

COVID-19 Neutralizing Antibody Detection Kit

Package Insert

EN

Cat: COVID-19-NG11 **Specimens:** Whole Blood/Serum/Plasma
Version: 05 **Effective Date:** 2021-06

For professional and in vitro diagnostic use only.

PRODUCT NAME

COVID-19 Neutralizing Antibody Detection Kit

PACKING

1 piece/pouch, 25 tests/box or 1 test/box

INTENDED USE

This product is intended for the qualitative detection of neutralizing antibodies for SARS-CoV-2 spike glycoproteins. The test results can help to identify individuals with an adaptive immune response to SARS-CoV-2, which is acquired from recent or prior infection or vaccination. The COVID-19 Neutralization Antibody Detection Kit should not be used to diagnose acute SARS-CoV-2 infection.

SUMMARY

The novel coronaviruses belong to the β genus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible. COVID-19 patients are the main source of infection. Asymptomatic carriers can also spread the virus to the others. 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 test strip in this kit includes a test line (T) and a control line (C). The S line is coated with anti-human IgG antibody. When a sample is loaded into the sample loading hole on Test Card, the sample moves on the Test Card under capillary effect. If SARS-CoV-2 neutralizing antibodies are present in the test sample, it will combine with the novel coronavirus conjugate to form immune complexes. The complexes will be detected by antibody coated on the T line and visualized as purple red bands. If T line doesn't appear, the test result is negative. As a product quality control, the C line should always appear at the control region indicating that proper volume of specimen has been added and the sample migration has occurred.

COMPOSITION

1. Test Card
2. Blood Sampling Needle
3. Blood Dropper
4. Buffer Bulb

STORAGE AND STABILITY

1. Store the product at temperature 2°C-30°C or 38°F-86°F, and avoid direct exposure to sunlight. The kit is stable within 2 years after production. Please refer to 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

3. cause inaccurate results.
3. The lot number and the expiration date are printed on the label.

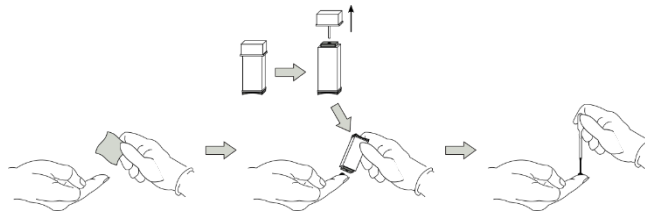
WARNINGS AND PRECAUTIONS

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 whole blood, serum, and plasma samples. Using other sample types may cause inaccurate or invalid test results. Please make sure that a proper amount of sample is added for testing. Too much or too little sample amount may cause inaccurate results.
4. For positive judgement, it can be confirmed as soon as a test line and a control line appear. That may take 3-15 minutes after a sample is loaded. For negative judgement, please wait for 15 minutes after sample loading. The result is invalid 20 minutes after sample loading.
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.

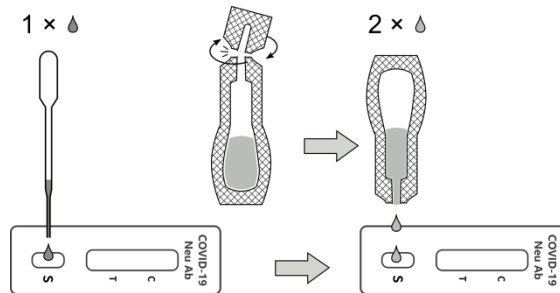
TEST PROCEDURES

Allow the test devices and specimens to restore to room temperature (15°C-30°C or 59°F-86°F) prior to testing.

1. Take out a test card from an aluminum foil pouch.
2. Disinfect the patient's finger tip with a piece of 70% alcohol wipe.
3. Open the blood sampling needle. Press the needle firmly on the finger tip until you hear a click sound. Discard the needle properly.



4. Hold the dropper vertically, transfer 1 drop of sample (about 10-20μL) into each antibody loading hole on the test card.
5. Twist to open the buffer bulb. Add 2 drops of buffer (about 70 μL) into each antibody loading hole immediately.
6. Read the result in 15 minutes. The result is considered inaccurate and invalid after 20 minutes.



INTERPRETATION OF RESULTS

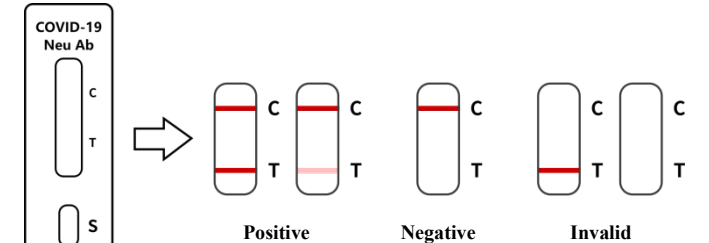
Positive (+): Red bands appear at both of C and T line in 15 to 20 minutes. A white band at the T line should be considered as a negative result.

A positive result indicates the presence of COVID-19 neutralizing antibody in tested sample.

Negative (-): A red band appears at C line while no red band appears at T line in 15 to 20 minutes after sample loading.

A negative result indicate that the tested sample doesn't contain COVID-19 neutralizing antibody, or the amount of COVID-19 neutralizing antibody is below the limit of detection of this kit.

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

Sensitivity, Specificity, & Total Accuracy

The product performance was evaluated with plasma specimens, from unvaccinated healthy donors and vaccinated donors.

Neutralizing Antibody		Vaccination		Total
		Positive	Negative	
COVID-19-NG11	Positive	120	1	121
	Negative	2	117	119
Total		122	118	240
		Sensitivity	Specificity	Total Accuracy
		98.4% [94.2%-99.8%]	99.2% [95.4%-100.0%]	98.8% [96.4%-99.7%]

Interference Test

1. No interference observed with endogenous substances tested below.

Substance	Test Level
Hemoglobin	20 mg/mL
Human serum albumin	20 mg/mL
Triglyceride	40 mg/mL
Oxalic acid	0.5 mg/mL
Bilirubin	0.5 mg/mL
Vitamin C	0.2 mg/mL

2. No interference observed with exogenous substances tested below.















Substance	Test Level
Acetaminophen	0.2 mg/mL
Acetoacetic Acid	0.2 mg/mL

Acetylsalicylic Acid	0.2 mg/mL
Benzoylcegonine	0.1 mg/mL
Caffeine	0.2 mg/mL
EDTA	0.8 mg/mL
Ethanol	1.0%
Gentisic Acid	0.2 mg/mL
β -Hydroxybutyrate	20 mg/mL
Methanol	1.0%
Phenothiazine	0.2 mg/mL
Phenylpropanolamine	0.2 mg/mL
Salicylic Acid	0.2 mg/mL

LIMITATIONS

1. This product is not intended for diagnosis of acute SARS-CoV-2 infection.
2. The level of neutralizing antibody may vary among different individuals, therefore, a negative result cannot completely exclude the possibility of recent viral infection or vaccination.
3. A positive result indicates that the tested sample has antibody level higher than the limit of detection of this product. However, the color intensity of test line may not correlate with the level of neutralizing antibodies.

INDEX OF SYMBOLS


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



New Gene (Hangzhou) Bioengineering Co., Ltd.

Room 1606, Floor 16, Building 5, 688 Bin'an Road, Changhe Street, Binjiang District, Hangzhou City, Zhejiang Province, P. R. China

SUNGO Europe B.V.

 Olympisch Stadion 24, 1076DE, Amsterdam, Netherlands