LEPU MEDICAL

2020

SARS-CoV-2

Antigen Rapid Test Kit

(Colloidal Gold Immunochromatography)

Sales Manager: Leo Liu

Mob/Whatsapp: +86 17612220223

Email: zhongyuan.liu@lepu-medical.com

Scan to know more about Lepu Medical

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

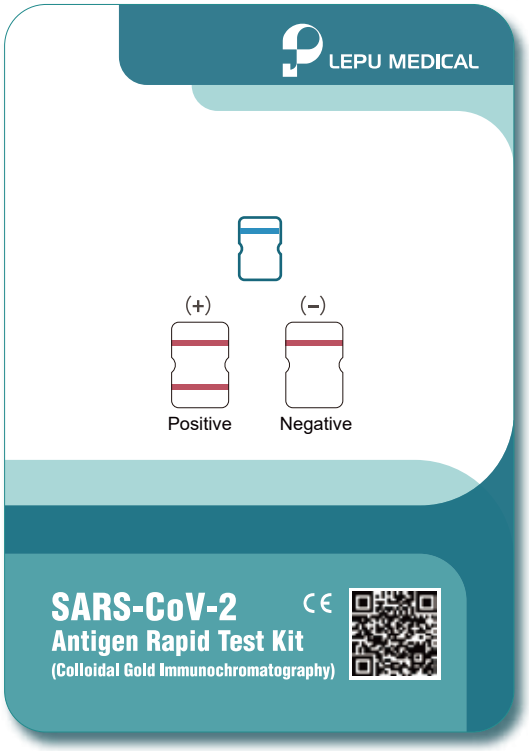
SARS-CoV-2 Antigen Rapid Test Kit
(Colloidal Gold Immunochromatography)
Catalogue

LEPU MEDICAL

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

Brochure

SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold Immunochromatography)



① Non-invasive

② Simple to use

③ Convenient, no devices required

④ Rapid, get result in 15 minutes

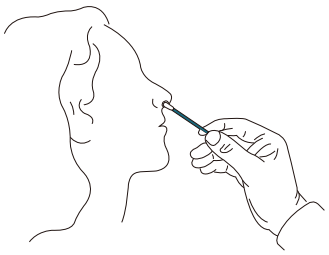
⑤ Stable, with high accuracy

⑥ Inexpensive, cost-efficiency

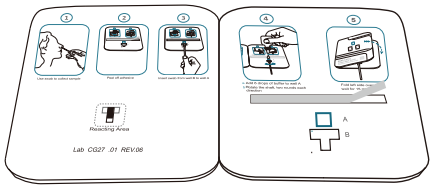
⑦ Eco-friendly, compared with plastic tray

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

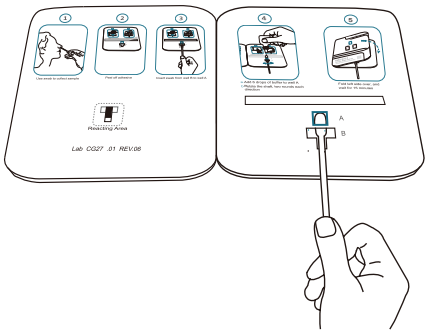
• Instruction



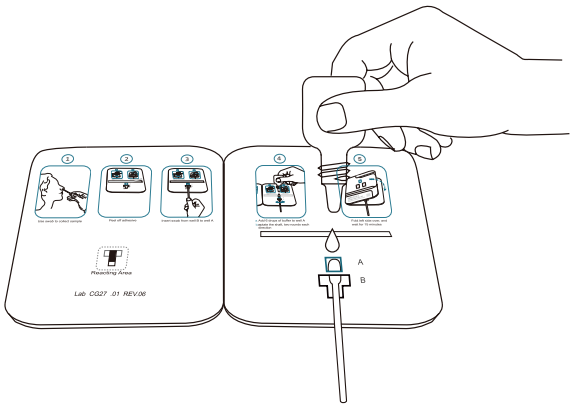
Step 1: Use swab to collect sample.



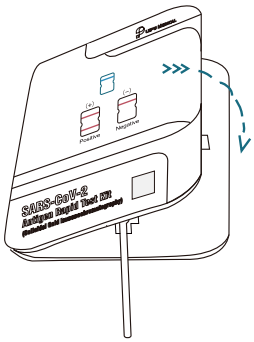
Step 2: Peel off adhesive.



Step 3: Insert swab from well B to well A.



Step 4: a. Add 6 drops of buffer to well A
b. Rotate the shaft, two rounds each direction.

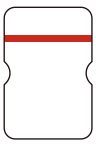


Step 5: Fold left side over, and wait for 15 minutes.

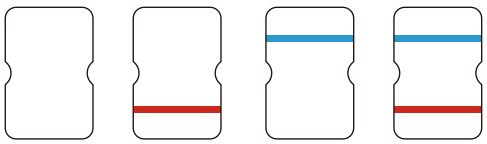
• Result Interpretation

Positive (+)

Negative (–)



Invalid



LEPU MEDICAL

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

SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold Immunochromatography)

CE

【Product name】

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.

【Intended Use】

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

【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 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.

【Principle】

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 pre-coated on the combination pad, matched SARS-CoV-2 N protein monoclonal antibody immobilized on the Test area (T) and corresponding antibody in the quality control area (C).
During testing, the N protein in the sample combines with the colloidal gold labeled SARS-CoV-2 N 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 immobilized in the Test area (T). The higher the contents of N protein in the sample, the more the conjugates captures and 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 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 purple stripe will appear in the quality control area (C). The purple stripe in the quality control area (C) is a criterion for the judgment of whether or not there is enough sample and whether or not the chromatography procedure is normal.

【Component】

The product consists of test 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.

Model	Test card	Instructions for use	Sample treatment solution
1 test/kit	1 test	1	1ml×1
5 tests/kit	5 tests	1	1ml×1
10tests/kit	10 tests	1	2ml×1
25 tests/kit	25 tests	1	3ml×2
50 tests/kit	50 tests	1	5ml×2
For each test card bag, it contains one test card and one package of desiccant.			

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.

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

【Sample Requirements】

The product is used to test the human nasal swab sample.
Sample collection: During the collection procedures for samples, take care to make proper protection, and 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.
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 same way to ensure that enough samples are taken.
Sample preservation: after sample collection, please complete the test within 1 hour.
The sample should come to room temperature before testing.

LEPU MEDICAL

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

SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold Immunochromatography)

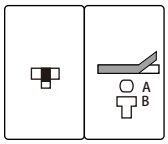
CE

【Test Method】

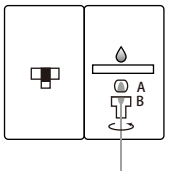
Please read the instruction for use carefully before performing the test. Before testing, restore the reagents and sample to room temperature.

1. 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 same way to ensure that enough samples are taken.
2. Before the test, the double-sided adhesive protective layer should be removed in advance to prevent liquid splashing. If the double-sided adhesive protective layer is torn off after adding diluent, it is easy to cause liquid splashing.
3. Thread the swab sample through the bottom of well B into well A.Add 6 drops of the diluent into well A. Do not drop the diluent into the other wells.Rotate the shaft ,two rounds each direction.
4. 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.
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.

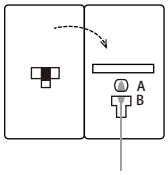
Remove the protective cover of the fixing glue.



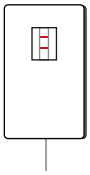
Thread the swab sample through the bottom of well B into well A.Drip the diluent to well A.Rotate the shaft ,two rounds each direction.



Stick the left and right sides together.



The test result will be shown after 15 min.



【The Explanation of the Testing Results】

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

Positive

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

Negative

• 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 card 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.

Invalid Invalid Invalid Invalid

【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 antigen of the clinical 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 card should be≥2.5mm.
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.
2 Detection Limit

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

SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold Immunochromatography)

CE

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 Cross-reactivity
Cross-reactivity: This test device has no cross reactivity with endemicity human coronavirus OC43, influenza a virus, influenza B virus, respiratory syncytial virus, adenovirus, EB virus, measles virus, cytomegalovirus, rotavirus, Norovirus, mumps virus, varicella zoster virus, mycoplasma pneumoniae, Human metapneumovirus.
7 Clinical Performance
210 clinical samples based on the nucleic acid detection method (PCR) test results were obtained for testing, 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:

SARS-CoV-2 Antigen Rapid Test Kit	Nucleic acid detection method (PCR)	
	Positive	Negative
Positive	69	1
Negative	6	134
Diagnostic Sensitivity	92.00% (95%CI: 83.63%-96.28%)	/
Diagnostic Specificity	/	99.26% (95%CI: 95.92%-99.87%)

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 test card bag contains desiccant, and it should not be taking orally.
5. When testing, please wear protective clothing, medical mask, gloves and goggles.
6. Do not use the test card with broken single packaging, unclear marks, and past the expiration date.
7. Dispose of used specimens, test cards and other waste in accordance with relevant local laws and regulations.
8. The test card should be used within 1 hour after being taken out of the aluminum foil bag.
9. The users should take samples according to the requirements of IFU.
10. Before the test, the double-sided adhesive protective layer should be removed in advance to prevent liquid splashing. If the double-sided adhesive protective layer is torn off after adding diluent, it is easy to cause liquid splashing.
11. 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】

	DO NOT USE IF PACKAGE IS DAMAGED		CONSULT INSTRUCTIONS FOR USE
	DO NOT REUSE		USE-BY DATE
4°C 30°C	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		

【Basic Information】

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

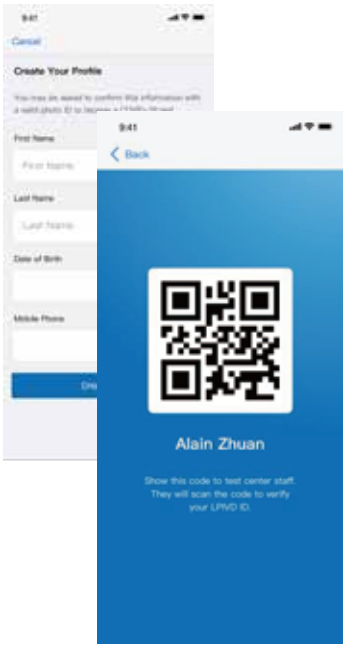
【Approval Date and Revision Date of the Instruction】

Approved on 2nd, Sept., 2020;
Version number: CE-InCG27 REV.06

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

App operation steps

Step 1: Download and register your account;



Step 2: Create user's profile and generate QR code;

Step 3: Wait the doctor to scan QR code on both smart phone and card;

Step 4: After generating results, doctors scan the QR code on the card again to input the result;

Step 5: Get the results after the doctor upload the result and have A LEPU PASS;

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

LEPU MEDICAL

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 Changjie

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

CE

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

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

LEPU MEDICAL

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

Revision history:

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

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

CIBG
Ministerie van Volksgezondheid, Welzijn en Sport

> Retouradres Postbus 16114 2500 BC Den Haag

Lepu Medical (Europe) Coöperatief U.A.
T.a.v. de heer A. Zhao
Abe Lenstra boulevard 36
8448 JB Heerenveen

Farmatec

Bezoekadres:
Hoftoren
Rijnstraat 50
2515 XP Den Haag

T 070 340 6161

http://hulpmiddelen.farmatec.nl

Inlichtingen bij:
M. Schmitz - Konte

medische_hulpmiddelen@minvws.nl

Ons kenmerk:
CIBG-20204312

Bijlagen
-

Uw aanvraag
3 september 2020

Correspondentie uitsluitend richten aan het retouradres met vermelding van de datum en het kenmerk van deze brief.

Datum: 7 september 2020
Betreft: aanmelding In-vitro diagnostica

Geachte heer Zhao,

Op 3 september 2020 ontving ik uw notificatie krachtens artikel 4, eerste lid van het Nederlandse Besluit in-vitro diagnostica (BIVD) om onder de bedrijfsnaam Beijing Lepu Medical Technology Co., Ltd met Europees gemachtigde Lepu Medical (Europe) Coöperatief U.A. onderstaand product als in-vitro diagnosticum op de Europese markt te brengen.

Het product staat geregistreerd als in-vitro diagnosticum onder nummer:

SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold Immunochromatography)
(geen merknaam) (NL-CA002-2020-53290)

Hiermee heeft u voldaan aan uw verplichting op grond van artikel 4, BIVD.

In alle verdere correspondentie betreffende bovenvermeld product verzoek ik u dit nummer te vermelden. Aan dit nummer kunnen geen verdere rechten ontleend worden, het dient alleen om de notificatie administratief te vergemakkelijken.

De registratie van in-vitro diagnostica als medisch hulpmiddel op grond van de Classificatiecriteria (Bijlage II) bij Richtlijn 98/79/EG betreffende medische hulpmiddelen voor in-vitro diagnostiek is onderhevig aan mogelijke revisies van Europese regelgeving inzake de classificatie van medische hulpmiddelen en aan voortschrijdend wetenschappelijk inzicht (zie artikel artikel 10, eerste lid van Richtlijn 98/79/EG).

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

Notificatie van in-vitro diagnostische medische hulpmiddelen impliceert dat de fabrikant, Beijing Lepu Medical Technology Co., Ltd de CE-conformiteitsmarkering heeft aangebracht op het desbetreffende product alvorens het in een EU-lidstaat in de handel te brengen. Zodoende garandeert Lepu Medical (Europe) Coöperatief U.A. dat het in-vitro diagnosticum voldoet aan de essentiële eisen zoals opgenomen in bijlage I bij Richtlijn 98/79/EG (en in het daarmee corresponderende onderdeel 1 bij het besluit)

Volledigheidshalve wijzen wij u erop dat een in-vitro diagnosticum moet voldoen aan de eisen uit het BIVD. Het BIVD is gebaseerd op Richtlijn voor in-vitro diagnostiek, 98/79/EG. Met name wijzen wij u op de Nederlandse-taaleis zoals deze in Nederland geldt, de eisen voor het ter beschikking houden van de technische documentatie en de plicht tot het hebben van een Post Marketing Surveillance- en vigilantiesysteem.

Tot slot merk ik op dat met uw notificatie - de administratieve notificatie als fabrikant - en deze brief geen sprake is van een oordeel over de status of kwalificatie van uw product: notificering betekent niet dat daadwerkelijk sprake is van een in-vitro diagnosticum in de zin van de onderhavige wet- en regelgeving. In voorkomende gevallen kan de Inspectie Gezondheidszorg en Jeugd (IGJ), belast met het toezicht op de naleving van het bij of krachtens de wet bepaalde, een standpunt innemen over de status van een product, waarbij het volgens vaste jurisprudentie uiteindelijk aan de nationale rechter is om te bepalen of een product onder de definitie van in-vitro diagnosticum valt.

De Minister voor Medische Zorg en Sport,
namens deze,

Afdelingshoofd
Farmatec

Dr. M.J. van de Velde

LEPU MEDICAL

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

SARS-CoV-2
Antigen Rapid Test Kit
(Colloidal Gold Immunochromatography)

CE

We Offer:	Sample treatment solution	
1 Test / Kit	1 ml *1	Confirm before order
5 Tests / Kit	1 ml *1	Confirm before order
10 Tests / Kit	2 ml *1	Confirm before order
25 Tests / Kit	3 ml *2	Standard Package
50 Tests / Kit	5 ml *2	Confirm before order
What's inside the box: (25 Tests / Kit)		
25 Test Cards		
Sample treatment solution: 3ml × 2		
1 Instruction of use: in 4 languages, EN /ES /RS /PB		
600 Tests Carton		
25 Tests / Kit	24 Kits	
Size	620*440*485mm	
Weight (Estimated)	21.1KG	

• One package offers:

25 Tests / Kit

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