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.

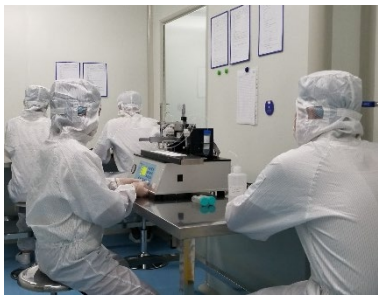
NEWGENE's manufacturing system meets GMP standards for medical devices, and is certified with ISO13485 by British BSI. Relevant in vitro diagnostic reagent products have obtained the EU CE certification. NEWGENE is also a member on the "allow list" issued by Chinese Ministry of Commerce for anti-epidemic 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, Malaysia*** **etc.,** and **Selftest of Germany, France, Czech,** Denmark, Belgium, Sweden, Austria, and passed the clinical **validation in** national lab in ***Germany, Switzerland, Malaysia, Ecuador, Zimbabwe etc.*** The products show good performance in sensitivity and specificity compared with international brand products and have exported to more than 50 countries and regions.










NEWGENE
Bioengineering

COVID-19 Antigen Detection Kit

Multiple Sampling Methods

Nasal Swab / Nasopharyngeal Swab / Oropharyngeal Swab / Sputum (Saliva)

Multiple Packaging Specifications

25 Tests/Box, 5 Tests/Box or 1 Test/Box

Global Recognition

Registered in 20+ Countries, Exported to 50+ Countries

Multiple Usage Scenarios

Professional Use & Home Use (Self-Testing)

Fast Detection

Results in 15 minutes

Superior Performance

High Sensitivity & Specificity

Contact Info

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

PRODUCT INTRODUCTION

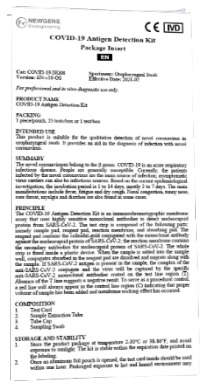
NEWGENE Bioengineering

COVID-19 Antigen Detection Kit
(Nasal Swab Sample)

N0.	Components	*25 Tests/Box*	*5 Tests/Box*	*1Test/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	1	1

25 Tests/Box

5 Tests/Box



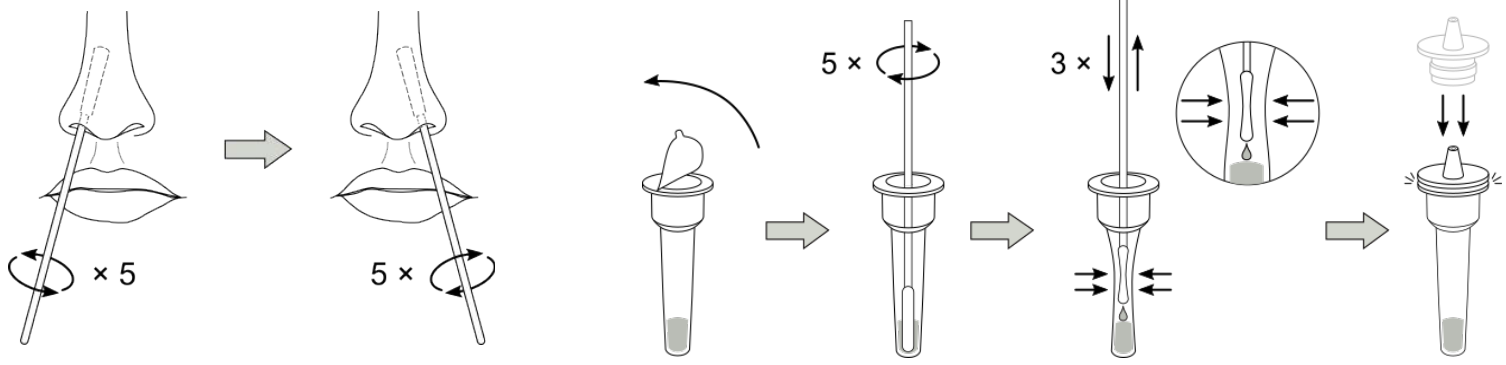
1 Test/Box

PRODUCT INTRODUCTION

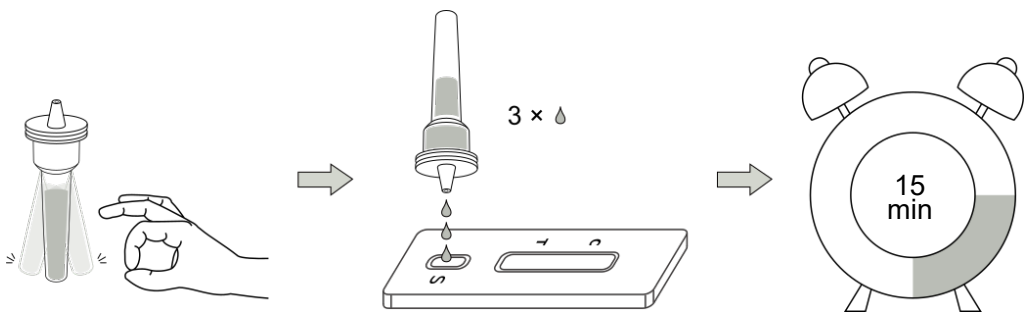
NEWGENE Bioengineering

Nasal Swab

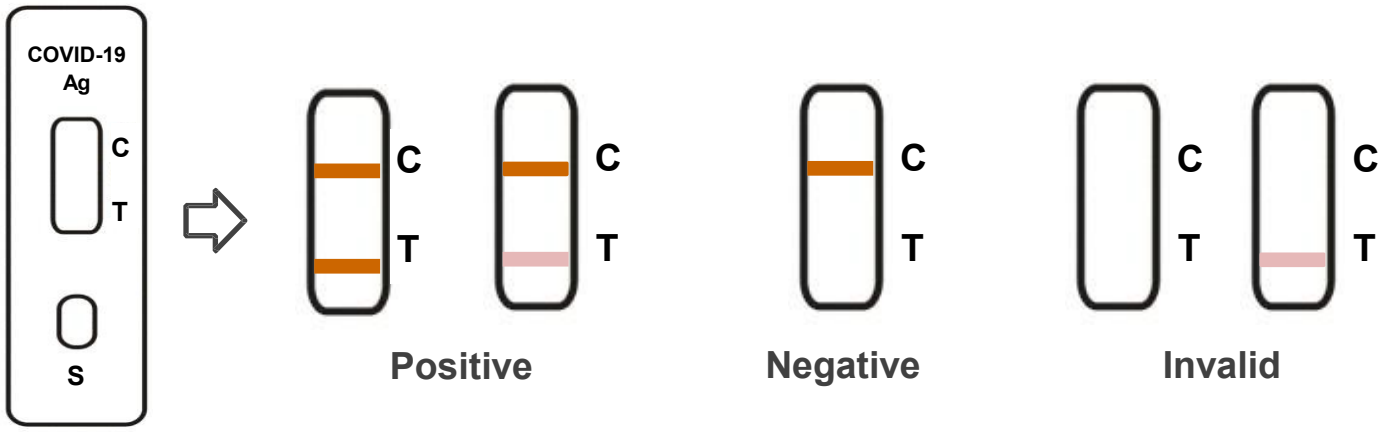
Test Procedures: Sampling



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%

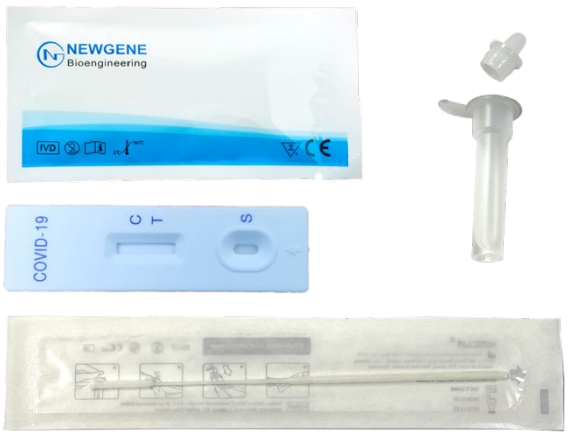
PRODUCT INTRODUCTION

NEWGENE Bioengineering

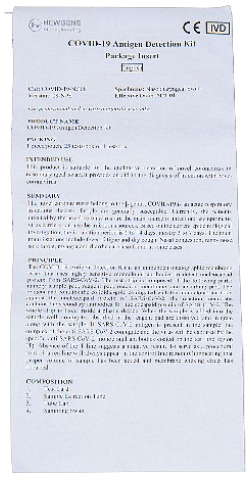
COVID-19 Antigen Detection Kit
(Nasopharyngeal Swab Sample)

N0.	Components	*25 Tests/Box*	*1Test/Box*
1	Test Card	25	1
2	Sample Extraction Tube & Tube Cap	25	1
3	Sampling Swab: *for Nasopharyngeal Swab*	25	1
4	Package Insert	1	1

25 Tests/Box



1 Test/Box

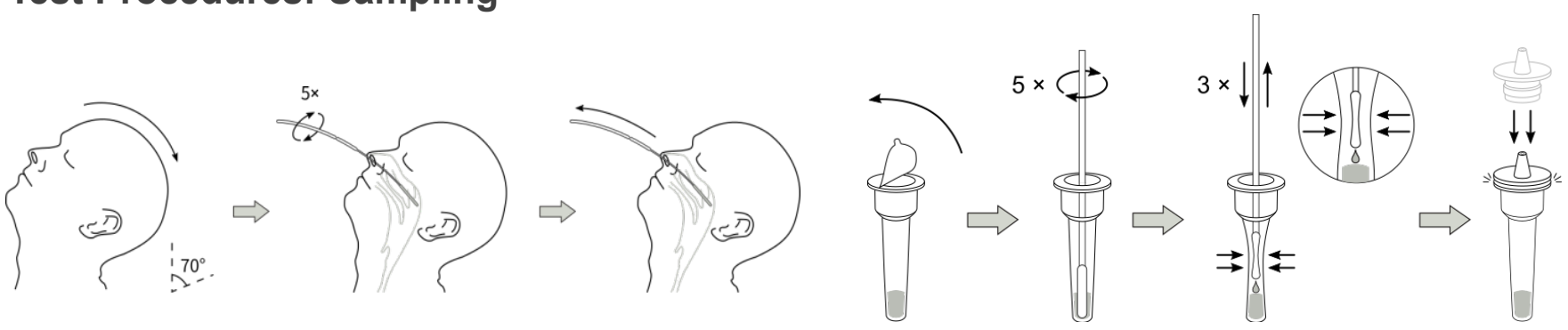


PRODUCT INTRODUCTION

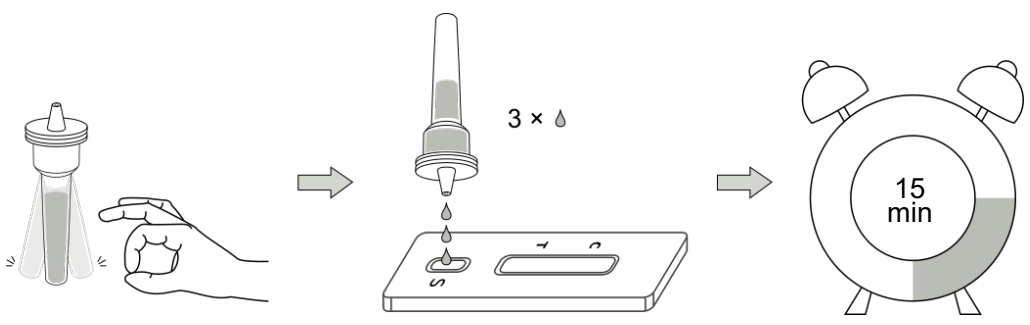
NEWGENE Bioengineering

Nasopharyngeal Swab

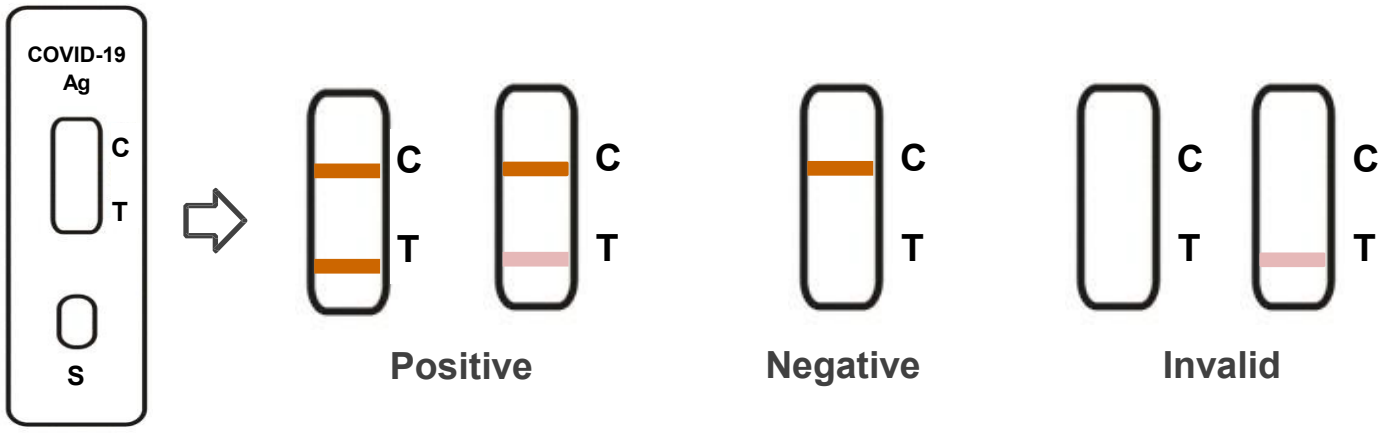
Test Procedures: Sampling



Test Procedures: Detection



Interpretation of Results



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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

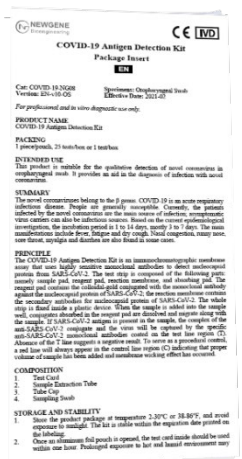
NEWGENE Bioengineering

COVID-19 Antigen Detection Kit
(Oropharyngeal Swab Sample)

N0.	Components	*25 Tests/Box*	*1Test/Box*
1	Test Card	25	1
2	Sample Extraction Tube & Tube Cap	25	1
3	Sampling Swab: *for Oropharyngeal Swab*	25	1
4	Package Insert	1	1

25 Tests/Box

1 Test/Box


COVID-19 Antigen Detection Kit
Package Insert
EN

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 oropharyngeal swab. 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 infection 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. Sampling Swab

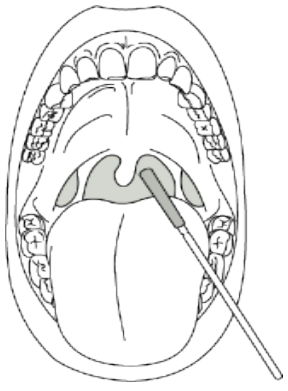
STORAGE AND STABILITY
1. Store the product package at temperature 2-30°C or 38-86°F, and avoid exposure to sunlight. The kit is stable within the expiration date printed on the labeling.
2. Once an aluminum foil pouch is opened, the test card inside should be used within one hour. Prolonged exposure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

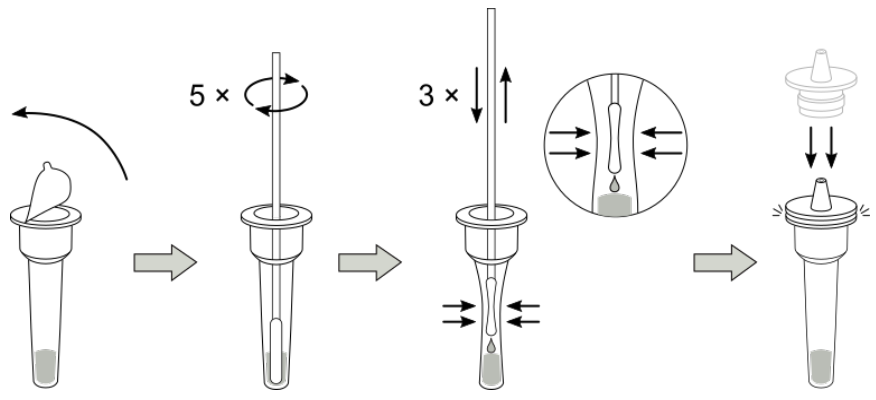
PRODUCT INTRODUCTION

NEWGENE Bioengineering

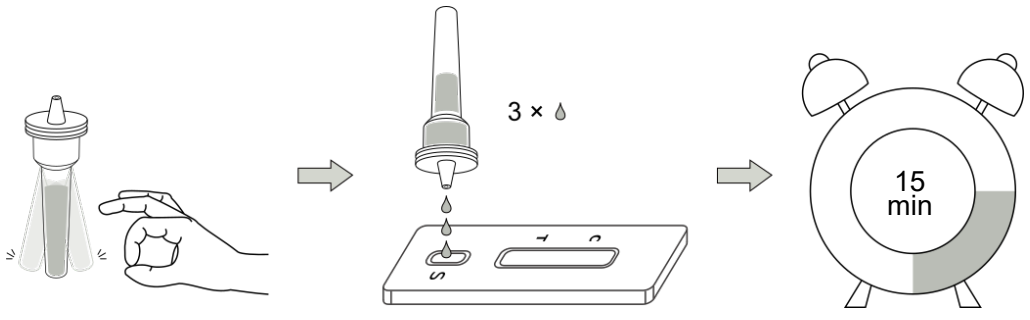
Oropharyngeal Swab

Test Procedures: Sampling

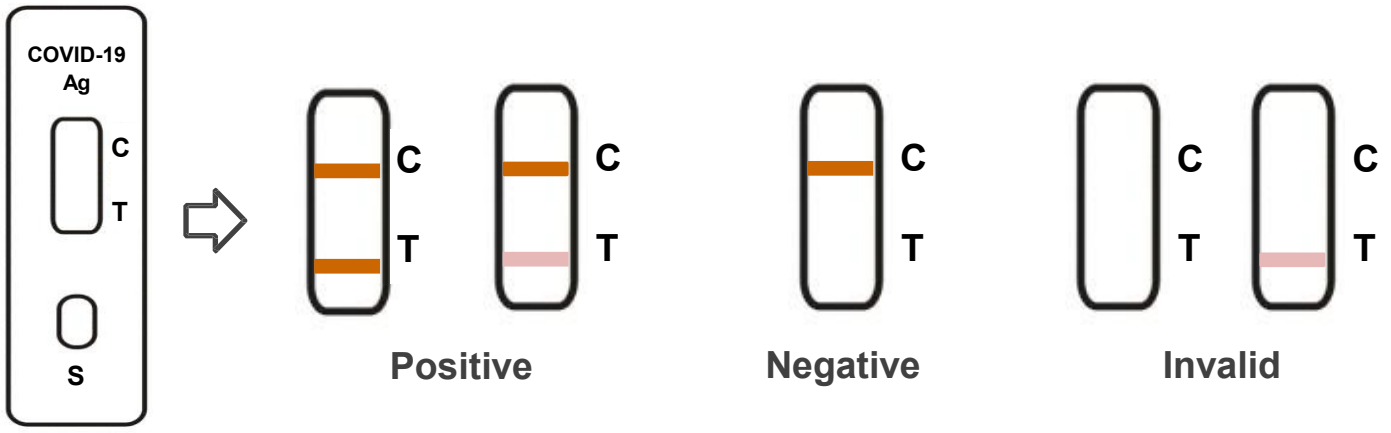




Test Procedures: Detection



Interpretation of Results



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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
(Sputum / Saliva Sample)

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

25 Tests/Box

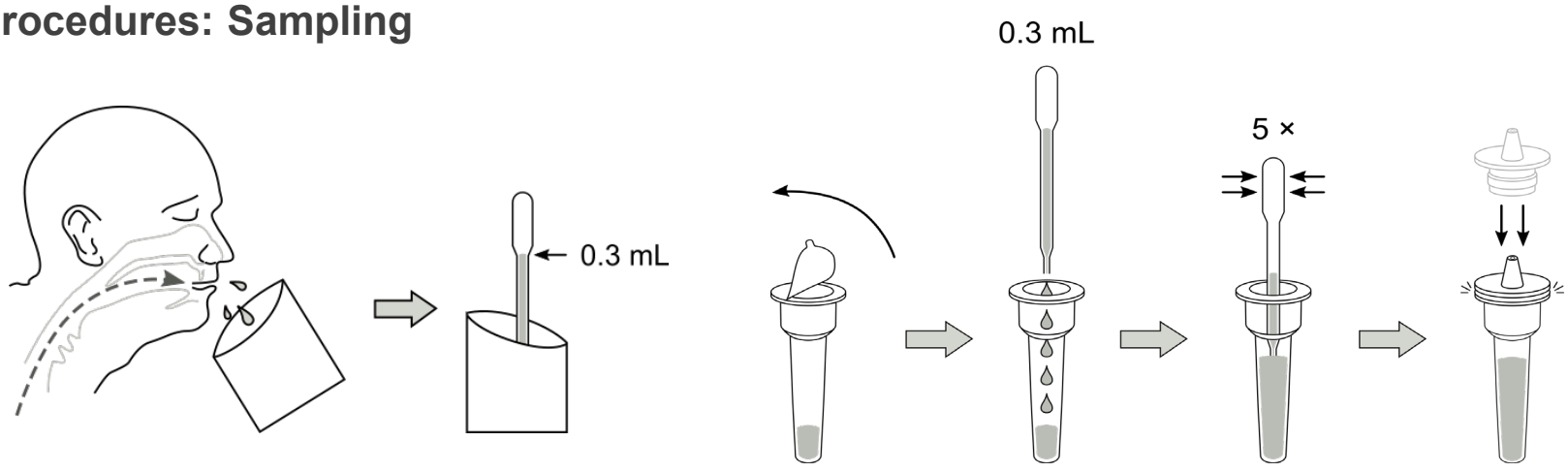
1 Test/Box

PRODUCT INTRODUCTION

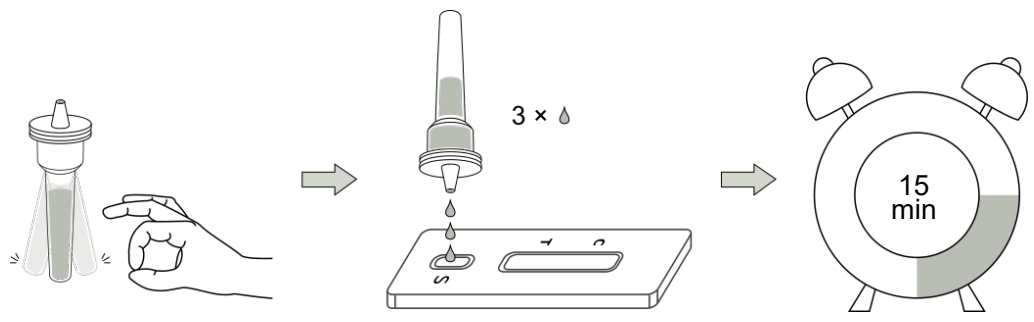
NEWGENE Bioengineering

Sputum / Saliva

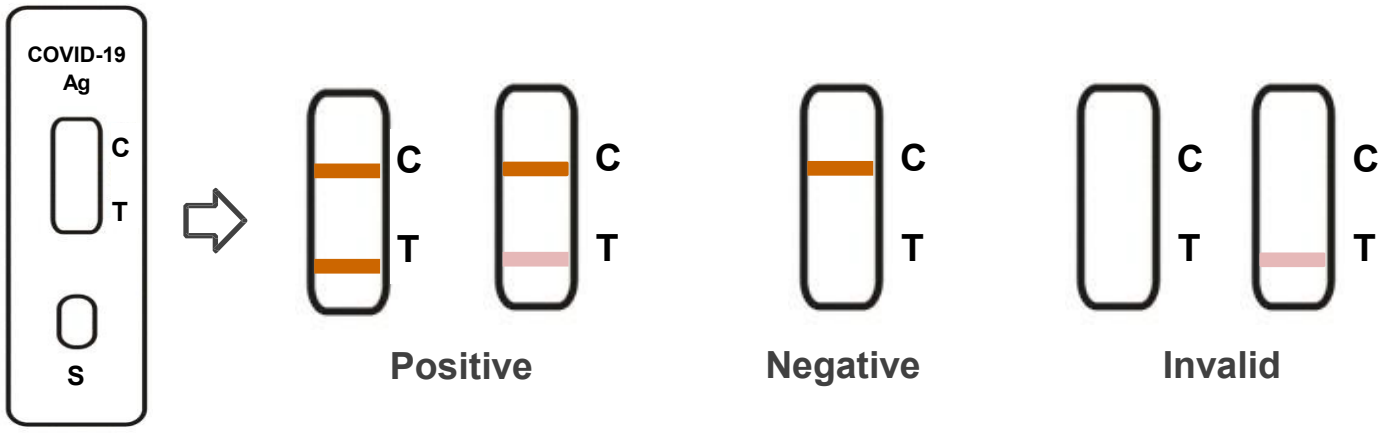
Test Procedures: Sampling



Test Procedures: Detection



Interpretation of Results



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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

Nasopharyngeal Swab: **NPS**
Nasal Swab: **NS**
Oropharyngeal Swab: **OS**
Sputum / 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)	0.34	0.38	0.32	0.36	0.35	0.4	0.39
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)	13.6	15.2	12.8	14.4	14	16	15.6
GW/Carton (kg)	15.1	16.7	14.3	15.9	15.5	17.5	16.9

5 Tests/Box

Sample	NS	
	Size (mm)	Weight (kg)
Inner box (mm)	193*85*42	0.081
Outer box (mm)	225*197*89	0.5
Carton	470*410*470	1.3
PCS/Inner Box	5	
Inner Boxes/Outer Box	5	
PCS/Carton	500	
Volume/Carton	0.09CBM	
NW/Carton (kg)	10	
GW/Carton (kg)	11.3	

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)	0.026	0.027	0.03	0.024	0.028	0.028	0.032
Outer box (mm)	305*197*88			277*182*112			
Outer box weight (kg)	0.78	0.80	0.88	0.73	0.83	0.83	0.93
Carton (mm)	630*420*470			590*570*395			
Carton weight (kg)	1.8			2.2			
PCS/Inner Boxes	1						
Inner Boxes/Outer Box	25						
PCS/Carton	500						
Volume/Carton	0.13CBM			0.133CBM			
NW/Carton (kg)	15.6	16	17.6	14.6	16.6	16.6	18.6
GW/Carton (kg)	17.4	17.8	19.4	16.8	18.8	18.8	20.4

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).

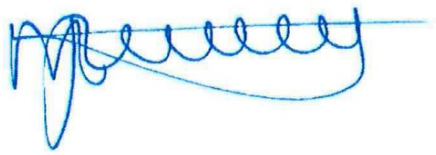
Notificatie van in-vitro diagnostische medische hulpmiddelen impliceert dat de fabrikant, New Gene (Hangzhou) Bioengineering Co., Ltd. de CE-conformiteitsmarkering heeft aangebracht op de desbetreffende producten alvorens deze in een EU-lidstaat in de handel te brengen. Zodoende garandeert SUNGO Europe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

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.™

Evaluation Records (Partially)

Pass the evaluation by PEI of Germany

Bundesinstitut für Impfstoffe und biomedizinische Arzneimittel
Federal Institute for Vaccines and Biomedicines

Paul-Ehrlich-Institut

26.03.2021

Comparative evaluation of the sensitivities of SARS-CoV-2 antigen rapid tests

Aim
Comparison of different antigen rapid tests with using identical sample material

Material
Pools from nasopharyngeal and oropharyngeal swabs.

Dry swabs were included in PBS; moist swabs were already included in the transport media of various compositions. Pools are random mixtures obtained from up to 10 samples of comparable CT values diluted 1:10 in negative samples in PBS. The CT values of a pool were determined by means of different PCR assays, and the putative number of RNA copies calculated with the aid of the INSTAND standards. In the case of the PCRs used, a CT value of 25 corresponds to around 10^5 RNA copies/mL. 18 samples each were analysed with CT<25, 23 samples with CT between 25 and 30, and 9 samples with CT>30. The replication of the virus in cell culture was determined as a possible correlate for infectiousness as another characteristic of the samples.

Method
The pools were aliquoted, frozen, shipped, and thawed for evaluation of the tests. For each test, 50 µL of the pool were analysed using the components of the test provided, e.g. swabs. Laboratories participating in the comparative evaluation included the Robert Koch-Institut, the Paul-Ehrlich-Institut, the reference laboratory for coronaviruses (Charité), and the Institute for Microbiology of the German Army (Bundeswehr).

Summary
This comparative evaluation of a large number of SARS-CoV-2 rapid antigen tests (point of care tests; POCT) of different designs and manufacturers with the same sample set allows an overview of the current state of art regarding sensitivity. The results do not allow any conclusions regarding specificity of the tests.

Those POCTs which have up to now been included in the evaluation and have been assessed as reflecting the current state of the art are listed in the table below. Other tests, which were assessed as not reflecting the state of the art were deleted from the list of the Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte, BfArM). This comparative evaluation is constantly continued, and the table is amended accordingly.

You should be aware that this comparative evaluation can only cover a random sample of the SARS-CoV-2 rapid antigen tests listed by the BfArM, thus eligible for refunding, and that few other products could not (yet) be taken into account, despite the interests on the part of the manufacturers/distributors.

Contact
Email: sarscov2ivd@pei

Paul-Ehrlich-Institut
Paul-Ehrlich-Str. 51-59
63225 Langen, Germany

www.pei.de

Bundesinstitut für Impfstoffe und biomedizinische Arzneimittel
Federal Institute for Vaccines and Biomedicines

Paul-Ehrlich-Institut

Name of Test	Manufacturer (Distributor)
Covid-19-Antigen-Test kit	New Gene (Hangzhou) Bioengineering Co., Ltd.

Evaluation Records（Partially)

Pass the evaluation by BAG of Switzerland

Vorlage Prüfbericht für Validationen / Verifikationen
Mikrobiologie
2469 / 2.0

Dr Risch

Validation

Sars-CoV-2 Antigen Test

with

COVID-19 Antigen Detection Kit
(Newgene(Hangzhou) Bioengineering)

Department of microbiology LMZ Dr Risch Pregassona

Validation interval:01/21 – 02/21

5 Conclusions

The comparable results with the R *** e Test makes the newgene test suitable to be introduced in Switzerland. It important to note the better sensitivity of that assay in comparison to R *** e

Evaluation Records (Partially)

Pass the evaluation by MDA of Malaysia

INSTITUTE FOR MEDICAL RESEARCH
KUALA LUMPUR

Performance of Newgene Bioengineering COVID-19 Antigen Detection Kit

Intended use
This product is suitable for the qualitative detection of novel coronavirus in nasopharyngeal swab or sputum samples. It provides an aid in the diagnosis of infection with novel coronavirus.

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

Test Principle
This kit is an immunochromatographic membrane assay that uses highly sensitive monoclonal antibodies to detect nucleocapsid from protein from SARS-CoV-2. When the sample is added into the sample well, colloidal-gold conjugated with the monoclonal antibody against the nucleocapsid protein of SARS-CoV-2 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 T line suggests a negative result. To serve as a procedural control, a red line will always appear in the control line region (C).

Test Kit
The evaluation was carried out using this kit with the lot number of 20210228-01, and the expiry date is Feb 27, 2022.

Instrument Used
NA

Reagent and Sample Preparation, Result Interpretation
Kindly refer to product package insert in the attachment

Sample Used
Sample type = Deep throat saliva (DTS)
Known Positive Sample= 50
Known Negative Sample= 50
Total samples used for analysis = 100

Performance Analysis

Test		Tested Kit Assay		Interpretation
		Positive	Negative	
IMR In-house Panel	SARS-CoV2 Positive (COVID-19)	48	2	Sensitivity= 96%
	SARS-CoV2 Negative (COVID-19)	0	50	Specificity = 100%

Comments
This kit was tested using DTS samples that had been tested positive using our RT-qPCR test system and the Ct values were ranged from 12 to 28. Saliva samples that had been tested negative using COVID-19 RT-qPCR test system and cultured samples of Influenza A H3, Influenza A pdm09, Adenovirus and Dengue were selected as negative panels.

Test performed by		Reviewed by	Approved by
E. Kav	Hayati		31/5/21
Pn. E. Kavithambigai A/P Ellan Evaluator 1/Officer in charge	Pn. Hariyati Md. Ali Evaluator 2 /Officer in charge	Dr. Ravindran A/L Thayan Head of Virology Unit, IDRC, IMR	Dr. Hj. Tahir bin Aris Director of IMR

Evaluation Records (Partially)

Pass the evaluation by Zimbabwe

NATIONAL MICROBIOLOGY REFERENCE LABORATORY

NEWGENECOVID 19 RAPID ANTIGEN TEST EVALUATION
AGAINSTCOVID 19 RT-PCR

COMPARISON REPORT

Conclusion

There was 100 % positive percent agreement between the NEWGENE SARS-CoV- 2 antigen test and SARS CoV-2 PCR test done using stored samples at NMRL. NEWGENE kit is recommended for use in Zimbabwe.

Evaluation team

Stanford Mupandasekwa Lab Scientist Signature _____ Date 26/2/2021

Boniface Muzividzi Lab Scientist Signature _____ Date 26/2/2021

Reviewed by:

Lucia Sisya Quality officer Signature _____ Date 26/02/2021

Agnes Juru Chief lab Scientist Signature _____ Date 26/2/21

Approved by:

Dr Sekesayi Zinyowera Coordinator Signature _____ Date 26/02/2021

NAT MICROBIOLOGY REFERENCE LAB
MINISTRY OF HEALTH & CHILD CARE
CHIEF MEDICAL DIRECTOR'S OFFICE
26 FEB 2021
P.O. BOX ST 749 HARARE, ZIMBABWE

Evaluation Records (Partially)

Pass the evaluation by 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. 16822166202000000008P, 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

Registration or Allowed List (Partially)

BfArM of Germany

Bundesinstitut
für Arzneimittel
und Medizinprodukte

Antigen-Tests zum direkten Erregernachweis des Coronavirus SA

Impressum Administration

Die nachfolgende Tabelle zeigt die Original-Tests mit ihrem vom Hersteller bzw. europäischen Bevollmächtigten vergebenen Handelsnamen. Eine Übersicht der jeweiligen deutschen Vertreiber und deren ggfs. abweichender Benennung finden Sie unter dem Link in der Spalte „Deutsche(r) Vertreiber".

Die Angabe „Evaluierung PEI" bildet die entsprechende, auf der Webseite des Paul-Ehrlich-Instituts (PEI) veröffentlichte Übersicht zur dortigen vergleichenden Evaluierung der Sensitivität von SARS-CoV-2 Antigenschnelltests ab (siehe Webseite des PEI).

- „Ja" bedeutet, dass der Test bereits mit positivem Ergebnis durch das PEI evaluiert wurde.
- „Nein" bedeutet, dass bislang keine entsprechenden Testergebnisse vorliegen.

Im Falle einer negativen Evaluierung durch das PEI streicht das BfArM den entsprechenden Test mit allen zugeordneten Vertreibern von seiner Liste.

new gene | Los | Aktionen | Zurücksetzen

Nach 'new gene' suchen

			Hersteller			Europäischer Bevollmächtigter					Sensitivität		Spezifität	
Test-ID	Handelsname des Herstellers / Europ. Bevollmächtigten	Evaluier… PEI	Name	Stadt	Land	Name	Stadt	Land	Deutsch… Vertreiber	Test…	%	95%iges Vertrauens intervall	%	95%ig Vertra interv
AT416/21	COVID-19 Antigen Detection Kit NG08 S	Ja	New Gene (Hangzhou) Bioengineering Co., Ltd.	Hangzhou	CN	SUNGO Europe B.V.	Amsterdam	NL	Det…	POC (ohne Gerät)	97,30	92,4 - 99,4	99,20	95,8 -
AT502/21	COVID-19 Antigen Detection Kit NG08 SN	Ja	New Gene (Hangzhou) Bioengineering Co., Ltd.	Hangzhou	CN	SUNGO Europe B.V.	Amsterdam	NL	Det…	POC (ohne Gerät)	97,10	93,4 - 99,1	99,20	97,3 -
AT331/21	COVID-19 Antigen Detection Kit NG08NS	Ja	New Gene (Hangzhou) Bioengineering Co., Ltd.	Hangzhou	CN	SUNGO Europe B.V.	Amsterdam	NL	Det…	POC (ohne Gerät)	98,00	90,3 - 99,3	99,10	95,2 -

1 - 3 von 3

ANSM of France

MINISTÈRE
DES SOLIDARITÉS
ET DE LA SANTÉ
Liberté
Égalité
Fraternité

PLATEFORME COVID-19 — Se connecter

Tests d'amplification génique

Tests RT-PCR de criblage

Accueil

Tests

Projets

Veille

Eaux usées

Statut: CE, HAS, CNR | Type de test: Antigénique | Sous-type de test: ---- | Cibles: -- | Type prélèvement: ---- | Rechercher: new gene

Cette liste a été constituée en l'état actuel des connaissances scientifiques et sur la base des informations remontées par les opérateurs (fabricant ou distributeur) à l'ANSM. Elle est susceptible d'être modifiée en fonction des évolutions de l'état de la connaissance.

3 tests affichés

NOM	FABRICANT	DISTRIBUTEUR	CE	CNR	HAS	SOUS-TYPE DE TEST
COVID -19 Antigen detection kit	New Gene (Hangzhou) Bioengineering	AITECH	✓	✓	✓	Antigénique non automatisé (dont TROD)

Registration or Allowed List (Partially)

Italy

http://www.salute.gov.it/interrogazioneDispositivi/RicercaDispositiviServlet?action=ACTION_MASCHERA

Dispositivo	2021549	S	COVID-19-NG02	NOVEL CORONAVIRUS ANTIGEN DETECTION KIT (COLLOIDAL GOLD)-Novel Coronavirus Antigen Detection Kit (Colloidal Gold) 88021	W0101060499 - TEST MULTIPARAMETRICI "POINT OF CARE" - ALTRI	IVD - Altro tipo di IVD	02/11/2020		FABBRICANTE	NEW GENE BIOENGINEERING CO., LTD			CN
									MANDATARIO	WELLKANG LTD.		GB4740528	GB
Dispositivo	2012166	N	COVID-19-NG04	NOVEL CORONAVIRUS SPIKE GLYCOPROTEIN DETECTION KIT (LIGAND-RECEPTOR COMPETITIVE CHROMATOGRAPHY)	W0105040619 - CORONAVIRUS	IVD - Altro tipo di IVD	21/10/2020		FABBRICANTE	NEW GENE BIOENGINEERING CO., LTD.			CN
									MANDATARIO	WELLKANG LTD		GB4740528	GB
Dispositivo	2050024	N	COVID-19-NG08	TEST RAPIDO COVID-19 SPUTUM	W0105040619 - CORONAVIRUS	IVD - Altro tipo di IVD	19/01/2021		FABBRICANTE	NEW GENE BIOENGINEERING CO., LTD.			CN
									MANDATARIO	SUNGO EUROPE B.V.		857821659B01	NL
Dispositivo	2012575	S	COVID-19-NG10	COVID-19 / INFLUENZA A / INFLUENZA B	W0105099099 - VIROLOGIA - TEST RAPIDI E "POINT OF CARE" - ALTRI	IVD - Altro tipo di IVD	22/10/2020		FABBRICANTE	NEW GENE BIOENGINEERING CO., LTD.			CN
									MANDATARIO	SUNGO EUROPE B.V.		857821659B01	NL

Switzerland

Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

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

Listen der validierten SARS-CoV-2-Schnelltests[1]
Listes des tests rapides validés pour le SARS-CoV-2
Lista dei test rapidi validati per il SARS-CoV-2

15.03.2021

Die Schnelltests sind ausschliesslich für **bestimmte Probematerialien** 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 sont validés exclusivement pour **certains types de prélèvements** et ne doivent ainsi être utilisés que pour ceux-ci. 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 testi rapidi sono validati solo per **certi tipi di campioni** e possono essere utilizzati solo per questo scopo. Le informazioni su come utilizzare i test rapidi sono disponibili sul sito internet dell'UFSP «Test COVID-19». — Sito web Test COVID-19

Validierte SARS-CoV-2-Schnelltests nach diagnostischem Standard zur Fachanwendung[2]
Tests rapides SARS-CoV-2 validés selon le standard diagnostic pour usage professionnel
Test rapidi SARS-CoV-2 validati secondo lo standard diagnostico per uso professionale

Hersteller Fabricant Azienda	Antigen Schnelltest Tests rapides antigéniques Test antigenici rapidi	TestKitCode for electronic declaration	nasopharyngeal	nasal	saliva	
New Gene (Hangzhou) Bioengineering Co. Ltd., China	COVID-19 Antigen Detection Kit	30 (new)	x			

Registration or Allowed List (Partially)

Portugal

Portugal https://www.Infarmed.pt/web/Infarmed/pesquisa-dispositivos

Infarmed
Autoridade Nacional do Medicamento e Produtos de Saúde, I.P.

COVID-19-NG08	New Gene (Hangzhou) Bioengineering Co., Ltd	62788353	DM Diagnóstico In Vitro (DIV)	NEWGENE	NG08	Outros (DIV não listado no anexo II da Directiva 98/79/CE e não destinado a auto diagnóstico)	COVID-19 ANTIGEN DETECTION KIT
COVID-19 ANTIGEN DETECTION KIT	New Gene (Hangzhou) Bioengineering Co., Ltd	63025426	DM Diagnóstico In Vitro (DIV)	NEWGENE	NG08	Outros (DIV não listado no anexo II da Directiva 98/79/CE e não destinado a auto diagnóstico)	COVID-19 ANTIGEN DETECTION KIT

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Czech

Žádost o notifikaci zdravotnického prostředku

Žadatel

Registrační číslo:	054535
Název:	Markmed s.r.o.
IČ:	02478170
Ulice:	Kubánské náměstí 1391
Obec:	Praha
PSČ:	10000
Stát:	Česká republika

Identifikace zdravotnického prostředku

Druh zdravotnického prostředku:	Diagnostický zdravotnický prostředek in vitro
Typ evidence zdravotnického prostředku:	Notifikace dle § 33
Činnost:	Distributor
Obchodní název zdravotnického prostředku:	Novel Coronavirus Spike Glycoprotein Detection Kit (Ligand-receptor Competitive Chromatography)
Jedná se o příslušenství?	Ne
Jedná se o soupravu/systém zdravotnických prostředků?	Ne
Míra zdravotního rizika zdravotnického prostředku:	IVD A

Registration or Allowed List (Partially)

Self-Test of Germany

Bundesinstitut
für Arzneimittel
und Medizinprodukte

BfArM, Kurt-Georg-Kiesinger-Allee 3, D-53175 Bonn

Simmons & Simmons LLP
Thierschplatz 6
80538 München

ABTEILUNG Medizinprodukte
BEARBEITET VON Dr. Laura van Diepen
TEL +49 (0)228 99 307- 3923
E-MAIL Laura.vanDiepen@bfarm.de

HAUSANSCHRIFT Kurt-Georg-Kiesinger-Allee 3
53175 Bonn
TEL +49 (0)228 99 307-0
FAX +49 (0)228 99 307-5207
E-MAIL poststelle@bfarm.de
INTERNET www.bfarm.de

Bonn, den 11.05.2021
GESCHZ 5640 -S-296/21

Per E-Mail: Caroline.VonNussbaum@Simmons-Simmons.com
Nachrichtlich: ec.rep@sungogroup.com; marketing@new-gene.com

Im Verfahren der Erteilung einer Sonderzulassung gemäß § 11 Abs. 1 MPG

5640-S-296/21	
aufgrund des Antrags vom 30.03.2021	
an	
New Gene (Hangzhou) Bioengineering Co., Ltd **Zang Yang** **Bin'an Street** **310052 Hangzhou** **China**	**„Inhaber der Sonderzulassung"**
im Antragsverfahren vertreten durch	
Simmons & Simmons LLP **Thierschplatz 6** **80538 München**	
für das Medizinprodukt	
Covid-19-Antigen-Testkit	**„betroffenes Medizinprodukt"**
des Unternehmens	
s.o. „Inhaber der Sonderzulassung"	**„Hersteller"**
mit dem europäischen Bevollmächtigten gem. § 3 Ziff. 16 MPG	
SUNGO Europe B.V. **Yana Zhang (Ms.)** **Olympisch Stadion 24** **1076DE Amsterdam** **Niederlande**	**„Europäischer Bevollmächtigter" und Verantwortlicher nach § 5 MPG**

ergeht folgender

Registration or Allowed List (Partially)

Self-Test of France

ansm
Agence nationale de sécurité du médicament et des produits de santé

REPUBLIQUE FRANÇAISE

DIRECTION DES DISPOSITIFS MEDICAUX, DES COSMETIQUES ET DES DISPOSITIFS DE DIAGNOSTIC IN VITRO

Saint-Denis, le 14 mai 2021

Dossier suivi par **Corine Maillard**
Tél. : +33 (0)1 55 87 31 14
E-mail : corine.maillard@ansm.sante.fr
N/Réf. : OTES

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

marketing@new-gene.com

Objet : dérogation pour le dispositif médical de diagnostic in vitro dénommé Kit autotest antigénique COVID-19

PJ : Cahier des charges version 13 avril 2021

Madame, Monsieur,

Vous avez formulé auprès de mes services une demande de dérogation afin de pouvoir mettre sur le marché en tant qu'autotest, le dispositif médical de diagnostic in vitro (DIV) de détection antigénique du virus SARS-CoV-2 visé en objet.

Ce produit n'a pas encore satisfait aux procédures de conformité applicables aux autotests et nécessaires à l'apposition du marquage CE telles que prévues par la directive 98/79/CE du Parlement européen et du Conseil du 27 octobre 1998 relative aux dispositifs médicaux de diagnostic in vitro relative, et dont le respect doit être préalable à la mise sur le marché des dispositifs médicaux de diagnostic in vitro ; il n'est notamment pas couvert, à ce jour, par un certificat CE de conformité délivré par un organisme notifié.

L'article 9 § 12 de la directive 98/79/CE précitée me permet toutefois de vous autoriser, à titre dérogatoire et sous conditions, à mettre sur le marché des dispositifs n'ayant pas fait l'objet de ces procédures de certification, mais dont l'utilisation présente un intérêt pour la protection de la santé.

Dans ce contexte et à cet égard, l'arrêté du 26 mars 2021 modifiant l'arrêté du 10 juillet 2020 prescrivant les mesures d'organisation et de fonctionnement du système de santé nécessaires pour faire face à l'épidémie de covid-19 dans le cadre de l'état d'urgence sanitaire, prévoit notamment qu'une telle dérogation est susceptible d'être accordée pour des autotests qui n'auraient pas complété leur évaluation de conformité permettant l'apposition du marquage CE, d'une part s'ils satisfont aux critères édictés par la Haute autorité de santé, d'autre part s'ils respectent le cahier des charges publié sur le site internet du Ministère chargé de la santé et de l'Agence nationale de sécurité du médicament et des produits de santé.

A cet égard, je note d'une part que vous avez d'ores et déjà apporté un certain nombre d'éléments de nature à garantir les performances du produit objet de votre demande, ainsi que des données quant à la praticabilité pour leur utilisation par une personne profane, d'autre part que les démarches que vous avez engagées auprès d'un organisme notifié en vue du marquage CE de ces produits, ont abouti à un contrat.

Registration or Allowed List (Partially)

Self-Test of Czech

MINISTERSTVO ZDRAVOTNICTVÍ
Palackého náměstí 375/4, 128 01 Praha 2

Praha 26. února 2021
Č. j.: MZDR 7614/2021-2/OLZP

MZDRX01EOP00

ROZHODNUTÍ

Ministerstvo zdravotnictví (dále jen „Ministerstvo“) jako orgán příslušný k rozhodnutí podle ustanovení § 12 odst. 1 písm. h) zákona č. 22/1997 Sb., o technických požadavcích na výrobky a o změně a doplnění některých zákonů, ve znění pozdějších předpisů ve spojení s § 4 odst. 8 nařízení vlády č. 56/2015 Sb., o technických požadavcích na diagnostické zdravotnické prostředky in vitro (dále jen „nařízení vlády“), na základě žádosti společnosti

Markmed, s.r.o.
se sídlem Kubánské náměstí 1391/11, 100 00 Praha 10, IČO: 024 78 170
(dále jen „žadatel“)

rozhodlo v souladu s ustanovením § 67 a násl. zákona č. 500/2004 Sb., správní řád, ve znění pozdějších předpisů (dále jen „správní řád“) tak, že

p o v o l u j e

žadateli uvést na trh a do provozu diagnostický zdravotnický prostředek in vitro **COVID-19 Antigen Detection Kit**, jehož výrobcem je New Gene (Hangzhou) Bioengineering Co., Ltd., se sídlem Room 1606, Floor 16, Building 5, 688 Bin'an Road, Changhe Street, Binjiang District, Hangzhou, Zhejiang, P.R. China, pro použití laickou osobou

a s t a n o v u j e

po dobu platnosti tohoto rozhodnutí žadateli následující povinnosti k zajištění ochrany veřejného zdraví:

- informovat odběratele o povinnosti v rámci testování zajistit při pozitivitě antigenního testu provedeného laickou osobou bezprostřední informování poskytovatele zdravotních služeb za účelem provedení konfirmačního testu,
- v případě zájmu odběratele zajistit proškolení určené osoby,
- hlásit Státnímu ústavu pro kontrolu léčiv každou nepříznivou událost, ke které během používání výrobku dojde.

Platnost povolení:.

Registration or Allowed List (Partially)

Self-Test of Denmark

LÆGEMIDDELSTYRELSEN
DANISH MEDICINES AGENCY

New Gene (Hangzhou) Bioengineering Co., Ltd.
Building 5, 688 Bin'an Road, Changhe Subdistrict, Hangzhou, Zhejiang,
P.R. China

8 April 2021
Case no. 2021040180
T +45 44889775
E jast@dkma.dk

The Danish Medicines Agency hereby authorises New Gene (Hangzhou) Bioengineering to place on the market/put into service the COVID-19 Antigen Detection Kit in Denmark.

The authorisation is conditional with the following terms and conditions.

Terms and conditions:

- *This authorisation is valid until 01.10.2021, or until the date when the device is **CE marked**, if this occurs before 01.10.2021. The manufacturer must inform the Danish Medicines Agency when the CE-mark has been acquired.*
- *The authorisation is limited to marketing/putting into service in Danish schools and Danish educational institutions.*
- *If the CE marking has not been achieved 01.07.2021 the manufacturer shall provide a status for the CE marking process.*
- ***New Gene Bioengineering** (manufacturer) shall establish a vigilance system, that ensures the collection and reporting to **The Danish Medicines Agency** of any incident, which occurs during the authorisation period.*
- *The manufacturer must ensure traceability of products through, for example, batch / LOT numbers.*
- *The information on the labelling and in the instruction for use (IFU) for the "COVID-19 Antigen Detection Kit" shall be in Danish, before distribution to the end-user.*
- *The labelling must clearly state that the products are placed on the market under this authorisation as a derogation from the conformity assessment procedures.*
- *The test must be accompanied by a detailed IFU, intended specifically for lay people and the intended user group (Danish educational institutions under supervision).*
- *Technical documentation for the product must be kept for a minimum of 5 years.*
- *A status shall be provided 01.07.2021 and by the end of this authorisation period of how many devices has been placed on the market under this authorisation.*

The authorisation covers the following product:

*Product: **COVID-19 Antigen Detection Kit***
Catalogue/ Model number(s): COVID-19-NG08
In Vitro Medical Device: General IVD, non-CE-marked for self-testing
Scope: immunoassay strip intended for the detection of SARS-CoV-2 nucleocapsid protein in human nasal swab samples.

Danish Medicines Agency
Axel Heides Gade 1
2300 Copenhagen S
Denmark
T +45 44 88 95 95
E dkma@dkma.dk
LMST.DK

Registration or Allowed List (Partially)

Self-Test of Belgium

Get approved and listed by Belgium famhp as self-tests.

nl fr en

Other information and services: www.belgium.be .be

famhp
federal agency for medicines and health products

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Home ▸ Human use ▸ Health Products ▸ Medical devices and their accessories ▸ COVID-19 ▸ Tests

Tests

Antibody and antigen tests for professional use

- New validation procedure for serological tests and antigenic tests
- List of the recommended tests

Self-tests

- List of SARS-CoV-2 antigen self-tests with a CE-certificate that can be sold in pharmacies to private persons
- Procedure for manufacturers to market SARS-CoV-2 antigen rapid tests for professional use as self-tests in Belgium (see Dutch or French)
- List of professional rapid tests that may be sold as self-tests

Notification of adverse reactions or incidents

PIL and SPC of a medicine

(PIL: patient information leaflet SPC: summary of product characteristics)

Search

afmps fagg

Lijst van SARS-CoV-2 antigentesten voor professioneel gebruik die van het FAGG een toelating hebben om als zelftest in de apotheek aan particulieren te worden verkocht
Liste des tests antigéniques du SARS-CoV-2 à usage professionnel qui sont approuvés par l'AFMPS pour être vendus aux particuliers en autotest en pharmacie
List of SARS-CoV-2 antigen tests for professional use that are approved by the FAMHP to be sold as self-tests to private individuals in pharmacies

versie/version 20.04.2021

Merk op dat de verkoop van deze zelftesten aan particulieren momenteel enkel toegelaten is in de apotheek. De apotheker informeert bovendien de koper over het gebruik van de zelftest en wijst erop dat een arts moet gecontacteerd worden in geval van een positief resultaat.
A noter que la vente de ces autotests à des particuliers n'est actuellement autorisée qu'en pharmacie. Le pharmacien informe également l'acheteur de l'utilisation de l'autotest et rappelle qu'un médecin doit être contacté en cas de résultat positif.
Note that the sale of these self-tests to private individuals is currently only allowed in pharmacies. The pharmacist also informs the purchaser about the use of the self-test and points out that a doctor should be contacted in case of a positive result.

Fabrikant/Fabricant/Manufacturer	Gemachtigde/répresentant autorisé/authorised representative	Naam van de test/Nom du test/Name of the test	Referentie/Référence/Reference	Datum toelating Date approbation Approval date
[redacted]	[redacted]	SARS-CoV-2 Rapid Antigen Test Nasal	9901-NCOV-03G	14/04/2021
[redacted]	[redacted]	BIOSYNEX COVID-19 Ag BSS self-test	859269 (1 test/kit) 859270 (5 tests/kit)	29/03/2021
New Gene (Hangzhou) Bioengineering Co, Ltd (CN)	SUNGO Europe B.V. (NL)	COVID-19 Antigen Detection Kit	COVID-19-NG08 (1 test/kit) COVID-19-NG08/5 (5 tests/kit)	20/04/2021

Registration or Allowed List (Partially)

Self-Test of Sweden

LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Beslut

Enheten för Medicinteknik

Datum: 2021-04-21 Dnr: 5.2.3-2021-029480

New Gene Bioengineering.
Rm. 1606, Floor 16, Building 5, 688 Bin'an Road, Changhe Street, Binjiang District, Hangzhou, Zhejiang,
P. R. China

Beträffande ansökan om dispens från kraven på procedur för bedömning av överensstämmelse gällande självtest

Beslut

Gibson Medical AB på uppdrag av New Gene (Hangzhou) Bioengineering Co., Ltd. (tillverkaren) ansökan om dispens från kraven på procedur för bedömning av överensstämmelse gällande produkten 'COVID-19 Antigentest - Självtest' beviljas.

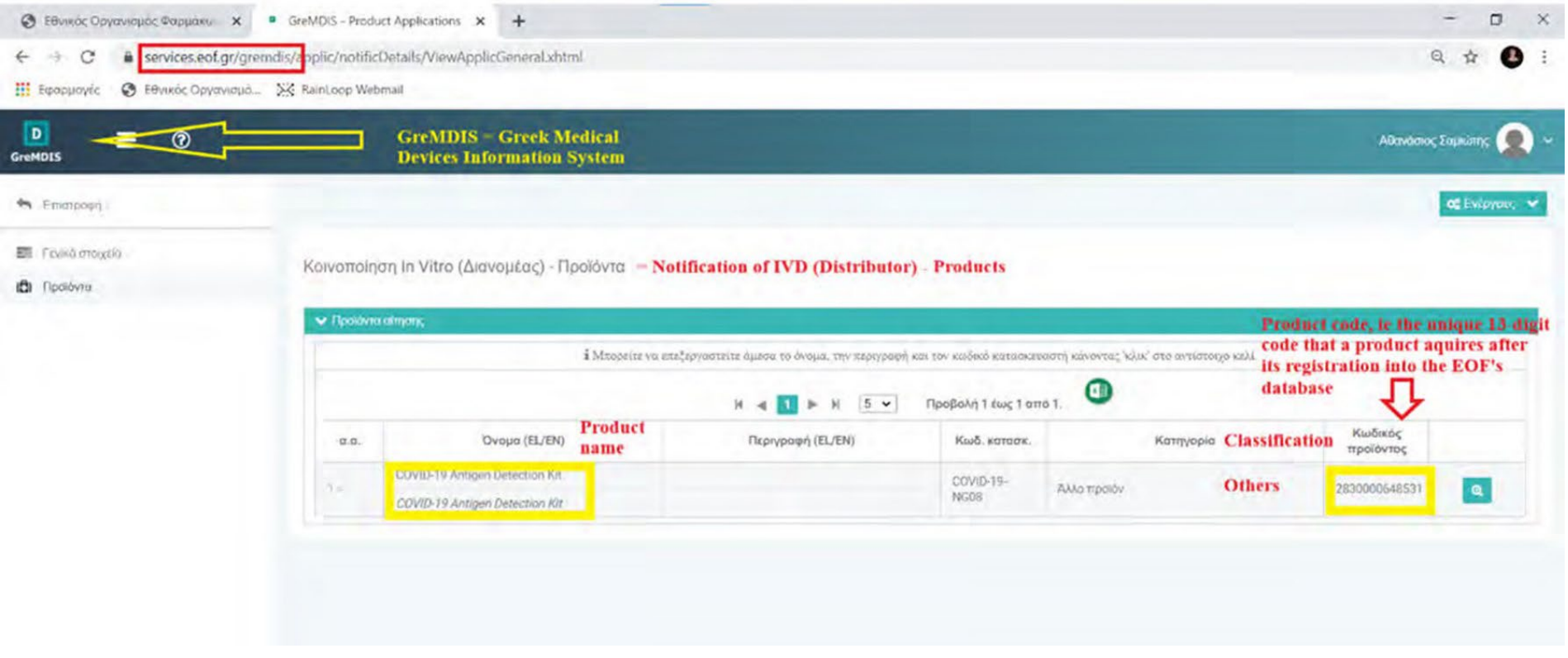
Dispensen gäller som längst fram till den 31 juli 2021 eller så snart produkten CE-märkts, om så blir fallet dessförinnan.

Dispens beviljas med följande villkor:

- Tillverkaren eller den som företräder tillverkaren ska vid dispensens utgång säkerställa att försäljningen (tillhandahållandet) av produkten till slutanvändaren upphör.
- Tillverkaren eller den som företräder tillverkaren ska upplysa berörda återförsäljare om att produkten har beviljats tillfällig dispens från kraven på procedur för bedömning av överensstämmelse som innefattar anmält organs granskning (extern oberoende organisation) avseende produktens konstruktion samt upplysa om att dispensen endast gäller inom Sverige.
- Tillverkaren eller den som företräder tillverkaren ska säkerställa att produktens medföljande information (bruksanvisning, förpackning) ska vara avsedd för självtestning (användning av lekmän i hemmiljö) och vara avfattad på svenska.
- Tillverkaren eller den som företräder tillverkaren ska säkerställa att medföljande bruksanvisning innehåller rådgivande information om de åtgärder som användaren skall vidta i händelse av ett positivt, negativt eller oklart resultat.
- Tillverkaren eller den som företräder tillverkaren ska i medföljande information (bruksanvisning, förpackning) informera om sannolikheten för ett falskt positivt eller falskt negativt resultat samt övriga begränsningar gällande testets tillförlitlighet som självtest samt vilka konsekvenser begränsningarna medför för den enskilde användaren.

Registration or Allowed List (Partially)

Greece



Hungary

OGYÉI Országos Gyógyszerészeti és Élelmezés-egészségügyi Intézet

Orvostechnikai Főosztály

1051 Budapest, Zrínyi utca 3.
Levélcím: 1372 Postafiók 450
Tel.: +36 1 886 9300, Fax: +36 1 886 9460
E-mail: ogyei@ogyei.gov.hu
Web: www.ogyei.gov.hu

Ügyiratszám: **OGYÉI/4321-3/2021**
Nyilvántartási szám: HU/CA01/4321/21
Tárgy: Nyilvántartásba vétel igazolása
Ügyintéző: Szlobodnyik Gábor

Az eszköz(ök) neve:

COVID-19 Antigen Detection Kit	db/doboz
tesztkazetta	25
minta extrakciós cső	25
tampon pálca	25
papír tasak	25
használati utasítás	1

A gyártó neve: New Gene (Hangzhou) Bioengineering Co.Ltd.
A gyártó kódja: CN/000000053699
A meghatalmazott képviselő neve: Sungo Europe B.V.
A meghatalmazott képviselő kódja: NL/492381971
A forgalmazó neve: Biosan Egészségügyi Kereskedelmi és Szolgáltató Kft.
A forgalmazó kódja: HU/10331701-2-41

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 Pustoł

Registration or Allowed List (Partially)

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 SA.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 Nº 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 SA.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 Nº 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 Nº 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 Nº 016-2011-SA y sus modificatorias, Decreto Supremo Nº 008-2017-SA y modificatorias, Ley Nº 29459 Ley de los Productos Farmacéuticos, Dispositivos Médicos y Productos Sanitarios, Decreto Legislativo Nº 1161, Decreto Legislativo que

DIGEMID – Dirección Ejecutiva de Dispositivos Médicos – V°B° – Unidad Funcional de Dispositivos, Médicos y Productos Sanitarios

Dirección General de Medicamentos, Insumos y Drogas – V°B° DDMP

www.digemid.minsa.gob.pe
Av. Parque de las Leyendas 240
San Miguel, Perú
T(511) 631-4300

"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

Registration or Allowed List (Partially)

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
Device category	Medical Device class C/D
GMDN	N/A
GMDN Term	N/A
Intended purpose	For epidemiological COVID-19 Screening
Conditional Approval	N/A

EUA No.: MD/2021/7674

Date of Authorization: March 4, 2021