LEPU TECHNOLOGY

CE

SARS-CoV-2 Antibody Test (colloidal gold immunochromatography)

【Product name】

SARS-CoV-2 Antibody Test
(colloidal gold immunochromatography)

【Model】

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

【Intended Use】

The product is intended for the qualitative detection of antibody content against SARS-CoV-2 in clinical samples (serum/plasma/whole blood).

【Summary】

Coronavirus, as a large virus family, is a single positive stranded RNA virus with envelope. The virus is known to cause major illnesses such as colds, Middle East Respiratory Syndrome (MERS), and Severe Acute Respiratory Syndrome (SARS). The novel virus, now known as SARS-CoV-2, was officially named by the World Health Organization on January 12, 2020. The core protein of SARS-CoV-2 is the N protein (nucleocapsid), which is a protein component located inside the virus. It is relatively conserved among β-coronaviruses and is often used as a tool for the diagnosis of coronaviruses. ACE2, as a key receptor for SARS-CoV-2 to enter cells, is of great significance for the research of viral infection mechanism.

【Measurement Principle】

The product is based on the principle of antigen-antibody reaction and immunoassay technique. The test device contains colloidal gold labeled SARS-CoV-2 recombinant protein, 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 SARS-CoV-2 IgM antibody level in the sample is at or above the limit of detection of the test, the SARS-CoV-2 IgM antibody in the sample binds to the colloidal gold labeled SARS-CoV-2 recombinant protein 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 SARS-CoV-2 IgG antibody level in the sample is at or above the limit of detection of the test, the SARS-CoV-2 IgG antibody in the sample binds to the colloidal gold labeled SARS-CoV-2 recombinant protein 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 SARS-CoV-2 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
5 tests/kit	5 tests	10	1	1*1ml
10tests/kit	10 tests	10	1	1*1.5ml
20 tests/kit	20 tests	20	1	1* 2.5ml
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 SARS-CoV-2 recombinant protein), 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 avoided 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.

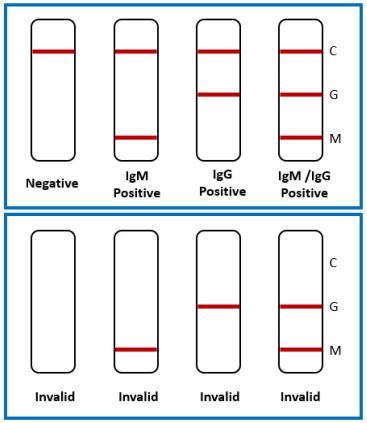
【Test Method】

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 ° C or in high humidity.
2. Place the kit on a clean platform.
   - Serum or plasma sample: Add one drop (about 10 uL) of serum or plasma sample to well A with a dropper, and then add two drops (about 80 uL) of sample dilution to well B, and start timing.
   - Whole blood sample: Add two drops (about 20 uL) of whole blood sample to sample well A with a dropper, and then add two drops (about 80 uL) 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】

- Positive (+): There appear purple stripes in both quality control area and either area M or G.
- Negative (-): There is only one purple stripe in the quality control area (C), and without purple stripe in either test area M and test area G.
- 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.



C: Quality Control Line M: IgM Detection line G: IgG Detection line

【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 SARS-CoV-2 antibody of the tested sample.

【Product Performance Index】

1 Physical Property

1.1 Appearance

The test card should be clean and integral, no burrs, no damage, no pollution; the material should be firmly attached; the label should be clear and not damaged. The sample dilution should be clear without impurities and flocs.

1.2 Liquid migration speed

The liquid migration speed should be no less than 10mm/min.

1.3 Membrane Strip Width

The membrane strip width of the testing strip should be≥2.5mm.

1.4 Sample dilution volume

The sample dilution volume should be no less than the indicated value.

2 Detection Limit

For the detection of sensitivity reference material, the positive detection rate should be no less than 90%.

3 Negative reference products compliance rate

For the detection of negative reference material, the negative detection rate should be 100%.

4 Positive reference products compliance rate

For the detection of positive reference material, the positive detection rate should be 100%.

5 Repeatability

For the detection of enterprise reference material P2 and P4, the results should be positive and the color rendering should be uniform.

6 Reproducibility

In different detection sites, the detection results of enterprise reference material P2 and P4 operated by different operators should be positive and the color rendering should be uniform.

7 Analytical Specificity

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

7.2 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.

8 Clinical Performance

220 clinical samples based on the nucleic acid detection method (PCR) test results were obtained, including 93 positive and 127 negative samples. The SARS-CoV-2 Antibody Test was compared with nucleic acid method (PCR) using the collected clinical samples. The results were summarized in the table below:

SARS-CoV-2 Antibody Test	Nucleic acid detection method (PCR)	
	Positive	Negative
Samples Quantity	93	127
IgM Positive	2	0
IgG Positive	20	3
IgM & IgG Positive	70	0
IgM & IgG Negative	1	124
Diagnostic Sensitivity	98.9%	/
Diagnostic Specificity	/	97.6%

【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		

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