LEPU TECHNOLOGY

CE

2019-nCoV Neutralization Antibody Test kit (colloidal gold immunochromatography)

【Product name】

2019-nCoV Neutralization Antibody Test kit

(colloidal gold immunochromatography)

【Model】

1 tests/kit, 5 tests/kit, 10 tests/kit, 20 tests/kit, 50 tests/kit(one test per bag for one person).

【Intended Use】

This product is used to qualitatively detect the 2019-nCoV neutralization antibodies in clinical samples (serum/plasma/whole blood).

【Summary】

Since the outbreak of novel coronavirus (2019-nCoV) has rapidly swept across many countries and continues to spread worldwide. All the countries are under tremendous pressure in the detection, prevention or treatment of 2019-nCoV. To cope with the epidemic situation, the only lasting solution is to successfully develop a safe and effective vaccine. In the process of vaccine development and marketing, the most important index to evaluate the effectiveness of the 2019-nCoV vaccine is the content of neutralizing antibody in subjects. So, the detection of 2019-nCoV neutralization antibodies are the priority among priorities in accelerating the fight of global epidemic.

【Measurement Principle】

The product is based on the principle of antigen-antibody reaction and immunoassay technique. The test device contains colloidal gold labeled 2019-nCoV Spike Protein (RBD), mouse-anti human IgG antibody immobilized in G test area, mouse-anti human IgM antibody immobilized in M test area and the corresponding antibody in quality control area (C).

During the test, when the 2019-nCoV IgM neutralization antibody level in the sample is at or above the limit of detection of the test, the 2019-nCoV IgM neutralization antibody in the sample binds to the colloidal gold labeled 2019-nCoV Spike Protein (RBD) which is pre-coated on a gold label pad. The conjugates migrate upward through capillary effect and would be captured by mouse-anti human IgM antibody immobilized in M test area subsequently and this produces a purple-red band appears in the M test area. When the 2019-nCoV IgG neutralization antibody level in the sample is at or above the limit of detection of the test, the 2019-nCoV IgG antibody in the sample binds to the colloidal gold labeled 2019-nCoV Spike Protein (RBD) which is pre-coated on a gold label pad. The conjugates migrate upward through capillary effect and would be captured by mouse-anti human IgG antibody immobilized in G test area subsequently and this produces a purple-red band appears in the G test area. If it is a negative sample, there is not a purple-red band appeared in the M and G test area. Regardless of the presence or absence of the 2019-nCoV neutralization antibody in the sample, a purple-red band will appear in the quality control area (C). The purple-red band in the quality control area (C) is a criterion for judging whether there is enough sample and whether the chromatography process is normal. It also serves as the internal control standard for reagents.

【Component】

Model	Test cassette	Dropper	Instructions for use	Sample dilution
1 tests/kit	1 tests	10	1	1ml
5 tests/kit	5 tests	10	1	1ml
10tests/kit	10 tests	10	1	1.5ml
20 tests/kit	20 tests	20	1	2.5ml
50 tests/kit	50 tests	50	1	5ml
For each test, it contains one testing cassette and one package of desiccant.				

The test cassette is composed of test strip and test strip shell. The test strip is composed of one gold standard mat (containing colloidal gold labeled 2019-nCoV Spike Protein (RBD)), sample mat, cellulose nitrate membrane (containing mouse-anti human IgM antibody immobilized in M area, mouse-anti human IgG antibody immobilized in G area and goat anti-mouse antibody immobilized in C area), absorbing paper, plastic carrier board.

【Storage and Stability】

It should be stored at 4℃ ~ 30℃, be kept dry and away from sunlight. The shelf life is 12 months.

For per test cassette, it should be used within 1 hour after unsealing. Production Date and Expiration date are shown in the package label.

【Sample Requirements】

The test can be performed with serum/plasma/whole blood.

The blood should be collected by professional medical staff, and it is advised of detecting serum/plasma in priority, and under emergency conditions or special conditions, the whole blood of patients can be used for rapid testing.

After collection of samples, it should be tested immediately. It is forbidden for long time placement of the sample under room temperature. For whole blood sample, if it can not be tested in time, it can preserve for 24 hours between 2 and 8℃. Serum/plasma samples can be preserved for 3 days under temperature between 2 and 8℃, and for long time storage, they should be stored under -20℃, and it should avoid repeated freeze-thaw cycles.

Before testing, the sample must be restored to room temperature, ready for application only after homogeneity.

The sample must be returned to room temperature before testing, and should be used after mixing.

Do not use samples with severe hemolysis, severe lipids, and jaundice.

【Test Method】

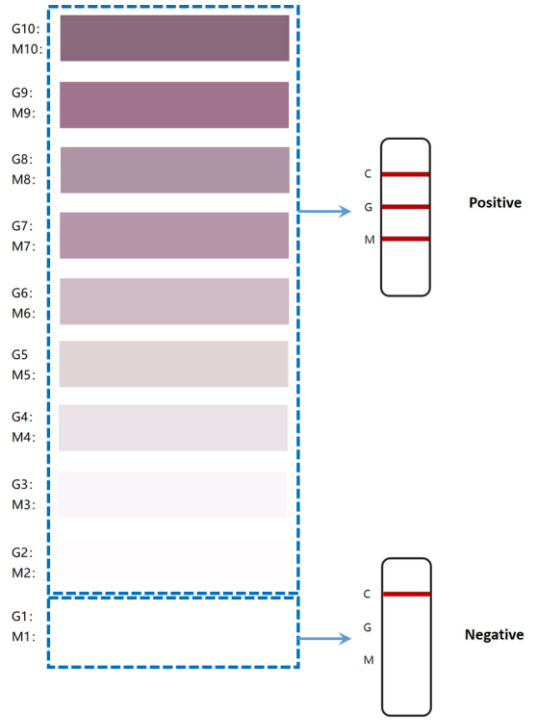
Please read the instruction for use carefully before performing the test. Before testing, restore the reagents and blood sample to room temperature.

1. Remove the test cassette from the packaging reagent bag and use it within 1 hour, especially in an environment with room temperature higher than 30 ℃ or in high humidity.
2. Place the kit on a clean platform.
   - Serum or plasma sample: Add one drop (about 10 μL) of serum or plasma sample to well A with a dropper, and then add two drops (about 80 μL) of sample dilution to well B, and start timing.
   - Whole blood sample: Add two drops (about 20 μL) of whole blood sample to sample well A with a dropper, and then add two drops (about 80 μL) of sample dilution to sample well B, and start timing.
3. Wait for the fuchsia band to appear. The test results should be read at 15 minutes. Do not read the results after 20 minutes.

【The Explanation of the Testing Results】

A Color Card is provided in this test kit. The test results need to be compared with the color card for judgment. The specific determination methods are as follows:

- Positive (+)：The purple red band appears in quality control area (C) and M/G test area. In comparison with the Color Card, the chroma of purple red band should be equal to or better than G2/M2 of Color Card.
- Negative (-)：The purple red band only appears in quality control area (c). There is no purple red band in the M/G test area or the chroma of purple red in M/G test area is weaker than G2/M2 of Color Card.
- Invalid: There is no purple stripe in the quality control area (C), indicating incorrect operating procedures or the test strip has already deteriorated. Under this conditions, it must read the instruction for use again carefully, and then use the new test strips to test again. If the problem still exists, stop using this lot number immediately and contact the local suppliers.



【Limitation of Procedure】

1. The test results of this product should be comprehensively judged by the physician in combination with other clinical information, and should not be used as the only criterion;
2. The product is used to test the 2019-nCoV neutralization antibody of the tested sample.

【Product Performance Index】

1 Analytical Specificity

1.1 Cross-reactivity: This test device has no cross reactivity with endemic human coronavirus OC43 antibody, endemic human coronavirus HKU1 antibody, endemic human coronavirus NL63 antibody, endemic human coronavirus 229E antibody, influenza A virus antibody, influenza B virus antibody, respiratory syncytial virus antibody, adenovirus antibody, rhinovirus antibody, enterovirus antibody, EB virus antibody, measles virus antibody, cytomegalovirus antibody, rotavirus antibody, norovirus antibody, mumps virus antibody, varicella-zoster virus antibody, and mycoplasma pneumoniae antibody.

1.2 Interfering substances:

The test results do not be interfered with the substance at the following concentration:

bilirubin concentration ≤250 μmol/l; triglycerides concentration≤ 15 mmol/l; hemoglobin concentration ≤10 g/dL; rheumatoid factor concentration ≤ 80RU/ml; anti-mitochondrial antibody concentration≤80 U/mL; antinuclear antibody concentration ≤ 80U/mL; the total IgG concentration ≤14g/L.

The test results do not be influenced by the following substance: α -interferon, zanamivir, ribavirin, oseltamivir, and paramivir, Lopinavir, ritonavir, abidol, levofloxacin, azithromycin, ceftriaxone, meropenem, tobramycin, histamine hydrochloride, phenylephrine, oxymetazoline, sodium chloride (containing Preservatives), beclomethasone, dexamethasone, flunisolide, triamcinolone, budesonide, mometasone and fluticasone.

2 Clinical Performance

A total of 184 samples were collected, including 72 positive samples and 112 negative samples. After comparing the test results of this product and GenScript sVNT Kit, the comparison results are summarized in the table below:

2019-nCoV Neutralization Antibody Test kit	GenScript sVNT Kit	
	Positive	Negative
Positive	69	4
Negative	3	108
Sample Quantity	72	112
Diagnostic Sensitivity, 95% CI	95.83% (88.45%~98.57%)	/
Diagnostic Specificity, 95% CI	/	96.43% (91.18%-98.60%)

【Precautions】

1. The test is only suitable for professionals to use *in vitro* auxiliary diagnosis. Do not use expired products.
2. Do not freeze or use after the expiration date (see the packaging for the expiration date).
3. Avoid excessive temperature and humidity in the experimental environment. The reaction temperature should be 15-30 ° C and the humidity should be below 70%.
4. The package bag contains desiccant, and it should not be taking orally.
5. It is recommended to use fresh blood for the sample collection. It is not recommended to use high-fat chyle, jaundice, and high rheumatoid factor samples. Do not use hemolyzed samples.
6. When testing, please wear protective clothing, medical mask, gloves and goggles.
7. Do not use the test card with broken single packaging, unclear marks, and past the expiration date.
8. Dispose of used specimens, test cards and other waste in accordance with relevant local laws and regulations.

【Explanation of Symbols】

	DO NOT USE IF PACKAGE IS DAMAGED		CONSULT INSTRUCTIONS FOR USE
	DO NOT REUSE		EXPIRY DATE
4℃ 30℃	TEMPERATURE LIMIT		DATE OF MANUFACTURER
	MANUFACTURER	LOT	BATCH CODE
	KEEP AWAY FROM SUNLIGHT		KEEP DRY
IVD	IN VITRO DIAGNOSTIC MEDICAL DEVICE	CE	CE MARK
EC REP	AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY		

Beijing Lepu Medical Technology Co., Ltd.
Building 7-1 No.37 Chaoqian Road, Changping District, Beijing, 102200, P.R. China
Tel: +86-10-80123964
Email: lepuservice@lepumedical.com
Web: en.lepumedical.com

EC REP
Lepu Medical (Europe) Cooperatief U.A.
Abe Lenstra Boulevard 36, 8448 JB, Heerenveen,The Netherlands
Tel: +31-515-573399 Fax: +31-515-760020

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