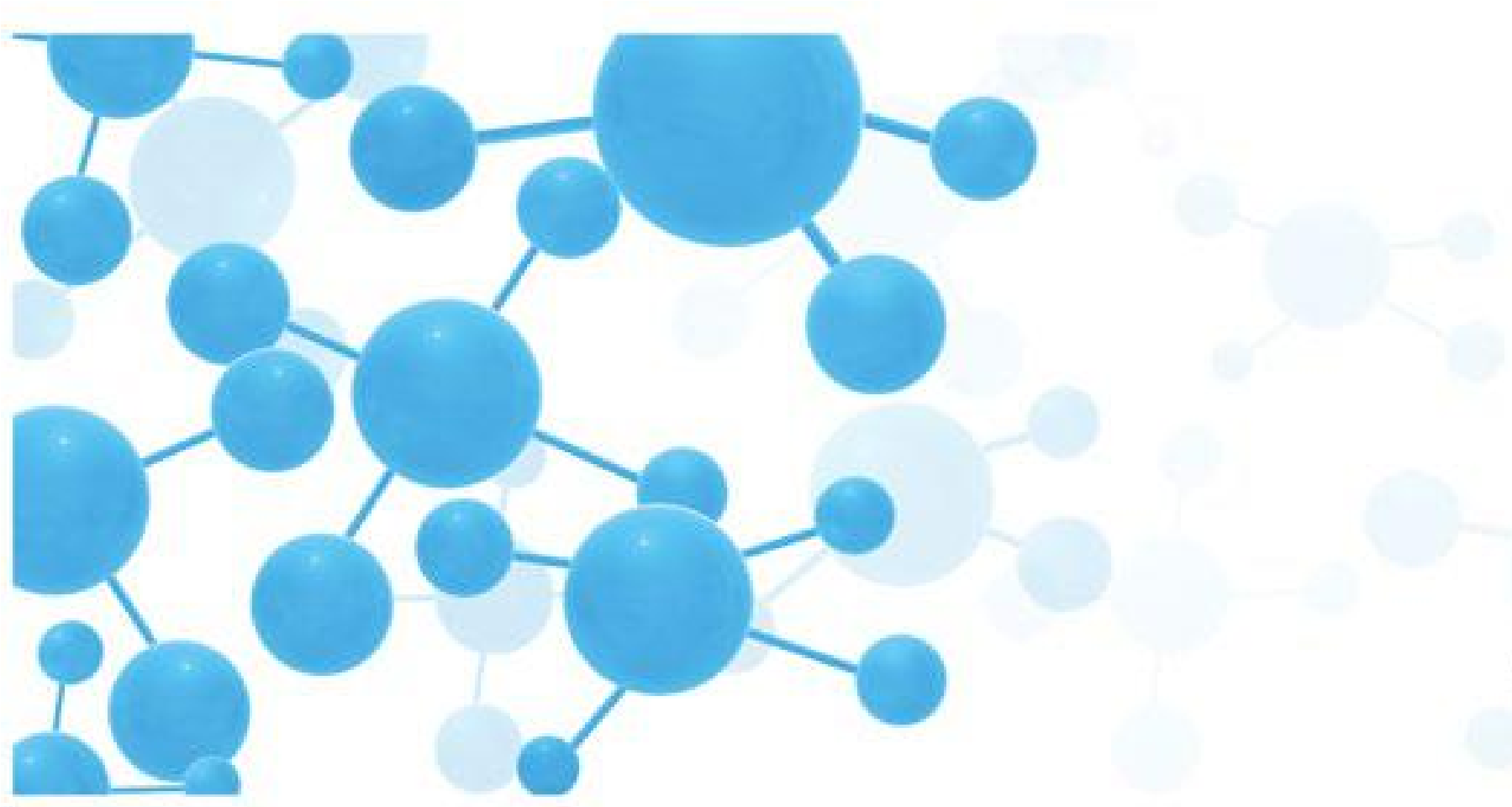
NEWGENE
Bioengineering



新冠抗原检测试剂产品（自测版）手册
Product Manual of COVID-19 Antigen Detection Kit - Nasal Swab (Self Testing)

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*** **etc.,** and passed the clinical **validation in** national lab in ***Germany, Switzerland, 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.








PRODUCT INTRODUCTION

NEWGENE Bioengineering

COVID-19 Antigen Detection Kit - Nasal Swab

N0.	Components	*5 Tests/Box*	*1Test/Box*
1	Test Card	5	1
2	Sample Extraction Tube & Tube Cap	5	1
3	Sampling Swab: *for Nasal Swab*	5	1
4	Package Insert	1	1

5 Tests/Box

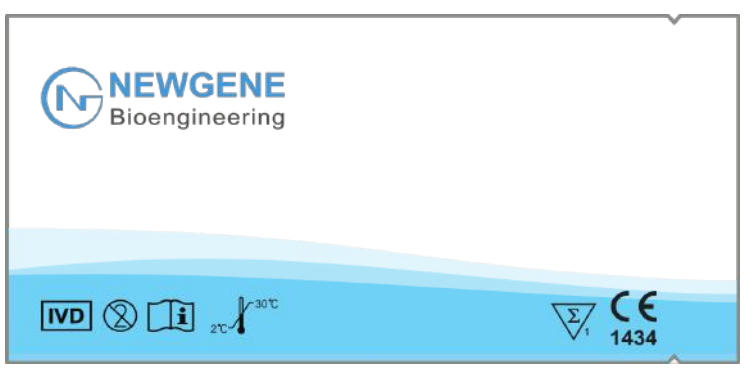
1 Test/Box

PRODUCT INTRODUCTION

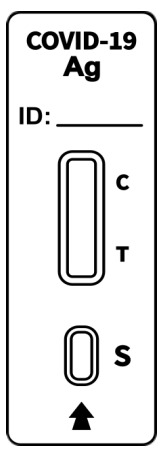
NEWGENE Bioengineering

COMPONENTS

Peel HERE



Aluminum Foil Pouch

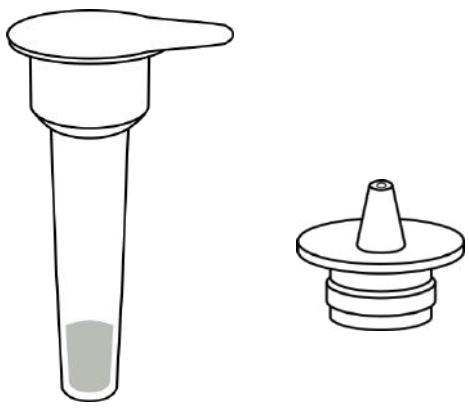


Result Window

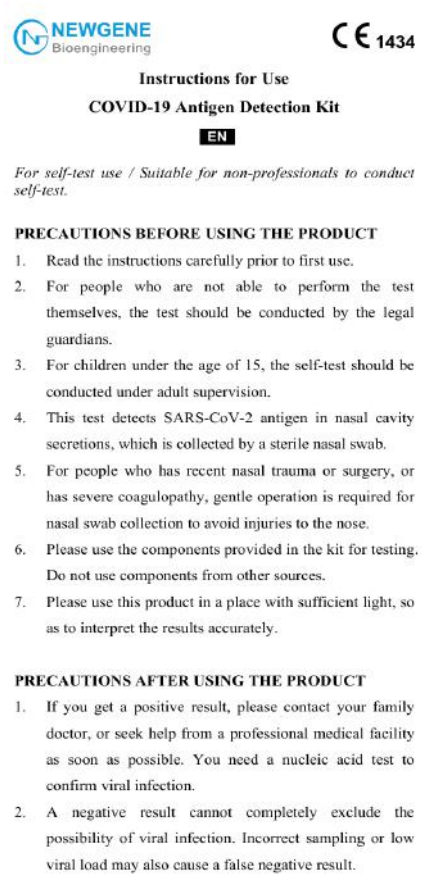
Loading Well “S”

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.

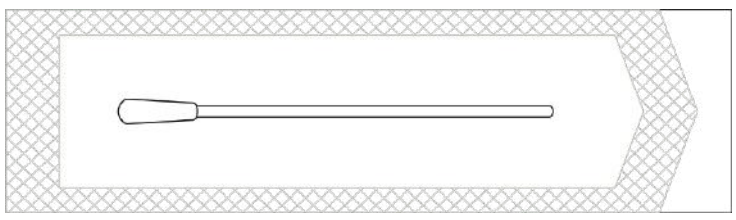
PRECAUTIONS BEFORE USING THE PRODUCT

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.

Instructions for Use



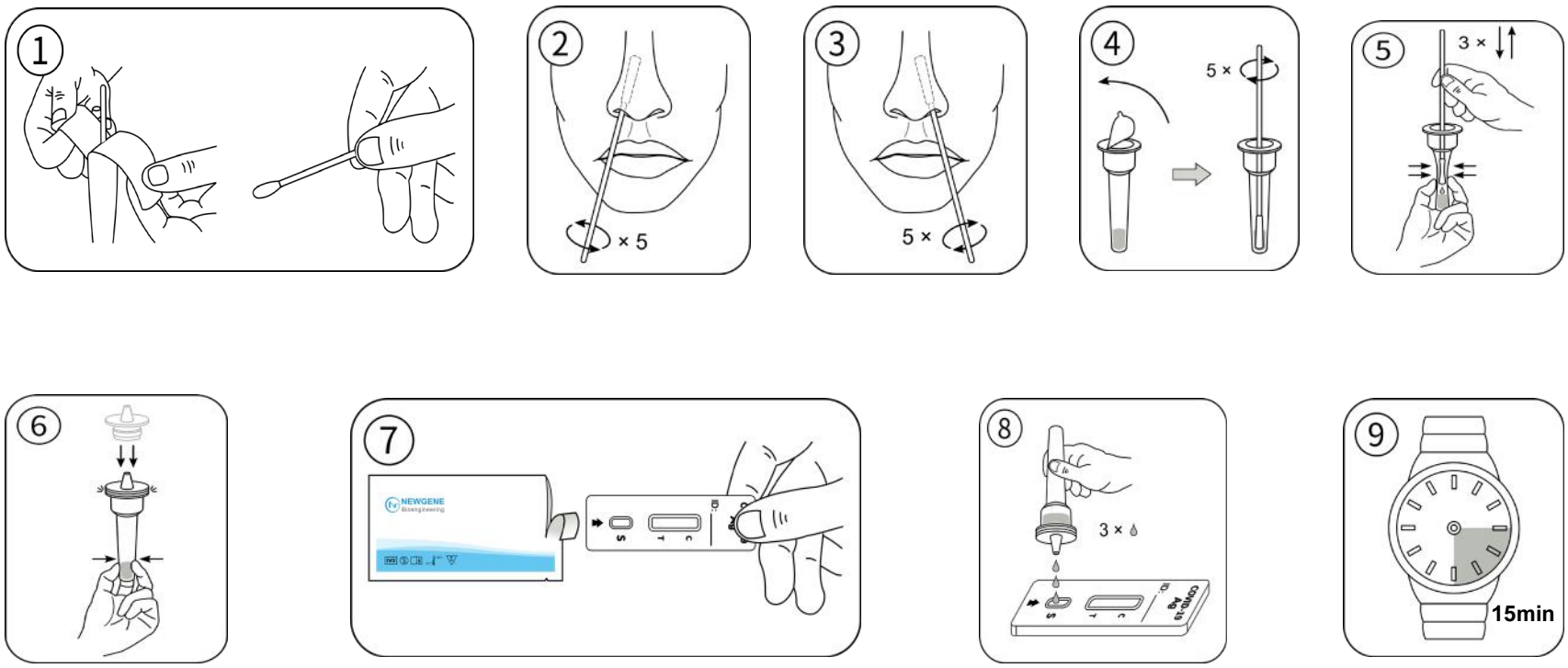
Peel **HERE**

Sampling Swab

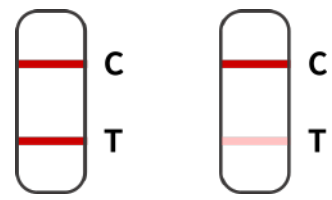
PRODUCT INTRODUCTION

NEWGENE Bioengineering

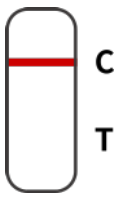
TEST PROCEDURES



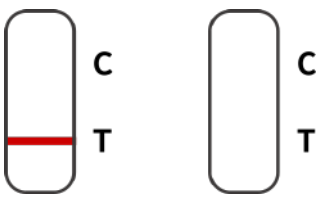
INTERPRETATION OF RESULTS



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.

PACKAGING INFORMATION

5 Tests/Box

Sample	Nasal Swab
Inner box (mm)	193*85*42
Inner box weight (kg)	0.081
Outer box (mm)	225*197*89
Outer box weight (kg)	0.5
Carton (mm)	470*410*470
Carton weight (kg)	1.3
PCS/Inner Boxes	1
Inner Boxes/Outer Box	25
PCS/Carton	500
Volume/Carton	0.09CBM
NW/Carton (kg)	10
GW/Carton (kg)	11.3

1 Test/Box

Sample	Nasal Swab
Inner box (mm)	143*83*15
Inner box weight (kg)	0.027
Outer box (mm)	305*197*88
Outer box weight (kg)	0.80
Carton (mm)	630*420*470
Carton weight (kg)	1.8
PCS/Inner Boxes	1
Inner Boxes/Outer Box	25
PCS/Carton	500
Volume/Carton	0.13CBM
NW/Carton (kg)	16
GW/Carton (kg)	17.8

CE CERTIFICATION（NOTIFIED BODY 1434）

NEWGENE Bioengineering

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 CERTIFICATION - REGISTRATION LETTER

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 – 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 CERTIFICATION

bsi.

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

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

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

Holds Certificate No: **MD 729179**

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

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

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

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

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

...making excellence a habit.™