COVID-19 (SARS-CoV-2) ANTIBODY TEST

COLLOIDAL GOLD IMMUNOCHROMATOGRAPHY

LEPU MEDICAL

ACCURATE

High-purity antibody with high accuracy

EFFICIENT

Test result is available in 15 mins

CONVENIENT

Suitable for whole blood test

COMPANY PROFILE

Lepu Medical Technology (Beijing) Co., Ltd. was established in 1999, and went public in 2009. Lepu Medical is specialized in developing, manufacturing and distributing high-tech medical devices and equipment. Today, Lepu Medical has grown into a global leading company with 32 primary subsidiaries worldwide in the fields of cardiovascular, neurovascular and peripheral vascular interventions, structural heart diseases, surgical cardiology, cardiac rhythm management, critical care, anesthesia, hematodialysis, general surgery, orthopedics and in vitro diagnostics with products include coronary stents, dilatation balloon catheters, interventional accessories, occlusion devices, mechanical heart valves, pacemakers, dialyzers, anesthesia products, ECG devices, patient monitors, oximeters, surgical staplers, orthopedic products, in vitro diagnostic products and angiography DSA systems.

FACILITIES

100,000 Class Cleaning Room

CERTIFICATES

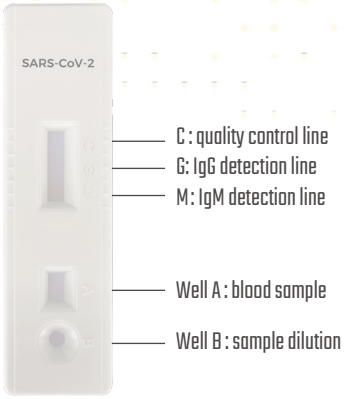
341 CFDA Certificates for Medical Device

194 CFDA Certificates for Medicine

126 CE Certificates

19 FDA Approvals

PRODUCT INFORMATION



[Sample Type] Whole blood / Plasma / Serum

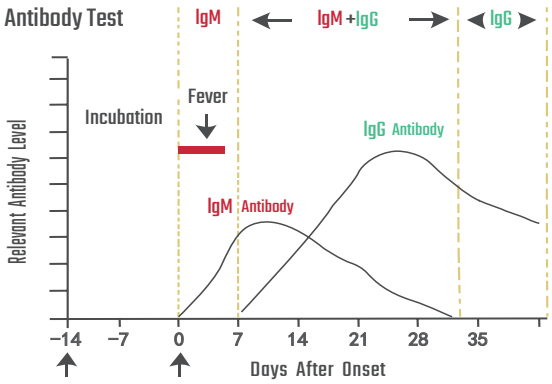
[Sample Volume] 20ul / 10ul / 10ul

[Reaction Time] 15 mins

[Packing Size] 20 tests per box

[Storage Condition] 4°C ~ 30°C

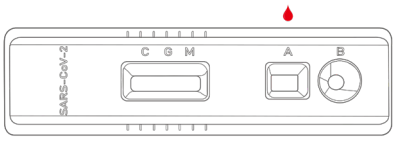
[Shelf Life] 12 months



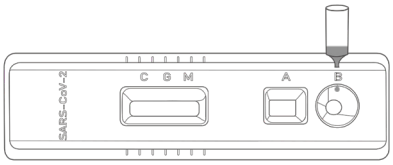
Antibodies will be secreted after virus invasion. Immunoglobulin M (IgM) comes out first, acting as the early sign of infection. Immunoglobulin G (IgG) comes out later, arising a more specific and stronger reaction against the virus.

Operation Steps

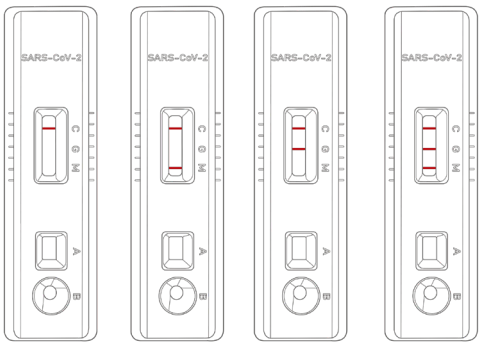
Step 1 Add 20ul of whole blood sample/ 10ul of serum or plasma sample to well A.



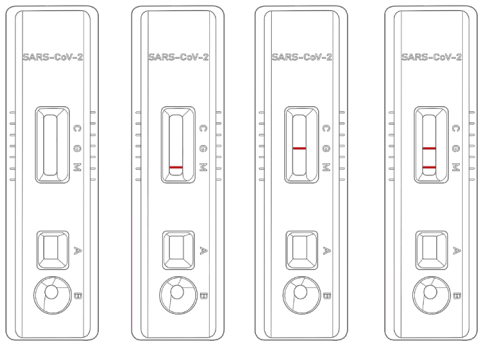
Step 2 Add two drops (about 80ul) of sample dilution to well B, and start timing.



Step 3 The test results should be read within 10-20 mins. Do not read the results after 20 mins.



Negative | IgM Positive | IgG Positive | IgM/IgG Positive



Invalid | Invalid | Invalid | Invalid

M : IgM detection line

G : IgG detection line

C : quality control line

Watch the operation video https://youtu.be/dcid-1u7He4

PRODUCT QUALIFICATIONS

CE CERTIFICATE

TÜVRheinland®

CE Technical Documentation Review Report

Applicant:	**BEIJING LEPU MEDICAL TECHNOLOGY CO., LTD.** Building 7-1, No.37 Chaoqian Road, Changping District, 102200 Beijing, China
Report Number:	**60357276-001**
Examination intent:	Examination the completeness of the Technical Documentation according to the requirements of the In Vitro Diagnostic Medical Devices Directive 98/79/EC Annex III
Product(s):	SARS-CoV-2 Antibody Test (Colloidal Gold Immunochromatography)
Type(s)/Model(s):	Cassette, 5 Tests/Kit, 10 Tests/Kit, 20 Tests/Kit
Classification:	Other IVD products (according to manufacturer's declaration)
Examination period:	Mar.27.2020
Date of expiry:	May.26.2024
Review result:	During the examination of the provided Technical Documentation (CE-CG25-1, Revision 1/0, Dated 2020-Mar-20) no Non-compliance according to the requirements of the In Vitro Diagnostic Medical Devices Directive 98/79/EC Annex III was detected.

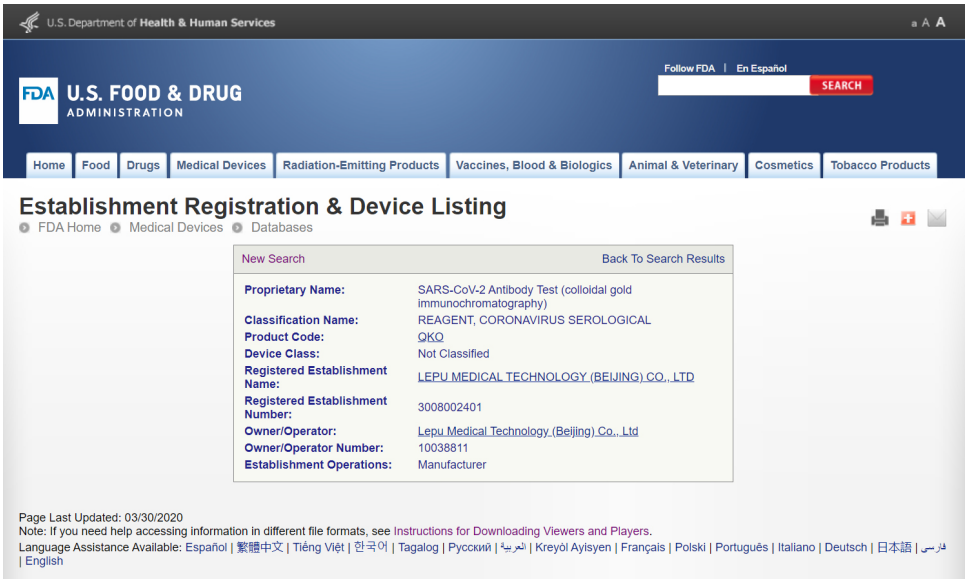
Yuhong CHEN
Vice General Manager | Medical Greater China
TÜV Rheinland (China) Ltd.

To verify the report validity, please send email to: service-gc@tuv.com

Unit 707, AVIC Bldg., No. 10B, Central Road, East 3rd Ring Road, Chaoyang District, Beijing, 100022, P.R.China

(Rev.02, 2020-03-27)

FDA NOTIFICATION



U.S. Department of Health & Human Services

FDA U.S. FOOD & DRUG ADMINISTRATION

Follow FDA | En Español

SEARCH

Home | Food | Drugs | Medical Devices | Radiation-Emitting Products | Vaccines, Blood & Biologics | Animal & Veterinary | Cosmetics | Tobacco Products

Establishment Registration & Device Listing

FDA Home > Medical Devices > Databases

New Search | Back To Search Results

Proprietary Name:	SARS-CoV-2 Antibody Test (colloidal gold immunochromatography)
Classification Name:	REAGENT, CORONAVIRUS SEROLOGICAL
Product Code:	QKO
Device Class:	Not Classified
Registered Establishment Name:	LEPU MEDICAL TECHNOLOGY (BEIJING) CO., LTD
Registered Establishment Number:	3008002401
Owner/Operator:	Lepu Medical Technology (Beijing) Co., Ltd
Owner/Operator Number:	10038811
Establishment Operations:	Manufacturer

Page Last Updated: 03/30/2020
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.
Language Assistance Available: Español | 繁體中文 | Tiếng Việt | 한국어 | Tagalog | Русский | العربية | Kreyòl Ayisyen | Français | Polski | Português | Italiano | Deutsch | 日本語 | فارسی | English

PRODUCT CLINICAL RESULTS

Clinical Institutions: Beijing Aipuyi Medical Inspection Center

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%