Ministero della Salute

Stampa | Scarica il dataset

Elenco dei dispositivi medici

Criteri di ricerca:
Denominazione fabbricante: **lepu**
Codice fiscale fabbricante:
Partita IVA / VAT number fabbricante:
Codice nazione fabbricante:
Denominazione mandatario:
Codice fiscale mandatario:
Partita IVA / VAT number mandatario:
Codice nazione mandatario:
Tipologia dispositivo:
Identificativo di registrazione attribuito dal sistema BD/RDM: **2081646**
Codice attribuito dal fabbricante:
Nome commerciale e modello:
Classificazione CND:
Descrizione CND:
Classe CE (valida solo per dispositivi medici di classe, impiantabili attivi e IVD):

Elenco dispositivi individuati

Dati aggiornati al:03/07/2021

DISPOSITIVO MEDICO/ASSEMBLATO									FABBRICANTE/ASSEMBLATORE				
TIPOLOGIA DISPOSITIVO	IDENTIFICATIVO DI REGISTRAZIONE BD/RDM	ISCRITTO AL REPERTORIO	CODICE ATTRIBUITO DAL FABBRICANTE/ASSEMBLATORE	NOME COMMERCIALE E MODELLO	CND	CLASSE CE	DATA PRIMA PUBBLICAZIONE	DATA FINE IMMISSIONE IN COMMERCIO	RUOLO AZIENDA	DENOMINAZIONE	CODICE FISCALE	PARTITA IVA/VAT NUMBER	NAZIONE
Dispositivo	2081646	N	SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold Immunochromatography) 02010282011500	SARS-COV-2 ANTIGEN RAPID TEST KIT(COLLOIDAL GOLD IMMUNOCHROMATOGRAPHY) 02010282011500	W0105099099 - VIROLOGIA - TEST RAPIDI E "POINT OF CARE" - ALTRI	IVD - Altro tipo di IVD	16/03/2021		FABBRICANTE	BEIJING LEPU MEDICAL TECHNOLOGY CO. LTD			CN
									MANDATARIO	LEPU MEDICAL (EUROPE) COOPERATIEF U.A.		851526019B01	NL

EU Common List of COVID-19 Rapid Antigen Tests

EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Public health, country knowledge, crisis management
Health Security and Vaccination

EU health preparedness:

A common list of COVID-19 rapid antigen tests, including those whose test results are mutually recognised, and a common standardised set of data to be included in COVID-19 test result certificates

Agreed by the Health Security Committee
on 17 February 2021

III. Rapid antigen tests of which the test results are mutually recognised

As stipulated in point 15 of the Council Recommendation of 21 January 2021, Member States will agree on a selection of rapid antigen tests of which they will mutually recognise the test results for public health measures, based on the information included in the common list (see Annex I).

The Health Security Committee agrees that, for rapid antigen test results to be mutually recognised, at least three Member States should be using a rapid antigen tests in practice. Based on this criterion, Member States agree that the results of the following rapid antigen tests will be mutually recognised for public health measures:

- Abbott Rapid Diagnostics, Panbio™ COVID-19 Ag Rapid Test
- AMEDA Labordiagnostik GmbH, AMP Rapid Test SARS-CoV-2 Ag
- Becton Dickinson, BD Veritor System for Rapid Deteciton os SARS-CoV-2
- **Beijing Lepu Medical Technology, SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold immunochromatography)**
- BIOSYNEX SWISS SA, BIOSYNEX COVID-19 Ag BSS
- CerTest Biotect S.L., CerTest SARS-CoV-2 CARD TEST
- Hangzhou Clongene Biotech, Clungene COVID-19 Antigen Rapid Test Kit
- Healgen Scientific Limited, Coronavirus Ag Rapid Test Cassette (Swab)
- LumiraDX UK LTd, LumiraDx SARS-CoV-2 Ag Test
- nal von minden GmbH, NADAL COVID -19 Ag Test
- Quidel Corporation, Sofia 2 SARS Antigen FIA
- SD BIOSENSOR, Inc., STANDARD F COVID-19 Ag FIA
- SD BIOSENSOR, Inc., STANDARD Q COVID-19 Ag Test
- Siemens Healthineers, CLINITEST Rapid COVID-19 Antigen Test
- Xiamen Boson Biotech Co, Rapid SARS-CoV-2 Antigen Test card
- Zhejiang Orient Gene Biotech Co.,Ltd, Coronavirus Ag Rapid Test Cassette (Swab)

VICIMED

Document No.: CE-DOC-CG27
Rev.: 1/0

Declaration of Conformity

Manufacture Address:	Beijing Lepu Medical Technology Co., Ltd. Building 7-1 No.37 Chaoqian Road, Changping District, Beijing, 102200, P.R. China
European Representative:	Lepu Medical (Europe) Cooperatief U.A. Abe Lenstra Boulevard 36, 8448 JB, Heerenveen, The Netherlands
Product information:	SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold Immunochromatography) Model: 1 test/kit; 5 tests/kit; 10 tests/kit; 25 tests/kit; 50 tests/kit
Classification:	Others (not in List A and List B)
Conformity Assessment Route:	Section 2 to 5 in annex III of IVDD 98/79/EC We herewith declare that the above mentioned products meet the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premise of the manufacturer.
General Applicable Directive:	DIRECTIVE 98/79/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 October 1998 on *in vitro* diagnostic medical devices
Standards Applied:	All applicable harmonized standards (published in the official journal of the European Communities on 25th March 2020). The applicable standards are listed in Annex 1.
Place, date of issue	Beijing, P.R. China, 3th, Sept., 2020
Signature of Management Representative	Zhao Chengjue

Beijing Lepu Medical Technology Co., Ltd.
Building 7-1 No.37 Chaoqian Road, Changping District, Beijing, 102200, P.R. China

CE

Annex 1

EN ISO 13485:2016 Medical devices – quality management systems - requirements for regulatory purposes

EN ISO 14971:2019 Medical devices – application of risk management to medical devices

EN ISO 15223-1:2016 Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements

EN 1041:2008+A1:2013 Information supplied by the manufacturer of medical devices

EN ISO 18113-1:2011 In vitro diagnostic medical devices – information supplied by the manufacturer (labelling) – Part 1: terms, definitions and general requirements

EN ISO 18113-2:2011 In vitro diagnostic medical devices – information supplied by the manufacturer (labelling) – Part 2: in vitro diagnostic reagents for professional use

EN ISO 23640:2015 In vitro diagnostic medical devices – evaluation of stability of in vitro diagnostic regents

EN 13612:2002/AC: 2002 Performance evaluation of in vitro diagnostic medical devices

IEC 62366-1:2015 Application of usability engineering to medical devices

Revision history:

Version	Revision history	Author	Date
1/0	First procedure	Wenna Li	3th, Sept., 2020

乐普科技
LEPU TECHNOLOGY

Declaration

To whom it may concern:

We, Beijing Lepu Medical Technology Co., Ltd, with principal place of business at No.37 Chaoqian Rd., Changping District, Beijing, China, would like to inform you that our SARS-CoV-2 Antigen Rapid Test Kit remain suitable for the detection of SARS-CoV-2 antigen even in the emergence of newly discovered variants including the United Kingdom variant and the South African variant.

It can be seen from Figure 1 that the new coronavirus (SARS-CoV-2) has four main structural proteins: Spike protein (S protein), Nucleocapsid protein (N protein), Membrane glycoprotein (M protein) , Envelope protein (E protein)。Among them, the S protein is a very important surface protein of the coronavirus, which is closely related to the infectious ability of the virus. It is the receptor binding site, cytolysis and the main antigen site；N protein is abundant in coronaviruses and is a highly immunogenic protein that participates in genome replication and cell signaling pathway regulation。S protein and N protein are the key raw materials of the new coronavirus immunoassay test kit, which are of great value for the diagnosis and investigation of the new coronavirus。

北京乐普医疗科技有限责任公司
BEIJING LEPU MEDICAL TECHNOLOGY CO.,LTD.
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生产地址：北京市昌平区科技园区超前路37号7-1楼
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咨询电话：400 060 1160

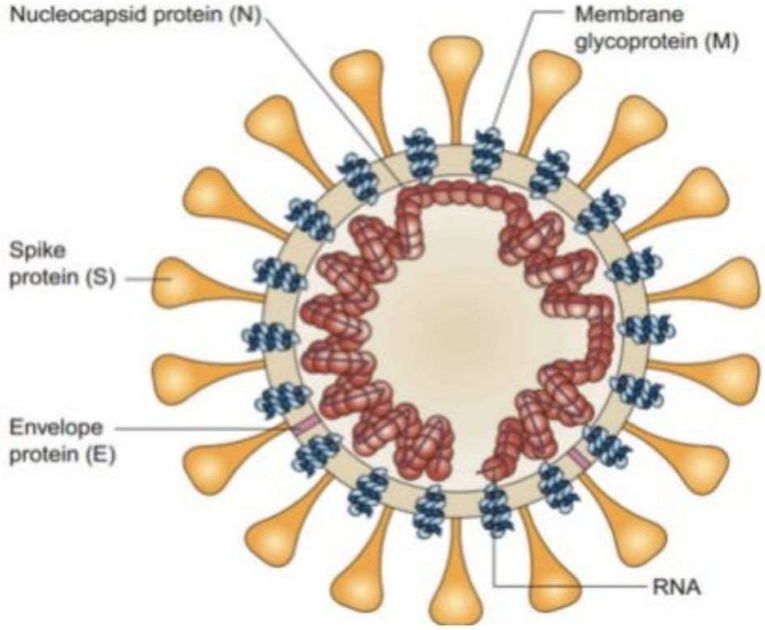
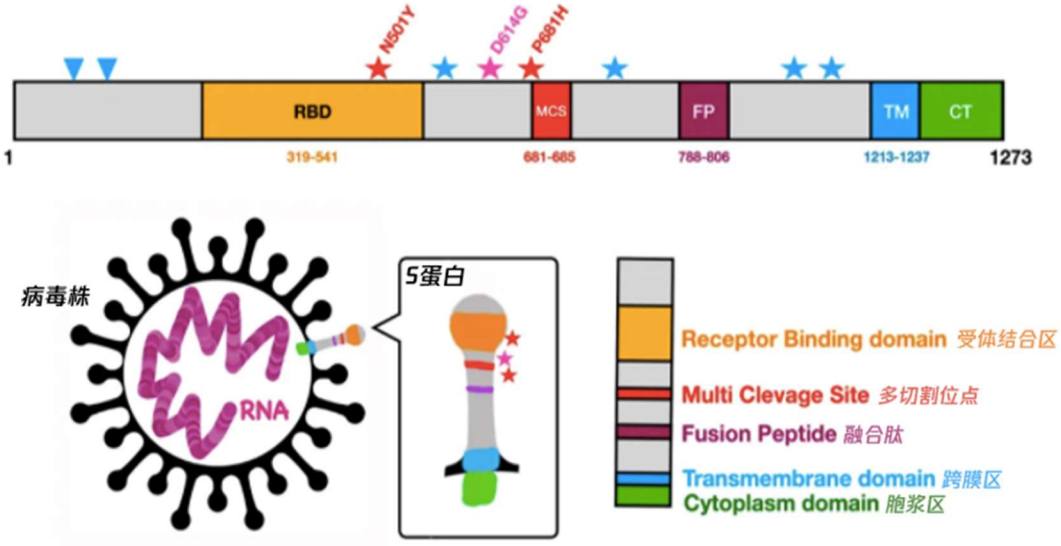


Figure1 New coronavirus schematic

The genome of the new coronavirus is composed of RNA, and the high recombination rate between RNA can easily cause the virus to mutate。After recombination, the RNA sequence changes, the amino acid sequence encoded by the nucleic acid changes, and the protein constituted by the amino acid changes accordingly, so that its antigenicity changes。The current sequencing results of the British mutant strain B.1.1.7 show that the mutant strain carries a variety of genetic mutations that may enhance its infectivity, and two of the most concerned mutations: One is the N501Y mutation in the receptor binding domain (RBD) of the spike protein (S protein), and the other mutation is P681H, which appears at the furin cleavage site of the spike protein. The South African 501.v2 Variant, which was subsequently reported, has the same N501Y mutation as the British

strain B.1.1.7, but is different in that it also contains mutations at two key sites, E484K and K417N, in the S protein receptor binding region, which has a potentially important effect on viral infection ability。



备注：Receptor Binding Domain (RBD):受体结合区；Multi Cleavage Site (MCS）多切割位点；Fusion Peptide (FP) 融合肽；Transmembrane domain (TD) 跨膜区；Cytoplasm domain (CT) 胞浆区

Figure2 Diagram of the distribution of gene mutations in British mutant virus strains

In summary, the mutation sites of both the British and South African mutants are in the spike protein (S protein), and the SARS-CoV-2 antigen detection kit produced by our company is labeled and coated with N protein monoclonal antibody, it recognizes the N protein on the surface of the virus, so currently our reagents are not affected by the British and South African variants

北京乐普医疗科技有限责任公司
BEIJING LEPU MEDICAL TECHNOLOGY CO.,LTD.
注册地址：北京市昌平区科技园区超前路37号
生产地址：北京市昌平区科技园区超前路37号7-1楼
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邮　　编：102200
网　　址：www.leputechnology.com
咨询电话：400 060 1160

EC Certificate

TÜVRheinland®

Full Quality Assurance System
Directive 98/79/EC on In Vitro Diagnostic Medical Devices,
Annex IV excluding (4, 6)

Registration No.: HL 2062714-1

Manufacturer: BEIJING LEPU MEDICAL TECHNOLOGY CO.,LTD.
Building 7-1, No. 37,
Chaoqian Road, Changping District
102200 Beijing
P.R. China

Products: Blood Glucose Monitoring Systems
Blood Glucose Test Strips
SARS-CoV-2 Antigen Rapid Tests for self-testing

The Notified Body hereby declares that the requirements of Annex IV, excluding section 4 and 6 of the directive 98/79/EC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex IV, section 5 of the aforementioned directive. For placing on the market of List A devices covered by this certificate an EC design-examination certificate according to Annex IV, section 4 and a verification of manufactured products according to section 6 is required.

Report No.: 190131772 110

Effective date: 2021-06-21

Expiry date: 2024-05-26

Issue date: 2021-06-21

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Dipl. Ing. Sven Hoffmann
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 98/79/EC concerning in vitro diagnostic medical devices with the identification number 0197.

LEPU MEDICAL

SARS-CoV-2

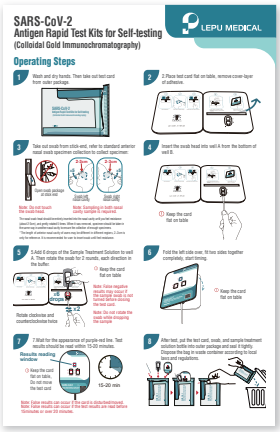
Antigen Rapid Test Kits for Self-testing

(Colloidal Gold Immunochromatography)

Marketing@lepu-medical.com

Swab

buffer



Operation Card

This product is a rapid, lateral flow immunoassay intended for the qualitative detection of SARS-CoV-2 nucleocapsid antigens from anterior nasal swabs that are self-collected by an individual aged 18 years or older or are collected by an adult from an individual younger than 18 years old. This test is intended for use in individuals with symptoms or other epidemiological reasons to suspect a COVID-19 infection. This product is intended to be used as an aid in the diagnosis of SARS-CoV-2 infection.

Product Feature

- Non-invasive
- Simple to use
- No prescription needed
- Rapid, get result in 15 minutes
- Stable, with high accuracy
- Inexpensive, cost-efficiency

Clinical performance

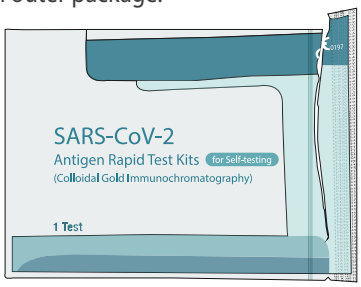
The clinical performance study for SARS-CoV-2 Antigen Rapid Test Kit was conducted in Germany. A total of 222 clinical samples were used to perform the test. The positive and negative samples were all confirmed by PCR. The diagnostic sensitivity and diagnostic specificity of the product was 95.9% (90.8-98.2%) and 100% (96.3-100.0%) respectively.
Results with correlation to Ct value of the positive samples were shown in the table below

Ct Value	Diagnostic sensitivity	95%CI
≤ 30	96.2 %	88.3-98.7%
≤ 32	96.0 %	90.0-98.4%
≤ 34	95.5%	90.0-98.1%
≤ 36	95.9 %	90.8- 98.2%

Operating Steps

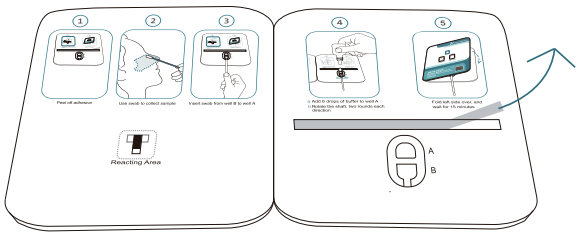
1

Wash and dry hands. Then take out test card from outer package.



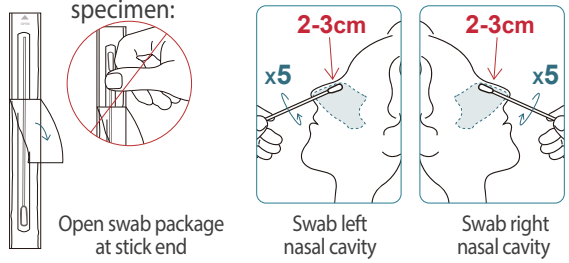
2

Place test card flat on table, remove cover-layer of adhesive.



3

Take out swab from stick-end, refer to standard anterior nasal swab specimen collection to collect specimen:



Open swab package at stick end

Swab left nasal cavity

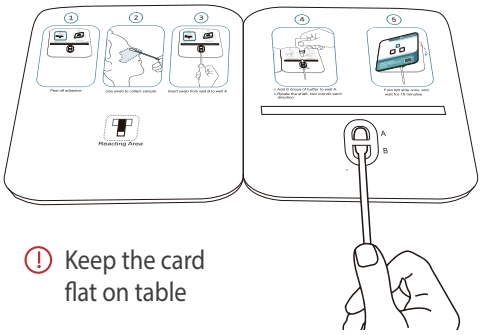
Swab right nasal cavity

Note: Do not touch the swab head. Note: Sampling in both nasal cavity sample is required.

The nasal swab head should be entirely inserted into the nasal cavity until you feel resistance (about 2-3cm), and gently rotated 5 times. When it was removed, specimen should be taken in the same way in another nasal cavity to ensure the collection of enough specimens. The length of anterior nasal cavity of users may be different in different regions, 2~3cm is only for reference. It is recommended for user to insert swab until feel resistance.

4

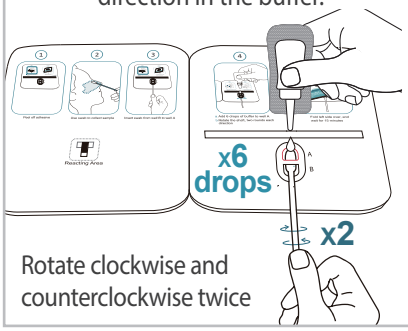
Insert the swab head into well A from the bottom of well B.



ⓘ Keep the card flat on table

5

Add 6 drops of the Sample Treatment Solution to well A. Then rotate the swab for 2 rounds, each direction in the buffer.



Rotate clockwise and counterclockwise twice

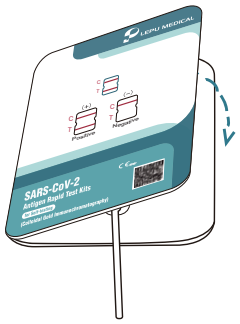
ⓘ Keep the card flat on table

Note: False negative results may occur if the sample swab is not turned before closing the test card.

Note: Do not rotate the swab while dropping the sample

6

Fold the left side over, fit two sides together completely, start timing.

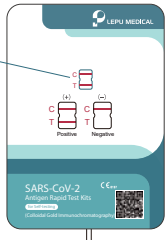


ⓘ Keep the card flat on table

7

Wait for the appearance of purple-red line. Test results should be read within 15-20 minutes.

Results reading window



ⓘ Keep the card flat on table, Do not move the test card

15-20 min

Note: False results can occur if the card is disturbed/moved.
Note: False results can occur if the test results are read before 15minutes or over 20 minutes.

8

After test, put the test card, swab, and sample treatment solution bottle into outer package and seal it tightly. Dispose the bag in waste container according to local laws and regulations.