Section A Device description and specifications including variants and accessories

A.1 Device description of the device

A.1.1 Product name

Generic Name: SARS-Cov-2 Antigen Rapid Test Kits for Self-testing (Colloidal Gold Immunochromatography)

A.1.2 Intended purpose

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.

Results are for the identification of the 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 definite 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.

A.1.3 Principle of the assay method

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 SARS-CoV-2 N protein mouse anti human monoclonal antibody pre-coated on the gold marked pad, and the conjugate moves upward under the capillary effect, and then is trapped by N protein mouse anti human monoclonal antibody conjugate 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.

A.1.4 Intended patient population

The test is used for individuals who meet COVID-19 clinical and / or epidemiological criteria.

A.1.5 Intended user

The anterior nasal swabs 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.

A.1.6 Basic principles of operation

A.1.6.1 Sample requirement:

This test kit is suitable for testing human anterior nasal swab specimens.

Specimen collection: During the collection process, relevant personnel should be well protected to avoid direct contact with the specimen. In case of accidental contact, timely disinfection should be carried out and necessary measures should be taken.

Anterior nasal swab specimen collection: During sampling, 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 the other nasal cavity to ensure the collection of enough specimens.

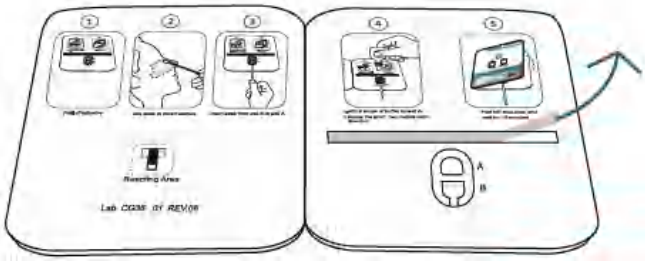
Specimen preservation: After the specimen are collected, please test immediately after sampling. Do not complete the test over 1 hour.

A.1.6.2 Test methods:

Please read the instruction manual completely before performing any test, and use the reagents and specimens after returning to room temperature.

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

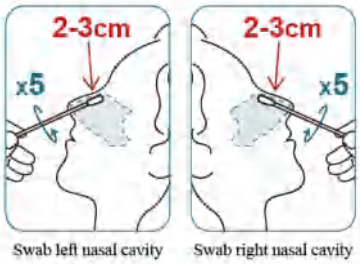
2.Place test card flat on table, remove cover-layer of adhesive.



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

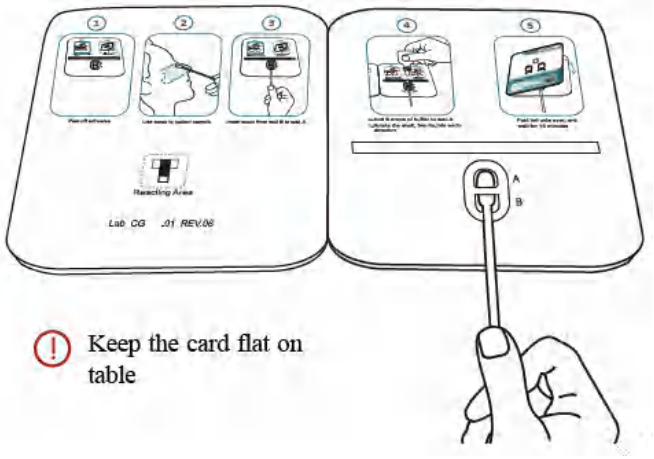
*The length of anterior nasal cavity of users may be different in different regions, 2~3cm is only for reference. Itis recommended for user to insert swab until feel resistance.

Note: Do not touch the swab head.

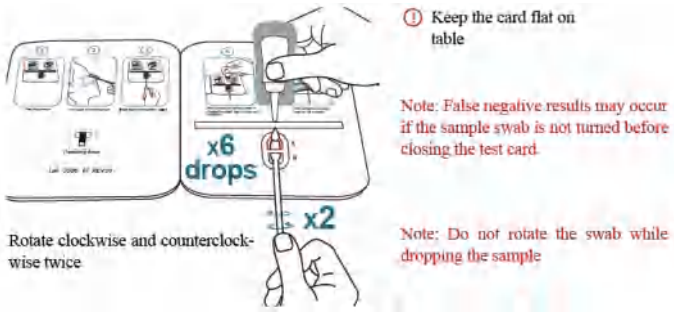


Note: Sampling in both nasal cavity sample is required.

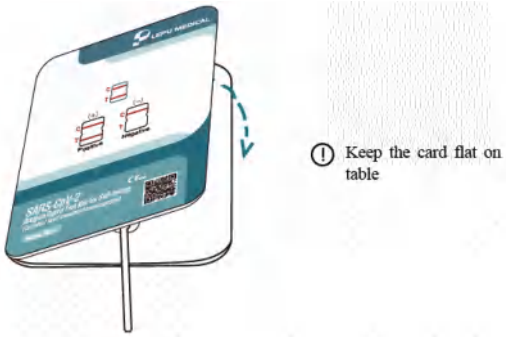
4.Insert the swab head into well A from the bottom of well B.



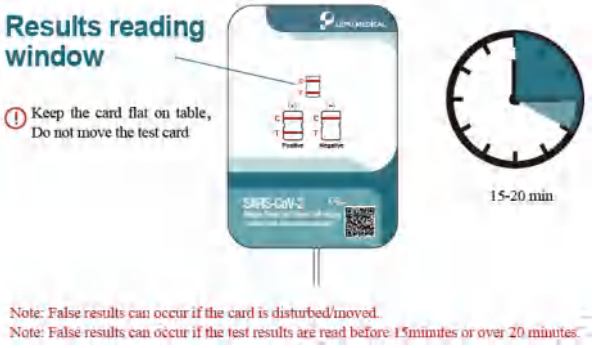
5. Add 6 drops of the Sample Treatment Solution to well A. Then rotate the swab for 2 rounds, each direction in the buffer.



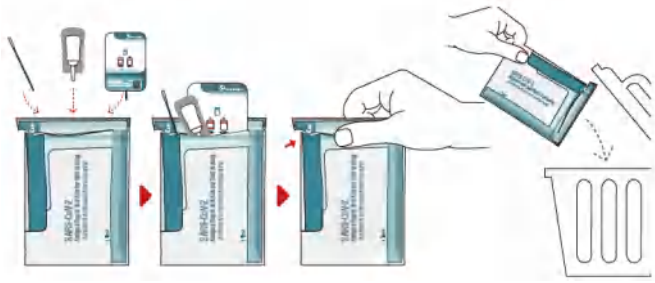
6.Fold the left side over, fit two sides together completely, start timing.



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

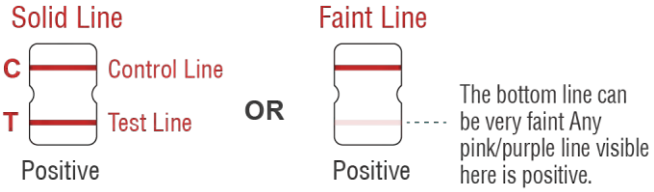


8.After test, put the test card, swab, and sample treatment solution bottle into outer package and seal it tightly. Dispose the bag in waste container according to local laws and regulations.



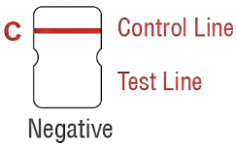
A.1.6.3 Explanation of Test Results:

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



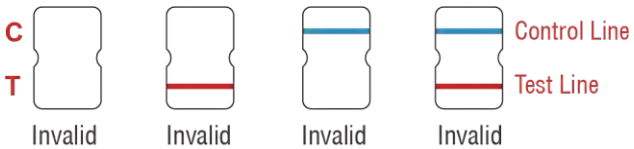
A positive test result means that you may have Corona Virus Disease 2019 (COVID-19). It is important to inform your health care provider of the results. Your healthcare provider will work with you to further confirm the diagnosis of COVID-19 and determine how best to care for you based on your test result(s) along with your medical history, symptoms and other related medical tests.

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



A negative test result means that proteins from SARS-CoV-2 which causes COVID-19 were not found in your sample.
Negative results are presumptive and confirmation with a molecular assay, if necessary, for patient management may be performed. Negative results should be considered in the context of an individual's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19.

● 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.



A.1.6.4 Limitations of the testing method

1. The test results of this product should be combined with other clinical information and comprehensively judged by physicians, and should not be used as the only criterion.

2. This product is only used to determine the novel coronavirus (SARS-CoV-2) antigen in the specimen.

3. A negative test result may occur if the level of antigen in a sample is below the detection limit of the test.

4. False negative results may occur if a specimen is improperly collected or handled.

5. Invalid results may occur if inadequate sample treatment buffer is used (e.g., <6 drops). False negative results may occur if excessive sample treatment buffer is used (e.g., > 6 drops).

6. False negative results may occur if specimen swabs are not twirled within the test card.

7. False negative results may occur if swabs are stored in their paper sheath after specimen collection.

8. False negative results are more likely after seven days or more of symptoms.

9. This test detects both viable (live) and non-viable SARS-CoV-2. Test performance depends on the amount of virus (antigen) in the sample and may or may not correlate with viral culture results performed on the same sample.

10. The performance of the SARS-CoV-2 Antigen Rapid Test Kits for Self-testing (Colloidal Gold Immunochromatography) was evaluated using the procedures provided in this product insert only. Modifications to these procedures may alter the performance of the test.

11. The presence of high concentration mupirocin may interfere with the product and may cause false positive results.

12. Positive test results do not rule out co-infections with other pathogens.

13. Negative test results are not intended to rule in other non-SARS viral or bacterial infections.

14. Negative results do not rule out COVID-19 infection and it may be necessary to obtain additional testing with a molecular assay, if needed for patient management.

15. False positive results may occur if a specimen is infected by SARS-COV-1 because of the cross-reaction in SARS-CoV-1 with product.

A.1.6.5 Internal Quality Control:

The product has a Test Line (T) and a Control Line (C) on the surface of the test card. Neither the Test Line (T) nor the Control Line (C) is visible in the result window before applying a specimen. The control line is used for procedural control and should always appear if the test procedure is performed properly and the test reagents of the control line are working.

A.1.7 Related Previous Submissions

This is the initial submissions.

A.2 Devices covered by the Technical Documentation

The device produced by Lepu Technology is an in vitro diagnostic reagent which is used to qualitatively detect the novel coronavirus (SARS-CoV-2) antigen in clinical specimens (anterior nasal swabs).

For the device, each box contains 1/5/10/25/50 tests card; 1/ instructions for use, 1 operation card, 1/5/10/25/50 bottles of sample treatment solution and 1/5/10/25/50 swabs. For each test card bag, it contains 1 test card and 1 bag of desiccant.

Type	1 test	5 tests	10 tests	25 tests	50 tests
Test card (Each test bag contains 1 test card and 1 bag of desiccant.)	1	5	10	25	50
Instructions for use	1	1	1	1	1
Operation card	1	1	1	1	1
Sample treatment solution	300μl×1	300μl×5	300μl×10	300μl×25	300μl×50
Swabs	1	5	10	25	50

The product consists of test card, instructions for use, operation card, sample treatment solution and nasal swab. And in each card inner bag, it includes one antigen test card and one package of desiccant.

The test card consists of paper shell, test strip, sample well and adhesive tape.

Paper shell provide the basic structure of proposed device. Other components of test card are attached on the paper shell.

Test strip is core reaction area of product, and is attached on the left side of paper shell.

Sample well consists of 2 interconnected wells A and B, and is attached on the right side of paper shell. During test, swab is inserted from well A into well B and sample treatment solution is added to well A.

Adhesive tape is used to stick the 2 sides of paper shell together completely, and is attached on the right side of paper shell.

The photo of the product is shown as the following picture.

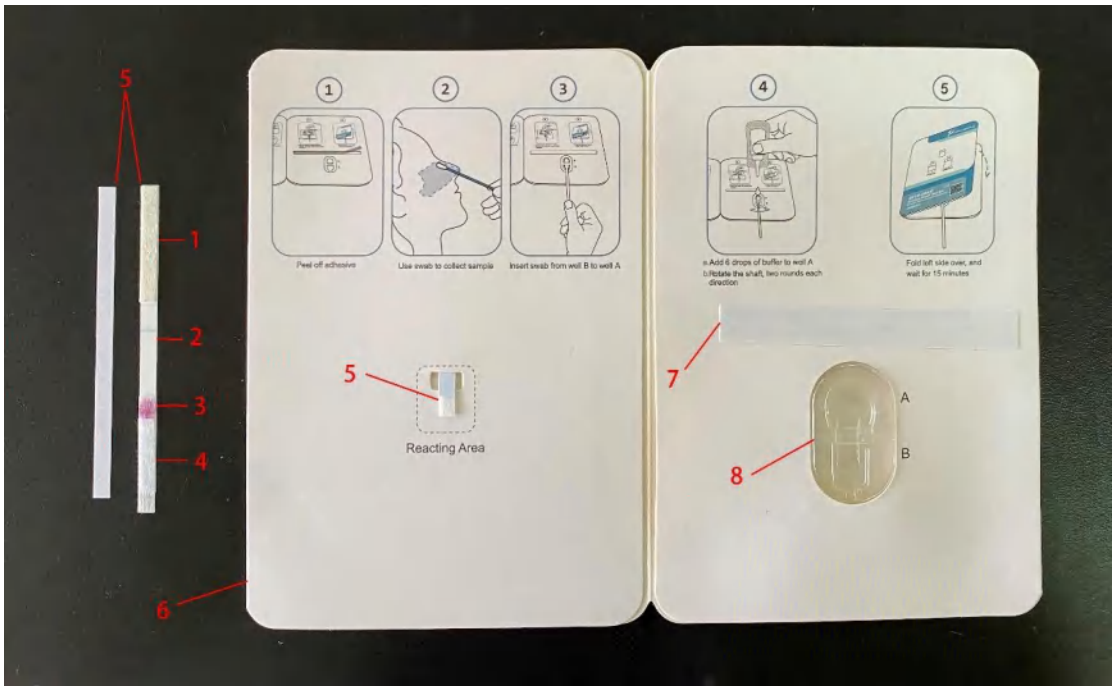


Fig.A.2 Basic structure of test card

1- Absorbing paper **2- Cellulose nitrate membrane** **3- Gold marked pad**

4- Sample pad **5- Plastic carrier board** **6- Paper shell**

7-Adhesive tape **8-Sample well**

A.3 Classification

Classification: Self-testing

Classification route: According to Annex II of the IVDD 98/79/EC, proposed device is not in List A and List B. According to the definition of "device for self-testing": any device intended to be used by lay persons in a home environment, the proposed device is intended to be used by medical professionals or non-professionals (or their families) and it can be used in hospital or home. So the classification of the proposed device is self-testing.

Conformity assessment route: Annex IV of IVDD 98/79/EC, except point 4 and 6.