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

FOR *IN VITRO* DIAGNOSTIC USE ONLY.
FOR SELF-TESTING.
PLEASE READ INSTRUCTIONS CAREFULLY BEFORE YOU PERFORM THE TEST.

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Test cassette: 1pc/bag

REF	Specification
1030-15-01	1 pc/Box
1030-25-01	5 pcs/Box
1030-45-01	25 pcs/Box
1030-55-01	50 pcs/Box

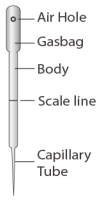
KIT CONTENTS

Test Cassette (individually in a foil pouch with desiccant)

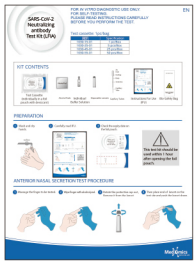
Alcohol Pads


Individual Buffer Solution


Disposable Lancet



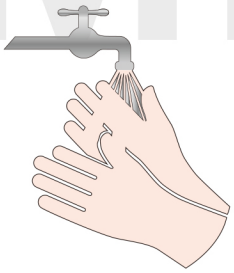
Capillary Tube


Instructions For Use (IFU)

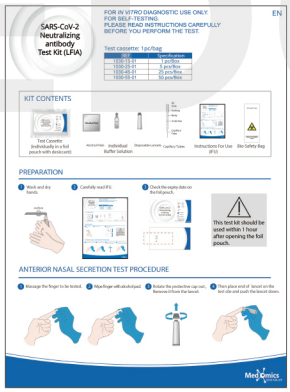
Bio-Safety Bag

PREPARATION

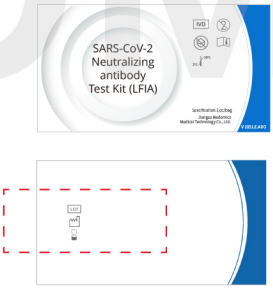
1 Wash and dry hands.



2 Carefully read IFU.



3 Check the expiry date on the foil pouch.



This test kit should be used within 1 hour after opening the foil pouch.

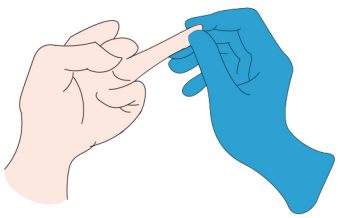
TEST PROCEDURE

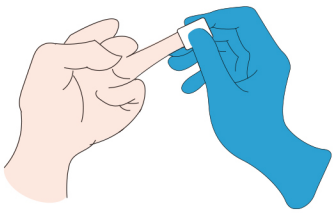
1 Massage the finger to be tested.

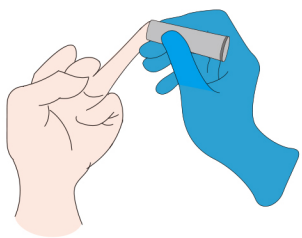
2 Wipe finger with alcohol pad.

3 Rotate the protective cap out , Remove it from the lancet.

4 Then place end of lancet on the test site and push the lancet down of the finger.







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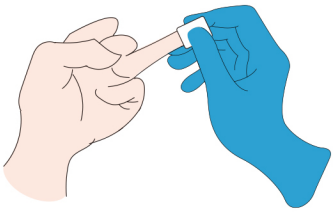
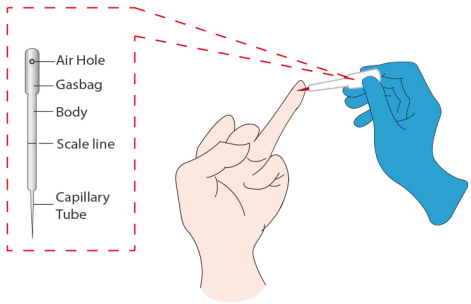
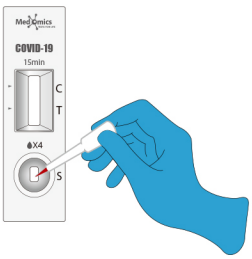
5 Wipe off the first drop of blood from your finger.



6 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.



7 Cover the air hole with fingers, squeeze the gasbag to inject the blood into the sample well on test cassette.



⚠ Open the foil pouch, then lay the test cassette on a clean flat surface

8 Twist to open the Individual buffer solution and add 4 drops of diluent into sample well.

9 Read the results within 15-20 mins.

⚠ Result observed after 20 mins is invalid

Dispose all those used materials into Bio-safety bag and seal well.

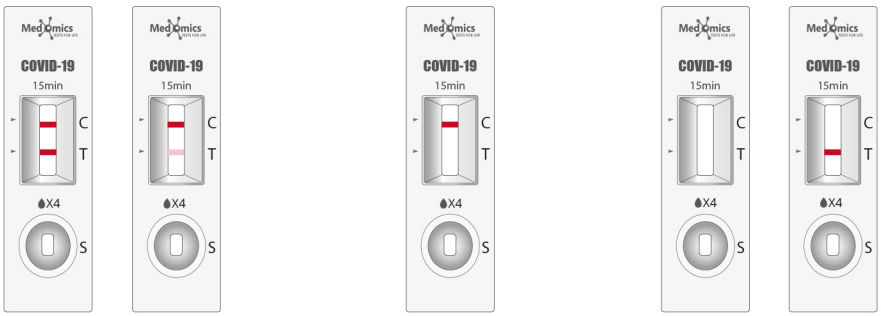
DISPLAY OF THE RESULT / EXPECTED VALUES

"C": Quality Control Line

"T": Detection Line

"S": Sample Well

Positive ➕ Negative ➖ Invalid ✖



- **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.
- **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.
- **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.

Note: The color intensity of the T line is related to the concentration of SARS-CoV-2 neutralizing antibody contained in the sample. The result should be determined by whether the T line is colored or not, regardless of the color intensity.

⚠ Please DO NOT take any decision of medical relevance without consulting your doctor/general practitioner.

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Introduction

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.

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 vaccinated individuals and recovered people.

Test Principle

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

Internal Quality Control

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.

Kit Contents

Specification	Test Cassette	Alcohol Pads	Individual Buffer Solution	Dispos-able Lancets	Capillary Tubes	Bio-Safety Bag	Instructions For Use
1 pc/Box	1	2	1	1	1	1	1
5 pcs/Box	5	10	5	5	5	5	1
25 pcs/Box	25	50	25	25	25	25	1
50pcs/Box	50	100	50	50	50	50	1

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
- Goat anti-mouse polyclonal antibody
- Mouse anti-human IgG monoclonal antibody

Warnings and Precautions

- This test kit is used for individuals 18 years and older.
- This test kit is used for in vitro diagnostics only.
- This test kit is used for self-testing.
- 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 the IFU 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.

Keep out of reach of children

CE Marked Device | Do Not Re-use | Do not use if package is damaged | Caution | REF Catalogue Number | IVD In Vitro Diagnostic Medical Device | LOT Batch code | Consult instructions for use | STERILE EO Sterilized using ethylene oxide | This way up

Date of manufacture | Use-by date | Contains sufficient for <n> tests | Temperature limit | EC REP Authorized representative in the European Community | Keep away from sunlight | Fragile, handle with care | Manufacturer | Keep dry | Stacking Limit By number

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Disposal Instructions

Put all used components back into bio-safety bag.
Follow the applicable regulations when disposing.

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.
• This test kit should be used within 1 hour after opening the foil pouch.

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.

Product Performance

Clinical 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

SARS-CoV-2 Neutralizing antibody Test Kit (LFIA) result	Virus 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 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 interfered with these drugs:Heparin, EDTA, phenylephrine, oxymetazoline, sodium chloride, beclomethasone, dexamethasone, flunisolide, triamcinolone acetonide, budesonide, mometasone, fluticasone, histamine hydrochloride, α-interferon, zanamivir, ribavirin, oseltamivir, peramivir, lopinavir, ritonavir, arbidol and tobramycin.

References

1.Wu Y, Wang F, Shen C, et al. A noncompeting pair of human neutralizing antibodies block COVID-19 virus binding to its receptor ACE2. Science. 2020;368(6496):1274-1278. doi:10.1126/-science.abc2241
2.Chi X, Yan R, Zhang J, et al. A neutralizing human antibody binds to the N-terminal domain of the Spike protein of SARS-CoV-2. Science. 2020;369(6504):650-655. doi:10.1126/science.abc6952

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