南京诺尔曼生物技术股份有限公司

Norman Biological Technology Co., Ltd

新型冠状病毒(2019-nCoV)抗原检测试剂盒（胶体金）

Novel Coronavirus (2019-nCoV) Antigen Testing Kit

(Colloidal Gold)

资料清单

Document List

1、 营业执照 Business License

2、 医疗器械生产许可证 Medical Device Production License

3、 对外贸易经营者登记表 Registration Form of Foreign Trade Operators

4、 ISO13485

5、 CE 证书 EC Declaration of Conformity

6、 出口销售白名单 White List for Export Antigen Covid-19

7、 产品介绍 Product Introduction

http://www.normanbio.com

1、 营业执照 **Business License**

2、 医疗器械生产许可证 **Medical Device Production License**

编号 320191666202012250063

统一社会信用代码

91320191674936331B (1/1)

营业执照

(副本)

扫描二维码登录“国家企业信用信息公示系统”了解更多登记、备案、许可、监管信息。

名　　称 南京诺尔曼生物技术股份有限公司

类　　型 股份有限公司(非上市、自然人投资或控股)

法定代表人 李红云

经营范围 医疗器械生产、销售；生物试剂（不含危化品）；体外诊断试剂（不含危化品）、仪器的研发、生产、销售及技术转让；企业投资、营销策划及咨询；物联网软件技术开发；自营和代理各类商品及技术的进出口业务。（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）

注册资本 6000万元整

成立日期 2008年07月16日

营业期限 2008年07月16日至******

住　　所 南京市江北新区药谷大道197号

登记机关 南京市江北新区管理委员会行政审批局

2020 年 12 月 25 日

国家企业信用信息公示系统网址：http://www.gsxt.gov.cn

市场主体应当于每年1月1日至6月30日通过国家企业信用信息公示系统报送公示年度报告。

国家市场监督管理总局监制

3、 对外贸易经营者登记表 **Registration Form of Foreign Trade**

医疗器械生产许可证

许可证编号：苏食药监械生产许 20110082 号

企业名称：南京诺尔曼生物技术股份有限公司

生产地址：南京市江北新区新锦湖路 3 号-1 中丹生态生命科学产业园一期 A 座 13 层、16 层 1602-1607 室；南京市江北新区药谷大道 197 号

法定代表人：李红云

企业负责人：何仕钊

生产范围：见产品登记表

住　　所：南京市江北新区药谷大道 197 号

发证部门：江苏省药品监督管理局

有效期限：至 2021 年 08 月 28 日

发证日期：2021 年 01 月 05 日

Operators

对外贸易经营者备案登记表

备案登记表编号：04090413　　统一社会信用代码：91320191674936331B

进出口企业代码：----------

经营者中文名称	南京诺尔曼生物技术股份有限公司		
经营者英文名称	Nanjing Norman Biological Technology Co., Ltd		
组织机构代码	---------	经营者类型（由备案登记机关填写）	私营股份有限公司
住　所	南京市江北新区药谷大道197号		
经营场所（中文）	南京市江北新区药谷大道197号		
经营场所（英文）	No.197 Pharmaceutical Valley Road ,Jiangbei New Area ,Nanjing,Jiangsu ,China		
联系电话	18068826668	联系传真	025-85670933
邮政编码	210000	电子邮箱	lihongyun@nrmchina.com
工商登记注册日期	2008-7-16	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	李红云	有效证件号	341125197009200046
注册资金	陆仟万元		（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

2021　年 01　月 05　日

4、　ISO 13485 证书

TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

Nanjing Norman Biological Technology Co., Ltd.
No. 197, Pharmaceutical Valley Road
Jiangbei New Area
Nanjing
210000 Jiangsu
China

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

(see attachment for scope and additional site included)

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:	2019-09-06
Certificate Registration No.:	SX 60137695 0001
An audit was performed. Report No.:	15096092 003
This Certificate is valid until:	2022-05-26

Certification Body

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

Date 2019-09-06

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Herbert Zhong

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

TÜVRheinland®

Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60137695 0001
Report No.: 15096092 003

Organization:
Nanjing Norman Biological Technology Co., Ltd.
No. 197, Pharmaceutical Valley Road
Jiangbei New Area
Nanjing
210000 Jiangsu
China

Scope:

Design/development, manufacture of in-vitro diagnostic reagents and instruments of chemiluminescence analysis and immune fluorescence analysis for professional clinical laboratory use

Sites included:

9th Floor, Building F6, No.9 Weidi Road, Jiangsu Life Science & Technology Park, Nanjing, 210000 Jiangsu, China
Manufacture of in-vitro diagnostic reagents of chemiluminescence analysis and immune fluorescence analysis for professional clinical laboratory use

13th, 16th Floor, Building A, Phase 1, Sino-Danish Eco Life Science Industrial Park, No.3-1 Xinjinhu Road, Jiangbei New Area, Nanjing, 210000 Jiangsu, China
Manufacture of in-vitro diagnostic reagents of chemiluminescence analysis and immune fluorescence analysis for professional clinical laboratory use

Certification Body

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

Date: 2019-09-06

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle

Herbert Zhong

Business Stream Products
Certification Department

TÜVRheinland®
LGA
Precisely Right.

TÜV Rheinland LGA Products GmbH · 90431 Nürnberg

Nanjing Norman Biological
Technology Co., Ltd.
No. 197, Pharmaceutical Valley Road
Jiangbei New Area
Nanjing
210000 JIANGSU
CHINA

Contact

Tel. +49 911 655-5225
Mail service@de.tuv.com

Date September 07, 2019

Application for : QMS
Certificate No. : SX 60137695 Sheet 0001
Device : Only for QM-System audit
Test requirement : EN ISO 13485:2016

Dear Madame or Sir,

Enclosed please find the
new certificate No. SX 60137695 0001
replacing the previous certificate.

Kind regards

Certification body

Herbert Zhong

Test sample: no, documentation available

TÜV Rheinland
LGA Products GmbH

Tillystraße 2
90431 Nürnberg

Tel. +49 911 655-5225
Fax +49 911 655-5226
Mail service@de.tuv.com
Web www.tuv.com/safety

5、 CE 证书 **EC Declaration of Conformity**

NORMAN
Biological Technology

EG-KONFORMITÄTSERKLÄRUNG · EC DECLARATION OF CONFORMITY
DÉCLARATION CE DE CONFORMITÉ · DICHIARAZIONE CE DI CONFORMITÀ

Name und Adresse des Herstellers: / Name and address of the manufacturer: / Nom et adresse du fabricant: / Nome e indirizzo del fabbricante:	Nanjing Norman Biological Technology Co., Ltd. No.197, Pharmaceutical Valley Road, Jiangbei New Area, Nanjing, 210000 Jiangsu, China

Wir erklären in alleiniger Verantwortung, dass / We declare under our sole responsibility that / Nous déclarons sous notre propre responsabilité que / Dichiariamo sotto la sola responsabilità che

das Medizinprodukt: / the medical device: / le dispositif médical: / il dispositivo medico:	Novel Coronavirus (2019-nCoV) Antigen Testing Kit (Colloidal Gold)
der Klasse: / of class: / de la classe: / di classe:	Others

nach Anhang IX der Richtlinie Directive 98/79/EC Annex II / according to annex IX of Directive 98/79/EC Annex II / selon l'annexe IX de la Directive 98/79/EC Annex II / secondo l'allegato IX della Directive 98/79/EC Annex II

den einschlägigen Bestimmungen der Medizinprodukte-Richtlinie 98/79/EC und deren Umsetzungen in nationale Gesetze entspricht. Die Erklärung gilt in Verbindung mit dem zum Produkt gehörigen „Endprüfprotokoll". /

meets the provisions of the directive 98/79/EC and its transpositions in national laws which apply to it. The declaration is valid in connection with the "final inspection report" of the device. /

remplit toutes les exigences de la directive sur les dispositifs médicaux 98/79/EC et de ses transpositions en droit national qui le concernent. La déclaration est valable si elle est associée au «rapport de l'inspection finale» du produit. /

soddisfa tutte le disposizioni della direttiva 98/79/EC e della loro trasposizione nel diritto nazionale che lo riguardano. Questa dichiarazione è valida in congiunzione con il "rapporto di ispezione finale" del prodotto.

Konformitätsbewertungsverfahren: / Conformity assessment procedure: / Procédure d'évaluation de la conformité: / Procedura di valutazione della conformità:	Directive 98/79/EC Annex III
Registrierungsnummer: / Registration number: / Numéro d'inscription: / Numero di registrazione:	DE/CA20/IVD-Caretechion-50/20

CE

EU Authorized Representative:
Caretechion GmbH
Niederrheinstr. 71, 40474 Duesseldorf, Germany

Ort, Datum / Place, date / Oct 9, 2020
Lieu, date / Luogo, data

Name und Funktion / Name and function /
Nom et fonction / Nome e funzione


取得国外标准认证或注册的医疗
不安全 | www.cccmhpie.org.cn/kywz.aspx
中国医药保健品进出口商会
服 务 产 业 链 | 助 力 国 际 化
English 登陆 | 注册
请输入关键词进行搜索
开具不可抗力相关事实性证明
取得国外认证和注册企业查询
首页
关于商会
新闻中心
行业服务
权威发布
商会会刊
企业风采
会员之家
加入商会
取得国外标准认证或注册的医疗物资和非医用口罩生产企业检索
诺尔曼
检索
企业名称（中文）
企业名称（英文）
产品类别
产品名称/型号
统一社会信用代码
国外注册认证情况
南京诺尔曼生物技术股份有限公司
Nanjing Norman Biological Technology Co., Ltd.
新型冠状病毒检测试剂
Novel Coronavirus (2019-nCoV) IgG/IgM Antibody Testing Kit (Colloidal Gold) Novel Coronavirus (2019-nCoV) Antigen Testing Kit (Colloidal Gold)
91320191674936331B
欧盟CE
友情链接
政府部门
副会长单位
国际机构
行业门户
关于我们 | 联系我们 | 会员之家 | 行业服务
地址：北京市东城区朝阳门内大街南竹杆胡同6号（北京INN大厦3号楼）11-12层
版权所有：中国医药保健品进出口商会 未经许可，不得转载
京ICP备:06034461号-1 京公网安备 11010102002916号
互联网药品信息服务资格证编号:（京）-非经营性-2020-0090
医保商会官方微信

7、 产品介绍 Product Introduction

NORMAN
Biological Technology

Novel Coronavirus (2019-nCoV) Antigen Testing Kit (Colloidal Gold)

Specification: 1/25 Tests

Nanjing Norman Biological Technology Co., Ltd.

Swab Test

- 【Materials provided】

Contents	25Test/Box	1Test/Box
Test Card	25	1
Antigen Extraction Tube	25	1
Antigen Extraction Reagent R1	1or25	1
Swab stick (Nasopharyngeal swab/ Oropharyngeal swab)	25	1

Saliva Test

- 【Materials provided】

Contents	25Test/Box	1Test/Box
Test Card	25	1
Antigen Extraction Tube	25	1
Antigen Extraction Reagent R1	1or25	1
Saliva Collection Set with Transfer pipette	25	1

- 【Materials required but not provided】

Timer/Mask/Nitrile gloves/workbench

Advantages

- No professional testing equipment is required
- Give the result within 20 minutes with high accuracy
- Store at room temperature and transport at normal temperature
- Valid for two years
- It is easy to operate without professional guidance

Product Quality

Passed the China Food and Drug Inspection and Testing Institute

Passed the performance test of two independent laboratories in the United States

Why Norman Antigen Test?

Screening of 2019-nCoV patients in nursing institutions such as nursing homes or teaching and management

detention centers, workplaces and schools

Rapid diagnosis of symptomatic suspected population, asymptomatic infected persons and suspected virus contacts

Plays a role in monitoring public health, assessing local 2019-nCoV infection rate and predicting disease development trend.

2019–nCoV antigen test Advantages VS PCR kit

- Operation, transportation and storage are simpler and more convenient than PCR.
- Fast results, regardless of site andinstrument limitations.
- Facilitate rapid screening on a large scaleand reduce retransmission during patient waiting periods.

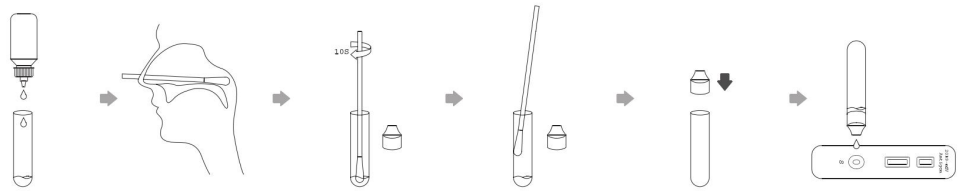
Detection method	operating collection	Test sample	Testing time	sample collection and processing
nucleic acid test	P2 laboratory kit	nose swab	long	sophisticated
antigen test (colloidal gold method)	No equipment required convenient	Nose swabs throat swabs	Timely delivery of results	general

Detection method	Equipment environment	Special equipment	Sample collection and processing	OPerator	Testing time	Accuracy of results	Transport and storage	Validity period
nucleic acid test	Biosafety laboratory	Professional equipment	Pharyngeal swab	Professional operators	2–4hours	Good sensitivity and specificity	Cold chain trsnsport, preservation	Usually 12 months
antigen test (colloidal gold method)	General environment	No need	Pharyngeal swab	General medical staff	20 minutes	Good sensitivity and specificity	Room temperature	24months

Detection method	Obvious disadvantage	Obvious advantage	Applicable scenarios
nucleic acid test	Slow detection,low coverage Dependence on equipment,limited number of tests	Accurate results	Accurate measurement of specific objects
antigen test (colloidal gold method)		Easy to operate,fast results,accurate results	Early screening,early diagnosis of mass,rapid screening at the primary level

User Manual

instruction for use (Nasopharyngeal Swab)



Add 6 drops of R1 to the extractor tube.

Collecting: Allow the patient's head to relax naturally, and slowly rotate the swab against the nostril wall into the nostril of the patient to the nasal palate, and then slowly rotate it out while wiping. Wipe the other nostril with the same swab, using the same method.

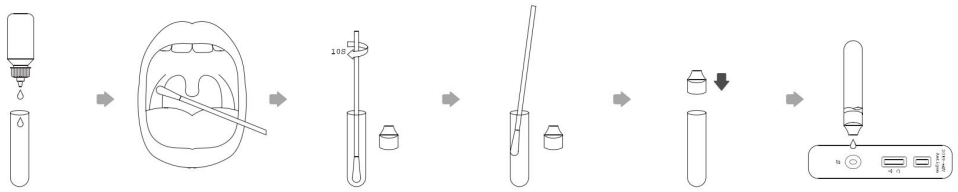
Place the swab specimen into the pre-added extractor tube, rotate the swab for about 10seconds.
Then crimp the extractor tube bottom and the swab head, to release the antigen from the swab.

Lift the hand swab and press the swab head against the tube wall at the same time, to release the remaining antigen liquid from the swab.

Throw out the hand swab, then install the beater on the extraction tube.

Put 2 drops into the sample hole of the test card, and start the timer for 20min.

instruction for use (Oropharyngeal Swab)



Add 6 drops of R1 to the extractor tube.

Collecting: Have the patient's head slightly tilted back, mouth open, and "ah" sound, exposing both sides of the pharyngeal tonsils. Use a hand swab to gently wipe the pharyngeal tonsils on both sides of the patient for at least 3 times, and then wipe them on the posterior pharyngeal wall for at least 3 times.

Place the swab specimen into thepre-added extractortube, rotate the swab for about 10seconds.
Then crimp the extractor tube bottom and the swab head, to release the antigen from the swab.

Lift the hand swab and press the swab head against the tube wall at the same time, to release the remaining antigen liquid from the swab.

Throw out the hand swab, then install the beater on the extraction tube.

Put 2 drops into the sample hole of the test card, and start the timer for 20min.

- instruction for use (Saliva)

IMPORTANT: Follow all guidance carefully to ensure an adequate specimen is collected for testing.

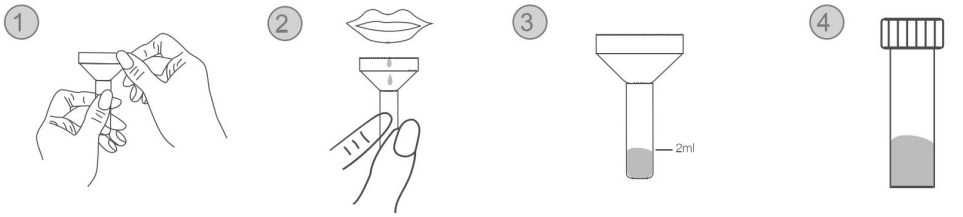
Do NOT eat, drink, smoke or chew gum for 30 minutes before saliva collection procedure.

Severe mouth ulcers and bronchitis may affect the collection

Contact infection should be avoided from different tested ones.

Using running water to clean mouth 30 minutes before saliva collection

Specimen preparation



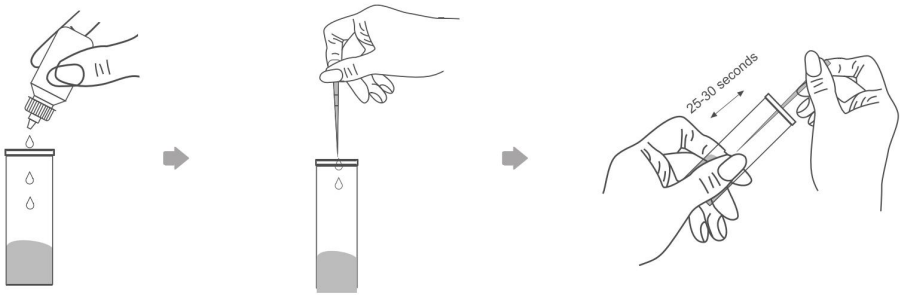
Set-up the Saliva Collecting Set

Collecting the Saliva

split it onto the oval funnel slightly till the saliva quantity could reach the 2ml Fill line，0.5ml Saliva without bubbles is sufficient

Seal the sample with the tube cap (to keep the sample)

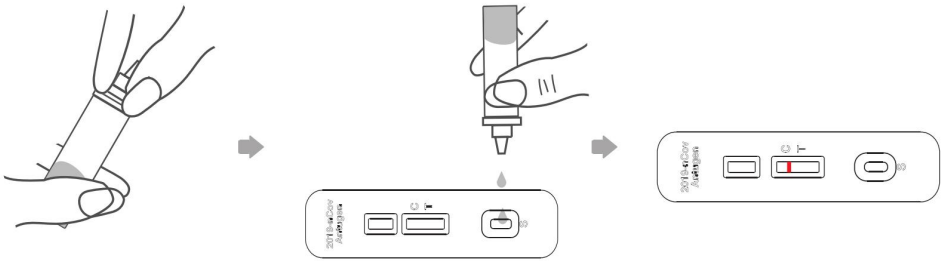
Test Procedure



Add 6 drops of extraction reagent to an extraction tube

Add 3 drops of saliva into the extraction tube with extraction reagent by plastic dropper.

Fully mix the saliva and extraction reagent for 25-30 seconds(Handling with vortex oscillator is better)



Install the beater on the extraction tube

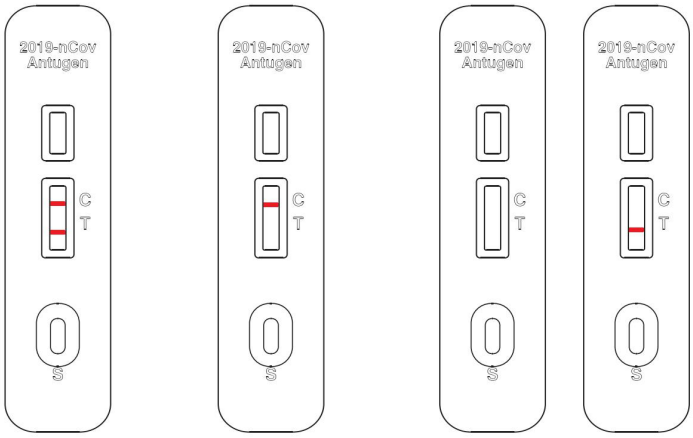
Add 2 drops of mixed liquor to the sample hole of test card

After 20 minutes, interpret the test result

Result analysis

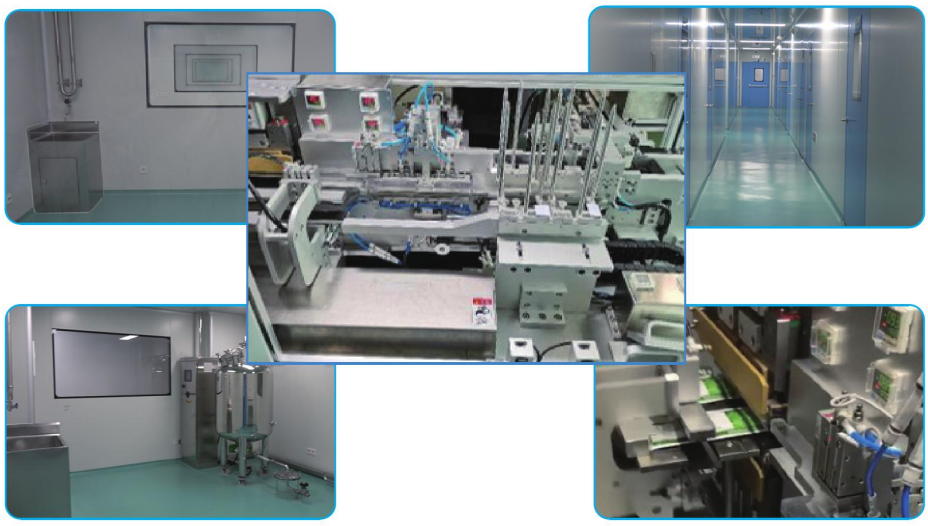
After 20 minutes, Read the results.

A strong positive result could be observed within 20 minutes, but a negative result must be viewd after 20 minutes, and the result after 30 minutes is no longer valid.



Positive Negative Invalid result

Production workshop&equipment



NORMAN R&D review

more than 60% of which hold a bachelor degree, 9 PhD and 36 master's degree.
Member of national medical clinical laboratory and in vitro diagnostic system Standardization Technical Committee (TC136) Member of China Medical Equipment Association Medical Inspection Branch. Governing unit of national health industry medical inspection branch .

- **7** Appearance patent and Software copyright
- **9** patent
- **40** Utility model patents
- **100** Recombinant and natural protein

Nanjing Norman Biological Technology Co., Ltd.

Independence,R&D and innovation

Focus on Medic diagnostic products.

As a innovative company specialized in medic diagnostic products, Nanjjing Norman Biological Technology Co.,Ltd was launched in 2008. On the basis of independent development,Norman has established and improved its own self R&D platform in the spectrum of material,reagents and equipment which could be verdicted as a comprehensive technical platform.

Norman independently produce the core materials and equipment platform in the industry chain,breaking the bottleneck in the industry ,in as to ensure the high quality products characterized by sound repeatablility and low tolerance in different batches and within the batches.