

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

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PRODUCT INTRODUCTION

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

25 Tests/Box



5 Tests/Box

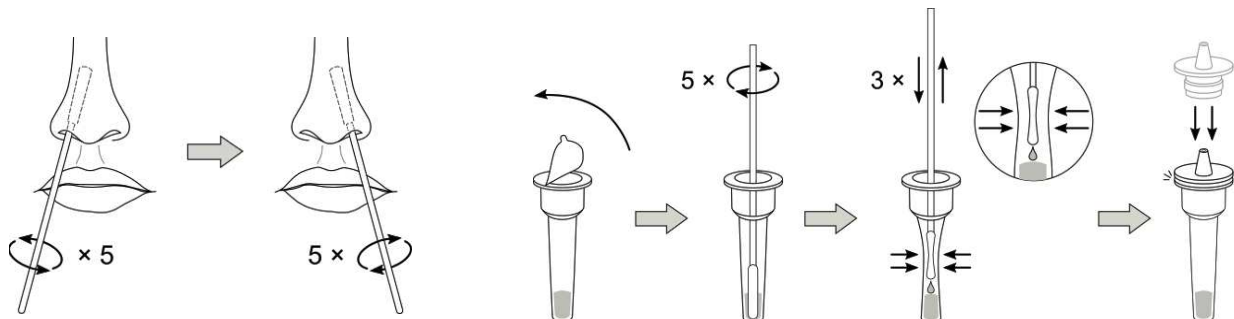


1 Test/Box

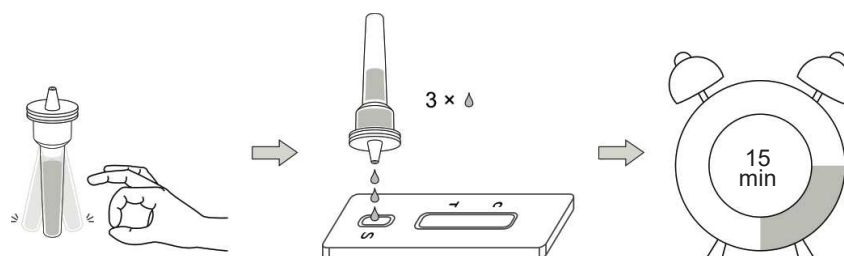


Nasal Swab

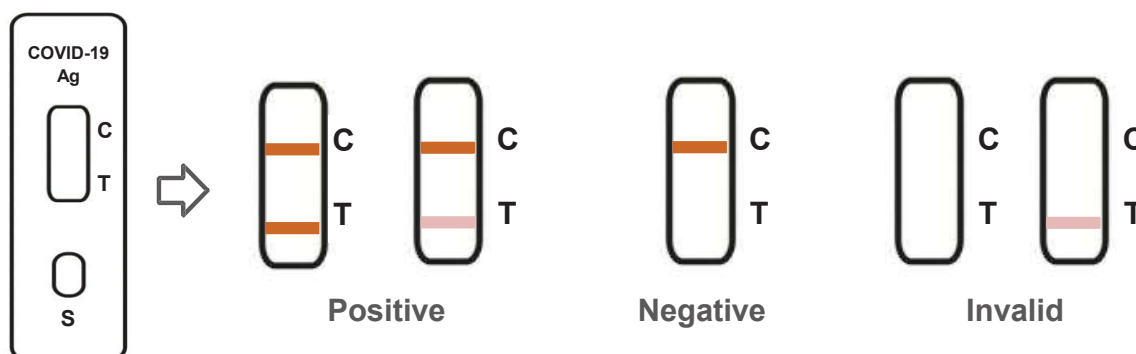
Test Procedures: Sampling



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

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

25 Tests/Box



1 Test/Box

