COVID-19 Neutralization Antibody Rapid Test Cassette (WB/S/P)

English

For professional use only.
For in vitro diagnostic use only.

[INTENDED USE]

The COVID-19 Neutralization Antibody Rapid Test Cassette is a lateral flow immunoassay designed for the qualitative detection of neutralizing antibodies to SARS-CoV-2 in human venous whole blood, serum, plasma and fingerstick whole blood.
The COVID-19 Neutralization Antibody Rapid Test Cassette is intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection. The COVID-19 Neutralization Antibody Rapid Test Cassette should not be used to diagnose acute SARS-CoV-2 infection.
At this time, it is unknown for how long antibodies persist following infection and if the presence of neutralizing antibodies confers protective immunity.
Results are for the detection of SARS CoV-2 total neutralizing antibodies. Antibodies to SARS-CoV-2 are generally detectable in blood several days after initial infection, although the duration of time neutralizing antibodies are present post-infection is not well characterized. Individuals may have detectable virus present for several weeks following seroconversion.
The sensitivity of the COVID-19 Neutralization Antibody Rapid Test Cassette early after infection is unknown. Negative results do not preclude SARS-CoV-2 infection. If infection is suspected, direct testing for SARS-CoV-2 is necessary.

[SUMMARY]

The novel coronaviruses (SARS-CoV-2) 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.

Infection with SARS-CoV-2 initiates an immune response, which includes the production of antibodies, or binding antibodies, in the blood. Not all binding antibodies can block cellular infiltration and replication of the SARS-CoV-2 virus. The subpopulation of the binding antibodies that can block cellular infiltration and replication of the virus are named neutralizing antibodies. It is unknown how long it takes for neutralizing antibodies to be produced, and if they are always produced after SARS-CoV-2 infection. While individuals infected with SARS-CoV-2 develop binding antibodies to the virus, not all of them develop neutralizing antibodies to SARS-CoV-2.

[PRINCIPLE]

The COVID-19 Neutralization Antibody Rapid Test Cassette consists of: 1) a burgundy colored conjugate pad containing recombinant SARS-CoV-2 recombinant antigens conjugated with colloid gold (SARS-CoV-2 conjugates), 2) a nitrocellulose membrane strip containing a test line and a control line (C line). The test line is pre-coated with the human ACE2 receptor protein, When an adequate volume of test specimen is dispensed into the sample well of the test cassette, the specimen migrates by capillary action across the cassette. The ACE2 receptor protein antibodies to SARS-CoV-2 S1-His fragment, if present in the specimen, will bind to all the SARS-CoV-2 S1-His fragment conjugates. Then the reagent pre-coated on the test band don't combine with the SARS-CoV-2 S1-His fragment conjugates, not forming a burgundy colored test line, indicating positive test result. To serve as a procedural control, a colored line will always appear at the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

[WARNINGS AND PRECAUTIONS]

- For *in vitro* diagnostic use only.
- For healthcare professionals and professionals at point of care sites.
- Do not use after the expiration date.
- Please read all the information in this leaflet before performing the test.
- The test cassette should remain in the sealed pouch until use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used test cassette should be discarded according to federal, state and local regulations.

[COMPOSITION]

Materials Provided

- 25 Test Cassettes: each cassette with desiccant in individual foil pouch
- 25 Buffers
- 25 Droppers
- 25 Lancets
- 25 Alcohol pads
- 1 Package Insert

Materials Required but not Provided

- Timer
- Pipette

[STORAGE AND STABILITY]

- Store as packaged in the sealed pouch at the temperature (4-30℃ or 40-86℉). The kit is stable within the expiration date printed on the labeling.
- Once open the pouch, the test should be used within one hour. Prolonged exposure to hot and humid environment will cause product deterioration.
- The LOT and the expiration date were printed on the labeling.

[SPECIMEN]

- The test can be used to test whole blood (venipuncture blood and capillary finger prick blood) /serum /plasma (EDTA, heparin, citrate) specimens.
- To collect whole blood, serum or plasma specimens following regular clinical laboratory procedures.
- Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear non-hemolyzed specimens.
- Store specimens at 2-8℃ (36-46℉) if not tested immediately. Store serum/ plasma/ anticoagulated venipuncture whole blood specimens at 2-8℃ (36-46℉) for up to 3 days. The serum/plasma specimens should be frozen at -20℃ (-4℉) for longer storage. Do not freeze whole blood specimens.
- Fingerstick whole blood should tested immediately after sampling.
- Avoid multiple freeze-thaw cycles. Prior to testing, bring frozen specimens to room temperature slowly and mix gently. Specimens containing visible particulate matter should be clarified by centrifugation before testing.
- Do not use samples demonstrating gross lipemia, gross hemolysis or turbidity in order to avoid interference on result interpretation.

[TEST PROCEDURE]

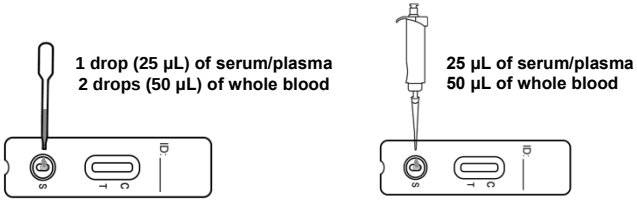
Allow the test device and specimens to equilibrate to temperature (15-30℃ or 59-86℉) prior to testing.

1. Remove the test cassette from the sealed pouch.
2. Apply the specimen to the test cassette.

For Venous whole blood, serum and plasma specimens

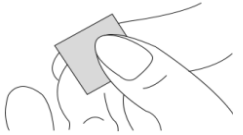
A. Hold the dropper vertically and transfer 1 drop (approx. 25 µL) of serum/plasma or 2 drops (approx. 50 µL) of whole blood into the specimen well (S) making sure that there are no air bubbles. **OR**
B. For better precision, transfer specimen by a pipette capable of delivering 25 µL of serum/plasma or 50 µL of whole blood into the specimen well (S).

A. B.

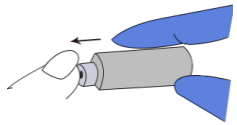


For fingerstick whole blood

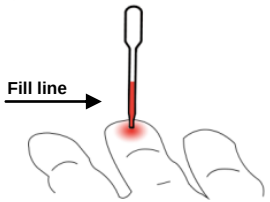
C-1. Clean the puncture site with an alcohol prep pad.



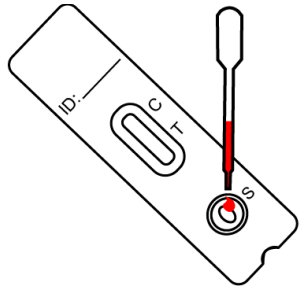
C-2. Carefully remove the cap from the safety lancet. Push the safety lancet firmly against the puncture site until it pricks the skin.



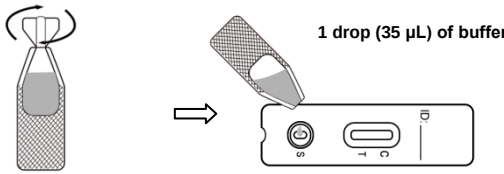
C-3. Lay the disposable dropper provided against the drop of blood until the whole blood collected is above fill line.



C-4. Add 2 drops of specimen from the dropper into the specimen well (S) making sure that there are no air bubbles.



3. Then, add 1 drop (approx. 35 µL) of buffer immediately into the specimen well (S).
4. Start the timer.
5. Wait for colored lines to appear. Interpret the test results at 15 minutes. Do not read results after 20 minutes.



(The picture is for reference only, please refer to the material object.)

[INTERPRETATION OF RESULTS]

Positive		**Only one color line appears on the control region or the test line appears but is lighter than the control line.** The lighter the T line, the higher the antibody titer.

Negative		**Two lines appear.** One colored line appears at the control region (C), and another colored line appears at the test region (T), the test line is equal to or darker than the control line.
Invalid		**Control line fails to appear.** Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test using a new test cassette. If the problem persists, discontinue using the lot immediately and contact your local distributor.

[QUALITY CONTROL]

A procedural control is included in the test. A colored line appearing in the control region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.
Control standards are not supplied with this kit. However, it is recommended that positive and negative controls be tested as good laboratory practice to confirm the test procedure and to verify proper test performance.

[LIMITATIONS]

- The COVID-19 Neutralization Antibody Rapid Test Cassette is limited to provide a qualitative detection. The intensity of the test line does not necessarily correlate to the concentration of the antibody in the blood.
- Each physician must interpret the results in conjunction with the patient's history, physical findings, and other diagnostic procedures.
- A positive result may not indicate previous SARS-CoV-2 infection. Consider other information including clinical history and local disease prevalence, in assessing the need for a second but different serology test to confirm an immune response.
- Proper sample collection is critical, and failure to follow the procedure may give inaccurate results. Improper sample collection, improper sample storage or repeated freezing and thawing of samples can lead to inaccurate results.

[PERFORMANCE CHARACTERISTICS]

Clinical Performance

Clinical study compare Plaque Reduction Neutralization Test
A study of 218 serum specimens was performed. The specimens were collected from SARS-CoV-2 RT-PCR positive and negative individuals (62 PRNT positive and 156 PRNT negative) using the COVID-19 Neutralization Antibody Rapid Test and the $PRNT_{50}$. The combined cohort consisted of samples from normal healthy people (n=156) and samples from RT-PCR confirmed SARS-CoV-2 positive patients (n=62). The COVID-19 Neutralization Antibody Rapid Test sample results were compared to a Plaque Reduction Neutralization Test performed to WHO guidelines.
The results are summarized in the following table.

COVID-19 Neutralization Antibody Rapid Test		Plaque Reduction Neutralization Test ($PRNT_{50}$)		Total
		Positive	Negative	
CLUNGENE®	Positive	60	0	60
	Negative	2	156	158
Total		62	156	218

Positive Percent Agreement (PPA): 96.8% (60/62) (95%CI: 88.98%~99.11%)
Negative Percent Agreement (NPA): 100.0% (156/156) (95%CI: 97.60% ~100.00%)

Clinical study in vaccinated individuals
The results of COVID-19 Neutralization Antibody after vaccination are summarized in the following table.

# of people vaccination	COVID-19 Neutralization Antibody Rapid Test		
	# of positive results	PPA	95% CI
26	26	100.0%	87.13%~100.00%

Limit of Detection (Analytical Sensitivity)

The study used neutralization antibody (NIBSC code: 20/136), which spiked into negative plasma specimens. The Limit of Detection (LoD) is 40 IU/mL.

Cross Reactivity (Analytical Specificity)

Cross-reactivity of COVID-19 Neutralization Antibody Test Cassette was evaluated using serum or plasma samples which contain antibodies to the pathogens listed below. No false positivity was found with the following:

Sample Category	Number of Samples	Negative	Positive
Anti-influenza A IgM	5	5	0
Anti-influenza A IgG	5	5	0
Anti-influenza B IgM	5	5	0
Anti-influenza B IgG	5	5	0
Anti-Hepatitis C Virus (HCV) IgM	5	5	0
Anti-Hepatitis C Virus (HCV) IgG	5	5	0
Anti-HBV IgG	5	5	0
Anti-HBV IgM	5	5	0
anti-Haemophilus influenzae IgG	5	5	0
anti-Haemophilus influenzae IgM	5	5	0
anti-229E IgG	5	5	0
anti-229E IgM	5	5	0
anti-NL63 IgG	5	5	0
anti-NL63 IgM	5	5	0
anti-OC43 IgG	5	5	0
anti-OC43 IgM	5	5	0
anti-HKU1 IgG	5	5	0
anti-HKU1 IgM	5	5	0
Antinuclear antibodies (ANA) ≤1:240	5	5	0
Anti-Respiratory syncytial virus (RSV) IgG	5	5	0
Anti-Respiratory syncytial virus (RSV) IgM	5	5	0
Anti-Human Immunodeficiency Virus (HIV)-1	5	5	0
Anti-HIV-2	5	5	0
Rheumatoid factor (RF) ≤825.00 IU/mL	5	5	0
Anti-Mycoplasma pneumoniae IgM	5	5	0
Anti-Chlamydia pneumoniae IgM	5	5	0
Anti-adenovirus IgM	5	5	0
Anti-Treponema pallidum	5	5	0
Anti-Cytomegalovirus IgG	5	5	0
Anti-Cytomegalovirus IgM	5	5	0

Interference

Potentially cross-reactive endogenous substances and some other common biological analytes were spiked at high concentrations into the Novel coronavirus positive and negative specimens and tested, separately. No cross reactivity or interference was observed to the device.

Analytes	Concentration	Specimens	
		Positive	Negative
Bilirubin Conjugated	10 mg/dL	+	-
Bilirubin Unconjugated	30 mg/dL	+	-
Hemoglobin	15 mg/mL	+	-
Triglycerides	1 g/dL	+	-
Albumin	20 mg/mL	+	-
Glucose	20 mg/mL	+	-
Uric Acid	200 µg/mL	+	-
EDTA	800 µg/mL	+	-
Heparin	12.5 IU/mL	+	-
Citrate	107 mmol/L	+	-
Oseltamivir phosphate	10 mg/mL	+	-
Arbidol	5 mg/mL	+	-
Zanamivir	5 mg/mL	+	-
Ribavirin	5 mg/mL	+	-
Tobramycin	5 µg/mL	+	-
Levofloxacin	200 mg/L	+	-
α-IFN	200 mg/L	+	-
Ceftriaxone	420 mg/L	+	-
Meropenem	210 mg/L	+	-

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Index of Symbol

Do not reuse	*In vitro* diagnostic medical device
Store between 4-30℃	Consult instructions for use
Lot number	Contains sufficient for <n> tests
Use by	Keep away from sunlight
Keep dry	Do not use if package is damaged
Manufacturer	Authorized representative in the European Community

Version No.: 1.0
Effective Date: May 31, 2021