SARS-CoV-2 Neutralizing Antibody Test (Whole Blood/ Serum/ Plasma)
Package Insert
Cat.-No. 0240007

A rapid test for the qualitative detection of neutralizing antibodies to SARS-CoV-2 in whole blood, serum, or plasma.
For professional in vitro diagnostic use only.

【INTENDED USE】
The SARS-CoV-2 Neutralizing Antibody (NAb) Test (Whole Blood/Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of neutralizing antibodies to SARS-CoV-2 in human whole blood, serum, or plasma as an aid in the diagnosis of the presence of neutralizing antibodies to SARS-CoV-2.

【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 infected people can also be an infectious source. 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 found in a few cases.
The SARS-CoV-2 Neutralizing Antibody Test (Whole Blood/Serum/Plasma) is a rapid test that utilizes a combination of Spike protein antigen coated colored particles for the detection of neutralizing antibodies to SARS-CoV-2 in human whole blood, serum or plasma.

【PRINCIPLE】
The SARS-CoV-2 Neutralizing Antibody Test (Whole Blood/Serum/Plasma) is a qualitative membrane based immunoassay for the detection of neutralizing antibodies to SARS-CoV-2 in whole blood, serum or plasma. In this test procedure, neutralizing antibodies capture reagent is immobilized in the test line region of the test. After specimen is added to the specimen well of the strip, it reacts with Spike protein antigen coated particles in the test. This mixture migrates chromatographically along the length of the test and interacts with the immobilized neutralizing antibodies capture reagent. If the specimen contains neutralizing antibodies to SARS-CoV-2, a colored line will appear in the test line region, indicating a positive result. If the specimen does not contain neutralizing antibodies to SARS-CoV-2, a colored line will not appear in this region, indicating a negative result. To serve as a procedural control, a colored line will always change from Blue to Red in the control line region, indicating that membrane wicking has occurred.

【REAGENTS】
The test cassette contains to specific Spike protein antigen conjugated gold colloid particles and neutralizing antibodies capture reagent coated on the membrane.

【PRECAUTIONS】
- For professional in vitro diagnostic use only. Do not use after expiration date.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- The used tests, specimens and potentially contaminated material should be discarded according to the local regulations.
- Humidity and temperature can adversely affect results.

【STORAGE AND STABILITY】
The kit can be stored at room temperature or refrigerated (2-30°C). The test cassette is stable through the expiration date printed on the sealed pouch. The test cassette must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

【SPECIMEN COLLECTION AND PREPARATION】
- The SARS-CoV-2 Neutralizing Antibody Test (Whole Blood/Serum/Plasma) can be performed using whole blood, serum, or plasma.
- Whole blood or plasma could be collected with tube containing Heparin or Citrate.
- To collect Fingerstick Whole Blood Specimens:
- Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.
- Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
- Puncture the skin with a sterile lancet. Wipe away the first sign of blood.
- Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.
- Add the Fingerstick Whole Blood specimen to the test cassette by using a dropper, capillary or micropipette measuring 10μL. The dropper provided with the test dispenses approximately 10μL in one drop even if more blood is aspirated in the dropper or capillary.
- Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.
- Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days. For long-term storage, specimens should be kept below -20°C. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
- If specimens are to be shipped, they should be packed in compliance with federal regulations for transportation of etiologic agents.

【MATERIALS】

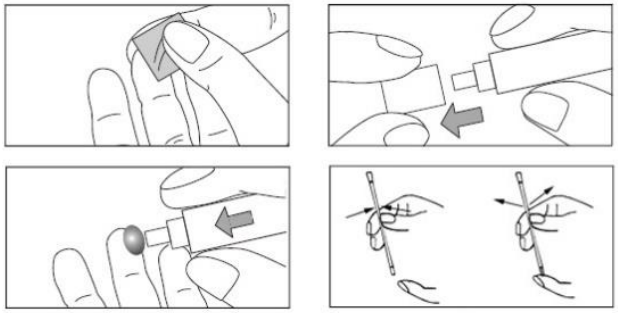
Materials provided

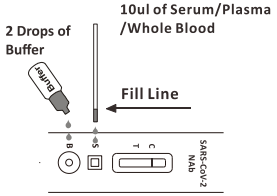
10 Test cassettes	10 capillaries (10 μl)
10 Lancets (for fingerstick whole blood only)	10 Alcohol Swabs
1 Buffer	1 Package insert

Materials required but not provided

Specimen collection containers	Centrifuge (for plasma only)
Micropipette	Timer

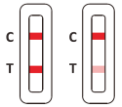
【DIRECTIONS FOR USE】
Allow the test cassette, specimen, buffer, and/or controls to reach room temperature (15-30°C) prior to testing.
Open the pouch, remove the test cassette and place it on a clean and level surface. Best results will be obtained if the assay is performed within one hour
1. Remove the buffer vial, sterile lancet and other materials. Twist off the tab of the buffer vial without squeezing. Then place it on a clean and level surface.
2. Carefully pull off the sterile lancet cap.
3. Use the provided alcohol swab to clean the puncture site.
4. Push the sterile lancet firmly onto the chosen site. Let a large drop of free-flowing blood collect at the puncture site. To increase blood flow, use the thumb and forefinger to gently apply pressure around the puncture site.
5. Add the blood specimen to the test cassette using either the disposable capillary included in the package.



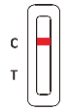


1. To use the Disposable Capillary:
   Hold the disposable dropper/capillary vertically, aspirate the blood from puncture site and draw the whole blood up to the Fill Line (approximately 10μl), and transfer the whole blood to the specimen well (S) of the test cassette, then add 2 drops of buffer (approximately 80μl) to the buffer well (B) and start the timer. Avoid touching the disposable capillary directly to the finger.
6. Wait for the colored line(s) to appear. Read results at 10 minutes. Do not interpret results after 20 minutes.

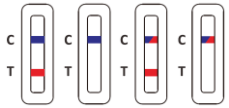
【INTERPRETATION OF RESULTS】



POSITIVE:* Two lines appear. The colored line in the control line region (C) changes from **Blue to Red**, and other colored lines should appear in test line region (T).
*NOTE: The intensity of the color in the test line region will vary depending on the concentration of neutralizing antibodies to SARS-CoV-2 in the specimen. Therefore, any shade of color in the test line region should be considered positive.



NEGATIVE: The colored line in the control line region (C) changes from **Blue to Red**. No line appears in test line region (T).



INVALID: Control line (C) is still completely or partially blue, or fails to completely change from **Blue to Red**. Insufficient buffer volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the procedure with a new test cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

【QUALITY CONTROL】
An internal procedural control is included in the test. A colored line appearing in the control line region (C) is an internal valid procedural control, it confirming adequate membrane wicking. Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

【LIMITATIONS】
1. The SARS-CoV-2 Neutralizing Antibody Test (Whole Blood/Serum/Plasma) is for in vitro diagnostic use only. The test should be used for the detection of neutralizing antibodies to SARS-CoV-2 in whole blood, serum or plasma specimens only.
2. Results from the SARS-CoV-2 Neutralizing Antibody Test (Whole Blood/Serum/Plasma) should not be used as the sole basis to diagnose or exclude the presence of neutralizing antibodies to SARS-CoV-2.
3. The continued presence or absence of neutralizing antibodies cannot be used to determine the success or failure of therapy or vaccination.
4. Results from immunosuppressed patients should be interpreted with caution.
5. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
6. This test should not be used for blood donor screening.
7. This test has not been reviewed by the FDA.

【PERFORMANCE CHARACTERISTICS】
In order to evaluate the clinical performance of SARS-CoV-2 Neutralizing Antibody Test (Whole Blood/Serum/Plasma), the comparator Microneutralization Assay (MNA) and SARS-CoV-2 Neutralizing Antibody Elisa Kit were used. The cutoff for the MNA comparator tests was established as indicated below:

Value Result (Dilution titer)	Result	Test Result Interpretation
⩾1:20	Positive	SARS-CoV-2 Neutralizing antibodies are detected at 50% viral neutralization.
＜1:20	Negative	SARS-CoV-2 Neutralizing antibodies are not detected at 50% viral neutralization.

Part 1: Clinical Performance using MNA_{50} titer as the comparator method with samples from convalescent patients, or healthy unvaccinated individuals
A total of 48 samples were retrospectively collected from convalescent patients, or healthy unvaccinated individuals (30 MNA_{50} positive and 18 MNA_{50} negative) and were evaluated with the SARS-CoV-2 Neutralizing Antibody Test.

Item		Microneutralization Assay (MNA_{50})		Total Result
SARS-CoV-2 NAB Test (Whole blood/Serum/Plasma)	Result	Positive	Negative	
	Positive	30	0	30
	Negative	0	18	18
Total Result		30	18	48

Relative Sensitivity: 30/(0+30) = >99.9% (95%*CI: 90.5%~100.0%);
Relative Specificity: 18/(18+0) = >99.9% (95%*CI: 84.7%~100.0%);
Accuracy: (30+18)/(30+0+0+18) = >99.9% (95%*CI: 93.9%~100.0%);
*CI means confidence interval.

Part 2: Clinical Performance using MNA_{50} titer as the comparator method with samples from vaccinated individuals, or healthy unvaccinated individual

A total of 44 samples were collected from vaccinated individuals (Inactivated SARS-CoV-2 Vaccine), or healthy unvaccinated individuals (26 MNA_{50} positive and 18 MNA_{50} negative) and were evaluated with the SARS-CoV-2 Neutralizing Antibody Test.

Item		Microneutralization Assay (MNA_{50})		Total Result
SARS-CoV-2 NAbTest (Whole blood/Serum/Plasma)	Result	Positive	Negative	
	Positive	26	0	26
	Negative	0	18	18
Total Result		26	18	47

Relative Sensitivity: 26/(0+26) = >99.9% (95%*CI: 89.1%~100.0%);
Relative Specificity: 18/(18+0) = >99.9% (95%*CI: 84.7%~100.0%);
Accuracy: (26+18)/(26+0+0+18) = >99.9% (95%*CI: 93.4%~100.0%);
*CI means confidence interval.

Part 3: Clinical Performance using Elisa kit as the comparator method with samples from vaccinated individuals, or healthy unvaccinated individual

A total of 60 samples were collected from vaccinated individuals (Inactivated SARS-CoV-2 Vaccine), or healthy unvaccinated individuals (30 Elisa positive and 30 Elisa negative) and were evaluated with the SARS-CoV-2 Neutralizing Antibody Test.

Item		Elisa Kit		Total Result
SARS-CoV-2 NAb Test (Whole blood/Serum/Plasma)	Result	Positive	Negative	
	Positive	30	0	30
	Negative	0	30	30
Total Result		30	30	60

Relative Sensitivity: 30/(0+30) = >99.9% (95%*CI: 90.5%~100.0%);
Relative Specificity: 30/(30+0) = >99.9% (95%*CI: 96.3%~100.0%);
Accuracy: (30+30)/(30+0+0+30) = >99.9% (95%*CI: 95.1%~100.0%);
*CI means confidence interval.

Cross-reactivity

The SARS-CoV-2 Neutralizing Antibody Test (whole blood/Serum/Plasma) has been tested for anti-influenza A virus, anti-influenza B virus, anti-RSV, anti-Adenovirus, HBsAb, anti-Syphilis, anti-H. Pylori, anti-HIV, anti-HCV and HAMA positive specimens. The results showed no cross-reactivity.

Interfering Substances

The following potentially interfering substances were added to SARS-CoV-2 neutralizing antibody negative and spiked positive specimens.

Analytes	Concentration	Result	
		Negative Specimen	Spiked with Positive Specimen
Acetaminophen	20 mg/dL	Negative	Positive
Caffeine	20 mg/dL	Negative	Positive
Albumin	2 g/dL	Negative	Positive
Acetylsalicylic Acid	20 mg/dL	Negative	Positive
Gentisic Acid	20 mg/dL	Negative	Positive
Ethanol	1%	Negative	Positive
Ascorbic Acid	2g/dL	Negative	Positive
Creatine	200mg/dl	Negative	Positive
Bilirubin	1g/dL	Negative	Positive
Hemoglobin	1000mg/dl	Negative	Positive
Oxalic Acid	60mg/dL	Negative	Positive
Uric acid	20mg/ml	Negative	Positive

None of the substances at the concentration tested interfered in the assay.

【BIBLIOGRAPHY】

1. Weiss SR, Leibowitz JL. Coronavirus pathogenesis. Adv Virus Res 2011; 81:85-164.
2. Cui J, Li F, Shi ZL. Origin and evolution of pathogenic coronaviruses. Nat Rev Microbiol 2019; 17:181-192.
3. Su S, Wong G, Shi W, et al. Epidemiology, genetic recombination, and pathogenesis of coronaviruses. TrendsMicrobiol 2016;24:490-502.

möLab GmbH
Dietrich-Bonhoeffer-Straße 9
40764 Langenfeld
Tel.: +49 2173 269900
Fax: +49 2173 2699029
info@moelab.de
www.moelab.de

CE

Index of Symbols

	Consult instructions for use	Σ	Tests per Kit		Do not use if pouch is perforated.
IVD	For In-vitro diagnostic use only		Use by		Do not re-use
0°C 30°C	Store between 2-30°C	LOT	Lot Number	REF	Catalog Number

RP5375200
Stand:2021-01-26