LEPU MEDICAL

KRÖNER
MEDIZINTECHNIK
Technik und Leidenschaft

SARS-CoV-2 Antigen Rapid Test

The Rapid Antigen Test for Novel Coronavirus (SARS-Cov-2) is an in vitro diagnostic test for the qualitative detection of novel coronavirus antigens in nasopharyngeal swabs and oropharyngeal swabs using the rapid immunochromatographic method. Identification is based on the monoclonal antibodies specific for the novel coronavirus antigen. This product is intended for professional use in the laboratory and at the point of care.

available at Rutronik24.com

Features

- High clinical sensitivity (92.00%) and specificity (99.26%)
- Rapid and reliable test results in 15 minutes
- Can be performed with nasal samples
- All test components are included
- Tested by Paul-Ehrlich-Institute
- Officially listed by the federal institute for pharmaceuticals and medical products

PU 25

Test carrier, package insert, sterilised swab, nozzle with filter and sample collection buffer

Airport | Hotel | Hospital | Station | Company | Personal

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 and corresponding antibody in the quality control area. 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. 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. Regardless of the presence or absence of the virus in the sample, a purple stripe will appear in the quality control area. The purple stripe in the quality control area is a criterion for the judgment of whether or not there is enough sample and whether or not the chromatography procedure is normal.

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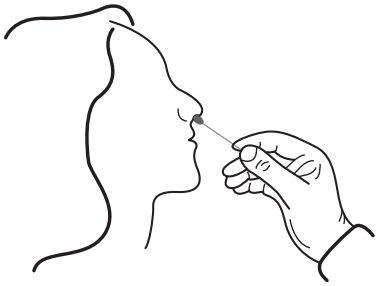
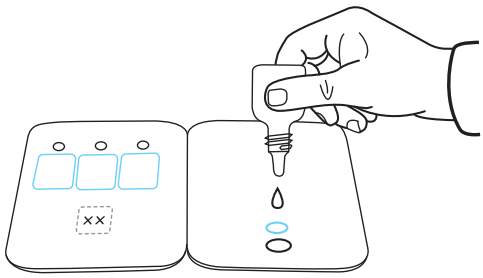
Instruction

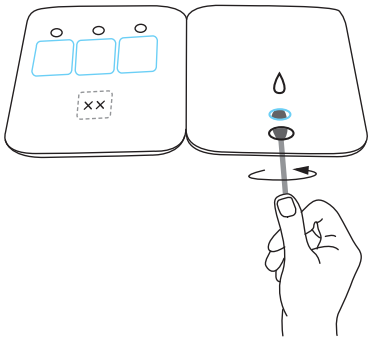
Operation steps



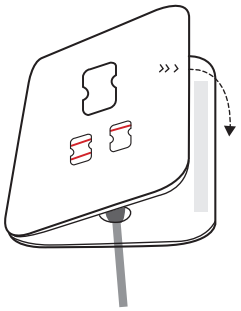
Step1: Collect the swab



Step2: Add 4 drops of buffer to hole A



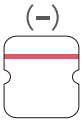
Step3: Insert the sample through hole B to hole A, rotate the swab clockwise first and counterclockwise, twice each.



Step4: Peel off the adhesive, and fold the left side over, wait for 15 minutes.

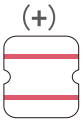
Result Interpretation

Negative



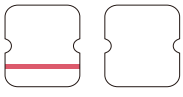
Top line only

Positive



Both bottom line and top line

Invalid



Bottom line only, or no line

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

【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
5 tests/kit	5 tests	1	1ml
10tests/kit	10 tests	1	2ml
25 tests/kit	25 tests	1	3ml
50 tests/kit	50 tests	1	6ml
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℃~ 30℃, 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】

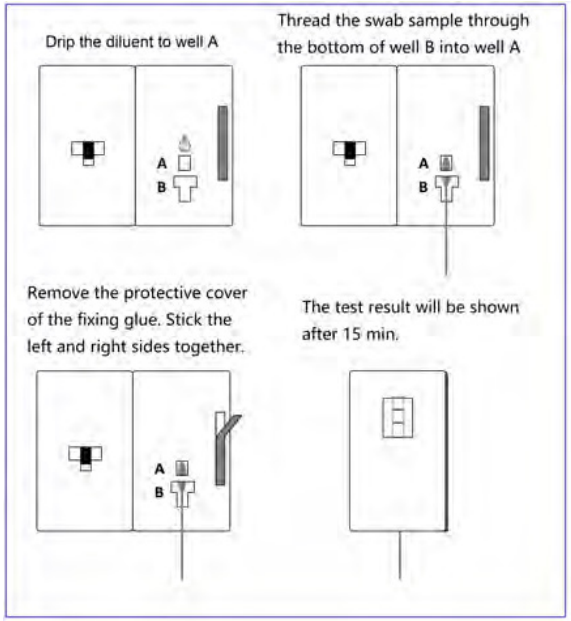
The product is used to test the human nasal swab sample. Sample collection: During the collection procedures for samples, take care to make proper protection, and avoid direct contact with the sample. In case of accidental contact, disinfection treatment should be carried out in time and necessary measures should be taken. Nasal swab sample: gently and slowly insert the swab into the nasopharynx through the nasal cavity. When resistance is encountered, the swab will arrive at the posterior nasopharynx. After a few seconds of suction, gently rotate the swab, then take out the swab to obtain the nasal swab sample. Sample preservation: after sample collection, please complete the test within 1 hour.

The sample should come to room temperature before testing.

【Test Method】

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

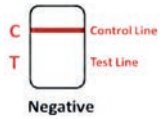
1. Remove the test card from the test card bag and use it within 1 hour, especially in the environment with room temperature higher than 30 ° C or in high humidity.
2. Place the test card on a clean platform. Drip 5 drops of the sample treatment solution to well A.
3. Thread the swab head through the bottom of well B into well A and rotate it two rounds clockwise and counterclockwise respectively in the sample treatment solution.
4. Remove the protective cover of the fixing glue. Stick the left and right sides together and start timing. Wait until the purple band appears. The test result should be read within 15-20 minutes.



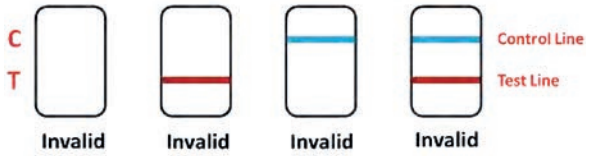
【The Explanation of the Testing Results】】

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

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



• 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.



【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
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 Analytical Specificity
6.1 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.
6.2 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.

【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 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.

【Explanation of Symbols】

	DO NOT USE IF PACKAGE IS DAMAGED		CONSULT INSTRUCTIONS FOR USE
	DO NOT REUSE		USE-BY DATE
	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】

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Approval Date and Revision Date of the Instruction:
Approved on 2nd, Sept., 2020;
Version number: CE-InCG27 REV.01

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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 Mingjue

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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