SARS-CoV-2 Neutralizing antibody Test Kit (LFIA)

INFECTIOUS DISEASE

Instructions For Use

Product Name | SARS-CoV-2 Neutralizing antibody Test Kit (LFIA)

Product Types And Specifications |

Type:Ⅰ/Ⅱ/Ⅲ Test cassette:1 pc/bag Kit:20pcs/box, 30pcs/box, 50pcs/box

Intended Use |

The SARS-CoV-2 Neutralizing antibody Test Kit(LFIA) is suitable for in vitro qualitative detection of SARS-CoV-2 neutralizing antibodies in human serum, plasma, or whole blood samples (capillary or venous) including samples prepared by commonly-used anticoagulants (K2EDTA, Na Citrate, Li-Heparin) from individuals with vaccine injection people and recovered people.Ⅱ SARS-CoV-2 Neutralizing antibody can bind to the pathogenic target proteins RBD and NTD on the surface of the virus, thereby preventing the virus from binding to cell surface receptors. The development of a vaccine depends on whether the neutralizing antibody is produced by immunization, so the detection of the neutralizing antibody is crucial to assess the effectiveness of the vaccine. SARS-CoV-2 Neutralizing antibody Test Kit(LFIA) can quickly and accurately detect neutralizing antibodies, which is of great significance for the development of COVID-19 vaccines, evaluation of effectiveness, and evaluation of neutralizing antibody levels in the population.

Summary |

With the global pandemic of the novel coronavirus disease (COVID-19), the number of infections and deaths continues to rise, and scientists from various countries are constantly looking for treatments for COVID-19. For the prevention of sudden major infectious diseases, neutralizing antibody therapy is an important strategy for effective prevention and treatment. Neutralizing antibodies are a kind of soluble protein secreted by adaptive immune response cells, it can recognize the virus surface protein and prevent it from binding to cell receptors. After the virus invades the human body, immune cells secrete neutralizing proteins into the blood. These antibodies prevent the virus from infecting cells by binding to the spike protein on the surface of the virus. Neutralizing Antibodies are expected to become a sharp edge against the novel coronavirus disease.

Test Principle |

This SARS-CoV-2 Neutralizing antibody Test Kit (LFIA) is immunochromatography based.

Type Ⅰ test cassette: 1) Colloidal gold-labeled recombinant SARS-CoV-2 protein NTD and mouse IgG; 2) One detection T line and one quality control C line fixed on a nitrocellulose membrane. T line is fixed with monoclonal mouse anti-human IgG antibody for detecting the SARS-CoV-2 Neutralizing antibody. The quality control antibody is fixed on the C line.

Type Ⅱ test cassette: 1) Colloidal gold-labeled recombinant SARS-CoV-2 protein RBD and mouse IgG; 2) One detection T line and one quality control C line fixed on a nitrocellulose membrane. T line is fixed with monoclonal mouse anti-human IgG antibody for detecting the SARS-CoV-2 Neutralizing antibody. The quality control antibody is fixed on the C line.

Type Ⅲ test cassette :1) Colloidal gold-labeled recombinant SARS-CoV-2 protein NTD and recombinant SARS-CoV-2 protein RBD and mouse IgG; 2)One detection T line and one quality control C line fixed on a nitrocellulose membrane. T line is fixed with monoclonal mouse anti-human IgG antibody for detecting the SARS-CoV-2 Neutralizing antibody. The quality control antibody is fixed on the C line.

When an appropriate amount of the sample to be tested is added to the sample well of the test cassette, the sample will move forward along the test strip under capillary action. If the sample contains neutralizing antibody, the antibody will recombine with the colloidal gold-labeled recombinant SARS-CoV-2 protein NTD/RBD. When the protein NTD/RBD is combined, the immune complex will be captured by the antibody immobilized on the membrane to form a red T line. The result is positive for the SARS-CoV-2 neutralizing antibody. If the detection T line does not show color, the result is negative.

Contents of the Kit |

One test kit contains: Test Cassettes | 1 Buffer Solution Bottle | 1 Package Insert

Type Ⅰ test cassette contains:
- A test strip in a plastic cassette
- Dried reagents with stabilizers
- Colloidal gold-labeled recombinant SARS-CoV-2 protein NTD
- Colloidal gold-labeled mouse IgG
- Goat anti-mouse polyclonal antibody
- Mouse anti-human IgG monoclonal antibody

Type Ⅱ test cassette contains:
- A test strip in a plastic cassette
- Dried reagents with stabilizers
- Colloidal gold-labeled recombinant SARS-CoV-2 protein RBD
- Colloidal gold-labeled mouse IgG
- Goat anti-mouse IgG polyclonal antibody
- Mouse anti-human IgG monoclonal antibody

Type Ⅲ test cassette contains:
- A test strip in a plastic cassette
- Dried reagents with stabilizers
- Colloidal gold-labeled recombinant SARS-CoV-2 protein NTD
- Colloidal gold-labeled recombinant SARS-CoV-2 protein RBD
- Colloidal gold-labeled mouse IgG
- Goat anti-mouse polyclonal antibody
- Mouse anti-human IgG monoclonal antibody

Warnings and Precautions |

- For human in vitro clinical diagnostics only.
- The product should only be used by healthcare professionals or trained technicians.
- After opening the sealed cassette pouch the test should be used within one hour.
- Do not immerse test cassette in water
- Do not freeze test cassette or buffer solution.
- Handle specimens in accordance to the OSHA Standard on Bloodborne Pathogens.
- Wear protective gloves, clothing, and eyewear.
- Wash hands thoroughly after handling specimens.
- Dispose of all used or damaged test cassettes, buffer solution bottle or other kit components as biohazardous materials.
- Do not use test cassette, buffer solution, or any other kit components if the pouch is damaged or the seal is broken.
- Do not use samples containing lipids, hemolysis, or turbidity which can affect results.
- This package insert must be read completely before performing the test. Failure to follow directions in package insert may yield inaccurate test results.
- Test results should be read between 15 and 20 minutes after a specimen is applied to the sample well. Results read after 20 minutes may give erroneous results.
- Do not use test cassette, buffer solution, or any kit component beyond the indicated expiration date.
- Bring all reagents to room temperature before use.

Storage Instructions |

The test kit should be stored away from direct sunlight at 2°C to 30°C with a shelf-life of 24 months. Do not freeze.

Sample Requirements |

- Suitable for human serum, plasma, or whole blood samples (capillary or venous) including samples prepared by commonly-used anticoagulants (K2EDTA, NaCitrate, Li- Heparin).
- Fresh samples should be collected and tested without inactivation.
- Not for use with heat inactivated or other inactivated human specimen (blood, serum, plasma).
- Serum and plasma samples can be stored at 2°C–8°C for 5 days. If long-term storage of serum or plasma samples is required, store at –20°C and avoid repeated freeze/thaw cycles.
- Anticoagulated whole blood samples can be stored at 2°C–8°C for 5 days.
- Before testing, samples stored in refrigerated or frozen storage should be slowly returned to room temperature and stirred. When particulates are clearly visible in the sample the precipitate should be removed by centrifugation before testing.

Test procedure |

Do not open pouch until ready to use. Prep necessary materials:

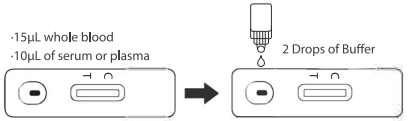
Test cassette | Buffer solution | Sampling Device | Timer | Any necessary personal protective equipment.

1. Obtain a specimen using standard laboratory or provider protocols. Using appropriate sampling device, obtain 15μL of fingerstick or venous whole blood specimen, or 10μL of serum or plasma using appropriate device.
- For intravenous sampling follow standard laboratory protocols.

2.Dispense the specimen into the Test Cassette sample well.
- Ensure that the entire collected sample is dispensed into the sample well.

3.Remove colored cap of the Buffer Solution bottle and dispense 2 drops into the Test Cassette sample well.
- Remove any air bubbles in the dropper• Test on a level surface at room temperature.

4.Allow test to run for 15 minutes. Read the results by viewing the detection window.
- Test results that have been run over 20 minutes are invalid.



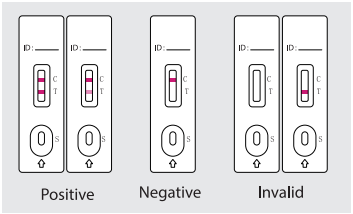
Test Method Limitations |

- This product is only used to detect the neutralizing antibodies of the SARS-CoV-2 in human blood, and cannot be used to detect other body fluids.
- This product is for qualitative testing only.
- Negative results may be caused by the low concentration of the SARS-CoV-2 neutralizing antibodies in the sample, and the possibility of neutralizing antibody cannot be completely ruled out.
- This test result is for clinical reference only, not the only basis for diagnosis, it needs to be combined with clinical and other test methods. The test results are combined with clinical and other inspection

results for comprehensive analysis and judgment.

• Interference factors: when the RF concentration in the sample is No more than 200IU/mL, the HAMA concentration No more than 200ng/mL, and the hemoglobin concentration No more than 5g/L,the interference factors would not affect to this method. When the above substances are higher than the above concentrations, the accuracy of the results may be affected. In this case, this method is not applicable.

Display of Results/Expected Values



1. Negative result: If only the quality control C line appears and the detection T line does not show color, it means that the SARS-CoV-2 neutralizing antibody has not been detected and the result is negative.
2. Positive result: If both the quality control C line and the detection T line appear, it means that the SARS-CoV-2 neutralizing antibody has been detected, and the result is positive for neutralizing antibody.
3. Invalid result: If the quality control C line cannot be observed, the result is invalid regardless of whether there is a detection line display, and the test should be repeated.

Internal Quality Control Procedure

Each Test Cassette has a built-in control. A red colored line in the detection window at the Control line can be considered an internal positive procedural control. The Control line will appear if the test procedure has been correctly performed. If the Control line does not appear; the test is invalid and a new test must be performed. If the problem persists, please contact your local vendor or Medomics for technical support.

Performance Characteristics

Clinical Agreement Validation Study | The performance of the SARS-CoV-2 Neutralizing antibody Test Kit (LFIA) was established with 135 neutralization test positive samples and 200 neutralization test negative samples.The result of the SARS-CoV-2 Neutralizing antibody Test Kit (LFIA) for 199 negative samples and 133 positive samples were consistent with neutralization test.

Testing was performed using one lot of the SARS-CoV-2 Neutralizing antibody Test Kit (LFIA). Confidence intervals for SARS-CoV-2 displayed a sensitivity of 98.52% (94.75%～99.82%) and a specificity of 99.50% (97.25%～99.99%).

Table 1: Summary Results

Neutralizing antibody test result	Neutralization test result		Total
	Positive	Negative	
Positive	133	1	134
Negative	2	199	201
Total	135	200	335

Table 2: Summary Statistics

Measure	Estimate	95% Confidence Interval
Sensitivity	98.52%	(94.75% ～99. 82 %)
Specificity	99.50%	(97.25% ～99.99%)
PPV	99.25%	(95.91% ～99.98%)
NPV	99.00%	(96.45 % ～99. 88 %)
Accuracy	99.10%	(97. 41 % ～99. 82 %)

Cross reactivity

Cross-reactivity of the SARS-CoV-2 Neutralizing antibody Test Kit (LFIA) was evaluated using specimens containing the antibodies and virus listed below.the results showed no cross reactivity with the following:

Endemic human coronavirus	H1N1	H3N2
H7N9	InfluenzaB	Rhinovir us/Enterovirus
Adenovirus	Respiratory tract syncytial virus	Human metapneumonia virus
Hepatitis B	Hepatitis C	HIV
Haemophilus influenza	Antinuclear antibody	Parainfluenza Virus 3

Interference

The test result of the SARS-CoV-2 Neutralizing antibody Test Kit (LFIA) are not be interfered with the substance at the following concentration.

Substannce	Concentration
RF	200 IU/m L
HAMA	200 ng/mL
Hemoglobin	100 g/L
Triglyceride	20 mM
Bilirubin	27 nmol/L
Serum albumin	180 g/L
Human IgG	90 g/L
Human IgM	4 g/L
Plasma cholesterol	2.5 g/L

External Quality Control Procedure

• Good laboratory practice recommends the use of external positive and negative controls to ensure the function of the test reagents and to evaluate the user ability to properly perform a test. It is recommended that external controls be performed with each new lot or shipment. If the controls do not perform as expected, review the instructions and repeat the test. Consult the laboratory director before performing patient tests and reporting results.

• Test performance can be evaluated using the SARS-CoV-2 Neutralizing antibody control available from Medomics. Follow instructions included in the kit for preparation, use, storage, and determination of appropriate values. Frequency of external control testing should be determined by your laboratory director and according to your laboratory standard quality control protocols. Upon confirmation of the expected results, the test is ready to use with vaccine injection populations and recovered populations.

• The use of negative and positive controls from other commercial kits has not been established.

Explanation of Symbols

Do Not Re-use

Keep away from sunlight

Do not use if package is damaged

Keep dry

Consult instructions for use

IVD — In Vitro Diagnostic Medical Device

CE Marked Device

REF — Catalogue Number

EC REP — Authorized representative in the European Community

LOT — Batch code

Date of manufacture

Manufacturer

Temperature Limit

Use-by date

Buffer Solution

Contains sufficient for <n> tests

Fragile, handle with care

This way up

Stacking Limit By number

EC REP

R Sight B.V.
Roald dahllaan 47,5629 MC,
Eindhoven. The Netherlands
Registration Number: 76704726
Tel: 0031640845545
E-mail: info@rsight.nl

Jiangsu Medomics Medical Technology Co.,Ltd.
F3,Building C,No.3-1 XinjinhuRoad,Jiangbei New Area, Nanjing,Jiangsu,China.
Tel: (+86)025-58601060/ (+86)025-58601213
Fax: 025-58601060
mail: info@medomics-dx.com.

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