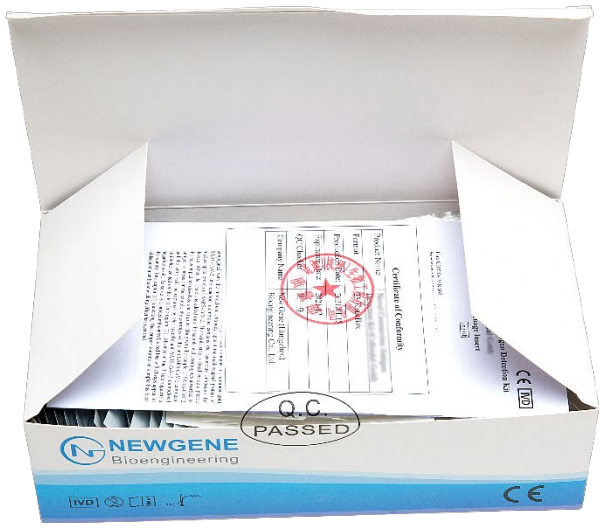
PRODUCT INTRODUCTION

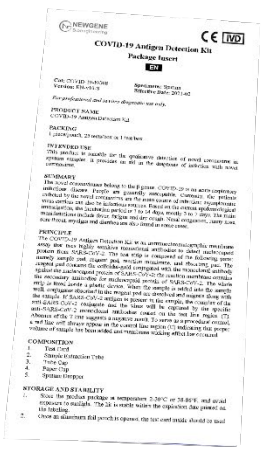
NEWGENE Bioengineering

COVID-19 Antigen Detection Kit

Product Code: COVID-19-NG08

25 Tests/Box





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

1 Tests/Box

NEWGENE Bioengineering

Product Feature

- Detected by **Sputum** Samples
- Multiple Packaging Specifications: 25 Tests/Box or 1 Test/Box
- Fast Detection: Result in 15 minutes.
- High Accuracy.
- Easy to Use.

Components

N0.	Components name	*25 Tests/Box*	*1Test/Box*
1	Test Card	*25	*1
2	Sample Extraction Tube	*25	*1
3	Tube Cap	*25	*1
4	Paper Cup	*25	*1
5	Sputum Dropper	*25	*1
6	Package Insert	*1	*1

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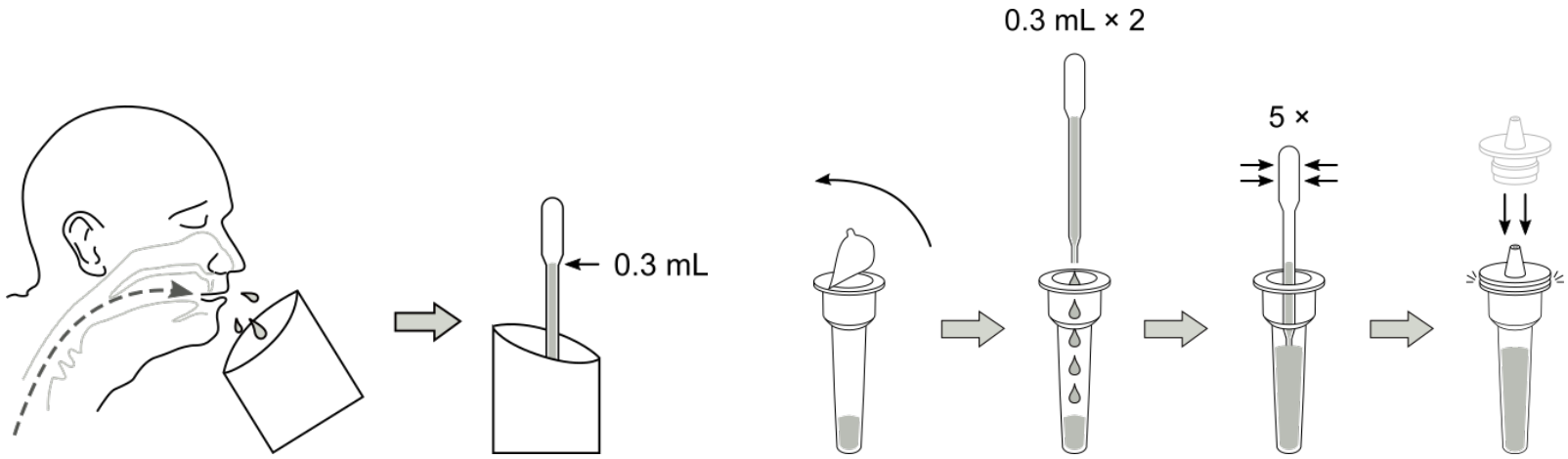
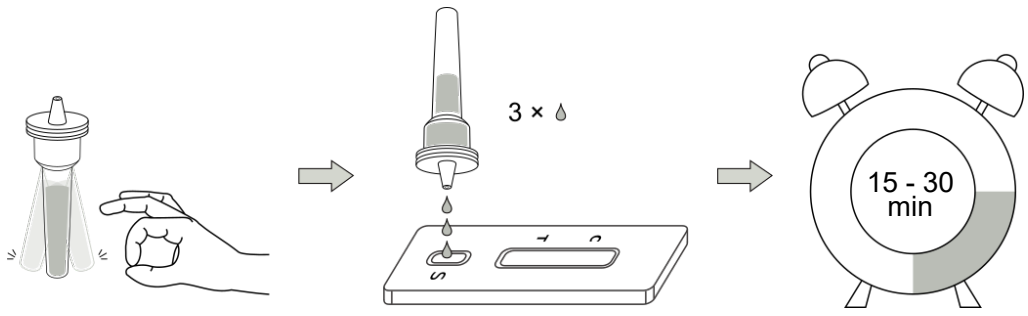
TEST PROCEDURES

NEWGENE Bioengineering

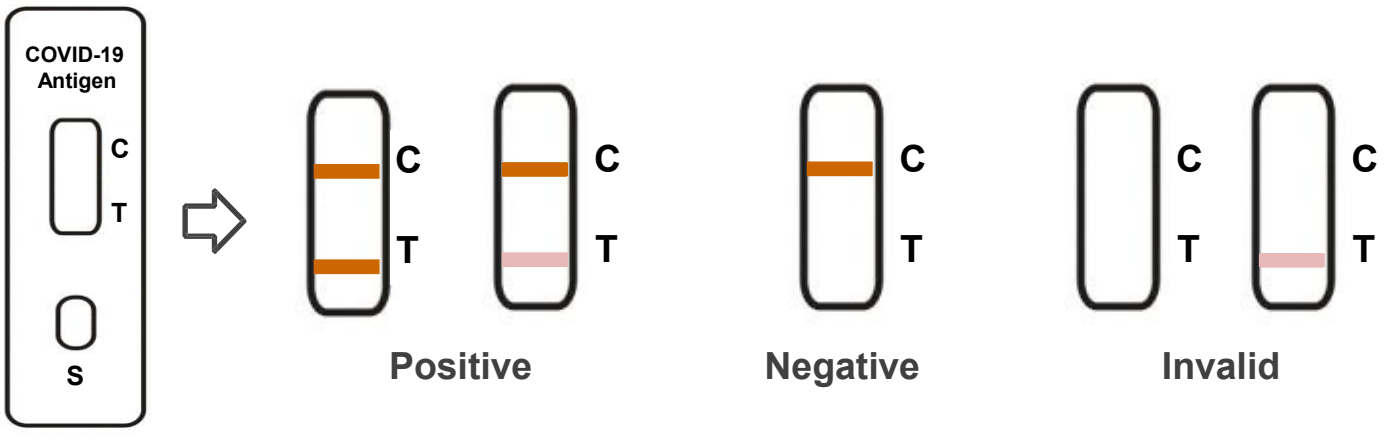
SAMPLING STEPS



DETECTION STEPS



INTERPRETATION OF RESULTS



Positive(+): Red bands appear at both of T and C line in 15 to 30 minutes.
Negative(-): A red band appears at C line while no red band appears at T line in 15 to 30 minutes after sample loading.
Invalid: As long as no red band appears at C line, it indicates that the test result is invalid, and should retest the sample with another test card.

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CE Certification – CIBG Registration Letter

NEWGENE Bioengineering

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
-

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.

Uw aanvraag
30 september 2020

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

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

NEWGENE Bioengineering

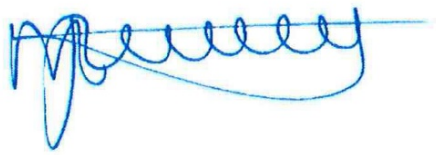
Notificatie van in-vitro diagnostische medische hulpmiddelen impliceert dat de fabrikant, New Gene (Hangzhou) Bioengineering Co., Ltd. de CE-conformiteitsmarkering heeft aangebracht op de desbetreffende producten alvorens deze in een EU-lidstaat in de handel te brengen. Zodoende garandeert SUNGO Europe 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

NEWGENE Bioengineering

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

Product Code: COVID-19-NG08

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.

Sungo global service

Signature:

Name/ Position: Mingfu Li / General Manager

Date: 29/09/2020

Place: Hangzhou, Zhejiang, China

Authorized Signature (S)

ISO 13485 Certification

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

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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

2021年01月29日 中国医药保健品进出口商会 分享

1月29日，清单继续更新，如需查询企业具体信息请在网站首页右上角“取得国外认证和注册企业查询”查询，如需查询整体清单请直接点击下载。

取得国外标准认证或注册的医疗物资生产企业清单20210129

诺迦（杭州）生物工程有限公司 New Gene (Hangzhou) Bioengineering Co., Ltd.	91330108MA2H3RX57K	CE	COVID-19 IgM/IgG Antibody Detection Kit (Colloidal Gold) (COVID-19-NG01) Novel Coronavirus Antigen Detection Kit (Colloidal Gold) (COVID-19-NG02) COVID-19 IgM/IgG Antibody Detection Kit (Quantum Dot Immunochromatography) (COVID-19-NG03) Novel Coronavirus Spike Glycoprotein Detection Kit (Ligand-receptor Competitive Chromatography) (COVID-19-NG04) Novel Coronavirus Ribonucleic Acid Detection Kit **COVID-19 Antigen Detection Kit** COVID-19 Antibody / Antigen Detection Kit COVID-19 / Influenza A / Influenza B Detection Kit COVID-19 Neutralizing Antibody Detection Kit

CFS (India as an example)

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

CE IVD

COVID-19 Antigen Detection Kit

Package Insert

EN

Cat: COVID-19-NG08 **Specimens:** Sputum
Version: EN-v10-S **Effective Date:** 2021-02

For professional and in vitro diagnostic use only.

PRODUCT NAME
COVID-19 Antigen Detection Kit

PACKING
1 piece/pouch, 25 tests/box or 1 test/box

INTENDED USE
This product is suitable for the qualitative detection of novel coronavirus in sputum samples. 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 virus carriers can also be infectious sources. 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 also found in some cases.

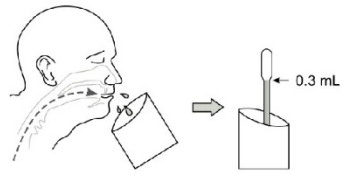
PRINCIPLE
The COVID-19 Antigen Detection Kit is an immunochromatographic membrane assay that uses highly sensitive monoclonal antibodies to detect nucleocapsid protein from SARS-CoV-2. The test strip is composed of the following parts: namely sample pad, reagent pad, reaction membrane, and absorbing pad. The reagent pad contains the colloidal-gold conjugated with the monoclonal antibody 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 absorbed in the reagent pad are dissolved and migrate along with the sample. If SARS-CoV-2 antigen is present in the sample, the complex of the anti-SARS-CoV-2 conjugate and the virus will be captured by the specific anti-SARS-CoV-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 effect has occurred.

COMPOSITION
1. Test Card
2. Sample Extraction Tube
3. Tube Cap
4. Paper Cup
5. Sputum Dropper

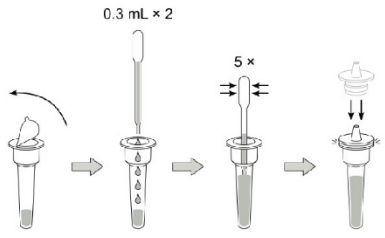
STORAGE AND STABILITY
1. Store the product package at temperature 2-30°C or 38-86°F, and avoid exposure to sunlight. The kit is stable within the expiration date printed on the labeling.
2. Once an aluminum foil pouch is opened, the test card inside should be used within one hour. Prolonged exposure to hot and humid environment may cause inaccurate results.
3. The lot number and the expiration date are printed on the labeling.

WARNINGS AND PRECAUTIONS
1. Read the instructions for use carefully before using this product.
2. This product is for professional use ONLY.
3. This product is applicable to sputum samples. Using other sample types may cause inaccurate or invalid test results.
4. Sputum comes from respiratory tract. It is the type of sample recommended by WHO.
5. Please make sure that a proper amount of sample is added for testing. Too much or too little sample amount may cause inaccurate results.
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.
7. This product is disposable. DO NOT recycle used components.
8. Dispose of used products, samples, and other consumables as medical wastes under relevant regulations.

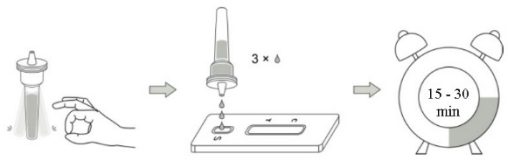
SAMPLE COLLECTION
1. Have the patient take a deep breath, and expectorate deep cough sputum into the paper cup or a sputum container.
   Note: If the patient has eaten or drunk just before sample collection, rinse the mouth with clean water.
2. Use the sputum dropper to transfer 0.6 mL of the sputum sample into sample extraction tube. The dropper draws up 0.3 mL sample at a time. Perform the sample transfer procedure twice.



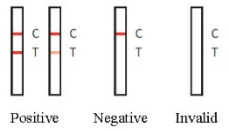
3. Peel off the aluminum foil seal from a sample extraction tube.
4. Transfer 0.6 mL sputum sample into sample extraction tube.
   Note: Sputum is highly viscous. Please strictly follow the instructions described above. Adding excessive or insufficient sputum sample may cause inaccurate results.
5. Squeeze the dropper 5 times to mix the sputum sample with sample extraction solution.
6. Insert the tube cap firmly on the sample extraction tube. Put the tube still for 1 minute to release viral antigens.



TEST PROCEDURES
Restore the test devices and specimens to room temperature (15-30°C or 59-86°F) prior to testing.
1. Flick the bottom of the tube to mix sample solution.
2. Take out a test card from an aluminum foil pouch. Place the test card on a table. Hold the tube upside down vertically. Squeeze the tube to expel 3 drops of sample solution into the loading well on a test card.
3. Read the result at 15 to 30 minutes. The result is considered inaccurate and invalid after 30 minutes.
   Note: DO NOT reload sample solution to the loading well of a used test card.



INTERPRETATION OF RESULTS
Positive(+): Red bands appear at both of T and C line in 15 to 30 minutes.
Negative(-): A red band appears at C line while no red band appears at T line in 15 to 30 minutes after sample loading.
Invalid: As long as no red band appears at C line, it indicates that the test result is invalid, and should retest the sample with another test card.



PRODUCT PERFORMANCE
Limit of Detection (LoD): the LoD of this product is about 0.05 ng/mL SARS-CoV-2 nucleocapsid protein solution.

Sensitivity, Specificity & Total Accuracy
The product performance was evaluated with clinical specimens, taking commercial RT-PCR kit as the gold standard.

Sputum		RT-PCR Positive	RT-PCR Negative	Total
COVID-19-NG08	Positive	109	1	110
	Negative	3	96	99
Total		112	97	209
		Sensitivity	**Specificity**	**Total Accuracy**
		97.3% [92.4%-99.4%]	99.0% [94.4%-100.0%]	98.1% [95.2%-99.5%]

Cross-Reactivity with Other Pathogens
No cross-reactivity observed with pathogens listed below:

Species	Test Level
Staphylococcus aureus	1×10^5 CFU/mL
Streptococcus pneumoniae	1×10^5 CFU/mL
Measles virus	1×10^6 pfu/mL
Mumps virus	1×10^6 pfu/mL
Adenovirus type 3	1×10^6 pfu/mL
Mycoplasma pneumoniae	1×10^5 CFU/mL
Parainfluenza virus 2	1×10^6 pfu/mL
Metapneumovirus	1×10^6 pfu/mL
Human coronavirus OC43	1×10^6 pfu/mL
Human coronavirus 229E	1×10^6 pfu/mL
Bordetella parapertussis	1×10^5 CFU/mL
Influenza B virus (Victoria Lineage)	1×10^6 pfu/mL
Influenza B virus (strain B/Yamagata/16/1988)	1×10^6 pfu/mL
2009 pandemic influenza A (H1N1) virus	1×10^6 pfu/mL
Influenza A (H3N2) virus	1×10^6 pfu/mL
Avian influenza A (H7N9) virus	1×10^6 pfu/mL
Avian influenza A (H5N1) virus	1×10^6 pfu/mL
Epstein-Barr virus	1×10^6 pfu/mL
Enterovirus CA16	1×10^6 pfu/mL
Rhinovirus	1×10^6 pfu/mL

Interference Test
No interference observed with materials listed below:

Materials	Test Level
Abidol	20 μg/mL
Aluminum hydroxide	20 μg/mL
Azithromycin	20 μg/mL
Beclomethasone	20 μg/mL
Bilirubin	20 μg/mL
Budesonide	20 μg/mL
Ceftriaxone	20 μg/mL
Dexamethasone	20 μg/mL
Flunisolide	20 μg/mL
Fluticasone	20 μg/mL
Hemoglobin	20 μg/mL
Histamine hydrochloride	20 μg/mL
Levofloxacin	20 μg/mL
Lopinavir	20 μg/mL
Meropenem	20 μg/mL
Mometasone	20 μg/mL
Mucin	20 μg/mL
Oseltamivir	20 μg/mL
Oxymetazoline	20 μg/mL
Paramivir	20 μg/mL
Phenylephrine	20 μg/mL
Ribavirin	20 μg/mL
Ritonavir	20 μg/mL
Sodium bicarbonate	20 μg/mL
Sodium chloride	20 μg/mL
Tobramycin	20 μg/mL
Triamcinolone acetonide	20 μg/mL
Zanamivir	20 μg/mL
α-interferon	20 μg/mL

LIMITATIONS
1. This product is intended for assisted diagnosis of viral infections only. A final clinical diagnosis should also consider factors like symptoms, results of other tests as well.
2. A negative result indicates that the viral load in tested sample is below the limit of detection of this product. It cannot completely exclude the possibility of viral infection of patient.
3. A positive result indicates that the tested sample has viral load higher than the limit of detection of this product. However, the color intensity of test line may not correlate with the severity of infection or disease progression of the patient.

INDEX OF SYMBOLS

	Consult instructions for use		Tests per kit	EC REP	Authorized representative in European Community
IVD	For in vitro diagnostic use only		Use by date		Do not reuse
	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 EC REP
SUNGO Europe B.V.
Olympiach Stadion 24, 1076DE Amsterdam, Netherlands