

COVID-19 Antigen Detection Kit

Package Insert

EN

Cat: COVID-19-NG08 **Specimens:** Nasopharyngeal Swab / Nasal Swab
Version: EN-v13-NPS-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 nasopharyngeal swab or 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
This product 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.

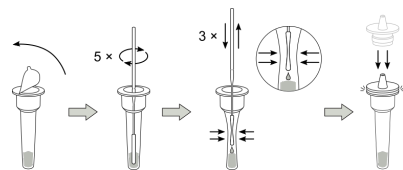
COMPOSITION
1. Test Card; 2. Sample Extraction Tube; 3. Tube Cap; 4. Sampling Swab

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 nasopharyngeal swab and 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.

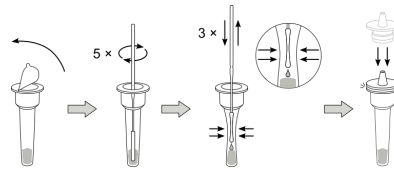
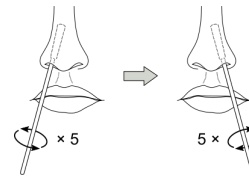
SAMPLE COLLECTION
Nasopharyngeal Swab Sample:
1. Tilt the patient's head back slightly for about 70°.
2. Gently insert the sampling swab into a nostril straight back (not upwards), along the floor of the nasal passage until reaching the posterior wall of the nasopharynx - generally one half the distance 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.
4. Slowly pull out the swab while rotating it.
5. Peel off the aluminum foil seal from a sample extraction tube.
6. Place the swab into sample extraction tube. Use the swab to stir in the solution at least 5 times.
7. 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.
8. Insert the tube cap firmly on the sample extraction tube. Put the tube still for 1 minute to release viral antigens.



Nasal Swab Sample:

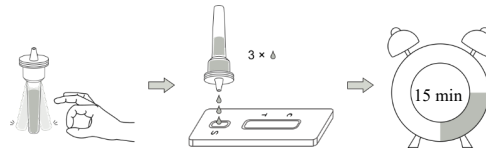
- Gently insert the entire absorbent tip of the sampling swab into one nostril. Do not insert the swab more than 3/4 of an inch (about 2.0 cm) into the nose. DO NOT force the swab, so as not to injure the nose.
- Gently rub and rotate the swab in a circular path 5 times for at least 20 seconds. Gently pull out the sampling swab.
- Using the same swab to repeat step 1 and 2 in the other nostril.
- Peel off the aluminum foil seal from a sample extraction tube.
- Place the swab into sample extraction tube. Use the swab to stir in the solution at least 5 times.
- 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.
- 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.

- Flick the bottom of the tube to mix sample solution.
- 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.
- Read the result at 15 minutes. **The result is considered inaccurate and invalid after 30 minutes.**
Note: DO NOT reload sample onto a used test card.

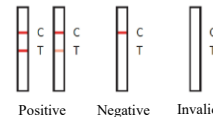


INTERPRETATION OF RESULTS

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.

Nasopharyngeal Swab	RT-PCR		
	Positive	Negative	Total
COVID-19-NG08	Positive	242	243
	Negative	5	118
Total	247	114	361
	Sensitivity	Specificity	Total Accuracy
	98.0%	99.1%	98.3%
	95% CI: [95.3%-99.3%]	95% CI: [95.2%-100.0%]	95% CI: [96.4%-99.4%]
Nasal Swab	RT-PCR		
	Positive	Negative	Total
COVID-19-NG08	Positive	168	170
	Negative	5	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
<i>Staphylococcus aureus</i>	1×10 ⁶ CFU/mL
<i>Streptococcus pneumoniae</i>	1×10 ⁶ CFU/mL
Measles virus	1×10 ⁶ pfu/mL
Mumps virus	1×10 ⁶ pfu/mL
Adenovirus type 3	1×10 ⁶ pfu/mL
<i>Mycoplasma pneumoniae</i>	1×10 ⁶ 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
<i>Bordetella parapertussis</i>	1×10 ⁶ 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
<i>Neisseria meningitidis</i>	1×10 ⁶ CFU/mL
Respiratory syncytial virus	1×10 ⁶ pfu/mL

Interference Test

No interference observed with materials listed below:
No interference observed with respiratory pathogens listed below:

Materials	Test Level	Species	Test Level
Abidol	20 μg/mL	<i>Staphylococcus aureus</i>	1×10 ⁶ CFU/mL
Aluminum hydroxide	20 μg/mL	<i>Streptococcus pneumoniae</i>	1×10 ⁶ CFU/mL
Azithromycin	20 μg/mL	Measles virus	1×10 ⁶ pfu/mL
Beclothemason	20 μg/mL	Adenovirus type 3	1×10 ⁶ pfu/mL
Bilirubin	20 μg/mL	<i>Mycoplasma pneumoniae</i>	1×10 ⁶ CFU/mL
Budesonide	20 μg/mL	Parainfluenza virus 2	1×10 ⁶ pfu/mL
Ceftriaxone	20 μg/mL	Metapneumovirus	1×10 ⁶ pfu/mL
Dexamethasone	20 μg/mL	SARS-CoV	1×10 ⁶ pfu/mL
Fluticasone	20 μg/mL	MERS-CoV	1×10 ⁶ pfu/mL
Fluimucil	20 μg/mL	Human coronavirus OC43	1×10 ⁶ pfu/mL
Fluticasone	20 μg/mL	Human coronavirus 229E	1×10 ⁶ pfu/mL
Hemoglobin	20 μg/mL	Human coronavirus NL63	1×10 ⁶ pfu/mL
Histamine hydrochloride	20 μg/mL	Human coronavirus HKU1	1×10 ⁶ pfu/mL
Levofloxacin	20 μg/mL	Influenza B virus (Victoria Lineage)	1×10 ⁶ pfu/mL
Lopinavir	20 μg/mL	Influenza B virus (strain B/Yamagata/16/1988)	1×10 ⁶ pfu/mL
Meropenem	20 μg/mL	2009 pandemic influenza A (H1N1) virus	1×10 ⁶ pfu/mL
Mometasone	20 μg/mL	Influenza A (H3N2) virus	1×10 ⁶ pfu/mL
Mucin	20 μg/mL	Influenza A (H7N9) virus	1×10 ⁶ pfu/mL
Oseltamivir	20 μg/mL	Avian influenza A (H5N1) virus	1×10 ⁶ pfu/mL
Oxymetazoline	20 μg/mL	Epstein-Barr virus	1×10 ⁶ pfu/mL
Paramivir	20 μg/mL	Enterovirus CA16	1×10 ⁶ pfu/mL
Phenylephrine	20 μg/mL	Rhinovirus	1×10 ⁶ pfu/mL
Ribavirin	20 μg/mL	Respiratory syncytial virus	1×10 ⁶ pfu/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

- 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.
- 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.
- 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		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		