[Performance Characteristics]

1. True positive rate
   Detection of 5 commercial COVID-19 neutralizing antibody positive reference materials, the true positive rate was ≥5/5.
2. True negative rate
   Detection of 20 commercial COVID-19 neutralizing antibody negative reference materials, the true negative rates was ≥20/20.
3. Minimum detection limit
   Detection of 3 commercial COVID-19 neutralizing antibody minimum detection limit reference materials. L1 is positive, L2 can be positive or negative, and L3 is negative.
4. Repeatability
   Detection of 1 commercial COVID-19 neutralizing antibody positive reference material for 10 times. COVID-19 neutralizing antibody showed 100% consistency in positive results.
5. Clinical performance

WESAIL COVID-19 Neutralizing Antibody Test Kit	Positive	Negative	Total
Positive	103	8	111
Negative	5	497	502
Total	108	505	613
Sensitivity	95.4% (103/108)		
Specificity	98.4% (497/505)		
Overall percent agreement	97.9% (600/613)		

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SYMBOL	DESCRIPTION
	Manufacturer
EC REP	Authorized representative in the European Community
IVD	*In Vitro* Diagnostic Medical Device
LOT	Batch Code
	Use-by date
	Temperature Limitation
CE	CE Mark
REF	Catalogue number
	Biological risks
	Do not re-use
	Contains Sufficient for <n> Tests
	Date of manufacture
	Keep Away From Sunlight
	Consult instructions for use
	Keep Dry

COVID-19 Neutralizing Antibody Test Kit

(For Medical Professional Use Only)

[Version No] 0000
[Issued Date] 2020-11-18
[Packaging Specifications]
1 test/kit, 20 tests/kit.

[Intended Use]

The COVID-19 Neutralizing Antibody Test Kit can be used for semi-quantitative detection of SARS-CoV-2 neutralizing antibody in human serum, plasma or whole blood samples, which assists in assessing the protective effect of the COVID-19 vaccination.

[Summary and Explanation]

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.
SARS-CoV-2 has several structural proteins including spike (S), envelope (E), membrane (M) and nucleocapsid (N). The viral Spike protein is an important receptor binding protein that is located on the surface of coronavirus. It contains a receptor binding domain (RBD), which can recognize the angiotensin converting enzyme-2 (ACE2) receptor on the surface of target cells, mediating the membrane fusion of coronavirus and cell. Those neutralizing antibodies develop either in response to natural infection or to vaccination, then subsequently bind to the virus and block infection. The interaction between the RBD of the viral spike glycoprotein and the neutralizing antibody, thereby specifically prevent cells from being infected by SARS-CoV-2. To measure a vaccine's effectiveness, it is critical to identify both the presence of these neutralizing antibodies as well as quantitatively assess the likely level needed to protect against future encounters with the virus.

[Principle]

This kit is based on the principle of lateral flow colloidal gold immunoassay and uses capture method to detect the neutralizing antibodies in the sample. If the sample contains the neutralizing antibodies, it forms a complex with the gold labeled antigen (RBD of the S1 spike antigen). The complex moves forward under the action of chromatography and reacts with the coated antibody (Mouse anti-human IgG monoclonal antibody) at the T band and develops color, indicating a positive result. If the sample does not contain the neutralizing antibody, no complex will be formed at the T band and no colored band will be shown, indicating a negative result. Regardless of whether the sample contains neutralizing antibody, the gold labeled quality control antigen on the conjugation pad will bind to the coated antibody at the C band and develop color.

[Supplied Kit Components]

Component	1 test/kit		20 tests/kit	
	Quantity	Specification	Quantity	Specification
Test Cassette	1	Individual package	20	Individual package
Sampling pipette	1	-----	21	21 tubes per bag
Diluent	1	120μL per dropper	1	2mL per bottle
Product Insert	1 Copy	-----	1 Copy	-----
Colorimetric Card	1	-----	1	-----
Lancet	1	-----	-----	-----
Alcohol Pad	1	-----	-----	-----

Note: Timer is needed but not provided. Lancets are needed but not provided in 20 tests/kit package. Various components of different batches of reagents cannot be used interchangeably in order to avoid false results.

[Warnings and Precautions]

1. This kit is for *in vitro* diagnostic use.
2. This kit is for medical professional use only.
3. Do not use cassettes which are damaged, or have an unclear label or expired.
4. Samples with invalid results must be retested.
5. The cassette is for one time use only. Used cassettes and samples should be treated as potential bio-hazardous materials.
6. Do not eat the desiccant in the foil pouch.
7. Do not reuse the used test cassette and pipette.

[Kit Storage and Product Shelf Life]

Store at room temperature (2 -30°C or 35.6-86°F) in a dry shady place. Avoid direct sunlight.
18 months of shelf life (production date to expiration date).

[Specimen Requirements]

1. Only serum, heparinized/EDTA-treated plasma or whole blood samples can be tested.
2. Samples should be collected in an approved blood collection device. Contaminated samples should not be used.
3. Samples are recommended to be tested immediately after collection, or stored at 2~8°C if not processed immediately.
4. Stability of serum/plasma samples:

Storage temperature	Shelf time
≤-20°C	1 month
2~8°C	24 hours
15~25°C	8 hours

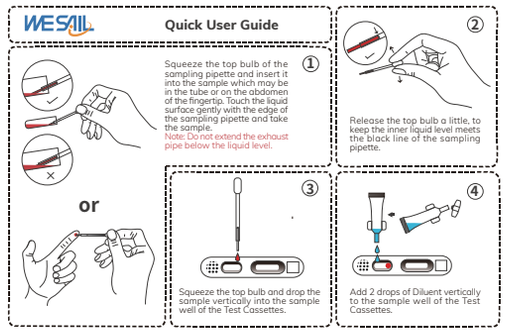
5. Whole blood samples should be tested within 4 hours at room temperature (15~25°C) or 24 hours at 2~8°C after collection. Whole blood samples should not be frozen in any case.
6. Serum/plasma samples should be tested within 8 hours at room temperature (15~25°C) or 24 hours at 2~8°C after collection. For longer storage, serum/plasma samples should be frozen at ≤-20°C and stored for no longer than 1 month.
7. Frozen samples should be warmed up to room temperature (15~25°C) before use.
8. Hemolytic or lipemic samples, or samples with high level of bilirubin should not be used.
9. Once frozen, serum/plasma samples should be thawed one time only. The samples must be mixed thoroughly after thawing, by LOW speed vortex or gently inverting, then centrifuged at ≥10,000g for at least 5 minutes to remove particulate matter prior to testing to ensure consistency of the results.

[Test Procedure]

Caution: Please read the product insert of the kit carefully.

Quick User Guide (1 test/kit)

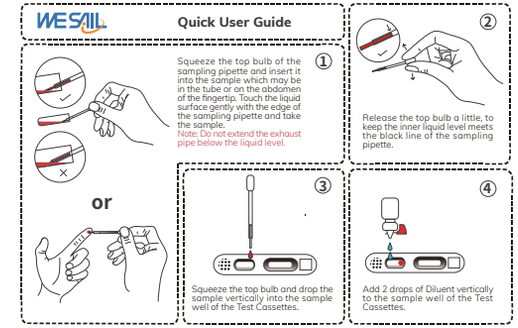
1. Equilibrate stored samples to room temperature prior to use.
2. Take out a WESAIL COVID-19 Neutralizing Antibody Test Kit cassette from the foil pouch. Take one drop (about 20μL) of serum, plasma or whole blood sample with sampling pipette and add it to the sample well.
3. Break the front end of the dropper, then add 2 drops (about 60μL) of Diluent vertically to the sample well.
4. Observe the result within 15 minutes, according to Colorimetric Card. Please do not read the result after 15 minutes.



Quick User Guide (1 test/kit)

Quick User Guide (20 tests/kit)

1. Equilibrate samples to room temperature prior to use.
2. Take out a WESAIL COVID-19 Neutralizing Antibody Test Kit cassette from the foil pouch. Take one drop (about 20μL) of serum, plasma or whole blood sample with sampling pipette and add it to the sample well, then add 2 drops (about 60μL) of Diluent vertically to the sample well.
3. Observe the result within 15 minutes, according to Colorimetric Card. Please do not read the result after 15 minutes.



Quick User Guide(20 tests/kit)

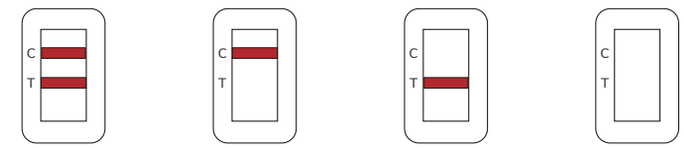
Caution: Keep the WESAIL COVID-19 Neutralizing Antibody Test Kit cassette in sealed foil pouch prior to use. The cassette should be used within 30 minutes once the foil pouch is opened. If the temperature is higher than 30°C or under conditions of high humidity, it should be used immediately after the foil pouch is opened.

[Disposal]

Disposal of bio-hazardous materials should follow the practices of your institution. Discard all materials in a safe and acceptable manner and in compliance with all federal, state, and local regulations.

[Result Interpretation]

Positive: colored bands appear at both test line (T) and control line (C). According to the color intensity of the test band (T) from faint to dark, the results can be divided into 4 levels as "+", "++", "+++", and "++++".
The test result of "+" is corresponding to "C7~C9", the test result of "++" is corresponding to "C5~C6", the test result of "+++" is corresponding to "C3~C4" and the test result of "++++" is corresponding to "C1~C2".
Negative: colored band appears at control line (C) only.
Invalid: absence of colored band at control line (C). The test procedures may not be followed correctly, or the cassette is deteriorated. It is recommended to retest the specimen.
Note: The color intensity of the test band (T) may vary according to the concentration of antibody in the sample. The lower the concentration, the weaker the intensity. The determination of a positive result should be based on the presence of the test band (T) and control band (C), regardless of whether the test band (T) is weaker than the control band (C).



[Limitations of the Procedure]

1. The test results of this product are for diagnostic aid only and cannot be used as the sole basis for confirming or excluding diagnosis. To achieve diagnostic purposes, the results should always be assessed in combination with clinical examination, medical history, and other laboratory data.
2. This product is only used for the semi-quantitative detection of neutralizing antibody in human serum, plasma, and whole blood samples.
3. This product is only intended for the initial screening test. The determination of vaccination effect should be made in conjunction with clinical observations, patient history, epidemiological information, and other laboratory evidence.
4. Subject to the limitations of the assay methodology, the questionable results should be verified with other test methodology.
5. Failure to follow the instructions for use may adversely affect test performance and/or invalidate the test result.
6. False negative results may occur if the concentration of neutralizing antibody in the sample is below the limit of detection.
7. False negative results may occur if the sample was collected at the early stage of vaccination.
8. Positive results may occur if the sample was collected from COVID-19 recovered patients without being vaccinated.