seconda sessione: per verificare la sensibilità del test antigenico, 10 campioni di saliva di operatori già testati come negativi nella prima sessione, sono stati positivizzati con materiale biologico di tamponi naso-faringei positivi della routine del laboratorio. Sono stati

新冠抗原卡通过意大利实验室评估，

特异性100%，敏感度90%

rilevati risultati del test antigenico salivare concordemente positivi per 9 campioni, mentre un campione salivare è risultato negativo al test antigenico rispetto al test molecolare su tampone naso-faringeo. Non si esclude che la negatività al risultato del test antigenico su saliva possa dipendere dalla qualità del campione (eccessivamente schiumoso). La sensibilità è risultata quindi pari al 90%.

Conclusioni: le prove effettuate presso la SC Microbiologia e Virologia U dell'AOU Città della Salute e della Scienza di Torino hanno confermato i dati di sensibilità e specificità del test StrongStep® SARS-CoV-2 Antigen Rapid Test - Liming Bio (LUME IMPORT SRL) richiesti dal capitolato di gara. Si sottolinea l'importanza di effettuare correttamente il prelievo, come da istruzioni del kit al fine di ottimizzare la sensibilità dello stesso.

A disposizione per qualsiasi chiarimento e comunicazione.

Si coglie l'occasione per porger distinti saluti.

Prof.ssa Cristina COSTA
Dirigente Medico di I livello
Vice-Direttore SC Microbiologia e Virologia U

S.C. Microbiologia Virologia U
Dirigente Medico - Matr. 78336R
Professoressa di seconda fascia
Prof.ssa Cristina COSTA

CMA 180000100599

CNAS 中国认可 检测 TESTING CNAS L0001

中国食品药品检定研究院

检验报告

报告编号：RZ202101942

检品名称：新型冠状病毒SARS-CoV-2核酸检测试剂盒（荧光PCR法）

生产单位/产地：南京黎明生物制品有限公司

检验目的：注册检验（国产体外诊断试剂/首次注册/质量标准复核）

检验依据：产品技术要求

UNIVERSIDADE FEDERAL DO ESPÍRITO SANTO
CENTRO DE CIÊNCIAS DA SAÚDE
POST-GRADUATE PROGRAMME IN INFECTIOUS DISEASES

巴西圣埃斯皮里托联邦大学对黎明新冠PCR性能评估报告

Improvement and evaluation of methods for the detection of SARS-Cov-2 in nasopharynx and oropharynx samples from patients with suspected infection.

Short Title: Improvement of methods for diagnosing COVID

Proponent: Moisés Palaci

Institutions:
Universidade Federal do Espírito Santo (Espirito Santo State University) - UFES
Centro de Ciências da Saúde (Center for Health Sciences) - CCS
Núcleo em Doenças Infecciosas (Center for Infectious Diseases) – NDI

Address: Av. Marechal Campos, 1468, Bonfim - Vitória / ES - Brazil

CEP: 29047-105

E-mail: mpalaci@ndi.ufes.br

Telephone / FAX: +55 (27) 3335-721

Version 1.0
Date: July 30, 2020

24. Conclusões Preliminares

Os reagentes dos kits usados, VIASURE SARS-CoV-2 Real Time PCR Detection Kit e StrongStep® Novel Coronavirus (SARS-CoV-2) Multiplex Real-Time PCR Kit, foram inicialmente ressuspendidos com água livre de RNase com adições respectivamente, 15ul e 13ul. O kit da Liming Bio demonstrou um bom desempenho quando analisado o controle interno Cy5 (red), demonstrando ser funcional na detecção dos genes S, ORF1ab e N do vírus SARS-CoV-2.

Porém ao analisar e interpretar os resultados dos pacientes positivos, sabidamente pelo kit VIASURE SARS-CoV-2 Real Time PCR Detection Kit, embora possuam o mesmo ponto de corte de Ct ≤ 38, foram encontradas divergências. Segundo a interpretação do kit da marca CerTest, o paciente é fortemente considerado positivo uma vez que o ORF1ab, considerado o maior gene do vírus, é amplificado, sendo o primeiro gene a ser analisado. Em seguida, é analisado o gene N e uma vez amplificado, o paciente é considerado automaticamente como positivo para SARS-CoV-2. Diferentemente do kit da Liming Bio, quando apenas um dos genes está abaixo do ponto de corte, o resultado não é considerado inconclusivo e sim é levado em conta a análise do quadro clínico do paciente e tendo pelo menos um dos sintomas do COVID-19, esse paciente é considerado positivo.

Diante dessa diferença na interpretação, segundo o kit da CerTest 25 dos 49 foram considerados como positivos para COVID-19 e quando interpretados com base na interpretação da Liming Bio, apenas 23 foram considerados positivos, considerando 2 pacientes positivos como inconclusivos, uma vez em que só amplificaram um dos três genes analisados.

Essas divergências na interpretação chamaram a atenção para ser feita uma análise de um n maior de apenas amostras sabidamente positivas, buscando confirmar que é difícil considerar uma amostra inconclusiva uma vez em que possuiu resultado positivo por um kit utilizado como rotina e características clínicas para a doença em si. Além disso, é de extremo interesse a amplificação desses mesmos pacientes por um terceiro kit utilizado na detecção do vírus, para uma comparação mais certeira e robusta.

Hospital Universitario de Getafe

SaludMadrid

马德里赫塔菲大学医院对黎明新冠PCR评估灵敏度98.77%，特异性98.13

INFORME DEL COMITÉ DE ÉTICA DE LA INVESTIGACIÓN CON MEDICAMENTOS (CEIm) DEL HOSPITAL UNIVERSITARIO DE GETAFE

D. Óscar Peñuelas Rodríguez, Vicepresidente del Comité de Ética de la Investigación con Medicamentos del Hospital Universitario de Getafe

CERTIFICA:

Que este Comité en su reunión del día 28 de enero de 2021 (A01/21) ha evaluado la documentación presentada por D. David Molina Arana, correspondiente al proyecto de Investigacion titulado: ***"Validación del kit de PCR en tiempo real multiplex para la detección de los genes RdRp (Orf1ab), S y N de SARS-CoV2 (StrongStep® kit)"***.

y considera que:

- Se cumplen los requisitos necesarios de idoneidad del Protocolo en relación con los objetivos del estudio y están justificados los riesgos y molestias previsibles para el sujeto.
- La capacidad del investigador y los medios disponibles son adecuados para llevar a cabo el estudio.
- El alcance de las compensaciones económicas previstas no interfieren con el respeto de los postulados éticos.

Por ello, este Comité emite **Informe Favorable** sobre la realización de dicho proyecto de Investigacion por, D. David Molina Arana, como Investigador principal, del Servicio de Microbiología.

Lo que firmo en Getafe, a 28 de enero 2021.

Fdo.: D. Óscar Peñuelas Rodríguez
Vicepresidente del CEIm
Hospital Universitario de Getafe

VALIDACIÓN DE LA TÉCNICA DE RT-PCR EN TIEMPO REAL (STRONG STEP®) PARA LA DETECCIÓN DE LOS GENES N, ORF1ab y S DE SARS-COV-2

Servicio de Microbiología. Hospital Universitario de Getafe, Madrid. Marzo 2021.

马德里赫塔菲大学医院对黎明新冠PCR评估灵敏度98.77%，特异性98.13

Introducción/Objetivos

El principal método de diagnóstico de la infección por SARS-CoV-2 es la detección de los ácidos nucleicos del virus en muestras de exudado nasofaríngeo. El elevado número de muestras y la importancia de un diagnóstico rápido y preciso hace necesario el desarrollo de técnicas de PCR rápidas, con una buena sensibilidad y especificidad y de fácil manejo a nivel de laboratorio.

El objetivo de este trabajo es la validación de una RT-PCR a tiempo real (Strong Step®, Liming Bio) para el diagnóstico molecular de SARS-CoV-2 en exudado nasofaríngeo.

Material y métodos

Se seleccionaron 188 muestras de exudado nasofaríngeo recogidas en medio de transporte universal de virus conservadas a -80ºC. Se utilizó el sistema automatizado Genolution (Alifax) para la extracción de ARN. Con el eluido obtenido se realizaron dos RT-PCR a tiempo real: Strong Step® como técnica molecular a validar y Allplex SARS-Cov-2 Assay (Seegene) como técnica convencional empleada en la rutina de diagnóstico de SARS-CoV-2. La técnica de RT-PCR Allplex tiene como genes diana los genes E, N y RdRP y S en combinación. Para control de la extracción y de la reacción se emplea un control interno exógeno. Las muestras se consideran positivas cuando se detectan uno o más genes en un Ct≤40. La técnica de RT-PCR Strong Step® tiene como diana los genes N, ORF1ab y el gen S. Como control de la extracción y la reacción se emplea un control interno endógeno (RNAse P humana). Las muestras se consideran positivas cuando se detectan dos o más genes con un Ct≤38. Las muestras en las que solo se detecta un gen se consideran inconcluyentes y requieren una confirmación. Los resultados discrepantes se comprobaron con una tercera técnica de RT-PCR.

Resultados

De las 188 muestras seleccionadas, 81 muestras fueron positivas y 107 negativas, confirmando las discrepantes por una tercera RT-PCR que detecta los genes S y ORF1ab. De las 81 muestras positivas, por Strong Step® 70 fueron positivas, 10 inconcluyentes y 1 negativa. De las 107 muestras negativas, 105 fueron negativas por Strong Step® y 2 resultaron inconcluyentes.

Los resultados de sensibilidad y especificidad (considerando los resultados inconcluyentes como positivos) se muestran en la siguiente tabla:

	Total	Strong Step® +	Strong Step® -	
Positivas	81	80	1	Sensibilidad: 98,77%
Negativas	107	2	105	Especificidad: 98,13%

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Telepon (021) 5201590 (Hunting) - Pes. 2029, 5006, 2900
Fax. (021) 52964838 Kotak Pos 203

GERMAS

Nomor : FK.03.01/3/2673/2021 11 Agustus 2021
Sifat : RAHASIA
Lampiran : 1 (satu) berkas
Hal : Pengantar Hasil Pengujian RT PCR

Yth. Pimpinan PT. Sansico Natura Resources
Grand ITC Permata Hijau, Kanto Diamond No. 11-12, Permata Hijau
Jakarta Selatan-12210

Sehubungan dengan surat dari Kepala Balai Besar Laboratorium Kesehatan Jakarta Nomor : FK.03.01/XL.1/2300/2021 tanggal 06 Agustus 2021 Merk **StrongStep® Novel Coronavirus (SARS CoV-2) Multiplex Real-Time PCR Kit (detection for three genes) (Lot. G2009003A/ NIE AKL 20303024595)** dengan ini kami sampaikan laporan hasil uji validasi RT PCR merk tersebut (terlampir).

Demikian kami sampaikan, atas perhatian dan kerjasamanya, kami ucapkan terima kasih.

Plt. Direktur Pengawasan Alat
Kesehatan dan Perbekalan
Kesehatan Rumah Tangga,

Lupi Trilaksono
NIP 197711272005021004

KEMENTERIAN KESEHATAN RI
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Telp. (021) 4212524, 42804339, Fax. (021) 4245516
Website : www.bblkjakarta.com Email : bblkjakarta@yahoo.co.id

Nomor : FK.03.01/XL.1/2300/2021
Perihal : Pengujian Sampel RT PCR

06 Agustus 2021

Yang Terhormat,
Direktur Pengawasan Alat Kesehatan dan PKRT
Ditjen Kefarmasian dan Alat Kesehatan Kemenkes RI
Di -
Tempat

Menindaklanjuti surat Direktur Pengawasan Alat Kesehatan dan PKRT Nomor FK.03.01/3/2371/2021 tanggal 12 Juli 2021 tentang Pengantar Pengujian Sampel RT PCR, bersama ini kami sampaikan laporan hasil uji validitas terhadap RT PCR SARS Cov-2 Merek

1. StrongStep Novel Coronavirus (SARS coV-2) *Multiplex Real-Time* PCR Kit (*detection for three genes*)

(hasil terlampir).

Atas perhatian dan kerjasamanya kami ucapkan terimakasih.

Kepala,

dr. Niken Wastu Palupi, MKM
NIP.196812312002122006

Tembusan :
- Kepala Pusat Biomedis dan Teknologi Dasar Kesehatan Badan Litbangkes Kemenkes RI

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Balai Besar Labkes Jakarta

LAPORAN HASIL PEMERIKSAAN

No Seri : 113/LK/VIII/2021

Nama Pengirim	:	Direktorat Jenderal Kefarmasian dan Alat Kesehatan Kemenkes RI	No. Lab	:	019526/BM/VII/2021
Nama Bahan Uji	:	Reagen RT PCR Sars-CoV-2 Kit	No. Instalasi	:	10523
Merek	:	StrongStep Novel Coronavirus (SARS-CoV-2) Multiplex Real Time PCR Kit (detection for three genes)	Tanggal diterima di Lab	:	28 Juli 2021
NIE	:	AKL 20303024595			
No. Lot/Batch	:	G2009003A	Tanggal Pemeriksaan	:	29 Juli – 05 Agustus 2021
Tanggal Kedaluwarsa	:	29/09/2021	Penanggung Jawab	:	dr. Nita Nurhidayati, Sp.MK
Alamat	:	Jl. HR. Rasuna Said Blok X5 Kav. 4-9, Jakarta Selatan 12950	SIP	:	12/2.104/31.71.08/-1.779.3/e/2017

1. Seluruh sampel

Reagen PCR Uji	Qrt-Pcr		Sensitivitas	Spesifisitas	NPP	NPN	Akurasi
	Positif	Negatif	(%)	(%)	(%)	(%)	(%)
Positif	60	0	100	100	100	100	100
Negatif	0	30					
Jumlah	60	30					

2. Sampel Positif CT 25-30

Reagen PCR Uji	Qrt-Pcr		Sensitivitas	Spesifisitas	NPP	NPN	Akurasi
	Positif	Negatif	(%)	(%)	(%)	(%)	(%)
Positif	30	0	100	100	100	100	100
Negatif	0	30					
Jumlah	30	30					

KALK

KEMENTERIAN KESEHATAN RI
DIREKTORAT JENDERAL PELAYANAN KESEHATAN
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LAPORAN HASIL PEMERIKSAAN

No Seri : 113/LK/VIII/2021

3. Sampel Positif CT 31-35

Reagen PCR Uji	Qrt-Pcr		Sensitivitas	Spesifisitas	NPP	NPN	Akurasi
	Positif	Negatif	(%)	(%)	(%)	(%)	(%)
Positif	30	0	100	100	100	100	100
Negatif	0	30					
Jumlah	30	30					

Mengetahui

KEPALA BALAI BESAR LABKES JAKARTA

dr. Niken Wastu Palupi, MKM
NIP. 195812312002122006

Jakarta, 06 Agustus 2021

KEPALA INSTALASI LABKES KLNIK

Yusnabeti, SKM, MKM.
NIP. 197308051992032001

PT. SANSICO NATURA RESOURCES

No : 001/SNR-SPH/VIII/2021

Jakarta, 06 Agustus 2021

Kepada Yth,
Direktur Pegawasan Alat Kesehatan dan PKRT
Kementerian Kesehatan Republik Indonesia
Jl. HR. Rasuna Said, Blok X.5 Kav. 4-9, 8th Floor
Kuningan, Kota Jakata Selatan
DKI Jakarta, 12950

Perihal : Surat Permohonan Hasil Uji Validasi PCR Test Kit

Dengan Hormat,
Perkenalkan kami dari PT Sansico Natura Resources yang bergerak dibidang distribusi alat-alat kesehatan, berdasarkan surat pemohonan uji validasi No. 001/SNR-SPH/VII/2021 tanggal 07 Juli 2021, kami bermaksud untuk mengajukan permohonan mengeluarkan hasil uji validasi kepada Direktorat Terkait. Berikut terlampir alat yang kami ajukan untuk izin uji validasi:

StrongStep® Novel Coronavirus (SARS CoV- 2) Multiplex Real-Time PCR Kit (detection for three genes)

Demikian surat permohonan ini kami sampaikan, mohon tanggapannya.

Atas perhatiannya kami ucapkan terimakasih.

Hormat Kami,

Rudy Ghozali
Direktur Utama

Head Office : Grand ITC Permata Hijau, Kanto Diamond No. 11-12, Permata Hijau, Jakarta Selatan – 12210, Indonesia
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ORIGINAL ARTICLE

Comparison of various serological assays for novel SARS-COV-2

María Simón Sacristan[1] · Ana Collazos-Blanco[1] · María Isabel Zamora Cintas[1] · Alicia Serrano García[1] · Carmen Ybarra de Villavicencio[1] · María Mateo Maestre[1]

Received: 2 June 2020 / Accepted: 28 October 2020

黎明新冠抗体性能评估发表于欧洲临床微生物学与传染病杂志

Abstract

Coronavirus disease-19 (COVID19), the novel respiratory illness caused by severe acute respiratory syndrome coronavirus (SARS-CoV-2), is associated with severe morbidity and mortality. The aim of our study was to compare different immunoassays. We evaluated three immunochromatographic test (The StrongStep®SARS-CoV-2 IgG/IgM kit, AllTest COV-19 IgG/IgM kit, and Wondfo® SARS-CoV-2 Antibody) and two chemiluminescence immunoassays (CMIA) (Covid-19 VIRCLIA® IgM+IgA/IgG monotest and the Abbott SARS-CoV-2 IgG assay) in COVID-19 patients. The assays were performed using serum samples of three group patients, i.e., healthy controls, patients with SARS-CoV-2 PCR positive, and patients with SARS-CoV-2 PCR negative clinically diagnosed of COVID-19 infection. The detection percentages of IgG with the StrongStep® SARS-CoV-2 IgG/IgM kit and AllTest COV-19 IgG/IgM kit were similar in both groups (83.3% and 80.6%, respectively in group 2, $p = 0.766$) and (42.9% and 50.0%, respectively in group 3, $p = 0.706$). There were some differences on IgM detection between StrongStep® SARS-CoV-2 IgG/IgM kit and AllTest COV-19 IgG/IgM kit (11.1% and 30.6%, respectively in group 2, $p = 0.042$ and 0.0% and 28.6%, respectively in group 3, $p = 0.031$). The positive rate of IgG in group 2 is higher compared to group 3 with the two immunoassays tested. We observe the same positive rates of IgG with the two CMIA. Our study shows excellent performance of CMIA compared to immunochromatographic test and confirms its potential use in the diagnosis of the new SARS-CoV-2.

Keywords Antibodies · Chemiluminescence immunoassays · IgG · IgM · Immunochromatographic tests · SARS-CoV-2

Introduction

Severe acute respiratory syndrome coronavirus (SARS-CoV-2) [1] was discovered in December 2019 in the city of Wuhan, China. It soon spread to other cities and countries, and on 11 March 2020 was proclaimed a pandemic by WHO. The clinical symptoms of most patients are fever, sore throat, cough, and shortness of breath [2].

RT-PCR (reverse transcription polymerase chain reaction) remained the gold standard for the diagnosis of infection due to SARS-CoV-2, which has led to 974,449 coronavirus disease-19 (COVID19) cases and 33,992 deaths by 19 October 2020 in Spain. Its sensitivity did not reach 100% but it remained better than that of methods based on the detection of antigens. However, RT-PCR takes a long time to get results and qualified personnel is necessary. In several cases, RT-PCR has shown false negatives in patients with pneumonia, showing clinical and radiographic evidence compatible with COVID19; these patients were considered as clinically diagnosed of SARS-CoV-2 according to the 5th edition of guideline on diagnosis and treatment of the novel coronavirus pneumonia.

María Simón Sacristan, Ana Collazos Blanco and María Isabel Zamora Cintas contributed equally to this work.

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黎明新冠抗体性能评估发表于国际传染伤杂志

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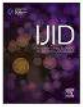

Performance assessment of 11 commercial serological tests for SARS-CoV-2 on hospitalized COVID-19 patients

C. Serre-Miranda, C. Nobrega, S. Roque, J. Canto-Gomes, C.S. Silva, N. Vieira, P. Barreira-Silva, P. Alves-Peixoto, J. Cotter, A. Reis, M. Formigo, H. Sarmento, O. Pires, A. Carvalho, D.Y. Petrovykh, L. Diéguez, J.C. Sousa, N. Sousa, C. Capela, J.A. Palha, P.C. Cunha, M. Correia-Neves

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Table 2. Assayed commercial tests to detect immunoglobulins specific for SARS-CoV-2 infection.

Assay	Supplier	Product	Catalog no.	Technology	Format	Assay Target	Obs
Semiquantitative assays	**Abbott** Diagnostics	SARS-coV-2 IgG assay	06R86	CLIA	IgG	N protein	Requires an Abbott Architect i2000
	Euroimmun	anti SARS-CoV-2 **IgG** ELISA kit	EI 2606-9601 G	ELISA	IgG	S1 protein	Requires a regular absorbance microplate reader
		anti SARS-CoV-2 **IgA** ELISA kit	EI 2606-9601 A	ELISA	IgA		
	Snibe Diagnostic	MAGLUMI® 2019-nCoV (SARS-CoV-2) **IgM** kit	130219016M	CLIA	IgM	S antigen and N protein	Requires a MAGLUMI chemiluminescence immuncassay system
		MAGLUMI® 2019-nCoV (SARS-CoV-2) **IgG** kit	130219015M	CLIA	IgG		
Qualitative assays	**Cellex**	qSARS-Cov-2 IgG/IgM Cassette Rapid Test	W6513C	LFIA	IgM/IgG	N and S Proteins	-
	Getein Biotech, inc	One step test for novel coronavirus (2019-nCoV) IgM/IgG antibody (colloidal gold)	CG2057	LFIA	Total Ig	N and S Proteins	-
	Innovita	2019-nCoV Ab test (colloidal gold), IgM/IgG whole blood/Serum/Plasma Combo	n/a	LFIA	IgM/IgG	N and S Proteins	-
	Liming Bio	StrongStep® SARS-CoV-2 IgM/IgG Test	502090	LFIA	IgM/IgG	Not specified	
	Leccurate	SARS-CoV-2 antibody test (colloidal gold immunochromatography)	K-20-RC-CoV-2	LFIA	IgM/IgG	Not specified	-
	Medomics	Rapid IgM-IgG Combined Antibody Test kit for SARS-CoV-2 (ICA)	n/a	LFIA	IgM/IgG	Not specified	-
	Render	COVID-19 IgM & IgG Test (immunocromatography)	3.2.01.6.1701	LFIA	IgM/IgG	Not specified	-
	SD Biosensor	Standard Q COVID-19 IgM/IgG Duo Test	Q-NCOV-01D	LFIA	IgM/IgG	N Protein	-

CLIA; Chemiluminescence Immunoassay; ELISA: Enzyme Linked Immuno-Sorbent Assay; LFIA; Lateral flow immunoassay; n/a: not available; N: nucleocapsid; S: spike