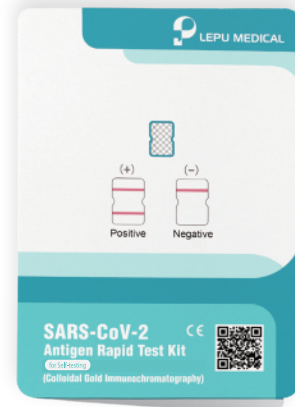


SARS-CoV-2

Antigen Rapid Test Kits **for Self-testing**

(Colloidal Gold Immunochromatography)

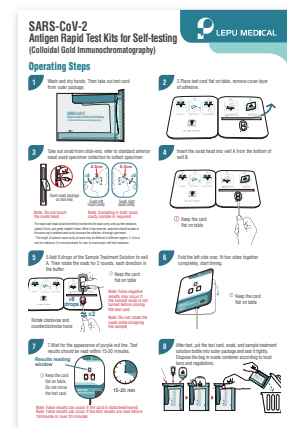




Swab



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

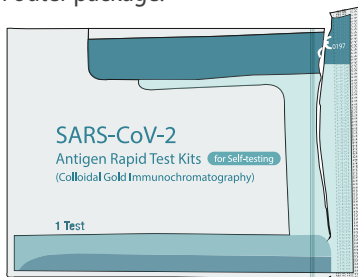
The clinical performance study for SARS-CoV-2 Antigen Rapid Test Kit was conducted in Germany. A total of 222 clinical samples were used to perform the test. The positive and negative samples were all confirmed by PCR. The diagnostic sensitivity and diagnostic specificity of the product was 95.9% (90.8-98.2%)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

Results with correlation to Ct value of the positive samples were shown in the table below

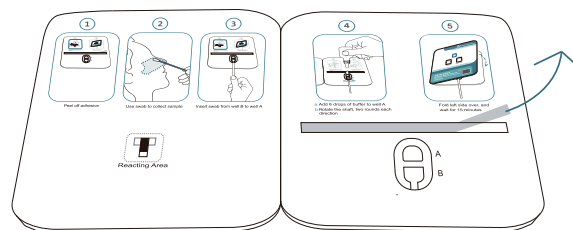
Ct Value	Diagnostic sensitivity	95%CI
≤ 30	96.2 %	88.3-98.7%
≤ 32	96.0 %	90.0-98.4%
≤ 34	95.5%	90.0-98.1%
≤ 36	95.9 %	90.8- 98.2%

Operating Steps

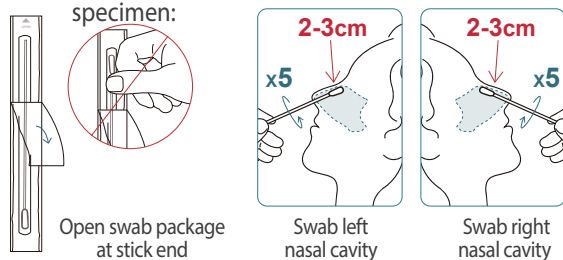
- 1 Wash and dry hands. Then take out test card from outer package.



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



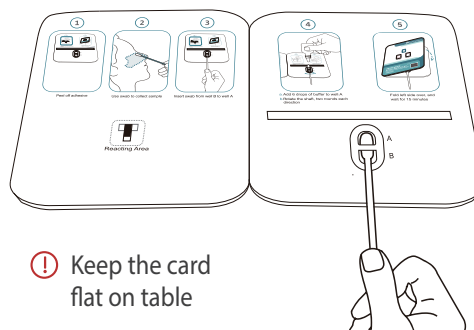
- 3 Take out swab from stick-end, refer to standard anterior nasal swab specimen collection to collect specimen:



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

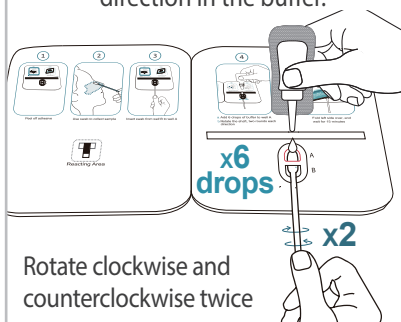
The nasal swab head should be entirely inserted into the nasal cavity until you feel resistance (about 2-3cm), and gently rotated 5 times. When it was removed, specimen should be taken in the same way in another nasal cavity to ensure the collection of enough specimens. The length of anterior nasal cavity 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.

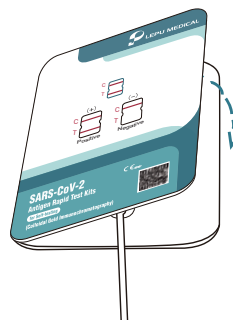


⚠ Keep the card flat on table

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.

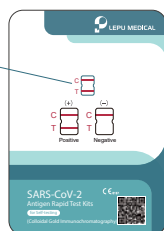


⚠ Keep the card flat on table

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

Results reading window

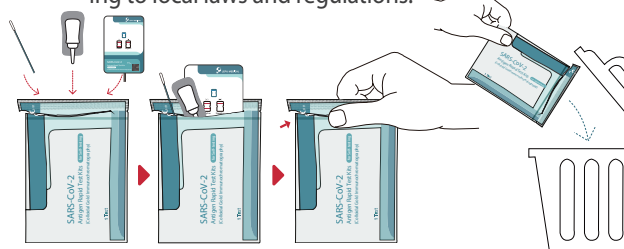
⚠ Keep the card flat on table, Do not move the test card



15-20 min

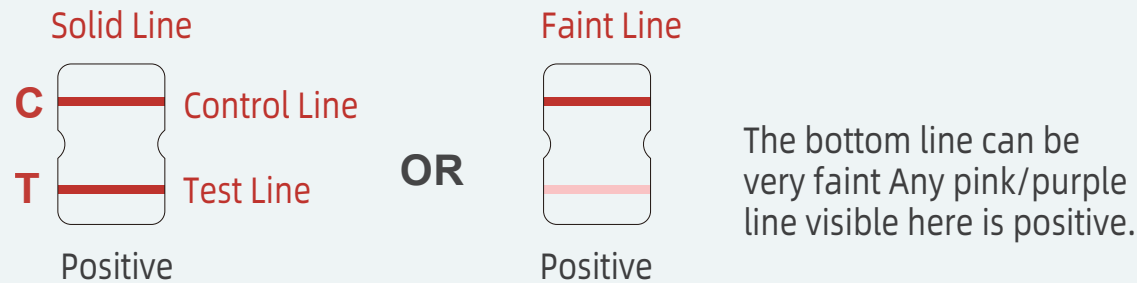
Note: False results can occur if the card is disturbed/moved.
Note: False results can occur if the test results are read before 15 minutes or over 20 minutes.

- 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.

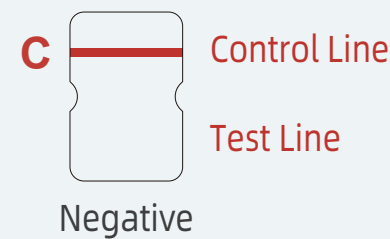


Interpretation of Test Results

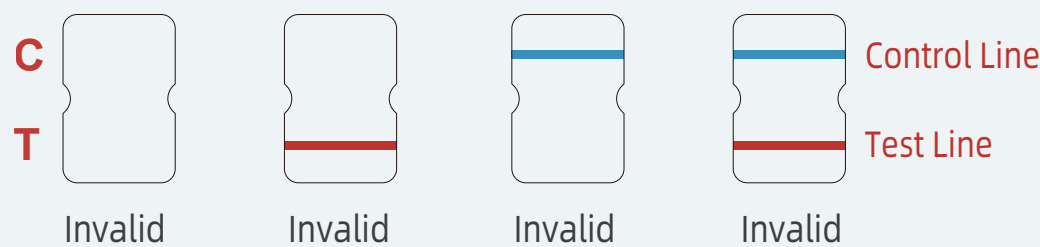
·Positive (+): A purple-red band appears in the Control Line (C) and Test Line (T).



·Negative (-): Only the Control Line (C) shows a purple-red band. No purple-red band appears in the Test Line (T).



·Invalid: If "no purple-red band appears in Control Line (C)" and "a blue band appears in the Control Line (C)" , it indicates that the operation process is incorrect or the test paper has been damaged. In this case, please read the instruction manual carefully again and retest with a new test paper. If the problem persists, please stop using this batch of products immediately and contact your local supplier.



Product specifications



Self-testing



Home



Test Site



Airport



Hotel



Corporation



Mass Screening



SARS-CoV-2 Antigen Rapid Test Kits for Self-testing (Colloidal Gold Immunochromatography)

For In-Vitro Diagnostic Use Only

[Packaging Specification]

1 test kit, 1 sample vial, 19 test strips, 27 test kits, 59 test kits

No.	Component number	Spec.
1	1 test kit	1 piece
2	1 sample vial	1 piece
3	19 test strips	19 pieces
4	1 test kit	1 piece
5	1 test kit	1 piece

[Products]

SARS-CoV-2 Antigen Rapid Test Kits for Self-testing (Colloidal Gold Immunochromatography)

[Intended Use]

This product is a rapid, lateral flow immunoassay intended for the qualitative detection of SARS-CoV-2 nucleocapsid antigen 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. Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen. The antigen is generally detectable in anterior nasal swab specimens during the acute phase of infection. Positive results indicate the presence of viral antigens, but the clinical correlation with past medical history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definitive cause of disease. Negative results should be treated as presumptive and confirmation with a molecular assay, if necessary, for patient management, may be performed. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions including infection control decisions. Negative results should be considered in the context of a patient's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19. Individuals who test negative and continue to experience COVID-like symptoms should seek follow up care from their healthcare provider.

[Introduction]

Coronavirus, as the broad family of viruses, is a single strand plus RNA virus with an envelope. The virus is known to cause major diseases such as cold, Middle East Respiratory Syndrome (MERS) and Severe Acute Respiratory Syndrome (SARS). The core protein of SARS-CoV-2 is N protein (Nucleocapsid), which is a protein component inside the virus. It is relatively conservative among β-coronaviruses and is commonly used as a diagnostic tool for coronavirus. As the key receptor for SARS-CoV-2 to enter cells, ACE2 is the standard for the study of viral infection mechanisms.

[Principle]

The current test kit is based on specific antibody-antigen reaction and immunoassay technique. The test strip consists of gold marked pad (coated with gold-marked SARS-CoV-2 N protein mouse anti human monoclonal antibody), sample pad, NC membrane (paired SARS-CoV-2 N protein mouse anti human monoclonal antibody coated on the test line (T) and goat anti-mouse IgG polyclonal antibody coated on the quality control line (C)) and absorbing paper. During the test, the N protein in the specimen binds to the gold-marked pad, and the conjugate moves upward under the capillary effect, and is trapped by N protein mouse anti human monoclonal antibody conjugated fixed in the Test Line (T). The higher the N protein content in the specimen, the more conjugates are trapped, and the darker the color of the Test Line (T). If there is no SARS-CoV-2 in the specimen or the virus content is below the detection limit, no color appears in the Test Line (T). A purple-red band will appear in the Control Line (C) regardless of whether there is a virus in the specimen. The purple-red band that appears in the Control Line (C) is the criteria for determining whether there is enough specimen and whether the chromatography process is normal.

[Main Components]

The product includes test cards, instruction for use, operation card, disposable sterile swabs and sample treatment solution. Each reagent kit contains 1 level conversion (SARS-CoV-2) antigen test card and 1 bag of desiccant.

Disposable sterile swab information:

Name	Application
Disposable sterile swab information	Nasal swab

CE 0123 MDD 93-42/EEC

Manufacturer 1: Zhejiang Gongsheng Medical Technology Co., Ltd. Beichang Industrial Area 318020 Hangzhou China

CE 0197 MDD 93-42/EEC

Manufacturer 2: Jiangsu Changfeng Medical Industry Co., Ltd. Taoyuan Town, Guangling District Yangzhou 225109 Jiangsu China

CE 0197 MDD 93-42/EEC

Manufacturer 3: Shenzhen KangDa Biological Technology Co., Ltd. Lixiangdian industrial zone, Xili street Nanshan district, Shenzhen 518057 Guangdong China

CE 0413 MDD 93-42/EEC

Manufacturer 4: Medico Technology Co., Ltd. Zhangbei Industrial Park, Longcheng Street, Longgang district, Shenzhen, 518109 Guangdong, China

CE 0197 MDD 93-42/EEC

Manufacturer 5: Goodwood Medical Care Ltd. 1-2 Floor, 5-919, Yongfeng Street, Jiazhou District, Dalian 116100 Liaoning China

CE 0197 MDD 93-42/EEC

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