

## COVID-19 Antigen Detection Kit

### Package Insert

English

**Cat:** COVID-19-NG08    **Specimens:** Sputum/Nasal Swab/Throat Swab/Stool  
**Version:** 05    **Effective Date:** 2020-12

*For professional and in vitro diagnostic use only.*

#### PRODUCT NAME

COVID-19 Antigen Detection Kit

#### PACKING

1 piece/pouch, 25 tests/box.

#### INTENDED USE

This product is suitable for the qualitative detection of novel coronavirus in sputum or nasal swab samples or throat swab samples or stool samples. It provides an aid in the diagnosis of infection with novel coronavirus.

#### SUMMARY

The novel coronaviruses belong to the  $\beta$  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. Cotton Swab
4. Paper Cup
5. Nasal Swab
6. Throat 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 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.

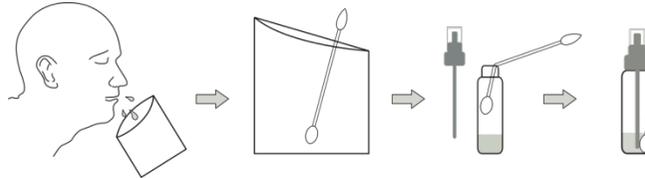
#### WARNINGS AND PRECAUTIONS

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 sputum samples, nasal swab samples, throat swab samples and stool samples. Using other sample types may cause inaccurate or invalid test results.
4. A class II bio-safety cabinet and personal protective equipment are highly recommended to process clinical sample with potential bio-hazard risks.
5. Please make sure that a proper amount of sample is added for testing. Too much or too little sample amount may cause inaccurate results.
6. For positive judgement, it can be confirmed as soon as both T and C line appear. That may take 3-15 minutes after the sample is loaded. For negative judgement, please wait for 15 minutes after sample loading. The result is invalid 30 minutes after sample loading.
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

##### Sputum Sample:

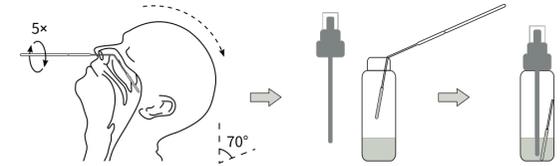
1. Spit a sputum sample into the paper cup or a sputum container. Use the cotton swab to pick up 10-50mg sputum samples (equivalent to the size of a match head).  
 Note: DO NOT put the cotton swab in mouth to collect sputum, which may take insufficient sample volume.
2. Open the cap of sample extraction tube, break the swab tip into the tube. Close the sample extraction tube and shake to mix the sample completely. Leave the swab in the extraction tube for one minute.



##### Nasal Swab Sample:

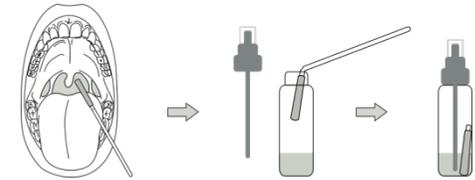
1. Tilt the patient's head back slightly for about 70°.
2. Gently insert swab into a nostril straight back (not upwards), along the floor of the nasal passage until reaching the posterior wall of the nasopharynx - generally one half the distance from the corner of the nose to the front of the ear (about 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.



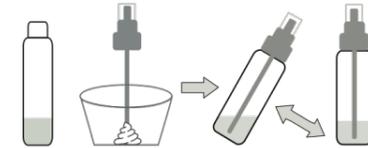
##### Throat Swab Samples:

1. Use the throat swab provided in the kit to swab over the lateral and posterior walls of pharynx, as well as the intratonsillar cleft.
2. Open the cap of sample extraction tube, break the swab tip into the tube. Close the sample extraction tube and shake to mix the sample completely. Leave the swab in the extraction tube for one minute.



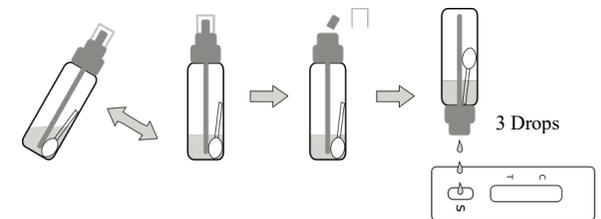
##### Stool Samples:

1. Unscrew the sampling bottle, use the sampling rod to pick up 10-50 mg of fresh stool samples (equivalent to the size of a match head).
2. Put them into the tube and shake to mix the sample completely.



#### 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.

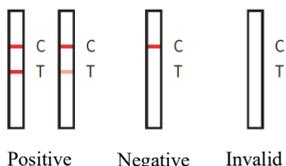
2. Read the result in 15 minutes. The result is considered inaccurate and invalid after 30 minutes.

### INTERPRETATION OF RESULTS

**Positive(+):** Both of T and C line appear in 15 minutes.

**Negative(-):** C line appears while no T line appears in 15 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.

Sputum	RT-PCR		Total	
	Positive	Negative		
COVID-19-NG08	Positive	109	1	110
	Negative	3	96	99
<b>Total</b>		112	97	209
	<b>Sensitivity</b>	<b>Specificity</b>	<b>Total Accuracy</b>	
	97.3%	99.0%	98.1%	

Nasal Swab	RT-PCR		Total	
	Positive	Negative		
COVID-19-NG08	Positive	98	1	99
	Negative	5	113	118
<b>Total</b>		103	114	217
	<b>Sensitivity</b>	<b>Specificity</b>	<b>Total Accuracy</b>	
	95.1%	99.1%	97.2%	

Throat Swab	RT-PCR		Total	
	Positive	Negative		
COVID-19-NG08	Positive	112	1	113
	Negative	5	100	105
<b>Total</b>		117	101	218
	<b>Sensitivity</b>	<b>Specificity</b>	<b>Total Accuracy</b>	
	95.7%	99.0%	97.2%	

Stool	RT-PCR		Total	
	Positive	Negative		
COVID-19-NG08	Positive	129	3	132
	Negative	5	112	117
<b>Total</b>		134	115	249
	<b>Sensitivity</b>	<b>Specificity</b>	<b>Total Accuracy</b>	
	96.3%	97.4%	96.8%	

### Cross-Reactivity with Other Pathogens

No cross-reactivity observed with pathogens listed below:

Species	Test Level
<i>Staphylococcus aureus</i>	1×10 <sup>5</sup> CFU/mL
<i>Streptococcus pneumoniae</i>	1×10 <sup>5</sup> CFU/mL
Measles virus	1×10 <sup>6</sup> pfu/mL
Mumps virus	1×10 <sup>6</sup> pfu/mL
Adenovirus type 3	1×10 <sup>6</sup> pfu/mL
<i>Mycoplasma pneumoniae</i>	1×10 <sup>5</sup> CFU/mL
Parainfluenza virus 2	1×10 <sup>6</sup> pfu/mL
Metapneumovirus	1×10 <sup>6</sup> pfu/mL
Human coronavirus OC43	1×10 <sup>6</sup> pfu/mL
Human coronavirus 229E	1×10 <sup>6</sup> pfu/mL
<i>Bordetella parapertussis</i>	1×10 <sup>5</sup> CFU/mL
Influenza B virus (Victoria Lineage)	1×10 <sup>6</sup> pfu/mL
Influenza B virus (strain B/Yamagata/16/1988)	1×10 <sup>6</sup> pfu/mL
2009 pandemic influenza A (H1N1) virus	1×10 <sup>6</sup> pfu/mL
Influenza A (H3N2) virus	1×10 <sup>6</sup> pfu/mL
Avian influenza A (H7N9) virus	1×10 <sup>6</sup> pfu/mL
Avian influenza A (H5N1) virus	1×10 <sup>6</sup> pfu/mL
Epstein-Barr virus	1×10 <sup>6</sup> pfu/mL
Enterovirus CA16	1×10 <sup>6</sup> pfu/mL
Rhinovirus	1×10 <sup>6</sup> 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 acetoneide	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

	Consult instructions for use		Tests per kit		Authorized representative
	For in vitro diagnostic use only		Use by date		Do not reuse
	Store between 2-30°C		Lot number		Catalogue number



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