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:V Test cassette:1 pc/bag
Kit:1 pc/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, Heparin) from individuals with vaccinated people and recovered people.

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. 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.

Test Principle |

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

1 Test Cassette | 1 Individual Buffer Solution | 1 Instructions for use | 2 Alcohol Pads | 1 Disposable Lancet | 1 Capillary Tube

Type V 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 |

- This test kit is used for individuals 14 years and older.
- This test kid is used for in vitro diagnostics only.
- This test kit is for professional, non-laboratory, and at-home use.
- This test kit should be used within 1 hour after opening the package, and samples from transport media will reduce sensitivity. The test cassette should not be used if being wet or polluted.
- Proper protection should be taken during testing to avoid splashing when adding sample.
- Dispose of all used or damaged test cassettes, lancet, capillary tube or other kit components as biohazardous materials.
- Handle specimens in accordance to the OSHA Standard on Bloodborne Pathogens.
- Wash hands thoroughly after handling specimens.
- 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.
- Not for use with heat inactivated or other inactivated human specimen (blood, serum, plasma).
- This package insert must be read completely before performing the test. Failure to follow directions in 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 components beyond the indicated expiration date.
- Bring all reagents to room temperature before use.

Storage Instructions |

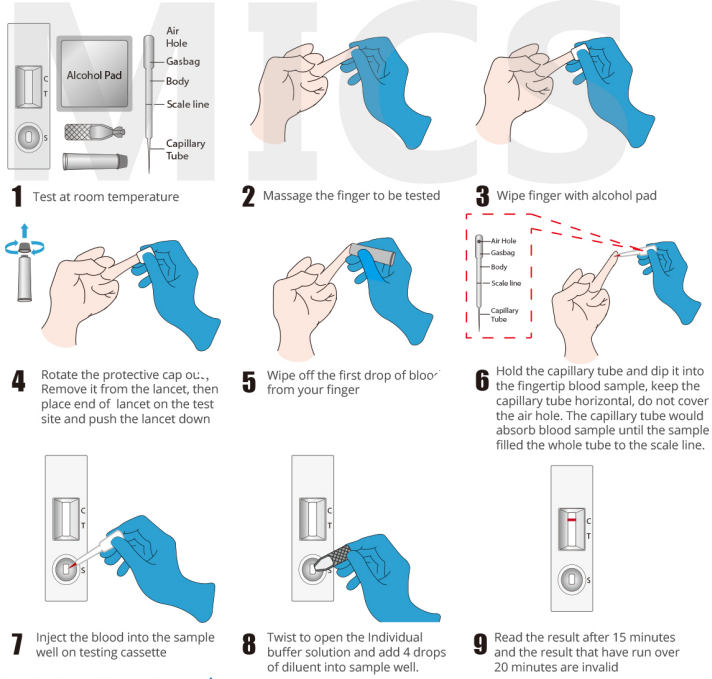
The test kit should be stored away from direct sunlight at 2℃ to 30℃ with a shelf-life of 24 months. Do not freeze.

Sample Requirements |

- Suitable for human serum, plasma, or whole blood samples (capillary or venous) including samples prepared by commonly-used anticoagulants (EDTA, Na Citrate, 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).
- The test should be performed using fresh serum, plasma and blood samples.

Test procedure |

Do not open pouch until ready to use.
Wash your hands thoroughly with soap and water, dry your hands before performing the test. Massage the selected fingertip to be tested, then clean the fingertip with alcohol pad provided in the kit.Remove the protective cap from the lancet, then place end of lancet on the test site and push the lancet down. Wipe off the first drop of blood from your finger using the same alcohol pad. Hold the capillary tube and dip it into the fingertip blood sample, keep the capillary tube horizontal, do not cover the air hole. The capillary tube would absorb blood sample until the sample filled the whole tube to the scale line. Cover the air hole with fingers, squeeze the gasbag to inject the blood into the sample well on test cassette. Twist to open the buffer capsule and squeeze all buffer into sample well. Read the result after 15 minutes and the result that have 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.
- The test result is negative, which may be caused by the low concentration of the SARS-CoV-2 neutralizing antibody 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.

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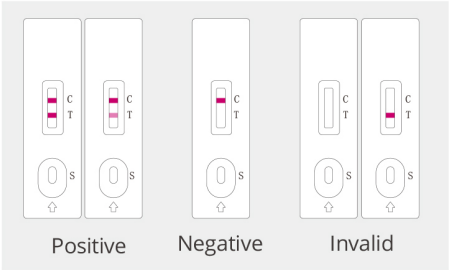
Display of Results/Expected Values



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 virus neutralization test test positive samples and 200 virus 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 antibody 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 syncytialvirus	Human metapneumonia virus
Hepatitis B	Hepatitis C	HIV
Haemophilus influenza	Antinuclear antibody	Parainfluenza Virus 3

Interference

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

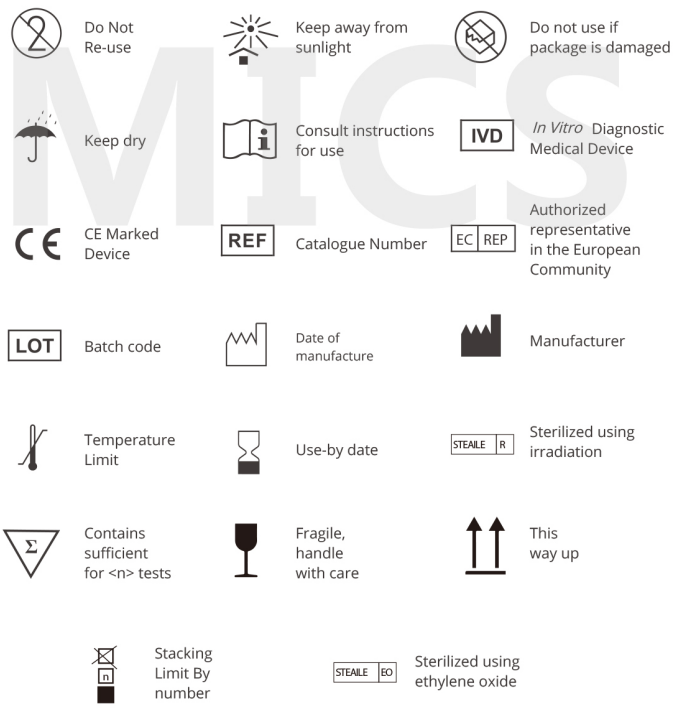
Substannce	Concentration
RF	200IU/mL
HAMA	200 ng/mL
Hemoglobin	5 mg/mL
Triglyceride	20 mM
Bilirubin	27 nmol/L
Serum albumin	180 g/L
Human IgG	90 g/L
Human IgM	4 g/L
Plasmacholesterol	2.5 g/L

The test results of the SARS-CoV-2 Neutralizing antibody Test Kit (LFIA) are not be interfered with these drugs:Heparin, EDTA, phenylephrine, oxymetazoline, sodium chloride, beclomethasone, dexamethasone, flunisolide, triamcinolone acetonide, budesonide, mometasone, fluticasone, histamine hydrochloride, a-interferon, zanamivir, ribavirin, oseltamivir, peramivir, lopinavir, ritonavir, arbidol and tobramycin.

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 determina-tion 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



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