PRODUCT INTRODUCTION 产品介绍

NEWGENE Bioengineering

COVID-19 Antigen Detection Kit
新型冠状病毒抗原检测试剂盒
(Sputum Sample)
(痰液样本)

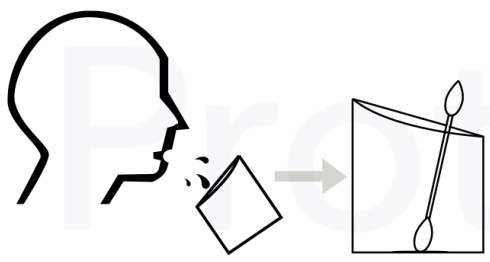
Product Feature 产品特点

1. Using Sputum Sample.
   使用痰液样本
2. Fast Detection: Result in 15 minutes.
   快速检测：15分钟即出结果
3. High Accuracy.
   准确率高
4. Easy to Use.
   使用方便

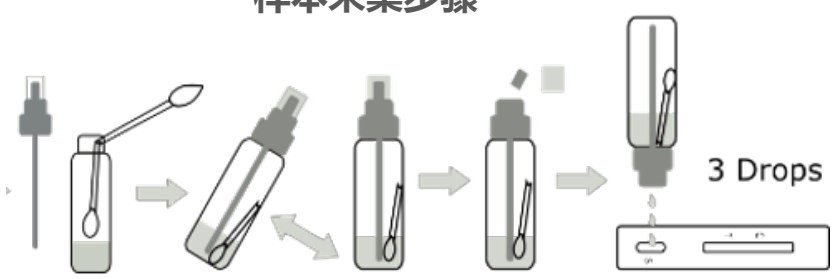
Components 产品包装 - 25PCS/Box

1. Test Card * 25
   检测试剂卡*25
2. Sample Extraction Tube * 25
   样本提取管*25
3. Cotton Swab * 25
   棉签*25
4. Paper Cup * 25
   纸杯*25
5. Package Insert * 1
   说明书*1

Test Procedure 检测流程

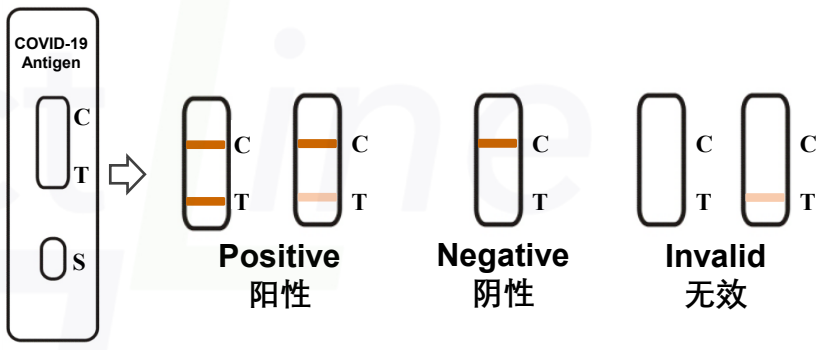


Sampling Steps
样本采集步骤



Detection Steps
检测步骤

Interpretation of Results 结果解读



New Gene (Hangzhou) Bioengineering Co., Ltd.
Website: www.new-gene.com
Email: marketing@new-gene.com
24-hour Hotline: (+86) 0571-5651 5020

PRODUCT INTRODUCTION 产品介绍

NEWGENE Bioengineering

COVID-19 Antigen Detection Kit
新型冠状病毒抗原检测试剂盒
(Throat Swab Sample)
(咽拭子样本)

Product Feature 产品特点

1. Using Sputum Sample.
   使用痰液样本
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   快速检测：15分钟即出结果
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   咽拭子*25
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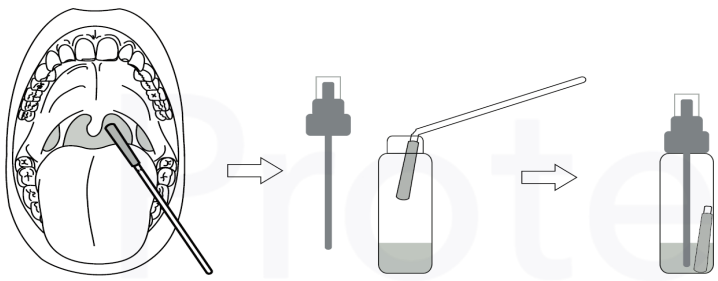
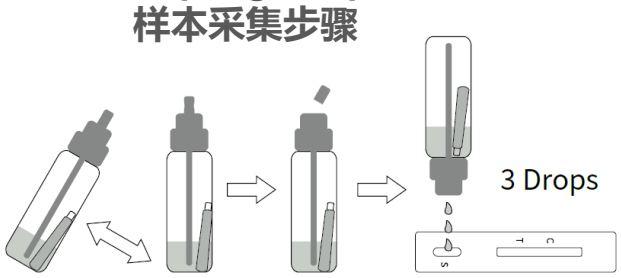
   说明书*1

Test Procedure 检测流程

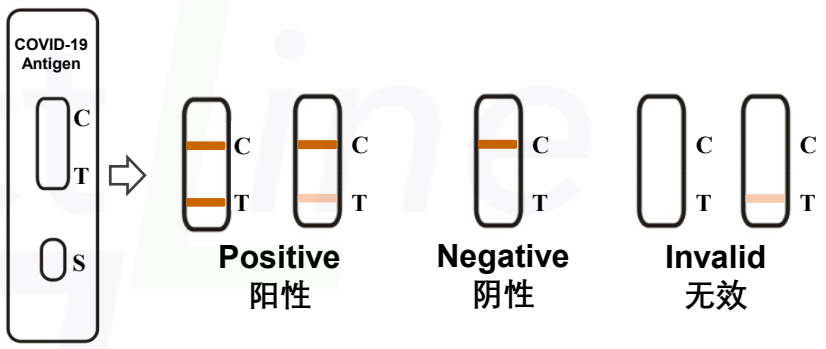


Sampling Steps
样本采集步骤



Detection Steps
检测步骤

Interpretation of Results 结果解读



New Gene (Hangzhou) Bioengineering Co., Ltd.
Website: www.new-gene.com
Email: marketing@new-gene.com
24-hour Hotline: (+86) 0571-5651 5020

CE Certification – CIBG Registration Letter
CE 认证 – 荷兰CIBG注册信

CIBG
Ministerie van Volksgezondheid, Welzijn en Sport

> Retouradres Postbus 16114 2500 BC Den Haag

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

Farmatec

Bezoekadres:
Hoftoren
Rijnstraat 50
2515 XP Den Haag

T 070 340 6161

http://hulpmiddelen.farmatec.nl

Inlichtingen bij:
M. Schmitz - Konte

medische_hulpmiddelen@
minvws.nl

Ons kenmerk:
CIBG-20204772

Bijlagen
-

Uw aanvraag
30 september 2020

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

Datum: 1 oktober 2020
Betreft: aanmelding In-vitro diagnostica

Geachte heer Luo,

Op 30 september 2020 ontving ik uw notificatie krachtens artikel 4, eerste lid van het Nederlandse Besluit in-vitro diagnostica (BIVD) om onder de bedrijfsnaam New Gene (Hangzhou) Bioengineering Co., Ltd. met Europees gemachtigde SUNGO Europe B.V. onderstaande producten als in-vitro diagnostica op de Europese markt te brengen.

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

COVID-19 / Influenza A / Influenza B Detection Kit
(geen merknaam) (NL-CA002-2020-53701)
COVID-19 Antibody / Antigen Detection Kit
(geen merknaam) (NL-CA002-2020-53700)
COVID-19 Antigen Detection Kit
(geen merknaam) (NL-CA002-2020-53699)
COVID-19 Neutralizing Antibody Detection Kit
(geen merknaam) (NL-CA002-2020-53702)
Novel Coronavirus Ribonucleic Acid Detection Kit
(geen merknaam) (NL-CA002-2020-53698)

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

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

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

CE Certification – CIBG Registration Letter
CE 认证 – 荷兰CIBG注册信

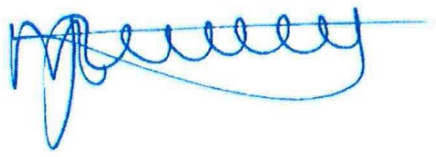
Notificatie van in-vitro diagnostische medische hulpmiddelen impliceert dat de fabrikant, New Gene (Hangzhou) Bioengineering Co., Ltd. de CE-conformiteitsmarkering heeft aangebracht op de desbetreffende producten alvorens deze in een EU-lidstaat in de handel te brengen. Zodoende garandeert SUNGO Europe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

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

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

De Minister voor Medische Zorg en Sport,
namens deze,

Afdelingshoofd
Farmatec



Dr. M.J. van de Velde

CE Certification – Declaration of Conformity
CE认证 – 符合性声明

CE

DECLARATION OF CONFORMITY

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

Manufacturer: New Gene (Hangzhou) Bioengineering Co., Ltd.

Address: Room 1606, Floor 16, Building 5, 688 Bin'an Road, Changhe Street, Binjiang District, Hangzhou City, Zhejiang Province, P. R. China

EC Representative: SUNGO Europe B.V.

Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

Product Name: **COVID-19 Antigen Detection Kit**

Specification: 25Tests/Box 1Test/Box

Classification: Others (IVDD)

Conformity Assessment Procedure: Annex III of In Vitro Diagnostic Directive (98/79/EC)

We herewith declare that the above-mentioned products meet the requirements of In Vitro Diagnostic Directive (98/79/EC) and the following harmonized standards.

EN 23640-2015	EN 13640:2002
EN 980:2016	EN 13641:2002
EN ISO 14971:2019	EN ISO 18113-1 2011
EN 13612:2002	EN ISO 18113-4 2011

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

Signature: Mingfu Li

Name/ Position: Mingfu Li / General Manager

Sungo global service

Authorized Signature (S)

Date: 29/09/2020

Place: Hangzhou, Zhejiang, China

ISO 13485 Certification
ISO 13485 体系认证

bsi.

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

New Gene (Hangzhou)
Bioengineering Co., Ltd.
Room 1606,16th Floor, No.5 Building
688 Bin'an Road
Binjiang District
Hangzhou
Zhejiang
310052
China

诺迦（杭州）生物工程有限公司
中国
浙江省
杭州市
滨江区
长河街道滨安路688号
5幢16层1606室
邮编：310052

Holds Certificate No: **MD 729179**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

Design and Development, Manufacture and Distribution of In-vitro Diagnostic Rapid Test Kit of Drug Abuse, Manufacture and Distribution of In-vitro Diagnostic Rapid Test Kit of Infectious Diseases.
药物滥用体外诊断快速检测试剂盒的设计，开发，制造和销售，传染病体外诊断快速检测试剂盒的制造和销售。

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2020-07-27
Latest Revision Date: 2020-07-27

Effective Date: 2020-07-27
Expiry Date: 2023-07-26

...making excellence a habit.™

Included in the “Export Allow List”
出口白名单企业

中国医药保健品进出口商会
服 务 产 业 链 | 助 力 国 际 化

首页 | 关于商会 | 新闻中心 | 行业服务 | 权威发布 | 商会会刊 | 企业

新闻中心 > 通知公告

动态更新：取得国外标准认证或注册的医疗物资生产企业清单

2020年07月07日 中国医药保健品进出口商会 分享

7月7日，取得国外标准认证或注册的医疗物资生产企业清单继续更新，其中，医用口罩清单新增49家企业，医用防护服清单新增5家企业，新型冠状病毒检测试剂清单新增9家企业。

诺迦（杭州）生物工程有限公司 New Gene (Hangzhou) Bioengineering Co., Ltd.	91330108MA2H3RX57K	欧盟CE

Certification for Safe Transport
货物运输鉴定

空 运
By Air

NO.2020107244

CNAS 中国认可 检验 INSPECTION CNAS IB0071

货物运输条件鉴定书

Certification for Safe Transport of Chemical Goods

非限制性货物

样品名称： 新型冠状病毒抗原检测试剂盒

Sample Name: COVID-19 Antigen Detection Kit

委托单位： 诺迦（杭州）生物工程有限公司

生产单位： 诺迦（杭州）生物工程有限公司

上海化工院检测有限公司 检验检测专用章

上化院 上海化工院检测有限公司
Shanghai Research Institute of Chemical Industry Testing Co., Ltd

空 运
By Air

空 运
By Air

Import & Export Qualification
进出口资质

对外贸易经营者备案登记表

统一社会信用代码： 91330108MA2H3RX57K

备案登记表编号： 04404553　　进出口企业代码： ----------

经营者中文名称	诺迦（杭州）生物工程有限公司		
经营者英文名称	New Gene (Hangzhou) Bioengineering Co., Ltd.		
组织机构代码	---------	经营者类型（由备案登记机关填写）	有限责任公司
住　所	浙江省杭州市滨江区长河街道滨安路688号5幢16层1606室		
经营场所（中文）	浙江省杭州市滨江区长河街道滨安路688号5幢16层1606室		
经营场所（英文）	Room 1606, 16/F, Building 5, 688 Bin'an Road, Changhe Subdistrict, Binjiang District, Hangzhou, Zhejiang		
联系电话	[redacted]	联系传真	----------
邮政编码	310052	电子邮箱	[redacted]
工商登记注册日期	2020-4-21	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	朱晓进	有效证件号	320981198511220039
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

签字（章）

2020 年 06 月 30 日

CFS (India as an example)
自由销售证明（以印度为例）

CIBG
Ministerie van Volksgezondheid, Welzijn en Sport

> Retouradres Postbus 16114 2500 BC Den Haag

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

Farmatec

Bezoekadres:
Hoftoren
Rijnstraat 50
2515 XP Den Haag

T 070 340 6161

http://hulpmiddelen.farmatec.nl

Inlichtingen bij:
T.I. van Langeveld - Baas

medische_hulpmiddelen@
minvws.nl

Ons kenmerk:
CIBG-20204982

Bijlagen
1

Uw aanvraag
14 oktober 2020

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

Datum: 20 oktober 2020
Betreft: exportverklaring(en) medische hulpmiddelen/AIMD/IVD/MDR/IVDR

Geachte heer Luo,

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

INDIA (29432)

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

Met vriendelijke groet,
Farmatec

T.I. van Langeveld - Baas

CFS (India as an example)
自由销售证明（以印度为例）

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

STATEMENT

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

SUNGO Europe B.V.
Olympisch Stadion 24
1076 DE Amsterdam
THE NETHERLANDS

acts as authorised representative of the manufacturer.

The manufacturer:

New Gene (Hangzhou) Bioengineering Co., Ltd.
Room 1606, Floor 16, Building 5, 688 Bin'an Road, Changhe Street, Binjiang District,
Hangzhou City, Zhejiang Province
CHINA

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

COVID-19 / Influenza A / Influenza B Detection Kit
COVID-19 Antibody / Antigen Detection Kit
COVID-19 Antigen Detection Kit
COVID-19 Neutralizing Antibody Detection Kit
Novel Coronavirus Ribonucleic Acid Detection Kit

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

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

This statement is valid until May 26, 2022.

The Hague, October 20, 2020

On behalf of the Minister for Medical Care and Sport
Farmatec | CIBG

Dr. M.J. van de Velde

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

Our reference: 20204982
Certificate number: 29432

NEWGENE Bioengineering

COVID-19 Antigen Detection Kit

Package Insert

Cat: COVID-19-NG08 **Specimens:** Sputum
Version: 03 **Effective Date:** 2020-10

For professional and in vitro diagnostic use only.

PRODUCT NAME

COVID-19 Antigen Detection Kit

PACKING
1 piece/bag, 25 pieces/box.

INTENDED USE
This product is suitable for the qualitative detection of novel coronavirus in sputum sample. It provides an aid in the diagnosis of infection with novel coronavirus.

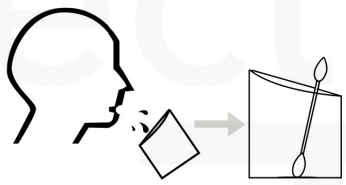
SUMMARY
The novel coronaviruses belong to the β genus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection; asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifestations include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases.

PRINCIPLE
The COVID-19 Antigen Detection Kit is an immunochromatographic membrane assay that uses highly sensitive monoclonal antibodies to detect nucleocapsid protein from SARS-CoV-2 in throat swab. The test strip is composed of the following parts: namely sample pad, reagent pad, reaction membrane, and absorbing pad. The reagent pad contains the colloidal-gold conjugated with the monoclonal antibodies against the nucleocapsid protein of SARS-CoV-2; the reaction membrane contains the secondary antibodies for nucleocapsid protein of SARS-CoV-2. The whole strip is fixed inside a plastic device. When the sample is added into the sample well, conjugates dried in the reagent pad are dissolved and migrate along with the sample. If SARS-CoV-2 antigen presents in the sample, a complex formed between the anti-SARS-2 conjugate and the virus will be captured by the specific anti-SARS-2 monoclonal antibodies coated on the test line region (T). Absence of the T line suggests a negative result. To serve as a procedural control a red line will always appear in the control line region (C) indicating that proper volume of sample has been added and membrane wicking has occurred.

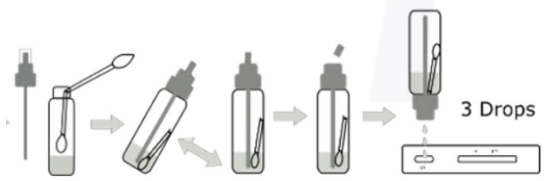
COMPOSITION
1. Test Card
2. Sample Extraction Tube
3. Cotton Swab
4. Paper Cup

STORAGE AND STABILITY
1. Store as packaged in the hermetic bag at the temperature (2-30°C or 38-86°F) and avoid direct sunshine. The kit is stable within the expiration date printed on the labeling.
2. Once open the hermetic bag, the test should be used within one hour. Prolonged exposure to hot and humid environment will cause product deterioration.
3. The lot number and the expiration date are printed on the labeling.

TEST PROCEDURE
Allow the test device and specimens to restore to room temperature (15-30°C or 59-86°F) prior to testing.



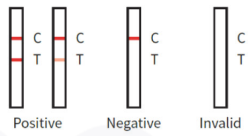
Sampling Steps



Detection Steps

1. Use the cotton swab to pick up 10-50 mg sputum samples (equivalent to the size of a match head). Open the cap of sample extraction tube, break the swab tip into the tube. Close the sample extraction tube and shake to mix the sample completely. Leave the swab in the extraction tube for one minute.
2. Take the test card from the packaging bag, place it on a table, cut off the protrusion of the collection tube, and add 3 drops of the sample solution into the sample loading hole vertically.
3. Read the result in 15 minutes. The result is considered inaccurate and invalid after 30 minutes.

INTERPRETATION OF RESULTS
Positive(+): Both of T and C lines are appeared in 15minutes.
Negative(-): C line is appeared while no T line appeared in 15 minutes after the sample is loaded.
Invalid: As long as the C line does not appear, it indicates that the test result is invalid, and should retest the sample with another test card.



NOTES
1. The COVID-19 Antigen Detection Kit is applicable to sputum samples. Blood, serum, plasma, urine and other samples may cause abnormal results.
2. Please make sure that a proper amount of sample is added for testing. Too much or too little sample amount may cause deviations in results.
3. For positive judgement, it can be confirmed as soon as both T and C line appeared. That may take 3-15 minutes after the sample is loading. For negative judgement, please wait for 15 minutes after sample loading. The result is invalid after 30 minutes after sample loading.
4. This product is disposable. DO NOT recycle.
5. Dispose of used products, samples, and other consumables as medical wastes under relevant regulations.
6. If the test line or control line is out of the test window, do not use the test card. The test result is invalid and retest the sample with another one.

INDEX OF SYMBOLS

	Consult instructions for use	Σ	Tests per kit	EC REP	Authorized Representative
IVD	For in vitro diagnostic use only		Use by		Do not reuse
2°C 30°C	Store between 2-30°C	LOT	Lot Number	REF	Catalogue number

New Gene (Hangzhou) Bioengineering Co., Ltd.
Room 1606, Floor 16, Building 5, 688 Bin'an Road, Changhe Street, Binjiang District, Hangzhou City, Zhejiang Province, P. R. China

SUNGO Europe B.V.
Olympisch Stadion 24, 1076DE
Amsterdam, Netherlands

NEWGENE Bioengineering

新型冠状病毒抗原检测试剂盒

说明书

编号: COVID-19-NG08 **样本**: 痰液
版本: 03 **生效时间**: 2020-10

仅供专业人员体外诊断使用

产品名称

新型冠状病毒抗原检测试剂盒

包装规格

1 人份/袋，25 人份/盒

预期用途

新型冠状病毒抗原检测试剂盒（胶体金法）用于定性检测痰液/粪便样本中的新型冠状病毒，可为诊断新型冠状病毒肺炎提供参考。

摘要

新型冠状病毒属于 β 属病毒。新型冠状病毒肺炎（COVID-19）是一种急性呼吸道传染病，人类容易受到感染。目前，被新型冠状病毒感染的患者是主要的感染源。无症状感染者也可以是传染源。根据目前的流行病学调查，潜伏期为 1 至 14 天，大部分为 3 至 7 天。主要表现包括发热、乏力和干咳。少数病例的症状还包括鼻塞、流鼻涕、喉咙痛、肌痛和腹泻。

检测原理

新型冠状病毒抗原检测试剂盒是一种免疫层析膜测定法，使用高度敏感的单克隆抗体从人的咽喉样本中检测 SARS-CoV-2 核衣壳蛋白。试纸由以下部分组成：样品垫，试剂垫，反应膜和吸收垫。试剂垫含有与抗 SARS-CoV-2 核衣壳蛋白的单克隆抗体结合的胶体金。反应膜中含有 SARS-CoV-2 核衣壳蛋白的双抗。整个试剂条被固定在塑料卡板中。当将样品添加到样品孔中时，在试剂垫中干燥的结合物会溶解并与样品一起迁移。如果样品中存在 SARS-CoV-2 抗原，则抗 SARS-2 结合物与病毒之间形成的复合物将被包被在测试线区域（T）上的特异性抗 SARS-2 单克隆抗体捕获。T 线不显示表示阴性结果。作为程序控制，红线将始终出现在控制线区域（C）中，表明已添加了适当的样品并且发生了膜芯吸效应。

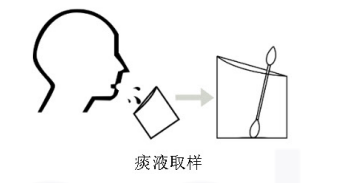
产品组成

1. 测试卡；
2. 样本提取管；
3. 棉签；
4. 纸杯。

储存条件

1. 将包装好的产品存放在密封袋中，温度为（2-30° C 或 38-86° F），避免阳光直射。 该试剂盒在标签上印刷的有效期内是稳定的。
2. 打开密封袋后请在 1 小时内使用。长时间暴露在炎热和潮湿的环境中会导致产品变质。
3. 批次和有效期印在标签上。

检测步骤
在检测之前，让检测试剂盒和样品保持在以下温度：15-30°C或59-86°F。



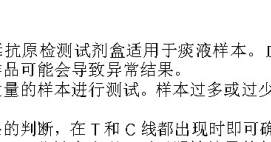
痰液取样

检测步骤

1. 痰液样本：使用棉签采集 10-50mg 新鲜痰液样本（相当于火柴头的大小）。 打开样本提取管的盖子，将棉签折断，头部放入管中。拧紧样本提取管的盖子并摇匀，使样品完全混合。使棉签头在提取管中浸泡 1 分钟。
2. 从包装袋中取出测试卡，将其放在桌子上，切掉收集管的突出部分，垂直向样品孔中滴入 3 滴样品溶液。
3. 在 15 分钟后读取结果。30 分钟后的检测结果不做参考。

结果解读

阳性 Positive (+): 在15分钟内出现T和C线。
阴性 Negative (-): 在样品添加15分钟内出现C线，而没有出现T线。
无效 Invalid: 只要没有出现C线，即表明本测试卡无效。 请使用另一张测试卡重新测试。



注意事项

1. 新型冠状病毒抗原检测试剂盒适用于痰液样本。血液，血清，血浆，尿液和其他样品可能会导致异常结果。
2. 请确保加入适量的样本进行测试。样本过多或过少都可能导致结果偏差。
3. 对于阳性结果的判断，在 T 和 C 线都出现时即可确认。结果可能在添加样品后的 3-15 分钟内出现。对于阴性结果的判断，请在添加样品后等待 15 分钟，出现 C 线，而没有 T 线。添加样本 30 分钟后的结果不做参考。
4. 该产品为一次性使用。请勿回收使用过的组件。
5. 试请按照国家医疗废弃物相关规定处理使用后的检测试剂，样品和其他废弃物。
6. 如果测试线或控制线在测试窗口之外，不要使用测试卡，请不要使用。否则，测试结果将是无效的，应更换一个新的试剂盒。

符号索引

	查阅使用说明	Σ	每套数量	EC REP	授权代表
IVD	仅用于体外诊断		使用者		请勿重复使用
2°C 30°C	储存温度为 2-30°C	LOT	批号	REF	目录号

诺迪（杭州）生物工程有限公司
中国浙江省杭州市滨江区长河街道滨安路 688 号 5 幢 16 层 1606 室

SUNGO Europe B.V.
Olympisch Stadion 24, 1076DE
Amsterdam, Netherlands

NEWGENE Bioengineering

CE

COVID-19 Antigen Detection Kit

Package Insert

Cat: COVID-19-NG08 **Specimens:** Throat Swab
Version: 02 **Effective Date:** 2020-10

For professional and in vitro diagnostic use only.

PRODUCT NAME
COVID-19 Antigen Detection Kit

PACKING
1 piece/bag, 25 pieces/box.

INTENDED USE
This product is suitable for the qualitative detection of novel coronavirus in throat swab sample. It provides an aid in the diagnosis of infection with novel coronavirus.

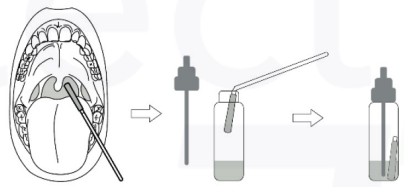
SUMMARY
The novel coronaviruses belong to the β genus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection; asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifestations include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases.

PRINCIPLE
The COVID-19 Antigen Detection Kit is an immunochromatographic membrane assay that uses highly sensitive monoclonal antibodies to detect nucleocapsid protein from SARS-CoV-2 in throat swab. The test strip is composed of the following parts: namely sample pad, reagent pad, reaction membrane, and absorbing pad. The reagent pad contains the colloidal-gold conjugated with the monoclonal antibodies against the nucleocapsid protein of SARS-CoV-2; the reaction membrane contains the secondary antibodies for nucleocapsid protein of SARS-CoV-2. The whole strip is fixed inside a plastic device. When the sample is added into the sample well, conjugates dried in the reagent pad are dissolved and migrate along with the sample. If SARS-CoV-2 antigen presents in the sample, a complex formed between the anti-SARS-2 conjugate and the virus will be captured by the specific anti-SARS-2 monoclonal antibodies coated on the test line region (T). Absence of the T line suggests a negative result. To serve as a procedural control a red line will always appear in the control line region (C) indicating that proper volume of sample has been added and membrane wicking has occurred.

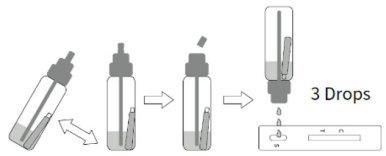
COMPOSITION
1. Test Card
2. Sample Extraction Tube
3. Throat Swab

STORAGE AND STABILITY
1. Store as packaged in the hermetic bag at the temperature (2-30°C or 38-86°F) and avoid direct sunshine. The kit is stable within the expiration date printed on the labeling.
2. Once open the hermetic bag, the test should be used within one hour. Prolonged exposure to hot and humid environment will cause product deterioration.
3. The lot number and the expiration date are printed on the labeling.

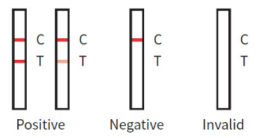
SAMPLE COLLECTION
1. Use the throat swab provided in the kit to swab over the lateral and posterior walls of pharynx, as well as the intratonsillar cleft.
2. Open the cap of sample extraction tube, break the swab tip into the tube. Close the sample extraction tube and shake to mix the sample completely. Leave the swab in the extraction tube for one minute.



TEST PROCEDURE
Allow the test device and specimens to equilibrate to temperature (15-30℃ or 59-86℉) prior to testing.
1. Take the test card from the packaging bag, place it on a table, cut off the protrusion of the collection tube, and add 3 drops of the sample solution into the sample loading hole vertically.
2. Read the result in 15 minutes. The result is considered inaccurate and invalid after 30 minutes.



INTERPRETATION OF RESULTS
Positive(+): Both of T and C lines are appeared in 15 minutes.
Negative(-): C line is appeared while no T line appeared in 15 minutes after the sample is loaded.
Invalid: As long as the C line does not appear, it indicates that the test result is invalid, and should retest the sample with another test card.



NOTES
1. The COVID-19 Antigen Detection Kit is applicable to throat swab sample. Blood, serum, plasma, urine and other samples may cause abnormal results.
2. Please make sure that a proper amount of sample is added for testing. Too much or too little sample amount may cause deviations in results.
3. For positive judgement, it can be confirmed as soon as both T and C line appeared. That may take 3-15 minutes after the sample is loading. For negative judgement, please wait for 15 minutes after sample loading. The result is invalid after 30 minutes after sample loading.
4. This product is disposable. DO NOT recycle.
5. Dispose of used products, samples, and other consumables as medical wastes under relevant regulations.
6. If the test line or control line is out of the test window, do not use the test card. The test result is invalid and retest the sample with another one.

INDEX OF SYMBOLS

	Consult instructions for use	Σ	Tests per kit	EC REP	Authorized Representative
IVD	For in vitro diagnostic use only		Use by		Do not reuse
2°C 30°C	Store between 2-30°C	LOT	Lot Number	REF	Catalogue number

New Gene (Hangzhou) Bioengineering Co., Ltd.
Room 1606, Floor 16, Building 5, 688 Bin'an Road, Changhe Street, Binjiang District, Hangzhou City, Zhejiang Province, P. R. China

CE

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Amsterdam, Netherlands

NEWGENE Bioengineering

CE

新型冠状病毒抗原检测试剂盒

说明书

编号: COVID-19-NG08 **样本**: 咽拭子
版本: 02 **生效时间**: 2020-10

仅供专业人员体外诊断使用

产品名称
新型冠状病毒抗原检测试剂盒

包装规格
1 人份/袋，25 人份/盒

预期用途
新型冠状病毒抗原检测试剂盒用于定性检测人咽喉中的新型冠状病毒，可为诊断新型冠状病毒肺炎提供参考。

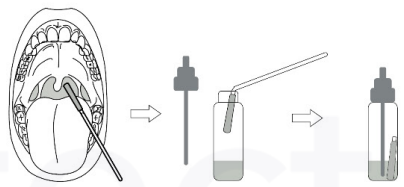
摘要
新型冠状病毒属于 β 属病毒。新型冠状病毒肺炎（COVID-19）是一种急性呼吸道传染病，人类容易受到感染。目前，被新型冠状病毒感染的患者是主要的感染源。无症状感染者也可以是传染源。根据目前的流行病学调查，潜伏期为 1 至 14 天，大部分为 3 至 7 天。主要表现包括发热、乏力和干咳。少数病例的症状还包括鼻塞、流鼻涕、喉咙痛、肌痛和腹泻。

检测原理
新型冠状病毒抗原检测试剂盒（胶体金）是一种免疫层析膜测定法，使用高度敏感的单克隆抗体从人的咽喉样本中检测 SARS-CoV-2 核衣壳蛋白。试纸由以下部分组成：样品垫，试剂垫，反应膜和吸收垫。试剂垫含有与抗 SARS-CoV-2 核衣壳蛋白的单克隆抗体结合的胶体金。反应膜中含有 SARS-CoV-2 核衣壳蛋白的双抗。整个试剂条被固定在塑料卡板中。当将样品添加到样品孔中时，在试剂垫中干燥的结合物会溶解并与样品一起迁移。如果样品中存在 SARS-CoV-2 抗原，则抗 SARS-2 结合物与病毒之间形成的复合物将被包被在测试线区域（T）上的特异性抗 SARS-2 单克隆抗体捕获。 T 线不显示表示阴性结果。作为程序控制，红线将始终出现在控制线区域（C）中，表明已添加了适当的样品并且发生了膜芯吸效应。

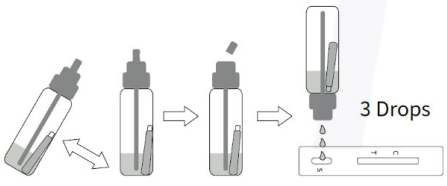
产品组成
1. 测试卡；
2. 样本提取管；
3. 咽拭子。

储存条件
1. 将包装好的产品存放在密封袋中，温度为（2-30° C 或 38-86° F），避免阳光直射。 该试剂盒在标签上印刷的有效期内是稳定的。
2. 打开密封袋后请在 1 小时内使用。长时间暴露在炎热和潮湿的环境中会导致产品变质。
3. 批次和有效期印在标签上。

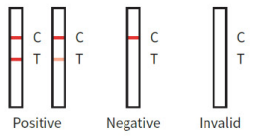
样本收集
1. 使用试剂盒中提供的咽拭子对咽侧壁和后壁以及扁桃体内间隙进行采样。
2. 打开样本提取管的盖子，将拭子折断，头部放入管中。盖上盖子并摇匀，将棉签头浸泡 1 分钟。



检测步骤
在检测之前，让检测试剂盒和样品保持在以下温度：15-30℃或 59-86°F。
1. 从包装袋中取出测试卡，将其放在桌子上，切掉收集管的突出部分，垂直向样品孔中滴入 3 滴样品溶液。
2. 在 15 分钟后读取结果。30 分钟后的检测结果不做参考。



结果解读
阳性 Positive (+): 在15分钟内出现T和C线。
阴性 Negative (-): 在样品添加15分钟内出现C线，而没有出现T线。
无效 Invalid: 只要没有出现C线，即表明本测试卡无效。 请使用另一张测试卡重新测试。



注意事项
1. 新型冠状病毒抗原检测试剂盒适用于咽拭子样本。血液，血清，血浆，尿液和其他样品可能会导致异常结果。
2. 请确保加入适量的样本进行测试。样本过多或过少都可能导致结果偏差。
3. 对于阳性结果的判断，在 T 和 C 线都出现时即可确认。结果可能在添加样品后的 3-15 分钟内出现。对于阴性结果的判断，请在添加样品后等待 15 分钟，出现 C 线，而没有 T 线。添加样本 30 分钟后的结果不做参考。
4. 该产品为一次性使用。请勿回收使用过的组件。
5. 试请按照国家医疗废弃物相关规定处理使用后的检测试剂，样品和其他废弃物。
6. 如果测试线或控制线在测试窗口之外，不要使用测试卡，请不要使用。否则，测试结果将是无效的，应更换一个新的试剂盒。

符号索引

	查阅使用说明	Σ	每套数量	EC REP	授权代表
IVD	仅用于体外诊断		使用者		请勿重复使用
2°C 30°C	储存温度为 2-30°C	LOT	批号	REF	目录号

诺迦（杭州）生物工程有限公司
中国浙江省杭州市滨江区长河街道滨安路 688 号 5 幢 16 层 1606 室

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Amsterdam, Netherlands

FAQ
NEWGENE Coronavirus Antigen Test

1 What is Coronavirus Antigen test?

Coronavirus Antigen test detects the virus itself by the specific proteins (i.e. Antigens) on its surface, so as to identify the existence of the virus.

NEWGENE technician is preparing the solution

2 What is the difference between Coronavirus Antigen test and Antibody test?

Antibody test is to detect the molecules (i.e. antibodies) that people produce after being infected with the virus. Antibody may take several days to produce after infection, and usually remain in the blood for several weeks after the patient recovers. That is, the cured patient can also be tested positive for a longer period of time. Therefore, the antibody test is useful in the diagnosis of COVID-19, but with limitations.

The Antigen test is to detect the virus, which directly relates to the infection itself.

3 What is the difference between Antigen test and nucleic acid test?

Antigen test is based on immune reaction, while nucleic acid test is based on genetic information. Therefore, Antigen test can be much faster than nucleic acid test (PCR) (15 minutes vs 4 hours). Certainly, the cost of speed is the sensitivity. That is, Antigen test is not as sensitive as nucleic acid test. PCR can detect micro amount of SARS-CoV-2 virus due to the amplification process of virus genetic information. This is also why PCR test often takes several hours and may cause aerosol contamination.

4 Advantages of Antigen test and precautions in application

Except for advantages of rapid test, it does not require laboratory processing and medical professionals to operate. Therefore, it is very suitable for large-scale general screening when lacking laboratory conditions and medical professionals. However, if human body contains a very low amount of virus, and with no obvious clinical symptoms, they are likely to be tested negative. The ability of such infected people to spread the virus is also much lower than that of ordinary patients. Therefore, for asymptomatic infected people, it is recommended to adopt nucleic acid for detection.

Antigen test helps to quickly identify people with high levels of infection (those who are most likely to infect others). Therefore, Antigen test can help prevent the spread of the pandemic, by identifying those who are most likely to spread the disease and isolating them from others. Thus, shift the focus to identify the most infectious people.

NEWGENE technicians are making samples

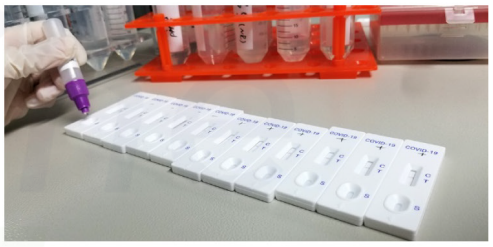
5 Precautions for Antigen test operations

Antigen test is to detect the virus itself, so sample selection is very important. We recommend sputum sample, since sputum is the secretion from respiratory tract where viruses cluster the most, so sputum is relatively easy for detection.

Because of the uneven distribution of the virus on the nasopharyngeal mucosa appearance, it is very likely that no virus or very small amount of virus is taken while sampling and lead to false negative result, when sampling via throat swab. Therefore, the accuracy will be lower than that of sputum.

In addition, studies have shown that after people are infected, the viruses can be detected in the digestive tract, especially in the intestinal stool. Therefore, if convenient (e.g. in hospital or at home), stool sample is another option for testing; Saliva samples mixed with sputum also have a certain probability of detection, although the amount of virus contained is lower than pure sputum.

For false negative testing result (PCR positive, Antigen test negative), if the patient has asymptomatic infection, it is recommended to take nucleic acid as standard, and if patients cough or have other symptoms, it's suggested to re-sampling and test again. Besides, S protein is selected as the testing object in the NEWGENE's Antigen test. S protein shows good specificity and usually does not cause false positive results.



NEWGENE technicians are testing different concentrations of standards

6 Others

The WHO has always been a supporter of Antigen testing. Experts pointed out that compared with conducting an accurate test every two weeks, conducting a relatively insensitive quick test twice a week can more effectively contain the spread of SARS-CoV-2. That is, the focus of the virus detection should be on identifying those who are likely to spread SARS-CoV-2, rather than locating anyone who is infected with SARS-CoV-2.

Delhi is the first place in India to start using rapid Antigen testing in June. By mid-July, the number of cases there had been reduced, and the daily death toll had also stabilized, indicating that Antigen testing played a certain role in controlling the spread of the virus. Although after cases declined, India began to lift the blockade restrictions and cause the infection to rise again.

The Philippine Association of Microbiology and Infectious Diseases has issued interim guidelines for clinicians and medical staff, stating that Antigen testing can be used as a substitute for PCR to diagnose coronavirus infection in people with symptoms in the early stage, especially during the acute infection period.

NewGene 新冠抗原检测 FAQ

1 新冠抗原检测是什么？

新冠抗原测试是通过检测样本中病毒表面的特定蛋白质（即抗原），从而识别病毒本身是否存在的一种检测方法。

NEWGENE 技术人员在配制溶液

2 新冠抗原检测与新冠抗体检测有什么区别？

抗体检测是检查人们感染病毒后产生的分子（即抗体）。抗体在感染后可能需要几天的时间才能形成，而且通常在病人恢复后还会在血液中存在数周，即痊愈的病人也可能抗体呈现较长时间的阳性，因此抗体测试在新冠诊断中的作用非常有限。

抗原检测是检测病毒本身，因此其与新冠是否感染是直接相关的。

3 抗原检测与核酸检测的区别在哪里？

抗原检测是免疫反应，核酸检测是遗传信息检测。因此，抗原检测可以比核酸检测（PCR）快得多（15 分钟 vs 4 小时）。当然，这种速度的代价是敏感度，即抗原检测并不像核酸检测那么敏感，PCR 因为有病毒遗传信息放大的过程，可以检测出极微量的 SARS-CoV-2 病毒，当然，这也是 PCR 检测往往需要数小时，并且可能会产生气溶胶污染的原因。

4 抗原检测的优势和应用注意事项

抗原检测除了快速的优势之外，也不需要在实验室进行处理，更不需要专业人员操作，因此，非常适用于在缺乏实验室条件和专业人员的大规模普筛场景。然而，如果一个人体内的病毒含量非常低，也没有明显的临床症状，测试可能会给出阴性结果，当然，这类被感染人群的传播病毒的能力也远低于普通新冠病人。因此，对于这类无症状感染者，建议使用核酸方法进行检测。

由于抗原有助于快速识别病毒含量高的人群，即最有可能传染他人的人群，因此抗原测试有助于阻止大流行，发现那些最有可能传播疾病的人并将他们与社区隔离开来，从而把重点转移到识别最具传染性的人群上。

NEWGENE 技术人员在进行喷金点膜、制作小样

5 抗原检测的操作注意事项

抗原检测因为是检测病毒本身，因此样本选取非常重要。我们推荐使用痰液样本，因为痰液是呼吸道的分泌物，而呼吸道是病毒最容易聚集的地方，因此痰液相对比较容易检测。

咽拭子样本由于可能在采样中因为鼻咽粘膜外表病毒分布不均匀，因此很有可能没有获取到病毒或者病毒采样量太少，所以可能会导致假阴性，因此，如果选取咽拭子样本做检测，检测准确率会比痰液低一些。

此外，研究表明，新冠病人在感染病毒后，消化道尤其是肠道粪便中会检测出病毒，因此如果条件允许的情况下（如在医院或者用户居家检测），粪便样本也是一种检测方式；混合了痰液的唾液样本也有一定的检出概率，尽管其中的病毒量要低于纯痰液。

对于检测中的情况出现的假阴性，即病人核酸确诊为阳性，但抗原检测为阴性，如果病人为无症状感染，建议以核酸作为标准。如果病人已有咳嗽或者其他相关症状，可以重新采样测试确诊。此外，NewGene 抗原检测中选取 S 蛋白作为检测对象，该蛋白特异性较好，一般不会出现假阳性，即其他非新冠病毒不会造成阳性结果。

NEWGENEN 技术人员正在测试不同浓度的标准品

6 其他内容

世卫组织一直是抗原检测的支持者，专家指出与每两周进行一次更精确的测试相比，用相对不敏感的快速测试每周两次可以更有效地遏制 SARS-CoV-2 的传播，即重点应该放在识别那些有可能向其他人传播 SARS-CoV-2 的人，而不是发现任何感染了 SARS-CoV-2 的人。

印度德里是印度第一个在 6 月开始使用快速抗原检测的地区。到 7 月中旬，那里的病例数量已经减少，每日死亡人数也趋于平稳，这表明抗原检测在控制病毒传播方面发挥了一定作用；尽管后期印度因为疫情下降，开始取消封锁限制并导致感染重新上升。

菲律宾微生物学和传染病学会发布了临床医生和医护人员的临时指南，指出抗原测试可以作为 PCR 的替代品，用于在出现症状的人在早期尤其是急性感染期确诊冠状病毒的感染。