



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

[ Product name

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

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

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

### [Summary]

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

# [Measurement Principle]

antibody immobilized in G test area, mouse-anti human IgM and immunoassay technique. The test device contains colloidal gold antibody immobilized in M test area and the corresponding labeled SARS-CoV-2 recombinant protein, mouse-anti human IgG antibody in quality control area (C). The product is based on the principle of antigen-antibody reaction

SARS-CoV-2 IgG antibody level in the sample is at or above the capillary effect and would be captured by mouse-anti human IgM gold labeled SARS-CoV-2 recombinant protein which is pre-coated SARS-CoV-2 IgM antibody in the sample binds to the colloidal sample is at or above the limit of detection of the test, the During the test, when the SARS-CoV-2 IgM antibody level in the recombinant protein which is pre-coated on a gold label pad. The sample binds to the colloidal gold labeled SARS-CoV-2 limit of detection of the test, the SARS-CoV-2 IgG antibody in the a purple-red band appears in the M test area. When the antibody immobilized in M test area subsequently and this produces on a gold label pad. The conjugates migrate upward through

> conjugates migrate upward through capillary effect and would be captured by mouse-anti human IgG antibody immobilized in G test purple-red band in the quality control area (C) is a criterion for purple-red band will appear in the quality control area (C). The or absence of the SARS-CoV-2 antibody in the sample, a band appeared in the M and G test area. Regardless of the presence area subsequently and this produces a purple-red band appears in control standard for reagents. chromatography process is normal. It also serves as the internal the G test area. If it is a negative sample, there is not a purple-red judging whether there is enough sample and whether the

### [Component]

For each feet, if contains one testing cassette and one package of desiceant	20 tests/kit 20 tests	10tests/kit 10 tests	5 tests/kit 5 tests	Model Test casselle
e one test	ests	ests	sis	cite
no cassette	20	10	10	Dropper
and one package	_			Instructions for use
of deciceant	1* 2.5ml	1*1.5ml	1*Im1	Sample

in C area), absorbing paper, plastic carrier board colloidal gold labeled SARS-CoV-2 recombinant protein), sample The test eassette is composed of test strip and test strip shell. The immobilized in G area and goat anti-mouse antibody immobilized antibody immobilized in M area, mouse-anti human IgG antibody mat, cellulose nitrate membrane (contaming mouse-anti human IgM test strip is composed of one gold standard mat (containing

# [Storage and Stability]

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

Production Date and Expiration date are shown in the package For per test cassette, it should be used within I hour after unscaling

# [Sample Requirements]

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

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

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

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

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

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

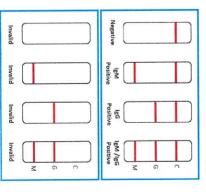
### L'Test Method

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

- Remove the test cassette from the packaging reagent bag and use it within I hour, especially in an environment with room temperature higher than 30 ° C or in high humidity
- Place the kit on a clean platform.
- to well B, and start timing. and then add two drops (about 80 uL) of sample dilution of scrum or plasma sample to well A with a dropper, Scrum or plasma sample: Add one drop (about 10 uL)
- and then add two drops (about 80 uL) of sample dilution whole blood sample to sample well A with a dropper, Whole blood sample: Add two drops (about 20 uL) of to sample well B, and start timing.
- 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
- either test area M and test area G. quality control area (C), and without purple stripe in Negative (-): There is only one purple stripe in the
- Invalid: There is no purple stripe in the quality control conditions, it must read the instruction for use again the test strip has already deteriorated. Under this immediately and contact the local suppliers. If the problem still exists, stop using this lot number carefully, and then use the new test strips to test again. area (C), indicating incorrect operating procedures or



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

# Limitation of Procedure

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

# Product Performance Index I

## 1 Physical Property

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

# 1.2 Liquid migration speed

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

# 1.3 Membrane Strip Width

The sample dilution volume should be no less than the indicated 1.4 Sample dilution volume The membrane strip width of the testing strip should be >2.5mm

### 2 Detection Limit

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

# 3 Negative reference products compliance rate

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

# 4 Positive reference products compliance rate

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

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

### 6 Reproducibility

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

S

# 7 Analytical Specificity

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

bilirubin concentration ≤250 µ mol/l; triglycerides concentration following concentration: The test results do not be interfered with the substance at the

≤15 mmol/l; hemoglobin concentration ≤10 g/dL; rheumatoid

concentration ≤80 U/mL; antinuclear antibody concentration ≤ 80U/mL; the total IgG concentration ≤14g/L. factor concentration \le 80RU/ml; anti-mitochondrial antibody

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

## 8 Clinical Performance

samples. The results were summarized in the table below:

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

SARS-CoV-2 Antibody Test	reducing acceptant member (1 city)	TOTAL TITO COLOR
	Positive	Negative
Samples Quantity	93	127
IgM Positive	2	0
IgG Positive	20	.,,
IgM & IgG Positive	70	(
IgM & IgG Negative		124
Diagnostic Sensitivity	98.9%	
Diagnostic Specificity	/	97.6%

### [ Precautions ]

- auxiliary diagnosis. Do not use expired products The test is only suitable for professionals to use in vitro
- packaging for the expiration date). Do not freeze or use after the expiration date (see the
- be 15-30 ° C and the humidity should be below 70% experimental environment. The reaction temperature should AVOID EXCESSIVE temperature and humidity ID
- taking orally. The package bag contains desiccant, and it should not be
- jaundice, and high rheumatoid factor samples. Do not use collection. It is not recommended to use high-fat chyle, It is recommended to use fresh blood for the sample hemolyzed samples.
- When testing, please wear protective clothing, medical mask gloves and goggles.

6

- marks, and past the expiration date Do not use the test card with broken single packaging, unclear
- 00 accordance with relevant local laws and regulations Dispose of used specimens, test cards and other waste in

# [Explanation of Symbols]

DO NOT REUSE	DO NOT USE IF PACKAGE IS DAMAGED:
M	<b>—</b>
EXPIRY DATE	CONSULT INSTRUCTIONS FOR USE

EC REP	IVD	•		4°C - 30°C
AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY	IN VITRO DIAGNOSTIC MEDICAL DEVICE	KEEP AWAY FROM SUNLIGHT	MANUFACTURER	TEMPERATURE
	3)	4);	LOT	3
	CE MARK	KEEP DRY	BATCH CODE	DATE OF MANUFACTURER

Beijing Lepu Medical Technology Co., Ltd. P.R. China Chaoqian Road, Changping District, Beijing, 102200 Address: 3th Floor and 5th Floor Building 7-1 No.37

Tel: +86-10-80123100

www.cn.lepumedical.com Email: international@lepumedical.com

Tel: +31-515-573399 C REP Heerenveen, The Netherlands Abe Lenstra Boulevard 36, 8448 JB Fax: +31-515-760020

Lepu Medical (Europe) Cooperatief U.A.

Approved on Feb. 07, 2020; Revised on Apr.3,2020 Version number: In CG25 REV.02 Approval Date and Revision Date of the Instruction





# (Colloidal Gold Immunochromatography)

#### [ Product name ]

SARS-CoV-2 Antigen Rapid Test Kit

(Colloidal Gold Immunochromatography)

Lest/kit; 5 tests/kit; 10 tests/kit; 25 tests/kit; 50 tests/kit

#### [ Intended Use ]

against SARS-CoV-2 in clinical samples (nasal swab). The product is intended for the qualitative detection of antigen

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

#### [ Principle ]

on the Test area (T) and corresponding antibody in the quality control area (C). pre-coated on the combination pad, matched SARS-CoV-2 N protein monoclonal antibody immobilized The current test card is based on the specific antibody-antigen reaction and immunoanalysis technology. The test card contains colloidal gold labeled SARS-CoV-2 N protein monoclonal antibody which is

the detection limit, then there is no color demonstrated in the test area (T). Regardless of the presence or absence of the virus in the sample, a pumple stripe will appear in the quality control area (C). The pumple stripe in the quality control area (C) is a criterion for the judgment of whether or not there is enough sample protein monoclonal antibody which is pre-coated on the combination pad. The conjugates migrate upward under capillary effect, and subsequently captured by the N protein monoclonal antibody innoabilized in and whether or not the chromatography procedure is normal the darker the color in the test area is. If there is no virus in the sample or the virus content is lower than the Test area (T). The higher the contents of N protein in the sample, the more the conjugates captures and During testing, the N protein in the sample combines with the colloidal gold labeled SARS-CoV-2 N

The product consists of lest cards, Instructions for use, sample treatment solution. And in each test card bag, it includes one SARS-CoV-2 antigen detection card and one package of desiccant.

INTANTAL	Trait care	montenens for use	Sample acament south
l test/kit	l test		[xini]
5 tests/kit	5 tests	-	Iml×1
Otests/kit	10 tests	-	2ml×1
25 tests/kit	25 tests	_	3ml×2
0 tests kit	50 tests		5ml×2

The test card consists of gold standard mat (coated with colloidal gold labelled SARS-CoV-2 N protein monoclonal antibody), sample mat, nitrocellulose membrane (Test area (T) is coated with an SARS-CoV-2 N protein monoclonal antibody; the quality control area (C) is coated with goat anti-mouse antibody), absorbing paper, and hydrophobic stiff card.

### L Storage and Stability 2

It should be stored at  $4^{\circ}\text{C} - 30^{\circ}\text{C}$ , be kept dry and away from sunlight. The shelf life is 12 months. For per test eard, it should be used within 1 hour after unscaling.

Production Date and Expiration date are shown in the package label.

The product is used to test the human nasal swab sample

avoid direct contact with the sample. In case of accidental contact, disinfection treatment should be carried out in time and necessary measures should be taken Sample collection: During the collection procedures for samples, take care to make proper protection, and

same way to ensure that enough samples are taken. Nasal swab sample: During sampling, the swab head should be completely inserted into the nasal cavity and gently rotated 5 times. After removal, the swab head should be sampled in the other nasal cavity in the The membrane strip width of the testing card should be 2.5mm

Sample preservation: after sample collection, please complete the test within 1 hour

The sample should come to room temperature before testing

#### [ Test Method ]

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

1. During sampling, the swab head should be completely inserted into the nasal cavity and gently rotated 5 that enough samples are taken. times. After removal, the swab head should be sampled in the other nasal cavity in the same way to ensure

splashing. If the double-sided adhesive protective layer is torn off after adding diluent, it is easy to cause Before the test, the double-sided adhesive protective layer should be removed in advance to prevent liquid

4. During the test, the test card should be placed on the horizontal desktop. The test card should be fixed and Do not drop the diluent into the other wells, Rotate the shaft ,two rounds each direction. Thread the swab sample through the bottom of well B into well A.Add 6 drops of the diluent into well A.

5. After covering the left side, gently press the adhesive position to make the two sides completely fit and start timing. Wait until the purple band appears. The test result should be read within 15-20 minutes.

emove the protective cover of the Thread the swab sample through the bottom of well B into well A.Drip the diluent to well A Rotate the shaft two rounds each direction



Stick the left and right sides togethe

sult will be shown after 15 min

€ 0 8

The Explanation of the Testing Results I

test area (T). Positive (+): There appear purple stripes in both quality control area (C) and either

cither test area (T). quality control area (C), and without purple stripe in Negative (-): There is only one purple stripe in the





 Invalid: There is no purple stripe in the quality control area (C), or there is blue stripe in the quality control
area (C), indicating incorrect operating procedures or the test eard has already deteriorated. Under this
condition, it must read the instruction for use again carefully, and then use the new test card to test again. If the problem still exists, stop using the products with same lot number and contact the local suppliers immediately.



## Limitation of Procedure

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;

The product is used to test the SARS-CoV-2 antigen of the clinical sample.

1.1 Appearance

1 Physical Property [ Product Performance Index ]

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

1.2 Liquid migration speed

1.3 Membrane Strip Width The liquid migration speed should be no less than 10mm/min

1.4 The preparation quantity of the diluent for the samples.
The volume of the diluents for the sample is no less than the indicated value.

3 Negative reference products compliance rate For the detection of sensitivity reference material, the positive detection rate should be no less than 90%

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%

Cross-reactivity: This test device has no cross reactivity with endemicity human coronavirus OC43, influenza a virus, influenza B virus, respiratory syneytial virus, adenovirus, EB virus, meastes virus. rendering should be uniform.

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

cytomegalovirus, rotavirus, Norovirus, mumps virus, varicella zoster virus, mycoplasma pneumoniae

including 75 positive and 135 negative samples. The SARS-CoV-2 Antigen Rapid Test Kit was compared with nucleic acid method (PCR) using the collected clinical samples. The results were summarized in the table below: 210 clinical samples based on the nucleic acid detection method (PCR) test results were obtained for testing 7 Clinical Performance

99.76% (95°aCT: 95.92%, 99.87%)	,	Dagnostic Specificity
,	92.00% (95%-CL 83.63%-96.28%)	ngan
13	6	Negative
	60	Positive
Negative	Positive	Test Kit
a method (PCR	Nucleic acid detection method (PCR)	SARS-CoV-2 Antigen Rapid

#### Precautions 1

- The test is only suitable for professionals to use in vitro auxiliary diagnosis. Do not use expired products.
- . Do not freeze or use after the expiration date (see the packaging for the expiration date).

  Avoid excessive temperature and humidity in the experimental environment. The reaction temperature should
- be 15-30 ° C and the humidity should be below 70%.
- The test card bag contains desiceant, and it should not be taking orally.
- 6. Do not use the test card with broken single packaging, unclear marks, and past the expiration date When testing, please wear protective clothing, medical mask, gloves and goggles
- Dispose of used specimens, test cards and other waste in accordance with relevant local laws and regulations The test card should be used within 1 hour after being taken out of the aluminum feil bag.
- splashing splashing. If the double-sided adhesive protective layer is tom off after adding diluent, it is easy to cause liquid The users should take samples according to the requirements of IFU.
   Before the test, the double-sided adhesive protective layer should be removed in advance to prevent liquid.
- Do not drop the diluent into the wrong well.
- 12. During the test, the test card should be placed on the horizontal desktop. The test card should be fixed and do not remove the test card.

## [ Explanation of Symbols ]

EC REP	WD	**		305.	$\otimes$	<b>(2)</b>
AUTHORIZED REPRESENTATIVE IN THE EUROPEAN	IN VITRO DIAGNOSTIC MEDICAL DEVICE	KIEF AWAY I ROM SUNLIGHT	MANUFACTURER	TEMPERATURE	DO NOT REUSE	DO NOT USE IF PACKAGE IS DAMAGED
	30	4	LOT	3		)me
	CF MARK	KEEP DRY	BATCH CODE	DATE OF MANUFACTURER	OSE-BY DATE	CONSULT INSTRUCTIONS FOR USE

### [ Basic Information ]

COMMUNITY



Beijing Lepu Medical Technology Co., Ltd. Address: 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

L Approval Date and Revision Date of the Instruction)