NEWGENE Bioengineering

CE IVD

COVID-19 Antigen Detection Kit

Package Insert

English

Cat: COVID-19-NG08 **Specimens:** Nasopharyngeal Swab/Sputum
Version: 06-NPS-S **Effective Date:** 2021-01

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 nasopharyngeal swab or sputum 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.

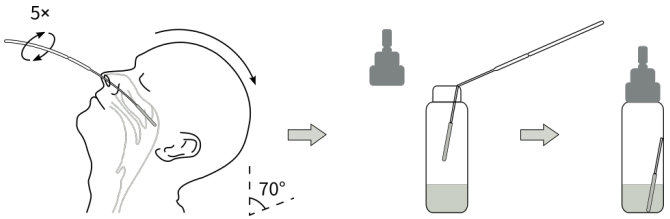
PRINCIPLE
The COVID-19 Antigen Detection Kit is an immunochromatographic membrane assay that uses highly sensitive monoclonal antibodies to detect nucleocapsid protein from SARS-CoV-2. The test strip is composed of the following parts: namely sample pad, reagent pad, reaction membrane, and absorbing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

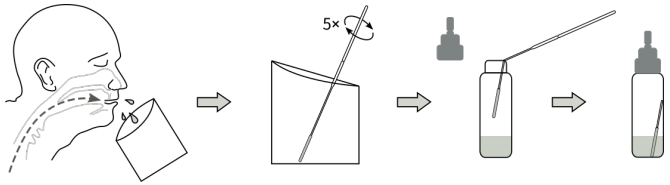
STORAGE AND STABILITY
1. Store the product package at temperature 2-30°C or 38-86°F, and avoid exposure to sunlight. The kit is stable within the expiration date printed on the labeling.
2. Once an aluminum foil pouch is opened, the test card inside should be used within one hour. Prolonged exposure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

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 nasopharyngeal swab and sputum samples. Using other sample types may cause inaccurate or invalid test results.
4. Sputum rather than saliva is the type of sample recommended by WHO. Sputum comes from the respiratory tract while saliva comes from the mouth. Testing results on saliva samples may be not as accurate as those on nasopharyngeal swab and sputum samples.
5. If sputum samples cannot be obtained from patients, nasopharyngeal swab samples should be used for testing.
6. Please make sure that a proper amount of sample is added for testing. Too much or too little sample amount may cause inaccurate results.
7. 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.
8. This product is disposable. DO NOT recycle used components.
9. Dispose of used products, samples, and other consumables as medical wastes under relevant regulations.

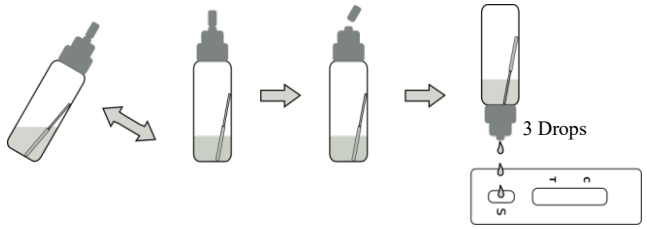
SAMPLE COLLECTION
Nasopharyngeal Swab Sample:
1. Tilt the patient's head back slightly for about 70°.
2. Gently insert a swab into a nostril straight back (not upwards), along the floor of the nasal passage until reaching the posterior wall of the nasopharynx - generally one half the distance from the corner of the nose to the front of the ear (about 4 to 6 cm or 1.6 - 2.5 inches).
   Note: Do not force swab - if an obstruction is encountered, try the other nostril.
3. Gently rub and roll the swab for 5 times, and pull out the swab slowly.
4. Open the cap of sample extraction tube, cut the swab tip and place the tip into the tube. Close the sample extraction tube and shake to mix the sample completely. Allow viral particles to release from the swab for one minute.



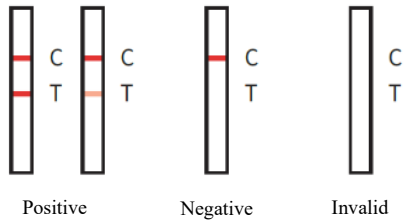
Sputum Sample:
1. Educate the patient about the difference between sputum and oral secretions (saliva).
2. Have the patient rinse the mouth with water, take a deep breath, and expectorate deep cough sputum into the paper cup or a sputum container.
3. Use the sampling swab to stir in the sputum sample for 5 times, and pick up a piece of sample (about 150 to 300 μL) with the swab.
   Note:
   1) DO NOT put the sampling swab in mouth to gather sputum, which may take insufficient sample volume.
   2) Avoid mixing saliva samples into the sputum sample. If there is a large amount of saliva, please re-take another sample.
4. Open the cap of sample extraction tube, cut the swab tip and place the tip into the tube. Close the sample extraction tube and shake to mix the sample completely. Allow viral particles to release from the swab for one minute.



TEST PROCEDURES
Restore the test devices and specimens to room temperature (15-30°C or 59-86°F) prior to testing.
1. Take out the test card from the aluminum foil pouch, place it on a table. Cut off the protrusion of the collection tube, and add 3 drops of the sample solution into the sample loading hole vertically.
2. Read the result at 15 to 30 minutes. The result is considered inaccurate and invalid after 30 minutes.



INTERPRETATION OF RESULTS
Positive(+): Both of T and C line appear in 15 to 30 minutes.
Negative(-): C line appears while no T line appears in 15 to 30 minutes after a sample is loaded.
Invalid: As long as the C line does not appear, 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, using commercial RT-PCR kit as the gold standard.

Nasopharyngeal Swab		RT-PCR Positive	RT-PCR Negative	Total
COVID-19-NG08	Positive	242	1	243
	Negative	5	113	118
Total		247	114	361
		Sensitivity	Specificity	Total Accuracy
		98.0% [95.3%-99.3%]	99.1% [95.2%-100.0%]	98.3% [96.4%-99.4%]

Sputum		RT-PCR Positive	RT-PCR Negative	Total
COVID-19-NG08	Positive	109	1	110
	Negative	3	96	99
Total		112	97	209
		Sensitivity	Specificity	Total Accuracy
		97.3% [92.4%-99.4%]	99.0% [94.4%-100.0%]	98.1% [95.2%-99.5%]

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
Human coronavirus OC43	1×10^6 pfu/mL
Human coronavirus 229E	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

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

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

	Consult instructions for use	Σ	Tests per kit	EC REP	Authorized representative in European Community
IVD	For in vitro diagnostic use only		Use by date		Do not reuse
2°C 30°C	Store between 2-30°C	LOT	Lot number	REF	Catalogue number

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EC REP
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