



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.**



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



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



## 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: 

Name/ Position: Mingfu Li / General Manager

Date: 11/08/2021

Place: Hangzhou, Zhejiang, China





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

Page: 1 of 1



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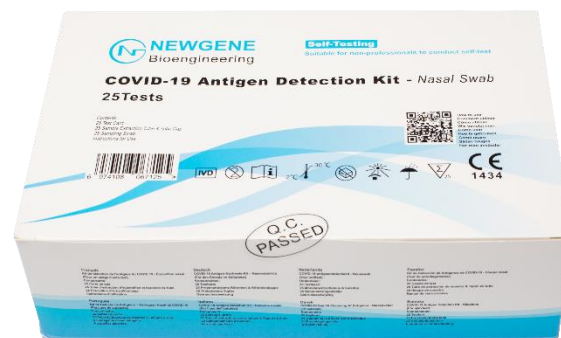
Self-Testing

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: <i>for Nasal Swab</i>	25	5	1
4	Package Insert	1	5	1

## 25 Tests/Box



## 5 Tests/Box



## 1 Test/Box





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 <sup>[2]</sup>		DE <sup>[2]</sup>		1501	16 June 2021
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## 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)<sup>1</sup>**  
**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 [Webseite Covid-19 Testung](#) dementsprechend anzuwenden. Informationen bezüglich des Einsatzes der Schnelltests finden Sie auf der BAG-Webseite Covid-19-Testung.

Les tests rapides pour auto-application sont validés pour les **prélèvements nasaux** uniquement et ne [Site internet Tests COVID-19](#) 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.

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

Hersteller Fabricant Azienda		Antigen Schnelltest Tests rapides antigéniques 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 :**

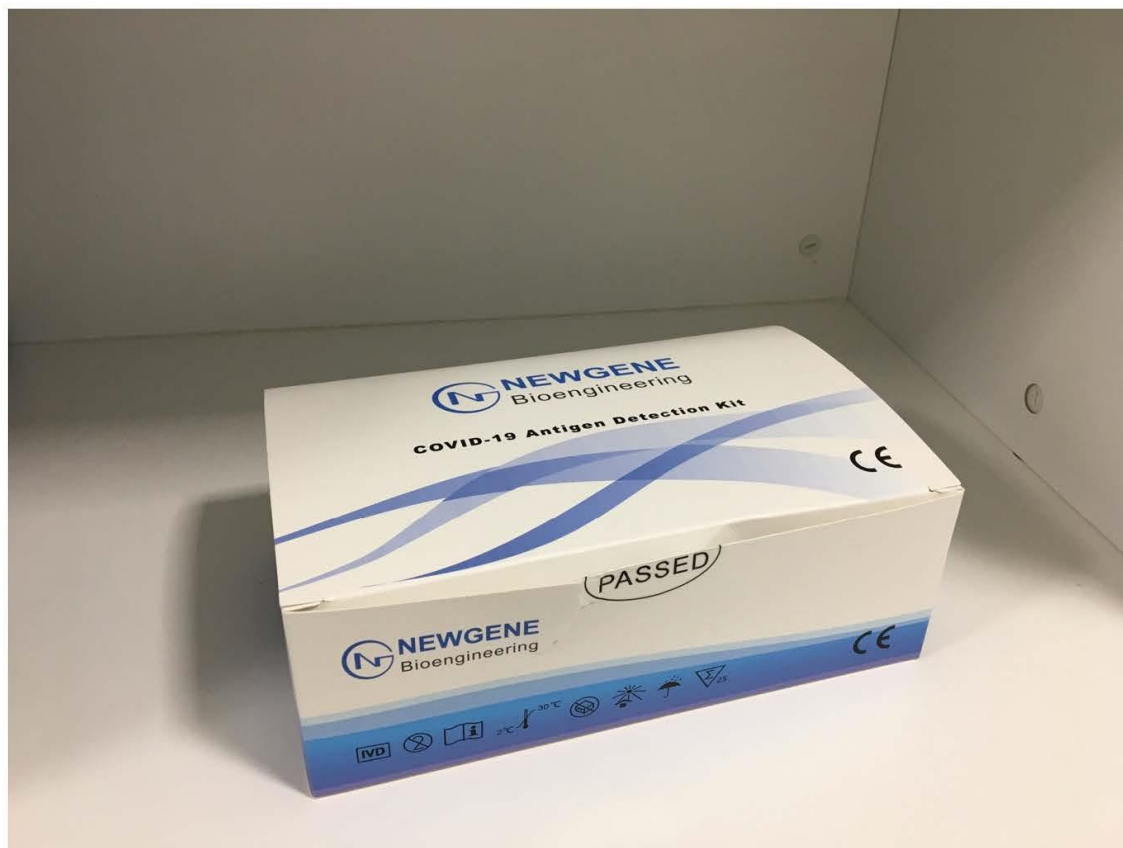
**Avvertenza importante:**

<sup>1</sup> 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 Ausnahmegewilligung 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'ordonnance 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.

## 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 18<sup>th</sup> 2021.  
Dr. G. Soldati  
CEO  
Molecular Diagnostic Laboratory  
Via Petrini 2  
CH-6900 Lugano, Switzerland



# Registration or Allowed List (Partially)

Antigen-Tests zum direkten Erregernachweis des Coronavirus SARS-CoV-2

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 Antigen-Schnelltests 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.

In Falle einer negativen Evaluierung durch das PEI streicht das BfArM den entsprechenden Test mit allen zugehörigen Vertriebern von seiner Liste.

Test-ID	Handelsname des Herstellers / Europ. Bezeichnung	Hersteller	Europäischer Bezeichnung	Sensitivität	Spezifität
AT41921	COVID-19 Antigen Detection Kit NG08 S	New Gene (Hangzhou) Bioengineering Co., Ltd.	SUNGO Europe B.V.	97,30	92,4 - 99,4
AT50221	COVID-19 Antigen Detection Kit NG08 SN	New Gene (Hangzhou) Bioengineering Co., Ltd.	SUNGO Europe B.V.	97,10	92,4 - 99,4
AT23201	COVID-19 Antigen Detection Kit NG08NS	New Gene (Hangzhou) Bioengineering Co., Ltd.	SUNGO Europe B.V.	98,00	96,3 - 99,3

## BfArM of Germany

Elenco dispositivi individuali  
Dati aggiornati al: 19/06/2021

TIPOLOGIA DEL DISPOSITIVO	IDENTIFICAZIONE DISPOSITIVO	SCRITTO AL REPERTORIO	CODICE ATTRIBUITO DAL FABBRICANTE/ASSEMBLATORE	NOBIE COMMERCIALE E MODELLO	CND	CLASSE CE	DATA PRIMA PUBBLICAZIONE	DATA FINE IMPOSIZIONE IN COMMERCIO	RUOLO AZIENDA	DENOMINAZIONE	CODICE FISCALE	PARTITA IVA/VAZ NUMBER	NADDE
Dispositivo	2038413	S	COVID-19-NG02	NOVEL CORONAVIRUS ANTIGEN DETECTION KIT (COLLOIDAL GOLD)	W101004019-CORONAVIRUS	IVD - altro tipo di IVD	12/11/2020		FABBRICANTE	NEW GENE (HANGZHOU) BIOENGINEERING CO., LTD.			CH
Dispositivo	2021549	S	COVID-19-NG02	NOVEL CORONAVIRUS ANTIGEN DETECTION KIT (MULTIPARAMETRIC POINT OF CARE- ATN)	W101004019-CORONAVIRUS	IVD - altro tipo di IVD	02/11/2020		FABBRICANTE	NEW GENE (HANGZHOU) BIOENGINEERING CO., LTD.			CH
Dispositivo	2104176	S	COVID-19-NG08	COVID-19 KIT DI RILEVAMENTO ANTIGENICO COVID-19 ANTIGEN DETECTION KIT (ELISA)	W101004019-CORONAVIRUS	IVD - altro tipo di IVD	11/05/2021		FABBRICANTE	NEW GENE (HANGZHOU) BIOENGINEERING CO., LTD.			CH
Dispositivo	2012166	N	COVID-19-NG04	NOVEL CORONAVIRUS SPIKE GLYCOPROTEIN DETECTION KIT (ELISA) RECEPTOR COMPETITIVE	W101004019-CORONAVIRUS	IVD - altro tipo di IVD	21/10/2020		FABBRICANTE	NEW GENE (HANGZHOU) BIOENGINEERING CO., LTD.			CH

## Italy

Portugal <https://www.lnfarmed.pt/web/lnfarmed/pesquisa-dispositivos>

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

## Portugal

Κοινωνία In Vitro (Ανοσοδιαγ- Γραμμάτιο - Notification of IVD (Distributor) - Products

Προϊόν	Παραγωγός (I.R.N.)	Κατ. αντιστ.	Κατηγορία	Classification	Καταλόγος προϊόντων
COVID-19 Antigen Detection Kit	New Gene (Hangzhou) Bioengineering Co., Ltd	COVID-19-NG08	Ανοσοδιαγ- Γραμμάτιο	Others	10000044031

## Greece

PLATEFORME COVID-19

Statut:  CE  CNR  HAS

Type de test: Antigénique

Sous-type de test: ---

Cibles: ---

Type prélevement: ---

Rechercher: Q 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	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Antigénique non automatisé (dont TROD)

## ANSM of France

Schweizerische Eidgenossenschaft  
Confédération suisse  
Confederazione Svizzera  
Confederaziun svizra

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

Listen der validierten SARS-CoV-2-Schnelltests  
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 Probenmaterialien validiert und nur dementsprechend anzuwenden. Informationen bezüglich des Einsatzes der Schnelltests finden Sie auf der BAG-Webseite Covid-19-Testing.  
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.  
I test 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».

[Webseite Covid-19 Testing](#)  
[Site internet Tests COVID-19](#)  
[Site web Test COVID-19](#)

Validierte SARS-CoV-2-Schnelltests nach diagnostischem Standard zur Fachwendung  
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 antigenico rapido	TestKitCode for electronic declaration	Handelsname / Nom commercial / Nome commerciale	CE	CNR	HAS
New Gene (Hangzhou) Bioengineering Co. Ltd., China	COVID-19 Antigen Detection Kit	30 (new)		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>

## Switzerland

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

## Czech

OGYÉI Országos Gyógyszerészeti és Élelmezés-egészségügyi Intézet  
Orvostechnikai Főosztály

1051 Budapest, Zrínyi úti 3.  
Levélám: 1372 Postafiók 450  
Tel: +36 1 686 9300. Fax: +36 1 686 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 pálcá	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

## Hungary