

SARS-CoV-2 Antigen Test kit



PRODUCT NAME

NEWGENE - COVID-19 Antigen Detection Kit

SPECIFICATION

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

Fast Detection : Results in 15 minutes

Superior Performance : High Sensitivity & Specificity

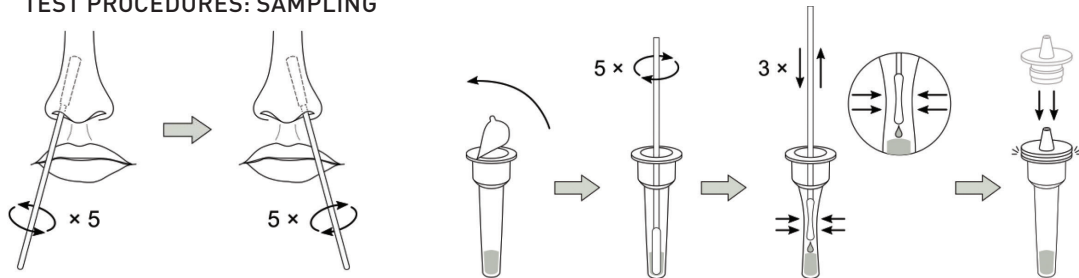
At present, NEWGENE COVID-19 Antigen Detection Kit has registered in many countries, including Germany, France, Italy, Switzerland, Belgium, Portugal, Czech, Denmark, Hungary, Greece, Poland, Moldova, Peru, Argentina, Ecuador, Kenya, Zimbabwe etc., and passed the clinical validation in national lab in 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

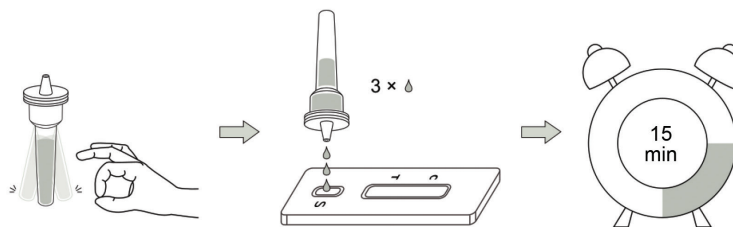
1. NASAL SWAB

Component	25 Tests/box	5 Tests/box	1 Test/box
Test Card	25	5	1
Sample Extraction Tube & Tube Cap	25	5	1
Sampling Swab: for Nasal Swab	25	5	1
Package Insert	1	1	1

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.

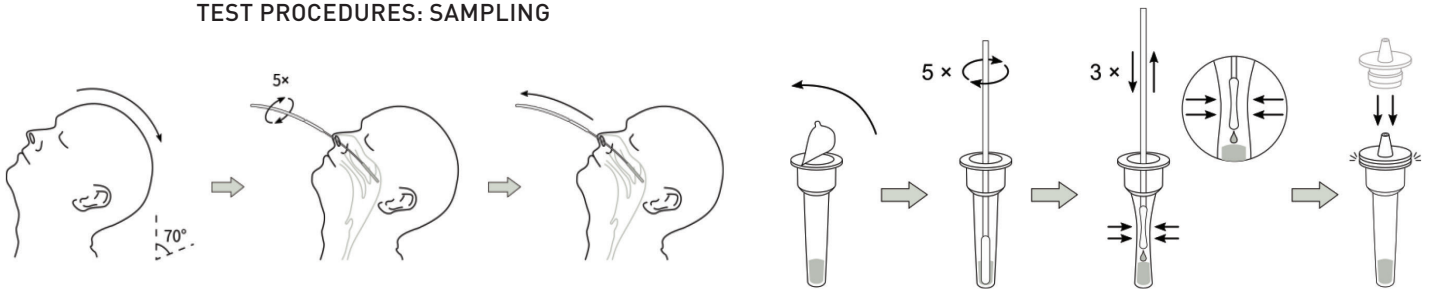
PERFORMANCE

Sensitivity	97.1%
Specificity	99.2%

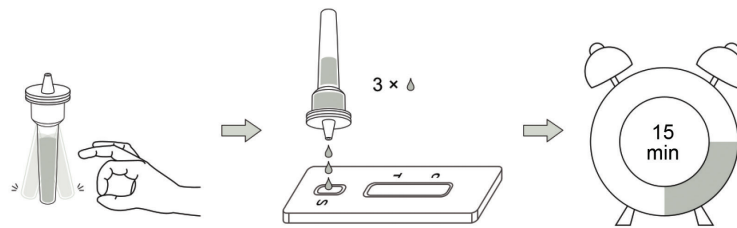
2. NASOPHARYNGEAL SWAB

Component	25 Tests/box	1 Test/box
Test Card	25	1
Sample Extraction Tube & Tube Cap	25	1
Sampling Swab: for Nasopharyngeal Swab	25	1
Package Insert	1	1

TEST PROCEDURES: SAMPLING



TEST PROCEDURES: DETECTION



INTERPRETATION OF RESULTS

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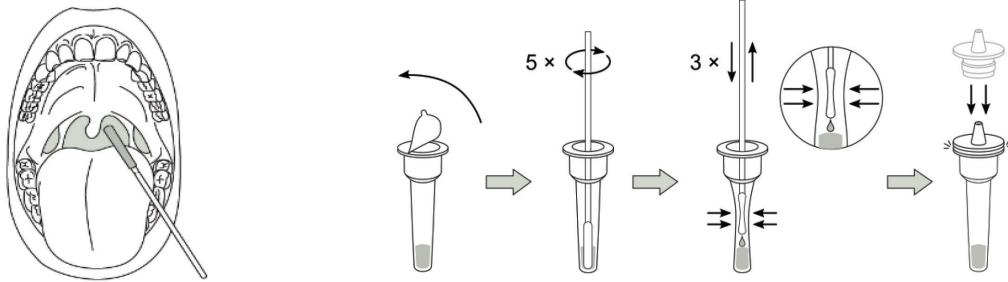
PERFORMANCE

Sensitivity	98,0%
Specificity	99,1%

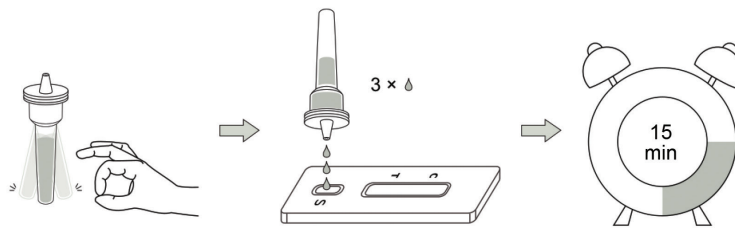
3. OROPHARYNGEAL SWAB

Component	25 Tests/box	1 Test/box
Test Card	25	1
Sample Extraction Tube & Tube Cap	25	1
Sampling Swab: for Oropharyngeal Swab	25	1
Package Insert	1	1

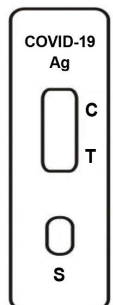
TEST PROCEDURES: SAMPLING

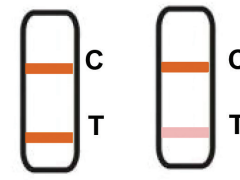


TEST PROCEDURES: DETECTION




INTERPRETATION OF RESULTS

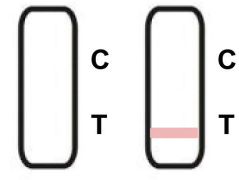




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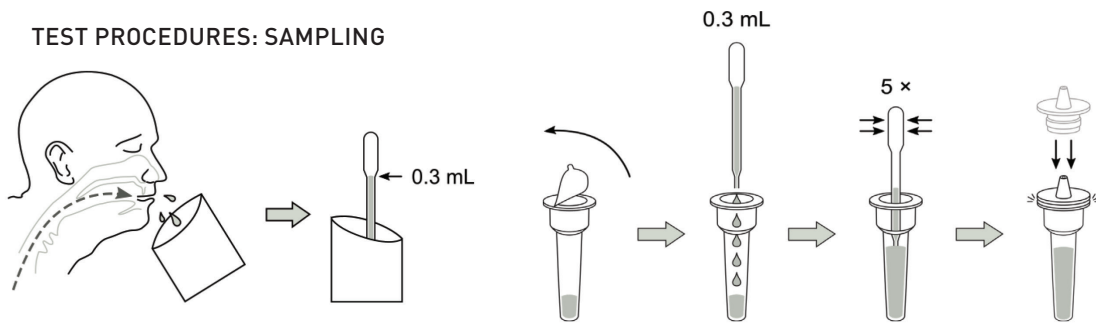
PERFORMANCE

Sensitivity	95,7%
Specificity	99,0%

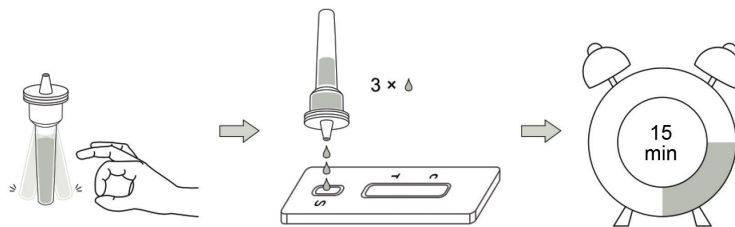
4. SPUTUM / SALIVA SAMPLE

Component	25 Tests/box	1 Test/box
Test Card	25	1
Sample Extraction Tube & Tube Cap	25	1
Paper Cup	25	1
Sputum Dropper	25	1
Package Insert	1	1

TEST PROCEDURES: SAMPLING



TEST PROCEDURES: DETECTION



INTERPRETATION OF RESULTS

COVID-19 Ag

C

T

S

Positive(+):
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PERFORMANCE

Sensitivity	97,3%
Specificity	99.2%

PACKAGING INFORMATION

Nasopharyngeal Swab: NPS
 Nasal Swab: NS
 Oropharyngeal Swab: OS
 Sputum / Saliva: S

BOXES

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



NEWGENE
 COVID-19 Antigen Detection Kit
 (Rapid Test)

CE (MD)

Low COVID-19 antigen
 Positive (H) (H)

For professional use only. Approval No. 2021/00107
 NEWGENE Bioengineering S.p.A.

INDICAZIONE
 1. Individuare il SARS-CoV-2 antigeno in 15 minuti.

CONTRAINDICAZIONE
 Non utilizzare per la diagnosi di altre infezioni virali.

CAUTELAZIONE
 Questo prodotto è destinato per l'uso professionale in laboratorio. È vietato l'uso casalingo. Leggere attentamente le avvertenze e le precauzioni riportate nel foglio illustrativo. Per informazioni rivolgersi al numero verde 800 20 20 20. Il kit non deve essere utilizzato per la diagnosi di COVID-19 in caso di sintomi sospetti.

AVVERTENZE
 Questo prodotto è destinato per l'uso professionale in laboratorio. È vietato l'uso casalingo. Leggere attentamente le avvertenze e le precauzioni riportate nel foglio illustrativo. Per informazioni rivolgersi al numero verde 800 20 20 20. Il kit non deve essere utilizzato per la diagnosi di COVID-19 in caso di sintomi sospetti.

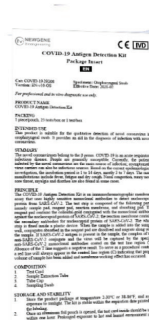
CONDIZIONI DI CONSERVAZIONE
 1. Conservare a temperatura ambiente (15°C - 30°C) e all'ombra.
 2. Evitare l'esposizione alla luce diretta del sole.
 3. Evitare l'umidità e l'umidità.

CONDIZIONI DI UTILIZZO
 1. Leggere attentamente il foglio illustrativo.
 2. Evitare l'uso casalingo.



5 TESTS/BOX

Sample	Size (mm)	NS	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



INTERPRETATION OF ICONS



Do not re-use



In vitro diagnostics
medical device



Contains sufficient
for <n>test



Manufacturer



CE mark



Keep dry



Keep away from sunlight



Store between 2-30°C



Batch code



Consult instructions
for use



Date of manufacture



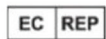
Use-by date



This way up



Do not use if packaging
is damaged



Authorized representative in the European Community

GENERAL INFORMATION



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