NEWGENE Bioengineering

CE IVD

COVID-19 Antigen Detection Kit

Package Insert

EN

Cat: COVID-19-NG08 **Specimens:** Nasal Swab
Version: EN-v13-NS **Effective Date:** 2021-03

For professional and in vitro diagnostic use only.

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 nasal swab samples. 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 infectious 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.

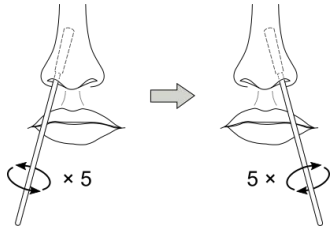
PRINCIPLE
The COVID-19 Antigen Detection Kit is an immunochromatographic membrane assay that uses highly sensitive monoclonal antibodies to detect nucleocapsid protein from SARS-CoV-2. The test strip is composed of the following parts: namely sample pad, reagent pad, reaction membrane, and absorbing 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

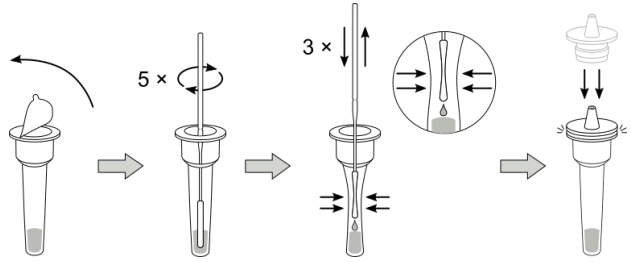
STORAGE AND STABILITY
1. Store the product package at temperature 2-30°C or 38-86°F, and avoid exposure to sunlight. The kit is stable within the expiration date printed on the label.
2. Once an aluminum foil pouch is opened, the test card inside should be used within one hour. Prolonged exposure to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

WARNINGS AND PRECAUTIONS
1. Read the instructions for use carefully before using this product.
2. This product is for professional use ONLY.
3. This product is applicable to nasal swab samples. Using other sample types may cause inaccurate or invalid test results.
4. Please make sure that a proper amount of sample is added for testing. Too much or too little sample amount may cause inaccurate results.
5. If the test line or control line is out of the test window, do not use the test card. The test result is invalid and retest the sample with another one.
6. This product is disposable. DO NOT recycle used components.
7. Dispose of used products, samples, and other consumables as medical wastes under relevant regulations.

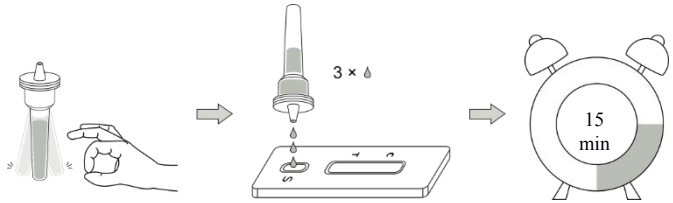
SAMPLE COLLECTION
1. Gently insert the entire absorbent tip of the sampling swab into one nostril. Do not insert the swab more than 3/4 of an inch (about 2.0 cm) into the nose. DO NOT force the swab, so as not to injure the nose.
2. Gently rub and rotate the swab in a circular path 5 times for at least 20 seconds. Gently pull out the sampling swab.
3. Using the same swab to repeat step 1 and 2 in the other nostril.



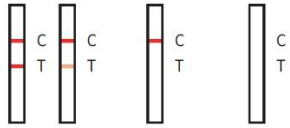
4. Peel off the aluminum foil seal from a sample extraction tube.
5. Place the swab into sample extraction tube. Use the swab to stir in the solution at least 5 times.
6. Squeeze the sample extraction tube, and move the swab up and down for at least 3 times to expel any sample solution from the swab. Discard the swab properly.
7. Insert the tube cap firmly on the sample extraction tube. Put the tube still for 1 minute to release viral antigens.



TEST PROCEDURES
Restore the test devices and specimens to room temperature (15-30°C or 59-86°F) prior to testing.
1. Flick the bottom of the tube to mix sample solution.
2. Take out a test card from an aluminum foil pouch. Place the test card on a table. Hold the tube upside down vertically. Squeeze the tube to expel 3 drops of sample solution into the loading well on a test card.
3. Read the result after 15 minutes. **The result is considered inaccurate and invalid after 30 minutes.**
   Note: DO NOT reload sample solution onto a used test card.



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.



PRODUCT PERFORMANCE
Limit of Detection (LoD): the LoD of this product is about 0.05 ng/mL SARS-CoV-2 nucleocapsid protein solution.

Sensitivity, Specificity & Total Accuracy
The product performance was evaluated with clinical specimens, taking commercial RT-PCR kit as the gold standard.

Nasal Swab		RT-PCR Positive	RT-PCR Negative	Total
COVID-19-NG08	Positive	168	2	170
	Negative	5	262	267
Total		173	264	437
		Sensitivity	**Specificity**	**Total Accuracy**
		97.1%	**99.2%**	**98.4%**
		95% CI: [93.4%-99.1%]	95% CI: [97.3%-99.9%]	95% CI: [96.7%-99.4%]

Cross-Reactivity with Other Pathogens
No cross-reactivity observed with pathogens listed below:

Species	Test Level
Staphylococcus aureus	1×10^5 CFU/mL
Streptococcus pneumoniae	1×10^5 CFU/mL
Measles virus	1×10^6 pfu/mL
Mumps virus	1×10^6 pfu/mL
Adenovirus type 3	1×10^6 pfu/mL
Mycoplasma pneumoniae	1×10^5 CFU/mL

Parainfluenza virus 2	1×10^6 pfu/mL
Metapneumovirus	1×10^6 pfu/mL
SARS-CoV	1×10^6 pfu/mL
MERS-CoV	1×10^6 pfu/mL
Human coronavirus OC43	1×10^6 pfu/mL
Human coronavirus 229E	1×10^6 pfu/mL
Human coronavirus NL63	1×10^6 pfu/mL
Human coronavirus HKU1	1×10^6 pfu/mL
Bordetella parapertussis	1×10^5 CFU/mL
Influenza B virus (Victoria Lineage)	1×10^6 pfu/mL
Influenza B virus (strain B/Yamagata/16/1988)	1×10^6 pfu/mL
2009 pandemic influenza A (H1N1) virus	1×10^6 pfu/mL
Influenza A (H3N2) virus	1×10^6 pfu/mL
Avian influenza A (H7N9) virus	1×10^6 pfu/mL
Avian influenza A (H5N1) virus	1×10^6 pfu/mL
Epstein-Barr virus	1×10^6 pfu/mL
Enterovirus CA16	1×10^6 pfu/mL
Rhinovirus	1×10^6 pfu/mL
Neisseria meningitidis	1×10^5 CFU/mL
Respiratory syncytical virus	1×10^6 pfu/mL

Interference Test

No interference observed with materials listed below:

Materials	**Test Level**
Abidol	20 μg/mL
Aluminum hydroxide	20 μg/mL
Azithromycin	20 μg/mL
Beclomethasone	20 μg/mL
Bilirubin	20 μg/mL
Budesonide	20 μg/mL
Ceftriaxone	20 μg/mL
Dexamethasone	20 μg/mL
Flunisolide	20 μg/mL
Fluticasone	20 μg/mL
Hemoglobin	20 μg/mL
Histamine hydrochloride	20 μg/mL
Levofloxacin	20 μg/mL
Lopinavir	20 μg/mL
Meropenem	20 μg/mL
Mometasone	20 μg/mL
Mucin	20 μg/mL
Oseltamivir	20 μg/mL
Oxymetazoline	20 μg/mL
Paramivir	20 μg/mL
Phenylephrine	20 μg/mL
Ribavirin	20 μg/mL
Ritonavir	20 μg/mL
Sodium bicarbonate	20 μg/mL
Sodium chloride	20 μg/mL
Tobramycin	20 μg/mL
Triamcinolone acetonide	20 μg/mL
Zanamivir	20 μg/mL
α-interferon	20 μg/mL

No interference observed with respiratory pathogens listed below:

Species	**Test Level**
Staphylococcus aureus	1×10^5 CFU/mL
Streptococcus pneumoniae	1×10^5 CFU/mL
Measles virus	1×10^6 pfu/mL
Adenovirus type 3	1×10^6 pfu/mL
Mycoplasma pneumoniae	1×10^5 CFU/mL

Parainfluenza virus 2	1×10^6 pfu/mL
Metapneumovirus	1×10^6 pfu/mL
SARS-CoV	1×10^6 pfu/mL
MERS-CoV	1×10^6 pfu/mL
Human coronavirus OC43	1×10^6 pfu/mL
Human coronavirus 229E	1×10^6 pfu/mL
Human coronavirus NL63	1×10^6 pfu/mL
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Avian influenza A (H5N1) virus	1×10^6 pfu/mL
Epstein-Barr virus	1×10^6 pfu/mL
Enterovirus CA16	1×10^6 pfu/mL
Rhinovirus	1×10^6 pfu/mL
Respiratory syncytical virus	1×10^6 pfu/mL

LIMITATIONS

1. This product is intended for assisted diagnosis of viral infections only. A final clinical diagnosis should also consider factors like symptoms, results of other tests as well.
2. A negative result indicates that the viral load in tested sample is below the limit of detection of this product. It cannot completely exclude the possibility of viral infection of patient.
3. A positive result indicates that the tested sample has viral load higher than the limit of detection of this product. However, the color intensity of test line may not correlate with the severity of infection or disease progression of the patient.

INDEX OF SYMBOLS

	Manufacturer		Date of manufacture	EC REP	Authorized representative in the European Community
	Consult instructions for use		Contains sufficient for <*n*> tests	IVD	*In vitro* diagnostic medical device
LOT	Batch Code		Use-by date	REF	Catalogue number
2°C 30°C	Store between 2-30°C		Do not re-use		Do not use if package is damaged
	Keep away from sunlight		Keep dry		

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EC REP

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