NEWGENE Bioengineering

CE 1434

Instructions for Use

COVID-19 Antigen Detection Kit - Nasal Swab

EN

For self-test use / Suitable for non-professionals to conduct self-test.

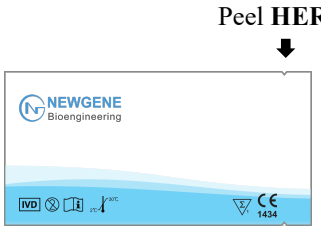
PRECAUTIONS BEFORE USING THE PRODUCT

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.

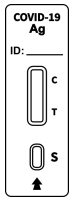
PRECAUTIONS AFTER USING THE PRODUCT

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.
3. If your nose is injured by sampling, please seek medical attention.
4. When the test is completed, please disinfect the swabs, test cards, and other used components with a household bleach spray or a 70%-75% alcohol spray.
5. Wrap the disinfected items and discard them in accordance with local regulations.
6. Wash the hands thoroughly after the test.

PRODUCT COMPONENTS



Aluminum Foil Pouch



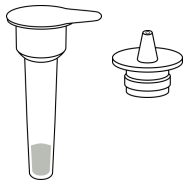
Result Window

Loading Well "S"

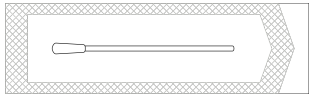
Test Card
(Packed in the pouch)

Desiccant
(Discard it.
Do not open)

Instructions for Use



Sample Extraction Tube & Tube Cap



Peel HERE

Sampling Swab

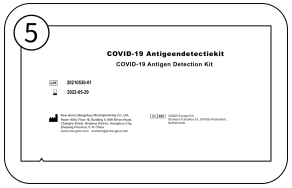
PREPARATION BEFORE THE TEST

- Put product components to room temperature (15-30°C or 59-86°F).

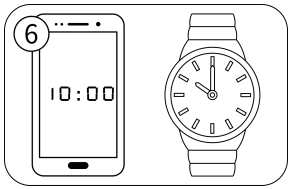
- Blow the nose to clear the nasal cavities.

- Wash hands and keep them dry.

- Read the instructions for use carefully.
- You can also scan the QR-code for operational video.



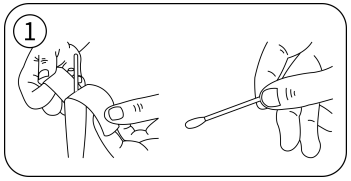
- Check the expiration date after the symbol ⌛ on the other side of aluminum foil pouch.
- **DO NOT use expired tests.**



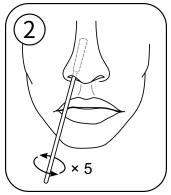
- Use your phone or watch as a timer.

- Use a household bleach spray, or a 70%-75% alcohol spray to disinfect used product components.

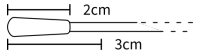
TEST PROCEDURES



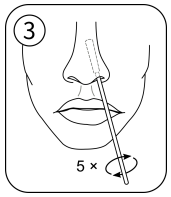
- Peel to open the package of sampling swab.
- **DO NOT touch the swab tip.**



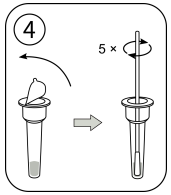
- Gently insert the swab tip 2-3cm into one nasal cavity.



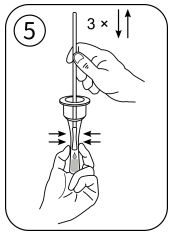
- Gently rotate the swab 5 rounds for 20 seconds to collect secretion in the nose.
- **DO NOT force the swab**, so as not to injure the nose.



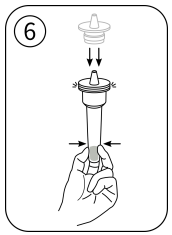
- Gently insert the same swab tip into the other nasal cavity.
- Gently rotate the swab 5 rounds for another 20 seconds



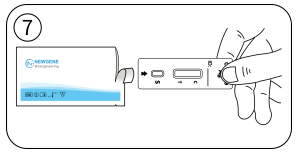
- Peel off the aluminum foil seal from a sample extraction tube.
- Place the swab into sample extraction tube. Stir the swab in the solution at least 5 rounds.



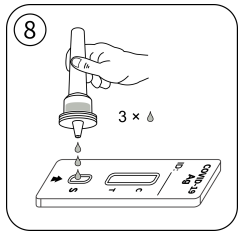
- Squeeze the tube with fingers.
- Move the swab up and down for at least 3 times to expel any sample solution from the swab.
- Take out the swab.



- Insert the tube cap firmly on the sample extraction tube.
- Gently squeeze the tube for 3 times to mix the sample solution.
- Put the tube still for 1 minute.



- Peel to open the aluminum foil pouch
- Take out the test card, and put it on a table.



- Hold the tube upside down.
- Squeeze to add 3 drops of sample solution into the loading well “S” on the test card.

- Read the result **after 15 minutes**.
- The result is considered **inaccurate and invalid after 30 minutes**.
- 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.

There is currently a suspicion of a COVID-19 infection. You are therefore encouraged to:

- Contact a doctor/general practitioner or the local health department immediately.
- Comply with local guidelines for self-isolation.
- Have a PCR confirmatory test performed.

Negative (-): A red band appears at C line while no red band appears at T line in 15 to 30 minutes after sample loading.

A negative result cannot completely exclude the possibility of viral infection. You are therefore encouraged to:

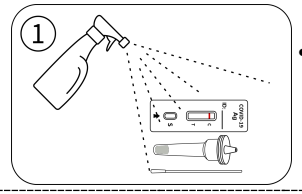
- Continue to comply with all applicable rules regarding contact with others and protective measures.
- An infection may also be present if the test is negative.
- In case of suspicion, repeat the test after 1 - 2 days because the coronavirus is not present in all phases of an infection can be precisely detected.

Invalid: If no red band appears at C line, it indicates that the test result is invalid. Retest with another test card.

If the test result is invalid:

- Possibly caused by incorrect test execution.
- Repeat the test.
- If the test results are still invalid, contact a doctor or a COVID-19 test center.

PROCEDURES AFTER RESULT INTERPRETATION



- Use a household bleach spray, or a 70% - 75% alcohol spray to disinfect used product components.

- Put used product components in a plastic bag.
- Close the bag and put it in another plastic bag. Dispose of the bag with household garbage.

- Wash the hands thoroughly.

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 most common symptoms include fever, dry cough, and tiredness. Some cases also report aches and pains, sore throat, diarrhea, conjunctivitis, headache, loss of taste or smell, a rash on skin, or discoloration of fingers or toes. The serious symptoms include difficulty breathing or shortness of breath, chest pain or pressure, loss of speech or movement. Without timely medical intervention, severe complications or even death may occur to COVID-19 cases.

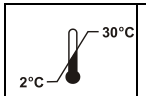
INTENDED USE

This product is suitable for people with symptoms similar to COVID-19, like cough, fever, fatigue and etc., to assist the early diagnosis of SARS-CoV-2 infection.
It can also be used to test people without COVID-19 symptoms to regularly monitor their health status.

TEST PRINCIPLE

The COVID-19 Antigen Detection Kit - Nasal Swab 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.

STORAGE AND STABILITY

	Store at 2°C to 30°C		Expire in 24 months (see package label)
	Keep away from sunlight		Keep dry
	Keep out of the reach of children		Do not use if package is damaged

WARNINGS AND PRECAUTIONS

1. People who are not able to perform the test alone should be tested by their legal guardians.
2. This product is applicable to nasal swab samples. Using other sample types may cause inaccurate or invalid test results.
3. Test within two hours after sample collection. Stale samples may cause inaccurate 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. Please wait 15 to 30 minutes after sample loading, and then read the test results. Incorrect waiting time may cause inaccurate results.
6. If the test line or control line is out of the test window, do not use the test card. The test result is invalid. Retest the sample with another test card.
7. This product is disposable. DO NOT recycle used components.
8. Disinfect used products, samples, and other consumables with a household bleach spray, or a 70% - 75% alcohol spray.
9. Wash the hands thoroughly before and after the test.

PRODUCT PERFORMANCE

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

Cross-Reactivity with Other Pathogens

No cross-reactivity observed with the following pathogens: *Staphylococcus aureus*, *Streptococcus pneumoniae*, Measles virus, Mumps virus, Adenovirus type 3, *Mycoplasma pneumoniae*, Parainfluenza virus 2, Metapneumovirus, SARS-CoV, MERS-CoV, Human coronavirus OC43, Human coronavirus 229E, Human coronavirus NL63, Human coronavirus HKU1, *Bordetella parapertussis*, Influenza B virus (Victoria Lineage), Influenza B virus (strain B/Yamagata/16/1988), 2009 pandemic influenza A (H1N1) virus, Influenza A (H3N2) virus, Avian influenza A (H7N9) virus, Avian influenza A (H5N1) virus, Epstein-Barr virus, Enterovirus CA16, Rhinovirus, *Neisseria meningitidis*, and Respiratory syncytical virus.

Interference Test

No interference observed with the following materials: Abidol, Aluminum hydroxide, Azithromycin, Beclomethasone, Bilirubin, Budesonide, Ceftriaxone, Dexamethasone, Flunisolide, Fluticasone, Hemoglobin, Histamine hydrochloride, Levofloxacin, Lopinavir, Meropenem, Mometasone, Mucin, Oseltamivir, Oxymetazoline, Paramivir, Phenylephrine, Ribavirin, Ritonavir, Sodium bicarbonate, Sodium chloride, Tobramycin, Triamcinolone acetonide, Zanamivir, α-interferon.
No interference observed with the following respiratory pathogens: *Staphylococcus aureus*, *Streptococcus pneumoniae*, Measles virus, Adenovirus type 3, *Mycoplasma pneumoniae*, Parainfluenza virus 2, Metapneumovirus, SARS-CoV, MERS-CoV, Human coronavirus OC43, Human coronavirus 229E, Human coronavirus NL63, Human coronavirus HKU1, Influenza B virus (Victoria Lineage), Influenza B virus (strain B/Yamagata/16/1988), 2009 pandemic influenza A (H1N1) virus, Influenza A (H3N2) virus, Avian influenza A (H7N9) virus, Avian influenza A (H5N1) virus, Epstein-Barr virus, Enterovirus CA16, Rhinovirus, Respiratory syncytical virus.

Sensitivity, Specificity & Total Accuracy

The product performance was evaluated with clinical specimens, using commercial RT-PCR kit as the reference method.

Nasal Swab	RT-PCR		Total
	Positive	Negative	
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%]

Generally speaking, in 100 RT-PCR confirmed virus containing samples, about 97 positive samples are also tested positive with this product. In 100 samples without virus, about 99 samples are also tested negative with this product.

LIMITATIONS

1. This product is intended for self-test diagnosis of COVID-19 only. The final diagnosis should not be determined solely on the result of a single test, but should be determined by a professional doctor after evaluating the clinical signs and the results of other examinations.
2. A negative result indicates that there is no virus in the sample, or the viral load is below the limit of detection of this product. It cannot completely exclude the possibility of viral infection of patient. Too early testing after exposure to the virus may also give a negative result. Please repeat the test after a few days if you suspect a virus infection
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.

4. Please follow the instructions strictly when storing and using the product. False negative results may also be caused by abnormal storage conditions, or incorrect sampling.
5. DO NOT use the test if the packaging is damaged. The test may have inaccurate result.
6. Samples collected from asymptomatic COVID-19 people may have false negative results, if not enough viruses are collected.
7. The amount of viral antigens in the sample will decrease with the duration of disease. Samples taken one week after symptom onset are more prone to false negative results

INDEX OF SYMBOLS

	Manufacturer		Date of manufacture
	Authorized representative in the European Community		Consult instructions for use
	Contains sufficient for <*n*> tests		*In vitro* diagnostic medical device
	Batch Code		Use-by date
	Catalogue number		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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REF: COVID-19-NG21
Specimens: Nasal Swab
Version: EN-v04-NS-HT
Effective Date: 2021-06