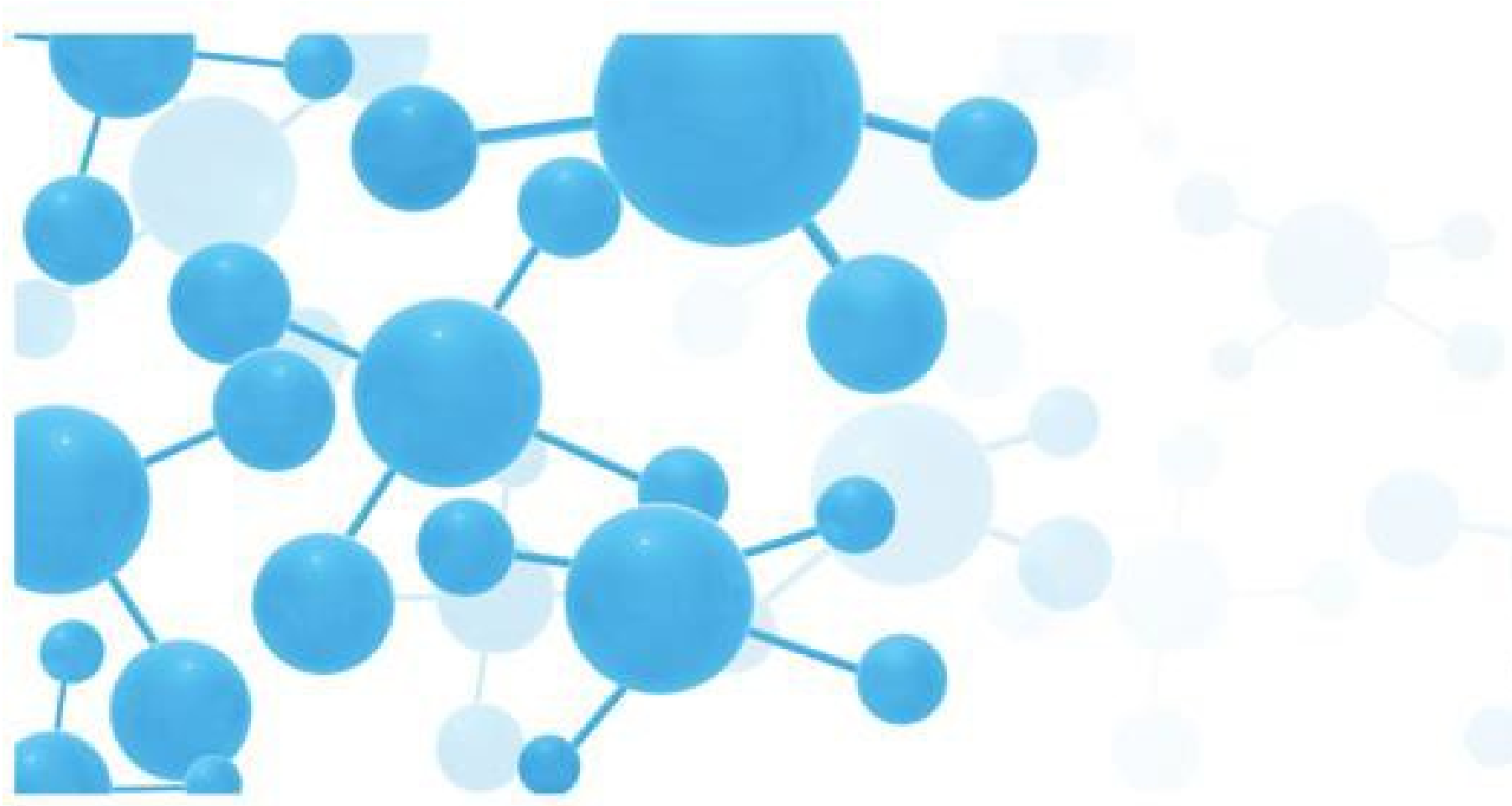
NEWGENE
Bioengineering



# 新冠抗原检测试剂产品手册
# Product Manual of COVID-19 Antigen Detection Kit

**诺迦（杭州）生物工程有限公司**
**New Gene (Hangzhou) Bioengineering Co., Ltd.**

# COMPANY PROFILE

New Gene (Hangzhou) Bioengineering Co., Ltd. is located in Hangzhou, China. It is a high-tech company engaged in the research, development, manufacture and distribution of biological products. It is committed to creating biological materials such as antigens and antibodies, in vitro diagnostic reagents and related devices, and also the complete industrial chain of artificial intelligence assisted diagnosis system. The product line covers a full range of in vitro diagnostic products such as immune diagnosis, molecular diagnosis, and microbiological testing. NEWGENE has profound technical accumulation and unique technological advantages in the areas of early cancer screening, rapid detection of infectious diseases, and rapid screening of geriatric diseases.

NEWGENE's manufacturing system meets GMP standards for medical devices, and is certified with ISO13485 by British BSI. Relevant in vitro diagnostic reagent products have obtained the EU CE certification. NEWGENE is also a member on the "allow list" issued by Chinese Ministry of Commerce for anti-epidemic products exporting.

At present, NEWGENE COVID-19 Antigen Detection Kit has **registered in** many countries, including ***Germany, France, Italy, Switzerland, Belgium, Portugal, Czech, Denmark, Hungary, Greece, Poland, Sweden, Moldova, Peru, Argentina, Ecuador, Kenya, Zimbabwe, South Africa, Malaysia, Thailand, Brunei, Congo*** **etc.,** and passed the clinical verification of multiple national laboratories. The products are suitable for children under 14 years old.








# CE CERTIFICATE – REGISTRATION LETTER

NEWGENE Bioengineering

**Self-test Approval of EU**

# CERTIFICATE

**EC Certificate No. 1434-IVDD-449/2021**

**EC Design-examination**
**Directive 98/79/EC concerning**
***in vitro* diagnostic medical devices**

Polish Centre for Testing and Certification certifies
that manufactured by:

**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**

in vitro diagnostic medical devices
for self-testing

## COVID-19 Antigen Detection Kit - Nasal Swab

in terms of design documentation, comply with requirements
of Annex III (Section 6) to Directive 98/79/EC (as amended)
implemented into Polish law,
as evidenced by the audit conducted by the PCBC
Validity of the Certificate: from 11.08.2021 to 27.05.2024

The date of issue of the Certificate: 11.08.2021

The date of the first issue of the Certificate: 11.08.2021

CE 1434

Issued under the Contract No. MD-116
Application No: 239/2021
Certificate bears the qualified signature.
Warsaw, 11.08.2021
Module A1

Elektronicznie podpisany przez Anna Małgorzata Wyroba
Data: 2021.08.11 09:14:18 +02'00'

Vice-President

**POLISH CENTRE FOR TESTING AND CERTIFICATION** 02-844 Warsaw, 469 Puławska Street, tel. +48 22 46 45 200, e-mail:pcbc@pcbc.gov.pl

# CE CERTIFICATE - DOC

NEWGENE Bioengineering

CE 1434

# 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

**EC Certificate No.:** 1434-IVDD-449/2021

**Product Name:** **COVID-19 Antigen Detection Kit – Nasal Swab**

**Specification:** 1Test/Box, 5Tests/Box, 25Tests/Box

**Classification:** Self Test (IVDD)

**Conformity Assessment Procedure:** Annex III (Section 6) to 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 13612:2002 | EN 13641:2002 |
| EN ISO 14971:2019 | EN ISO 18113-1 2011 |

Signature: Mingfu Li

Name/ Position: Mingfu Li / General Manager

Date: 11/08/2021

Place: Hangzhou, Zhejiang, China

# ISO 13485 CERTIFICATE

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.™

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.
An electronic certificate can be authenticated online.
Printed copies can be validated at www.bsi-global.com/ClientDirectory or telephone +86 10 8507 3000.

Information and Contact: BSI, John M. Keynesplein 9, 1066 EP Amsterdam The Netherlands. Tel: +31 (0) 20 3460 780
BSI Group The Netherlands B.V., registered in the Netherlands under number 33264284, at John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands
A Member of the BSI Group of Companies.

# PRODUCT INTRODUCTION

NEWGENE Bioengineering

Self-Testing

CE 1434

## COVID-19 Antigen Detection Kit - Nasal Swab

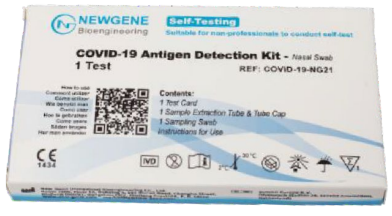
| No. | Components | *25 Tests/Box* | *5 Tests/Box* | *1 Test/Box* |
|---|---|---|---|---|
| 1 | Test Card | 25 | 5 | 1 |
| 2 | Sample Extraction Tube & Tube Cap | 25 | 5 | 1 |
| 3 | Sampling Swab: *for Nasal Swab* | 25 | 5 | 1 |
| 4 | Package Insert | 1 | 5 | 1 |

### 25 Tests/Box



### 5 Tests/Box


### 1 Test/Box

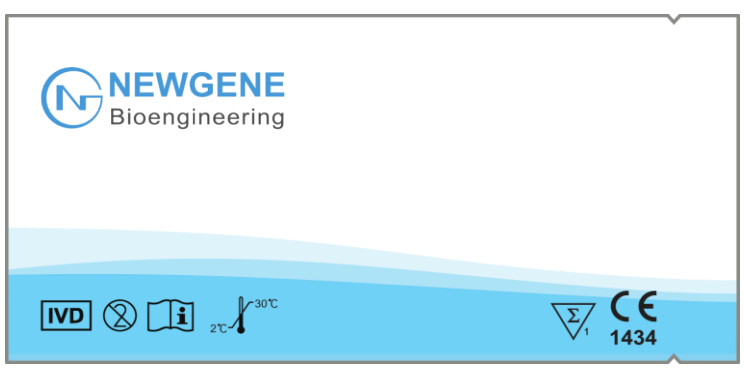



# PRODUCT INTRODUCTION

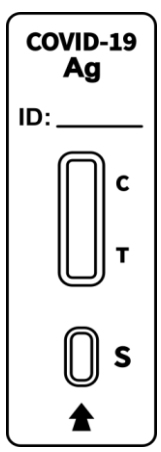
NEWGENE Bioengineering

## COMPONENTS

Peel HERE




**Aluminum Foil Pouch**

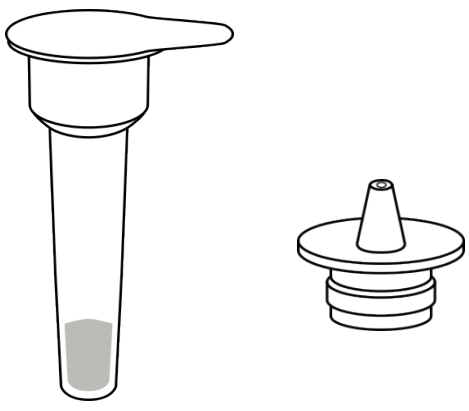



Result Window

Loading Well "S"

**Test Card**
(Packed in the pouch)


**Desiccant**
(Discard it.
Do not open)



**Sample Extraction Tube & Tube Cap**

NEWGENE Bioengineering CE 1434

**Instructions for Use**

**COVID-19 Antigen Detection Kit**

EN

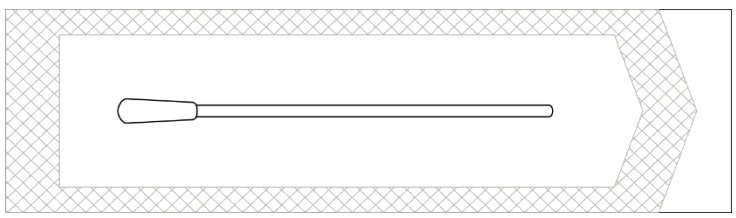
*For self-test use / Suitable for non-professionals to conduct self-test.*

**PRECAUTIONS BEFORE USING THE PRODUCT**

1. Read the instructions carefully prior to first use.
2. For people who are not able to perform the test themselves, the test should be conducted by the legal guardians.
3. For children under the age of 15, the self-test should be conducted under adult supervision.
4. This test detects SARS-CoV-2 antigen in nasal cavity secretions, which is collected by a sterile nasal swab.
5. For people who has recent nasal trauma or surgery, or has severe coagulopathy, gentle operation is required for nasal swab collection to avoid injuries to the nose.
6. Please use the components provided in the kit for testing. Do not use components from other sources.
7. Please use this product in a place with sufficient light, so as to interpret the results accurately.

**PRECAUTIONS AFTER USING THE PRODUCT**

1. If you get a positive result, please contact your family doctor, or seek help from a professional medical facility as soon as possible. You need a nucleic acid test to confirm viral infection.
2. A negative result cannot completely exclude the possibility of viral infection. Incorrect sampling or low viral load may also cause a false negative result.



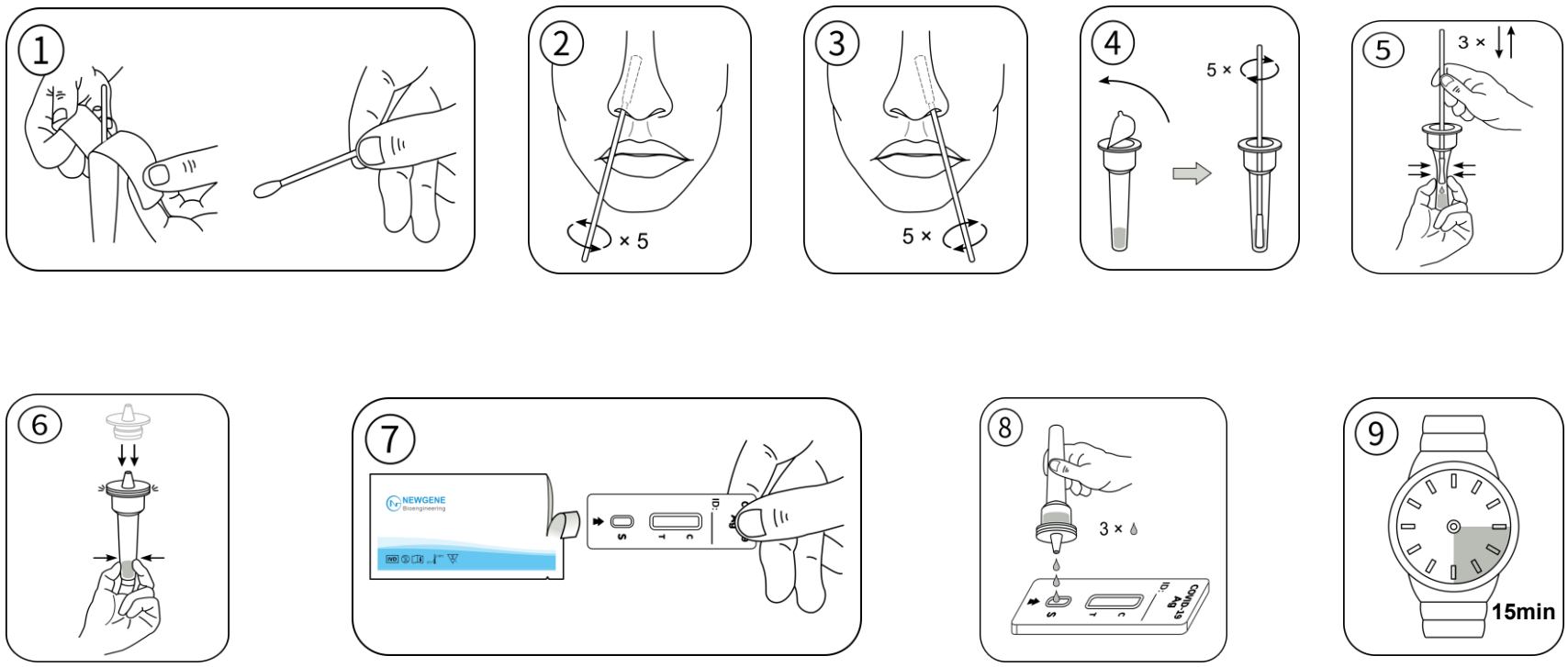
Peel **HERE**

**Sampling Swab**

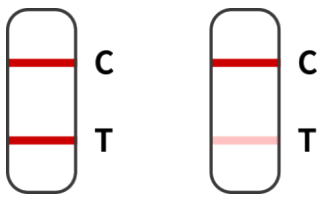
# PRODUCT INTRODUCTION

NEWGENE Bioengineering

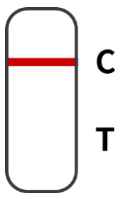
## TEST PROCEDURES



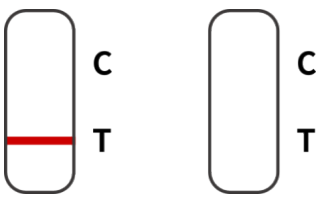

## INTERPRETATION OF RESULTS




**Positive (+):** Red bands appear at both of T and C line in 15 to 30 minutes.
A white band at the T line should be considered as a negative result.




**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:** If no red band appears at C line, it indicates that the test result is invalid.
Retest with another test card.

# CE CERTIFICATE – 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

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).

**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.*

# CE CERTIFICATE – CIBG REGISTRATION LETTER

NEWGENE Bioengineering

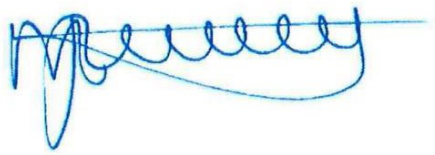
Notificatie van in-vitro diagnostische medische hulpmiddelen impliceert dat de fabrikant, New Gene (Hangzhou) Bioengineering Co., Ltd. de CE-conformiteitsmarkering heeft aangebracht op de desbetreffende producten alvorens deze in een EU-lidstaat in de handel te brengen. Zodoende garandeert SUNGO Europe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

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)*

# PRODUCT INTRODUCTION

NEWGENE Bioengineering

## COVID-19 Antigen Detection Kit

(Nasal Swab)

*For Professional Use*

| No. | Components | *25 Tests/Box* | *5 Tests/Box* | *1 Test/Box* |
|---|---|---|---|---|
| 1 | Test Card | 25 | 5 | 1 |
| 2 | Sample Extraction Tube & Tube Cap | 25 | 5 | 1 |
| 3 | Sampling Swab: *for Nasal Swab* | 25 | 5 | 1 |
| 4 | Package Insert | 1 | 5 | 1 |

**25 Tests/Box**



**5 Tests/Box**

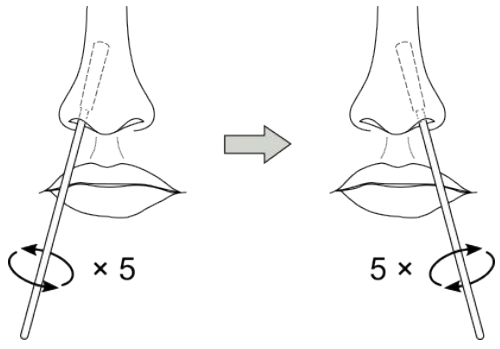


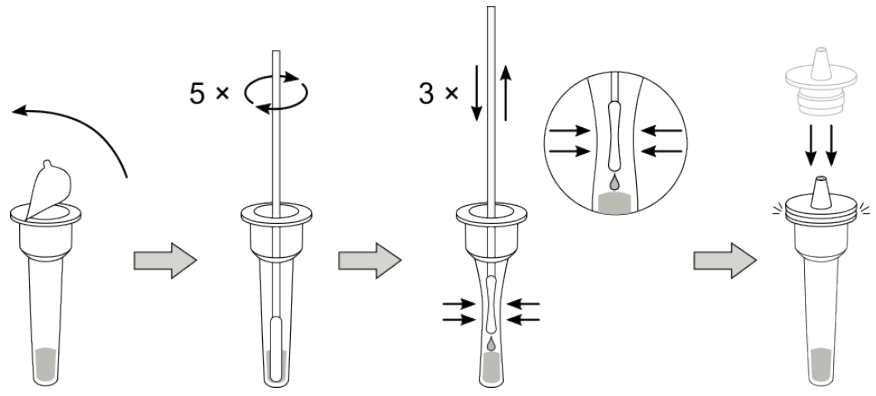
**1 Test/Box**


# PRODUCT INTRODUCTION

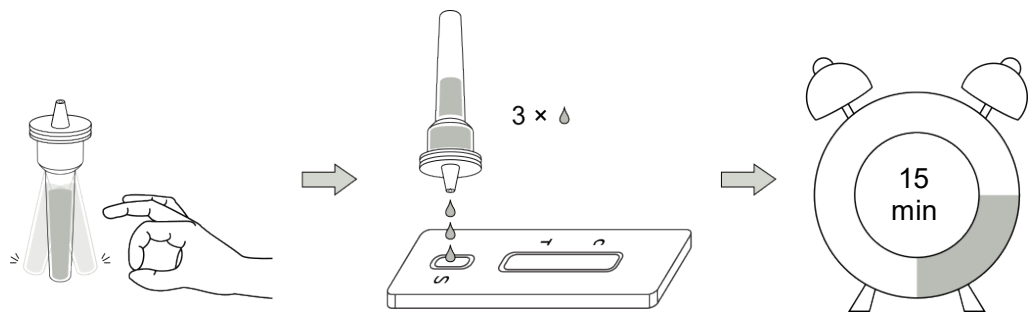
NEWGENE Bioengineering

## Test Procedures: Sampling

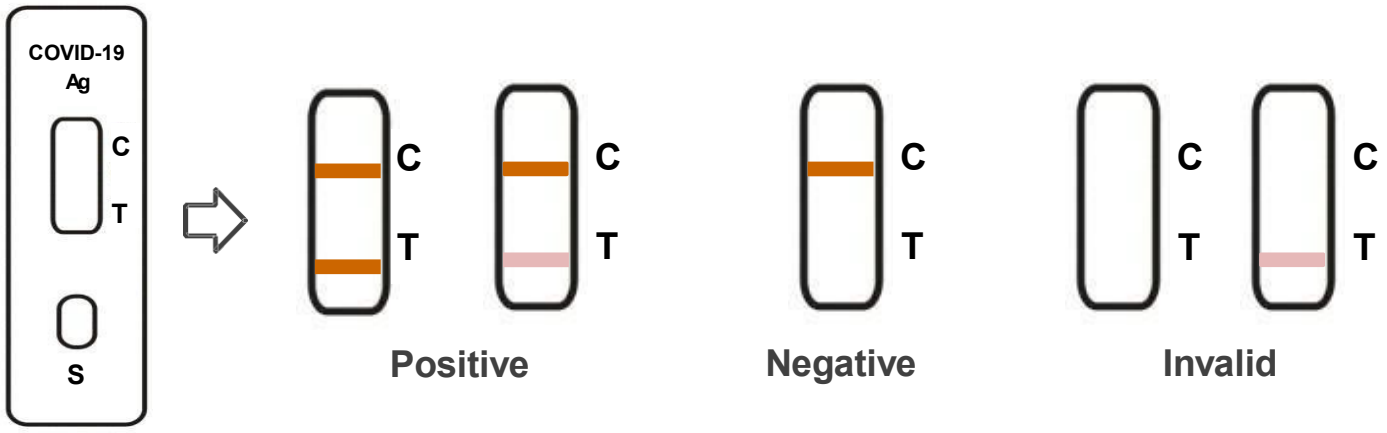



## Test Procedures: Detection




## Interpretation of Results




**Positive(+):** Red bands appear at both of T and C line in 15 to 30 minutes. A white band at the T line should be considered as a negative result.
**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.

## Performance

| Sensitivity | Specificity |
|---|---|
| 97.1% | 99.2% |

# PRODUCT INTRODUCTION

NEWGENE Bioengineering

## COVID-19 Antigen Detection Kit

(Nasopharyngeal Swab)

*For Professional Use*

| No. | Components | *25 Tests/Box* | *5 Tests/Box* | *1 Test/Box* |
|---|---|---|---|---|
| 1 | Test Card | 25 | 5 | 1 |
| 2 | Sample Extraction Tube & Tube Cap | 25 | 5 | 1 |
| 3 | Sampling Swab: *for Nasopharyngeal Swab* | 25 | 5 | 1 |
| 4 | Package Insert | 1 | 5 | 1 |

**25 Tests/Box**


**5 Tests/Box**

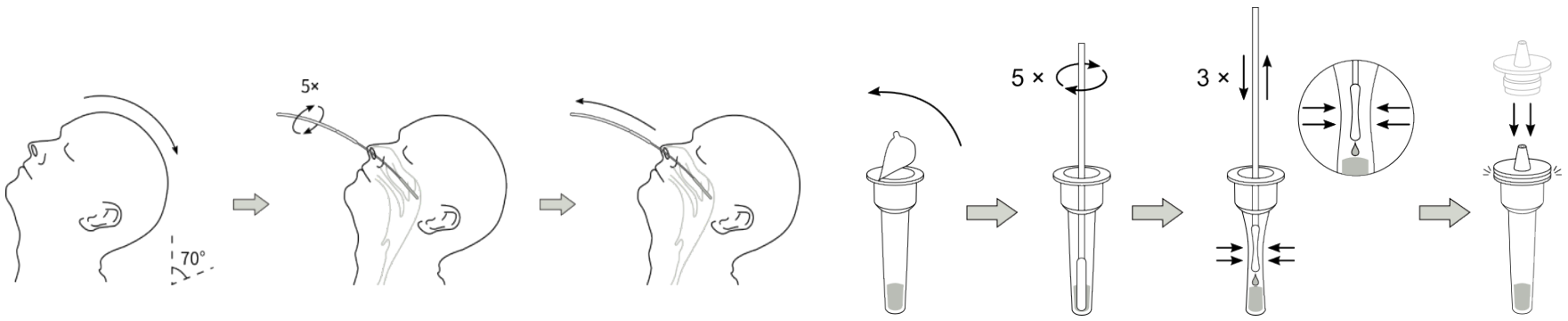


**1 Test/Box**

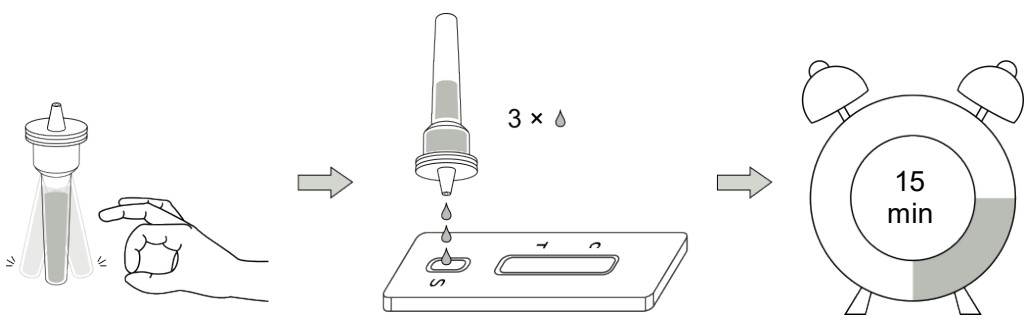

# PRODUCT INTRODUCTION

NEWGENE Bioengineering

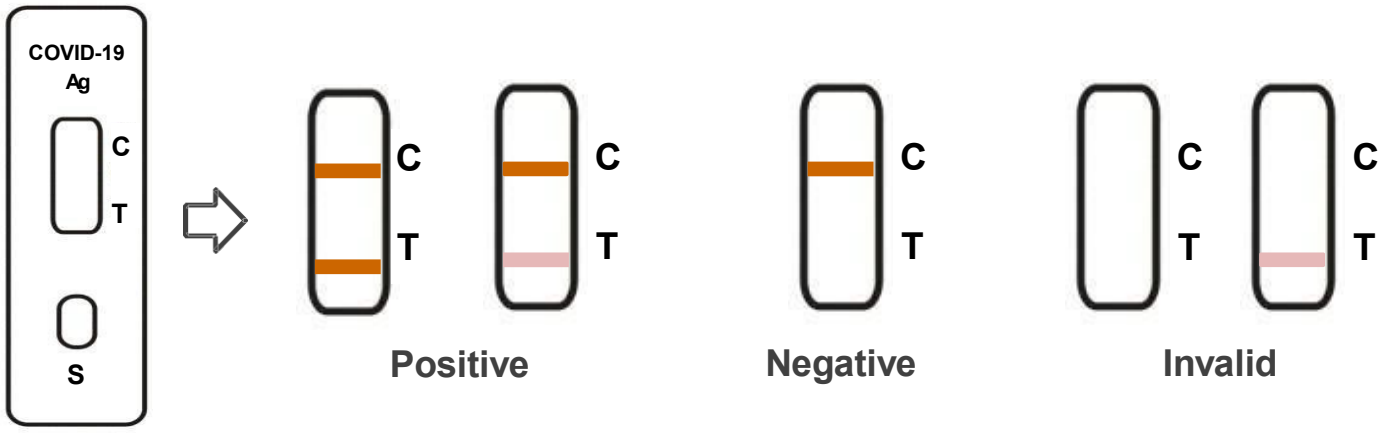
## Test Procedures: Sampling




## Test Procedures: Detection




## Interpretation of Results




**Positive(+):** Red bands appear at both of T and C line in 15 to 30 minutes. A white band at the T line should be considered as a negative result.
**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.

## Performance

| Sensitivity | Specificity |
|---|---|
| 98.0% | 99.1% |

# PRODUCT INTRODUCTION

NEWGENE Bioengineering

## COVID-19 Antigen Detection Kit

(Oropharyngeal Swab)

*For Professional Use*

| No. | Components | *25 Tests/Box* | *5 Tests/Box* | *1 Test/Box* |
|---|---|---|---|---|
| 1 | Test Card | 25 | 5 | 1 |
| 2 | Sample Extraction Tube & Tube Cap | 25 | 5 | 1 |
| 3 | Sampling Swab: *for Oropharyngeal Swab* | 25 | 5 | 1 |
| 4 | Package Insert | 1 | 5 | 1 |

**25 Tests/Box**


**5 Tests/Box**

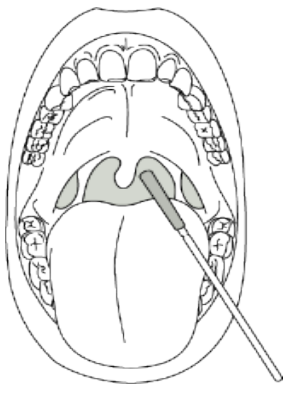


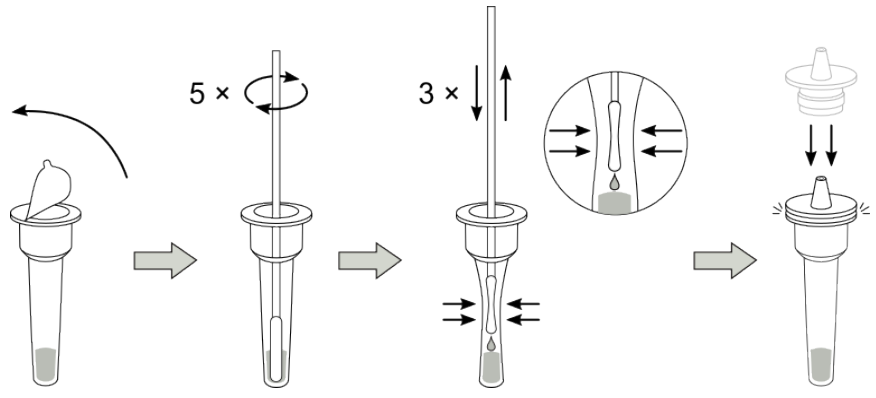
**1 Test/Box**


# PRODUCT INTRODUCTION

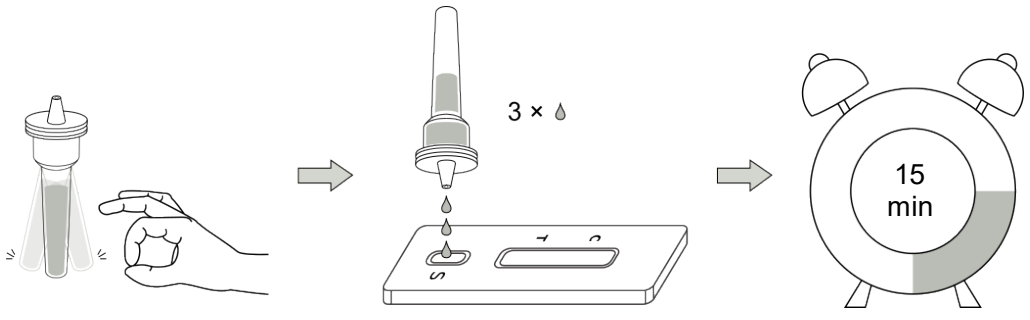
NEWGENE Bioengineering

## Test Procedures: Sampling

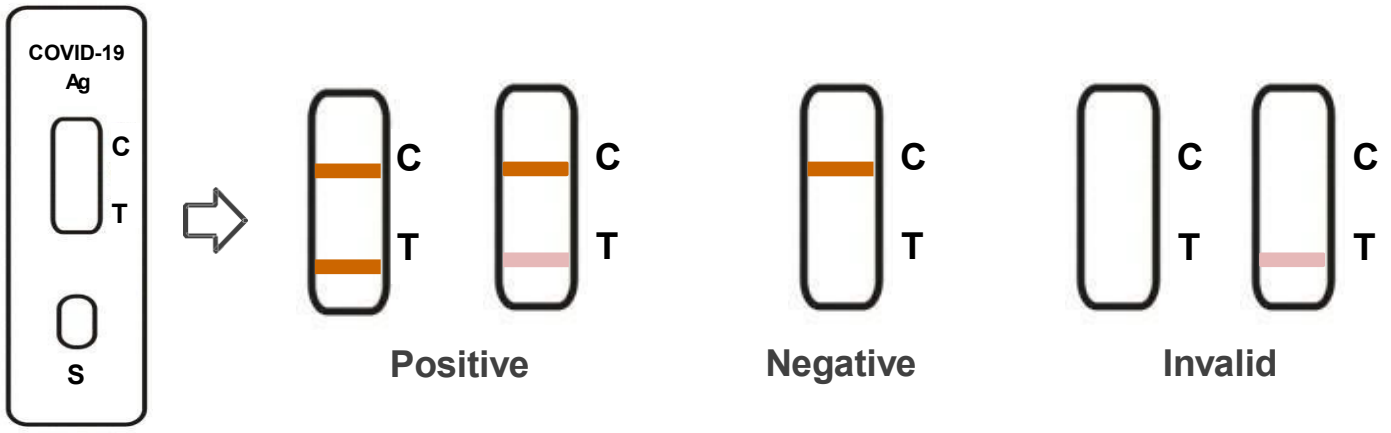





## Test Procedures: Detection




## Interpretation of Results




**Positive(+):** Red bands appear at both of T and C line in 15 to 30 minutes. A white band at the T line should be considered as a negative result.
**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.

## Performance

| Sensitivity | Specificity |
|---|---|
| 95.7% | 99.0% |

# PRODUCT INTRODUCTION

NEWGENE Bioengineering

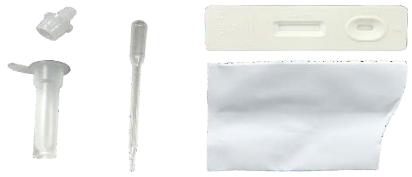
## COVID-19 Antigen Detection Kit

(Saliva)

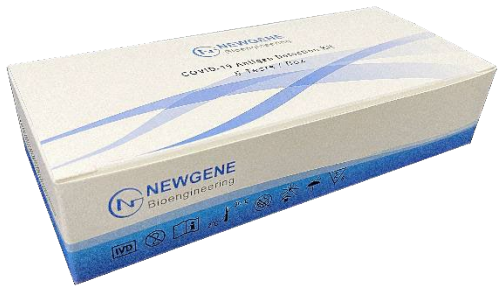
*For Professional Use*

| No. | Components | *25 Tests/Box* | *5 Tests/Box* | *1 Test/Box* |
|---|---|---|---|---|
| 1 | Test Card | 25 | 5 | 1 |
| 2 | Sample Extraction Tube & Tube Cap | 25 | 5 | 1 |
| 3 | Paper Cup | 25 | 5 | 1 |
| 4 | Sputum Dropper | 25 | 5 | 1 |
| 5 | Package Insert | 1 | 5 | 1 |

### 25 Tests/Box



### 5 Tests/Box



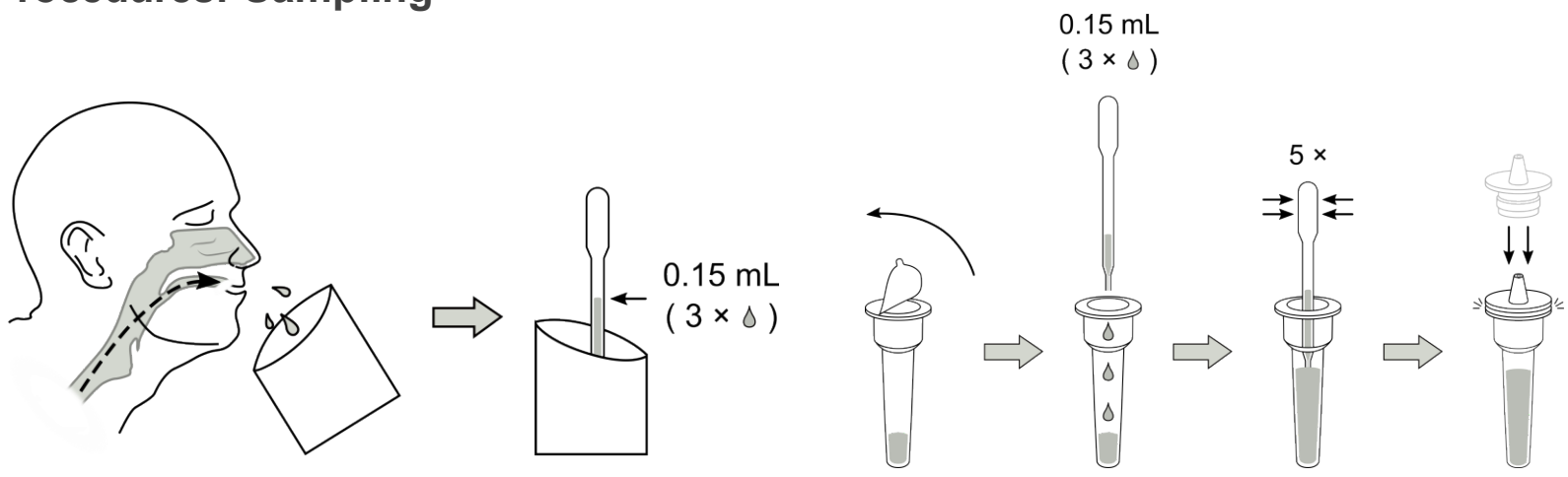


### 1 Test/Box

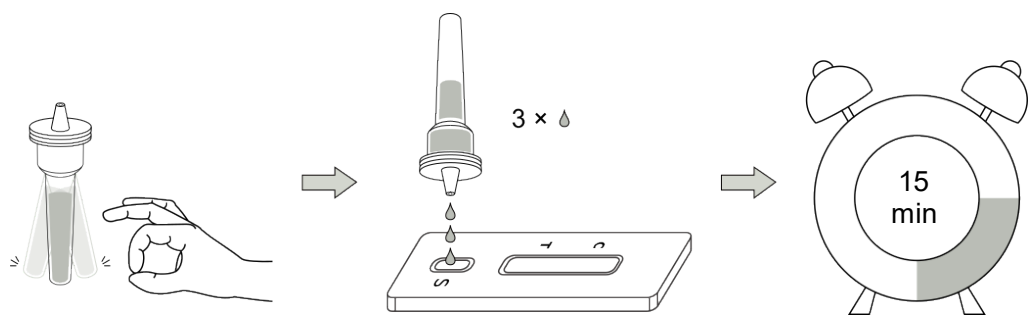

# PRODUCT INTRODUCTION

NEWGENE Bioengineering

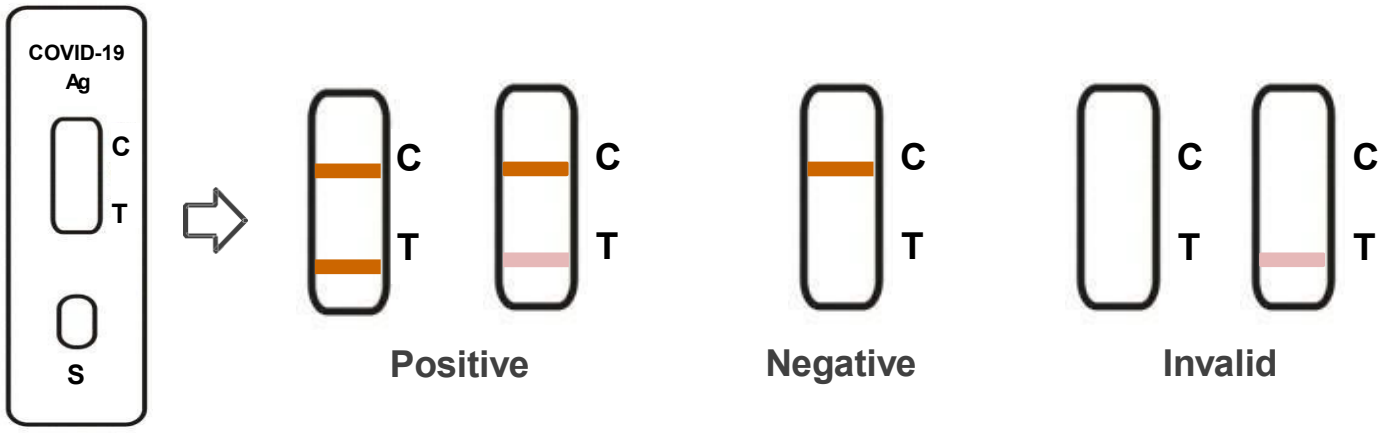
## Test Procedures: Sampling




## Test Procedures: Detection




## Interpretation of Results




**Positive(+):** Red bands appear at both of T and C line in 15 to 30 minutes. A white band at the T line should be considered as a negative result.
**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.

## Performance

| Sensitivity | Specificity |
|---|---|
| 97.3% | 99.2% |

# PACKAGING INFORMATION For Professional Use

Nasopharyngeal Swab: **NPS**
Nasal Swab: **NS**
Oropharyngeal Swab: **OS**
Saliva: **S**

## 25 Tests/Box

| Sample | NPS | NPS+S | NS | NS+S | OS | OS+S | S |
|---|---|---|---|---|---|---|---|
| Box (mm) | 230*140*80 | | | | | | 230*120*67 |
| Box weight (kg) | 0.36 | | | | | | |
| Carton (mm) | 585*485*425 | | | | | | 510*490*360 |
| Carton weight (kg) | 1.5 | | | | | | 1.3 |
| PCS/Box | 25 | | | | | | |
| Boxes/Carton | 40 | | | | | | |
| PCS/Carton | 1000 | | | | | | |
| Volume/Carton | 0.12CBM | | | | | | 0.09CBM |
| NW/Carton (kg) | 14.3 | | | | | | 15.6 |
| GW/Carton (kg) | 15.8 | | | | | | 16.9 |

## 5 Tests/Box

| Sample | S | NS | NS+S | NPS | OS | NPS+S | OS+S |
|---|---|---|---|---|---|---|---|
| Inner box (mm) | 193*85*42 | | | | | | |
| Outer box (mm) | 225*197*89 | | | | | | |
| Outer box weight (kg) | 0.5 | | | | | | |
| Carton (mm) | 470*410*470 | | | | | | |
| Carton weight (kg) | 1.4 | | | | | | |
| PCS/Inner Boxes | 5 | | | | | | |
| Inner Boxes/Outer Box | 20 | | | | | | |
| PCS/Carton | 500 | | | | | | |
| Volume/Carton | 0.09CBM | | | | | | |
| NW/Carton (kg) | 10 | | | | | | |
| GW/Carton (kg) | 11.4 | | | | | | |

## 1 Test/Box

| Sample | S | NS | NS+S | NPS | OS | NPS+S | OS+S |
|---|---|---|---|---|---|---|---|
| Inner box (mm) | 143*83*15 | | | 170*66*15 | | | |
| Inner box weight (kg) | 0.027 | | | 0.028 | | | |
| Outer box (mm) | 305*197*88 | | | 277*182*112 | | | |
| Outer box weight (kg) | 0.8 | | | 0.83 | | | |
| Carton (mm) | 630*420*470 | | | 590*570*395 | | | |
| Carton weight (kg) | 1.8 | | | 2.2 | | | |
| PCS/Inner Boxes | 25 | | | | | | |
| Inner Boxes/Outer Box | 20 | | | | | | |
| PCS/Carton | 500 | | | | | | |
| Volume/Carton | 0.13CBM | | | 0.133CBM | | | |
| NW/Carton (kg) | 16.5 | | | 16.6 | | | |
| GW/Carton (kg) | 18.3 | | | 18.8 | | | |

# PACKAGING INFORMATION Self-Testing

## 25 Tests / Box

| Sample | Nasal Swab |
|---|---|
| Box (mm) | 230x120x75 |
| Box weight (kg) | 0.27 |
| Carton (mm) | 520X480X400 |
| Carton weight (kg) | 1.5 |
| PCS/Box | 25 |
| Boxes/Carton | 40 |
| PCS/Carton | 1000 |
| Volume/Carton | 0.1CBM |
| NW/Carton (kg) | 11 |
| GW/Carton (kg) | 12.5 |

## 5 Tests / Box

| Sample | Nasal Swab |
|---|---|
| Inner box (mm) | 122x68x49 |
| Outer box (mm) | 258X128X75 |
| Outer box weight (kg) | 0.38 |
| Carton (mm) | 550X530X395 |
| Carton weight (kg) | 1.4 |
| PCS/Inner Boxes | 5 |
| Inner Boxes/Outer Box | 40 |
| PCS/Carton | 1000 |
| Volume/Carton | 0.11CBM |
| NW/Carton (kg) | 15.6 |
| GW/Carton (kg) | 17kg |

## 1 Test / Box

| Sample | Nasal Swab |
|---|---|
| Inner box (mm) | 122X83X15 |
| Outer box (mm) | 255X170X105 |
| Outer box weight (kg) | 0.68 |
| Carton (mm) | 545X530X370 |
| Carton weight (kg) | 1.8 |
| PCS/Inner Boxes | 25 |
| Inner Boxes/Outer Box | 20 |
| PCS/Carton | 500 |
| Volume/Carton | 0.10CBM |
| NW/Carton (kg) | 12.45 |
| GW/Carton (kg) | 14.25 |

# EU Common List

EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Public health, country knowledge, crisis management
**Health Security**

## EU health preparedness:

## A common list of COVID-19 rapid antigen tests and a common standardised set of data to be included in COVID-19 test result certificates

### Agreed by the Health Security Committee

*This document was agreed by the HSC on 17 February 2021*

**Annex I**

**Common list of COVID-19 rapid antigen tests**

*A first update was agreed by the HSC on 10 May 2021; A second update was agreed by the HSC on 16 June 2021; A third update was agreed by the HSC on 7 July 2021; A fourth update was agreed by the HSC on 14 July 2021; A fifth update was agreed by the HSC on 23 July 2021.*

**IMPORTANT: A (interim) grace period of 8 weeks applies whenever updates are made to Annex I, the common list of COVID-19 rapid antigen tests**

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| New Gene (Hangzhou) Bioengineering Co., Ltd. | COVID-19 Antigen Detection Kit | Yes | 98% sensitivity Nasal swab | **DE:** Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 92,5% at <Ct30 and 100% at <Ct25) | | DE[2] | | DE[2] | | 1501 | 16 June 2021 |

# Evaluation Report (Nasal Swab)

**Validation protocol for the**

**Newgene bioengineering COVID-19 Rapid Antigen Test**


**Testing laboratory:**
Molecular Diagnostic Laboratory
Via Petrini 2
CH-6900 Lugano
Switzerland

**Discussion and Conclusion.**

In conclusion, the Newgene antigen detection test is highly precise and accurate (**100% specificity and 95.1% sensitivity**), it is non-invasive and mimics the PCR results very closely where PCR is considered the golden standard technique. The device can easily be operated and used by non-medically trained personnel, does not need a laboratory setting and could be intended for regular use by regular people.

Lugano, June 18th 2021.
Dr. G. Soldati
CEO
Molecular Diagnostic Laboratory
Via Petrini 2
CH-6900 Lugano, Switzerland

# Evaluation Report (Children under the age of 14)

**Discussion**

In the present study, the COVID-19 Antigen Detection Kit - Nasal Swab by New Gene (Hangzhou) Bioengineering Co., Ltd. has shown highly reliable performance in sample from children under the age of 14. Compared to conventional RT-PCR tests, the rapid antigen tests can meet a wider range of test needs. As the antigen tests take only 20 to 30 minutes, they are feasible for use in emergency scenarios where a test result is demanded immediately. Also, the rapid antigen tests doesn't require special instruments and training to use, they are also capable for resource limited scenarios like point-of-care testing and self-test by laypeople. Therefore, the implementation of rapid antigen test may totally change the strategies to control COVID-19. Community residents can conduct the rapid antigen test in a frequent manner, like twice or three times a week, to identify COVID-19 cases in the early stage of infection. This strategy may help to stop the transmission of COVID-19 as early as possible.

In summary, the COVID-19 Antigen Detection Kit - Nasal Swab has shown satisfying sensitivity, specificity, and total accuracy in the present evaluation. It can be used as a rapid tool to assist the early diagnosis of COVID-19 cases in children under the age of 14.

**Signatures**

Operator: 09563 mgr Ewa Miłosz DIAGNOSTA LABORATORYJNY Date: 21.07.2021

Reviewer: 09893 dr Paweł Chrzan DIAGNOSTA LABORATORYJNY Date: 21.07.2021

# Evaluation Report (Saliva)

**Result Analysis:**

The test results of RT-PCR and the COVID-19 Antigen Detection Kit are summarized in 2×2 table below.

| | | RT-PCR Reagent | | Total |
|---|---|---|---|---|
| | | Positive | Negative | |
| Antigen Test | Positive | 204 | 0 | 204 |
| | Negative | 16 | 200 | 216 |
| Total | | 220 | 200 | 420 |

Sensitivity (%) = 204 ÷ (204 + 16) × 100% = 92,73%; 95% CI: 88,46% ~ 95,79%

Specificity (%) = 200 ÷ (0 + 200) × 100% = 100,0%; 95% CI: 98,17% ~ 100,00%

Total accuracy (%) = (204 + 200) ÷ (204 + 0 + 16 + 200) × 100% = 96,19%;

95% CI: 93,89% ~ 97,81%

The 95% Confidence Intervals of sensitivity, specificity, and total accuracy are calculated following the binomial distribution.

Analysis results by Kappa consistency test shows that the Kappa value = 0,9239 (95% CI: 0,8875 ~ 0,9604). As Kappa≥0.75, it suggests good consistency between the COVID-19 Antigen Detection Kit and the COVID-19 RT-PCR detection reagent. Therefore, the COVID-19 Antigen Detection Kit has shown reliable performance on detecting SARS-CoV-2 virus in saliva samples from suspected COVID-19 patients.

(+++) - positive - intensity of line T similar or higher than line C

(++) - positive - intensity of line T lower than line C

(+) - positive - border intensity of line T

(-) - negative - line T is absent

**Signatures**

Operator: 09530 mgr Janusz Partyka DIAGNOSTA LABORATORYJNY Date: 12.08.2021

Reviewer: 0930 dr Paweł Chrzan DIAGNOSTA LABORATORYJNY Date: 12.08.2021

# Registration or Allowed List (Partially)

## Self-test Approval in Switzerland

Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

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

**Sars-CoV-2-Antigen-Schnelltests zur Eigenanwendung (Sars-CoV-2 Selbsttest)[1]**
**Tests rapides pour l'antigène du SARS-CoV-2 pour auto-application (autotest SARS-CoV-2)**
**Test rapidi dell'antigene SARS-CoV-2 per uso proprio (test autodiagnostici SARS-CoV-2)**

**03.09.2021**

Die Schnelltests zur Eigenanwendung sind ausschliesslich für den **nasalen Abstrich** validiert und nur dementsprechend anzuwenden. Informationen bezüglich des Einsatzes der Schnelltests finden Sie auf der BAG-Webseite Covid-19-Testung. — Webseite Covid-19 Testung

Les tests rapides pour auto-application sont validés pour les **prélèvements nasaux** uniquement et ne doivent donc être utilisés qu'en conséquence. Ces informations sur l'emploi prévu des tests rapides sont disponibles sur le site web de l'OFSP Tests COVID-19. — Site internet Tests COVID-19

I test rapidi per uso proprio sono convalidati solo per i **tamponi nasali** e dovrebbero essere usati solo di conseguenza.. Le informazioni su come utilizzare i test rapidi sono disponibili sul sito internet dell'UFSP «Test COVID-19». — Sito web Test COVID-19

| **Hersteller<br>Fabricant<br>Azienda** | | **Antigen Schnelltest<br>Tests rapides antigéniques<br>Test antigenici rapidi** |
|---|---|---|
| Abbott Rapid Diagnostics | Germany | Panbio™ COVID-19 Antigen Self-Test |
| ACON Biotech (Hangzhou) Co. Ltd. | China | Flowflex SARS-CoV-2 Antigen Rapid Test (Self-Testing) |
| Becton, Dickinson and Company (BD) | United States | BD Kit for Rapid Detection of SARS-CoV-2 |
| BIOSYNEX SWISS S.A. | Switzerland | BIOSYNEX Autotest antigénique COVID-19 Ag |
| Hangzhou AllTest Biotech Co., Ltd | China | ALLTEST SARS-CoV-2 Antigen Rapid Test (Nasal Swab) |
| Hangzhou AllTest Biotech Co., Ltd | China | JusChek SARS-CoV-2 Antigen Rapid Test (Nasal Swab) |
| New Gene (Hangzhou) Bioengineering Co., Ltd. | China | COVID-19 Antigen Detection Kit - Nasal Swab |
| Roche (SD BIOSENSOR) | Switzerland | SARS-CoV-2 Rapid Antigen Test Nasal |
| Siemens Healthineers | Germany | CLINITEST® Rapid COVID-19 Antigen Self-Test |
| Xiamen Boson Biotech Co., Ltd. | China | Rapid SARS-CoV-2 Antigen Test Card |

**Wichtige Hinweise:**
**Information importante :**
**Avvertenza importante:**

[1] Diese Liste beinhaltet SARS-CoV-2-Antigen-Schnelltest, welche die Anforderungen nach Art. 24 der Covid-19-Verordnung 3 erfüllen und zudem entweder eine CE-Zertifizierung als Produkt zur Eigenanwendung einer benannten Stelle besitzen oder eine Ausnahmebewilligung durch Swissmedic als Produkt zur Eigenanwendung besitzen.
Cette liste inclut les tests rapides pour la recherche de l'antigène du SARS-CoV-2 qui remplissent les exigences de l'art. 24 de l'ordonannce 3 COVID-19 et qui sont soit certifiés CE comme dispositif d'autotest par un organisme notifié ou qui ont une dérogation de Swissmedic pour l'auto-application.
Questo elenco comprende i test rapidi per l'antigene SARS-CoV-2 che soddisfano i requisiti dell'art. 24 dell'ordinanza 3 COVID-19 e che hanno una certificazione CE da parte di un organismo notificato come prodotto per uso proprio o un'esenzione di Swissmedic come prodotto per uso proprio.

# Registration or Allowed List (Partially)

## Self-test Approval in Malaysia



### 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.

| NO | COMPANY NAME | PRODUCT NAME | MANUFACTURER | IDENTIFIER | DETECTION | SAMPLE TYPE |
|---|---|---|---|---|---|---|
| 11 | Dewina Consult Sdn Bhd | NEWGENE Bioengineering COVID-19 Antigen Detection Kit | New Gene (Hangzhou) Bioengineering Co., Ltd. P.R. China | COVID-19-NG08 | RTK-Antigen (Self-test) | Saliva or Nasal swab |

Updated 13 August 2021

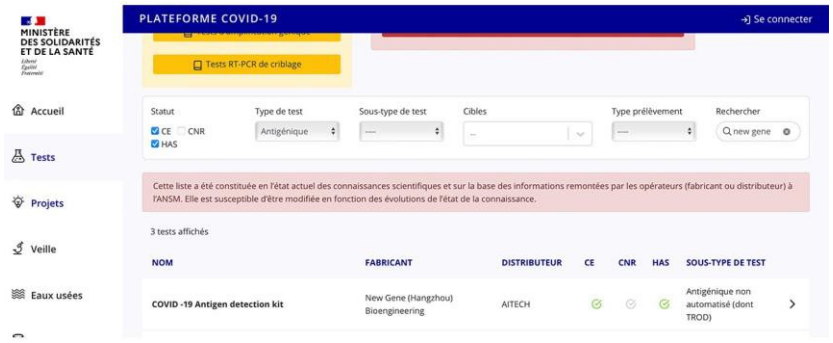
## Self-test Approval in Thailand

**รายชื่อชุดตรวจสำหรับ COVID-19 ประเภท Rapid Test Antigen หรือ Antigen Test Kits**
**แบบตรวจแอนติเจนด้วยตนเอง (COVID-19 Antigen Test Self-Test Kits)**
**ที่ได้รับการอนุญาตให้ผลิต/นำเข้า จากสำนักงานคณะกรรมการอาหารและยา**
**ข้อมูล ณ วันที่ 25 ตุลาคม 2564**

| ลำดับที่ | ชื่อผลิตภัณฑ์ | ชื่อผู้นำเข้า | ชื่อผู้ผลิต | วันที่ได้รับอนุญาต (วัน/เดือน/ปี) | เลขที่ใบรับรองประเมินเทคโนโลยี | ลิงค์วีดีโอขั้นตอนการใช้ชุดตรวจ |
|---|---|---|---|---|---|---|
| 81 | COVID-19 Antigen Detection Kit ยี่ห้อ NEWGENE<br>รหัสสินค้า COVID-19-NG08<br>ขนาดบรรจุ 25 ชุดทดสอบต่อกล่อง (Nasal swab)<br>  | บริษัท บิสซิเนสอะไลเม้นท์ จำกัด (มหาชน)<br>โทร. 0 2636 6828-9 | New Gene (Hangzhou) Bioengineering Co., Ltd. China | 25/10/2564 | T 6400416 | |

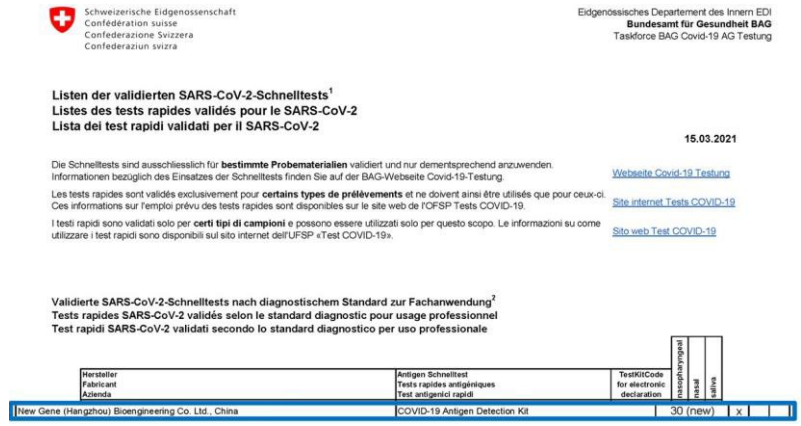
# Registration or Allowed List (Partially)


## BfArM of Germany



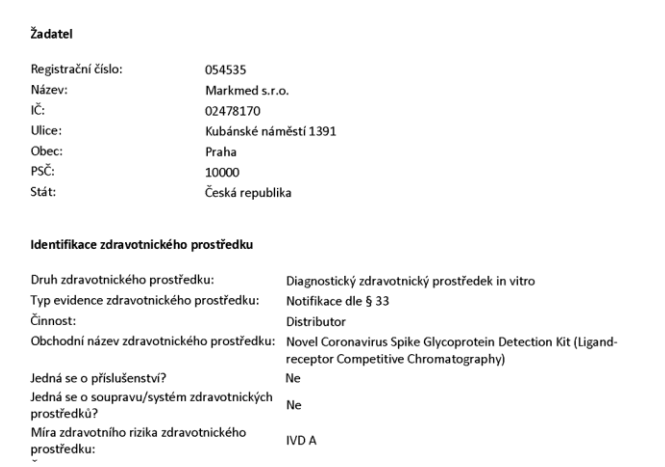

## ANSM of France


## Italy

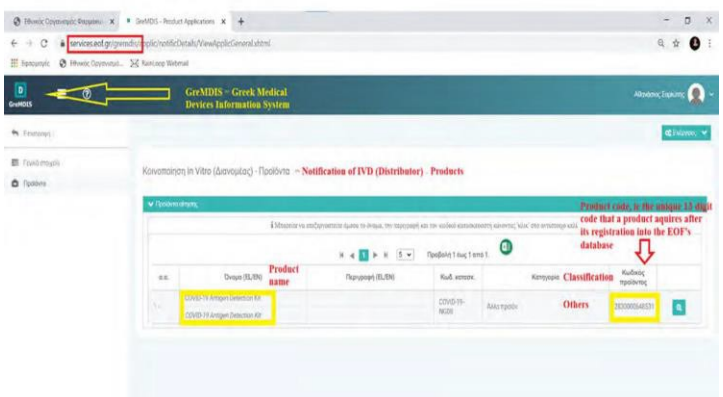



## Switzerland

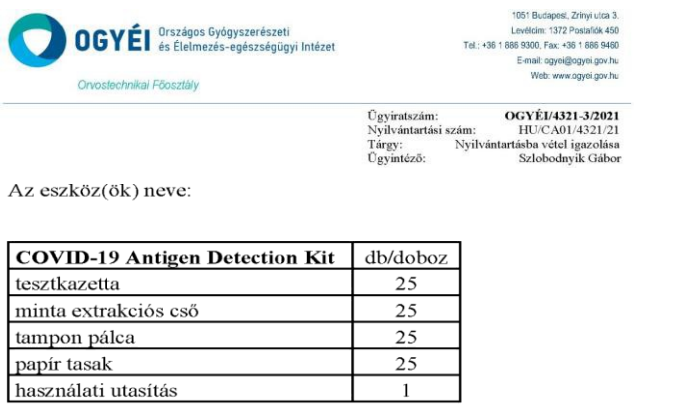

## Portugal




## Czech




## Greece




## Hungary

# Registration or Allowed List (Partially)

## Poland

**Urząd Rejestracji**
**Produktów Leczniczych, Wyrobów Medycznych i Produktów Biobójczych**

Al. Jerozolimskie 181C, 02-222 Warszawa; tel. +48 22 492-11-00; fax +48 22 492-11-09
NIP 521-32-14-182 REGON 015249601

Warszawa, 2021-04-01

**ZAŚWIADCZENIE NR 80 / 2021**

**Cavassi Steel sp. z o.o.**
**Al. Jerozolimskie 89/43**
**02-001 Warszawa**

Na podstawie art. 217 § 2 pkt 2 w związku z art. 218 § 1 ustawy z dnia 14 czerwca 1960 r. Kodeks postępowania administracyjnego (Dz.U. z 2020 r. poz. 256 ze zm. ), po rozpatrzeniu wniosku z dnia 26.03.2021 r.:

**Prezes Urzędu Rejestracji Produktów Leczniczych, Wyrobów Medycznych i Produktów Biobójczych**

**zaświadcza że:**

po analizie danych pochodzących ze zgłoszeń i powiadomień, o których mowa w art. 64 ust. 1 ustawy z dnia 20 maja 2010 r. o wyrobach medycznych (Dz. U. z 2020 r. poz. 186 i 1493.) stwierdzono, że w dniu 29.03.2021 roku wpłynęło powiadomienie od dystrybutora: Cavassi Steel sp. z o.o., Al. Jerozolimskie 89/43, 02-001 Warszawa dotyczące:

**Zestaw do wykrywania antygenu COVID-19 / COVID-19 Antigen Detection Kit**

**Wytwórca: New Gene (Hangzhou) Bioengineering Co., Ltd, Room 1606, Floor 16, Building 5, 688 Bin'an Road, Changhe Str, 310052, Hangzhou City, Zhejiang Province, Chiny**

**Autoryzowany przedstawiciel: SUNGO Europe B.V, Olimpisch Stadion 24, 107DE Amsterdam, Holandia**

**Dystrybutor: Cavassi Steel Sp. z o.o., Al. Jerozolimskie 89/43, 02-001 Warszawa**

*Prezes Urzędu informuje, że wydane zaświadczenie potwierdza powiadomienie, jednocześnie nie potwierdza, że powiadomienie zostało złożone jako kompletne i prawidłowe oraz nie rozstrzyga, że ww. wyroby są wyrobami medycznymi do diagnostyki in vitro w rozumieniu ustawy z dnia 20 maja 2010 r. o wyrobach medycznych (Dz. U. z 2020 r. poz. 186 i 1493.) ani, że spełniają wymagania zawarte w w/w ustawie.*

z upoważnienia Prezesa
ZASTĘPCA DYREKTORA
Departament Informacji
o Wyrobach Medycznych
Anna Pusiol

## Peru

PERÚ | Ministerio de Salud | Viceministerio de Salud Pública | Dirección General de Medicamentos, Insumos y Drogas

"Decenio de la Igualdad de Oportunidades para Mujeres y Hombres"
"Año de la Universalización de la Salud"

R.D. N° 6450 -2020/DIGEMID/DDMP/UFDM/MINSA

**RESOLUCION DIRECTORAL**

Lima, 09 SEP. 2020

Visto el trámite virtual, del expediente **N° 20-062595-1 del 14 de Agosto del 2020 y Anexo 1 del 03 de Setiembre del 2020,** presentados por el **Sr. Yin Li**, Representante Legal de la **DROGUERÍA GRAND TAI LATIN AMERICA S.A.C.,** con domicilio en **Av. Los Frutales N° 1030 Urb. Camino Real, La Molina - Lima, SOLICITANDO AUTORIZACIÓN EXCEPCIONAL PARA LA IMPORTACIÓN Y USO DE DISPOSITIVO MEDICO SIN REGISTRO SANITARIO O EN CONDICIONES NO ESTABLECIDAS EN EL REGISTRO SANITARIO, EN SITUACIONES DE EMERGENCIA DECLARADA;**

**CONSIDERANDO:**

Que, el artículo 16° de la Ley N° 29459 Ley de los Productos Farmacéuticos, Dispositivos Médicos y Productos Sanitarios señala que "La Autoridad Nacional de Salud (ANS), (...) autoriza la importación, la fabricación y el uso de productos farmacéuticos, dispositivos médicos y productos sanitarios sin registro sanitario o en condiciones no establecidas en el registro sanitario entre otros, en situaciones de urgencia o emergencia declarada...";

Que, el artículo 20° del Decreto Supremo N° 016-2011-SA y modificatorias, establece que "La Autoridad Nacional de Salud (ANS), a través de la Autoridad Nacional de Productos Farmacéuticos, Dispositivos Médicos o Productos Sanitarios, autoriza (...) la importación, fabricación y el uso de productos farmacéuticos, dispositivos médicos, productos sanitarios sin registro sanitario o en condiciones no establecidas en el registro sanitario, en los siguientes casos debidamente calificados: (...) a) Uso en situaciones de urgencia o emergencia declarada. Para estos casos se presenta la copia de la Resolución de declaración de emergencia emitida por la Autoridad competente y el listado de los productos o dispositivos con sus especificaciones técnicas;

Que, mediante el expediente **N° 20-062595-1 del 14 de Agosto del 2020 Y Anexo 1 del 03 de Setiembre del 2020, la DROGUERÍA GRAND TAI LATIN AMERICA S.A.C.,** solicita la **AUTORIZACIÓN EXCEPCIONAL PARA LA IMPORTACIÓN Y USO DEL DISPOSITIVO MÉDICO DE DIAGNÓSTICO IN VITRO EXTRANJERO: Novel Coronavirus Spike Glycoprotein Detection Kit, fabricado por: New Gene (Hangzhou) Bioengineering Co., Ltd. - China;**

**Que, en el marco de lo dispuesto en el Decreto Supremo N° 008-2020-SA, Decreto Supremo que declara en Emergencia Sanitaria a nivel nacional por el plazo de noventa (90) días calendario y dicta medidas de prevención y control del COVID-19, de fecha 11 de marzo del 2020, Decreto Supremo N° 044-2020-PCM, Decreto Supremo que declara Estado de Emergencia Nacional por las graves circunstancias que afectan la vida de la Nación a consecuencia del brote del COVID-19 de fecha 15 de marzo del 2020 y Decreto Supremo N° 094-2020-PCM, Decreto Supremo que establece las medidas que debe observar la ciudadanía hacia una nueva convivencia social y prorroga el Estado de Emergencia Nacional por las graves circunstancias que afectan la vida de la Nación a consecuencia del COVID-19 de fecha 23 de mayo del 2020 y ante el incremento de casos de COVID-19 a nivel nacional, se considera procedente autorizar excepcionalmente la importación y el uso del Dispositivo Médico de Diagnóstico In Vitro sin registro sanitario por la situación de emergencia declarada durante el periodo que dure la emergencia sanitaria declarada por el Ministerio de Salud debido a la existencia del COVID-19.**

Que, se ha evaluado la documentación presentada por el administrado, en aplicación de lo establecido en el art. 20° del Reglamento para el Registro, Control y Vigilancia Sanitaria de Productos Farmacéuticos, Dispositivos Médicos y Productos Sanitarios aprobado mediante Decreto Supremo N° 016-2011-SA y sus modificatorias, por lo que corresponde otorgarle la autorización excepcional solicitada;

De conformidad a lo dispuesto por el Decreto Supremo N° 016-2011-SA y sus modificatorias, Decreto Supremo N° 008-2017-SA y modificatorias, Ley N° 29459 Ley de los Productos Farmacéuticos, Dispositivos Médicos y Productos Sanitarios, Decreto Legislativo N° 1161, Decreto Legislativo que

1/2

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Av. Parque de las Leyendas 240
San Miguel, Perú
T(511) 631-4300

EL PERÚ PRIMERO

## Argentina

"2020 - AÑO DEL GENERAL MANUEL BELGRANO"

**Ministerio de Salud**
Secretaria 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: **Novel Coronavirus Spike Glycoprotein Detection Kit (Ligand-receptor Competitive Chromatography)**
**Marca: NEWGENE**

Indicación de uso: **Este producto es adecuado para la detección cualitativa y cuantitativa del nuevo coronavirus (SARS-CoV-2) en muestras de vías respiratorias o muestras fecales. Esta tira se puede aplicar a la detección rápida de SARS-CoV-2 y es adecuada para hospitales, empresas, escuelas, tropas, comunidades y familias.**
**Los síntomas comunes de la infección humana con el coronavirus incluyen síntomas respiratorios, fiebre, tos, dificultad para respirar. En los casos más graves, la infección puede provocar neumonía, síndrome respiratorio agudo severo, insuficiencia renal e incluso la muerte.**

Descripción: **COMPOSICIÓN**
**Tarjeta de prueba desechable; Hisopo de algodón; Tubo de extracción de muestras; Taza de muestra;**

**PRINCIPIO**
**El SARS-CoV-2 invade las células humanas mediante la unión específica de su**

Página 1 de 4 Página 1 de 4

El presente documento electrónico ha sido firmado digitalmente en los términos de la Ley N° 25.506, el Decreto N° 2628/2002 y el Decreto N° 2683/2003.-

## Kenya

MINISTRY OF HEALTH

PHARMACY AND POISONS BOARD

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

**IN-VITRO DIAGNOSTIC EMERGENCY USE AUTHORIZATION**

This Emergency Use Authorization is issued to **New Gene (Hangzhou) Bioengineering Co., Ltd,**for distribution and sale of***Novel Coronavirus Antigen Detection Kit (Colloidal Gold)***

| | |
|---|---|
| Emergency use Authorization (EUA) No. | **MD/2021/7674** |
| EUA valid until | End of COVID -19 Pandemic or EUA revocation |

## Ecuador

Ministerio de Salud Pública
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:** 30/10/2020

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. 168221682020000008P, ingresada el 08/10/2020, se emite el siguiente informe:

**Datos del producto analizado**

| | |
|---|---|
| **Nombre de producto:** | 18-988 Reactivos/Kits para Ensayos de DIV, Química Clínica, Ensayo Rápido |
| **Clasificación:** | DIV DIAG UU G6VIR RIII |
| **Fabricante:** | NEW GENE (HANGZHOU) BIOENGINEERING CO., LTD. |
| **Solicitante:** | ANDRADE PACHECO JORGE LUIS |

**Resultados**

**Análisis Documental Técnico**

**Fecha de elaboración de informe:** 2020-10-30 14:25:20
**Técnico responsable del análisis:** VERONICA ELIZABETH PORTERO LOPEZ
**Líder responsable del análisis:** FERNANDO FABIAN JIMENEZ SALAZAR

**Resultados del análisis:** Aceptado

**Conclusión:** Aceptado

## Congo

République Démocratique du Congo

Ministère de la Santé
**Secrétariat Général**
*Direction Générale de Lutte contre la Maladie*
Direction des Laboratoires de Santé

**AUTORISATION ANNUELLE DE MISE SUR LE MARCHE D'UN DISPOSITIF MEDICAL A USAGE DE DIAGNOSTIC IN VITRO N°MS DIR. LABO/SD/0.14./20.21**

**DISPOSITIF ENREGISTRE SOUS LE N°MS.DIR.LABO/D1/0.14./20.21**

*Le Ministère de la santé représenté par la Direction des Laboratoires de Santé, autorise en République Démocratique du Congo la mise sur le marché d'un* ***réactif*** *de diagnostic in vitro dont détails ci-dessous :*

**A. Identification sommaire du dispositif :**

- **Dénomination** : Kit de test d'autodiagnostic du Covid-19 Newgene
- **Destination** : Détection rapide d'Ag Sars-Cov2
- **Commercialisation** : auto test rapide d'Ag Sars-Cov2

**B. Détails techniques :** *(à compléter avec la fiche technique)*

## South Africa

SAHPRA
South African Health Products Regulatory Authority

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: MDT 70020
Licence: 00002c00Mb_v2

Dear Sir/ Madam,

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

## Brunei

**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 **6 September 2021**.

| NO | PRODUCT NAME | MANUFACTURER | DETECTION | SAMPLE TYPE |
|---|---|---|---|---|
| 8 | NEWGENE Bioengineering COVID-19 Antigen Detection Kit | New Gene (Hangzhou) Bioengineering Co., Ltd. China | Antigen | Sputum/ Nasopharyngeal |