Product Specifications

Product:
Novel Coronavirus (COVID-19) Antigen Test Kit (Colloidal Gold) for self-testing

Manufacturer:
Hangzhou Laihe Biotech Co., Ltd.

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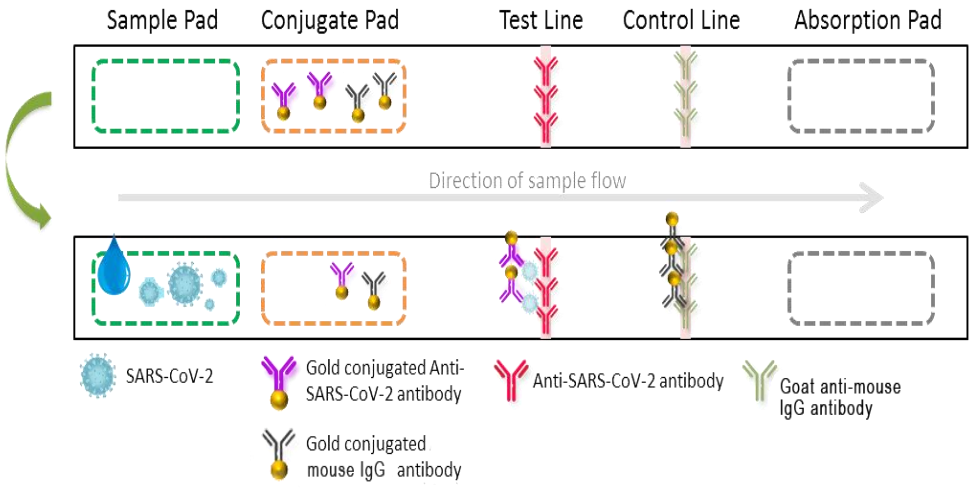
1.1. Short Description of Product

The Novel Coronavirus (COVID-19) Antigen Test Kit (Colloidal Gold) for self-testing developed by LYHER® is intended for the qualitative detection of the antigens(N-proteins) of novel coronavirus in nasal swabs specimens from patients with clinical suspicion of COVID-19 infection. This product is intended to be used as a self-testing IDV for patients from the age of 16. For children under the age of 16, a legal guardian will perform the test or the test will be done under their supervision. It is a rapid test device. The test results can be read within 15 minutes after adding the specimen.

1.2. Device description and Feature

1.2.1. Principle of assay method

LYHER® Novel Coronavirus (COVID-19) Antigen Test Kit (Colloidal Gold) for self-testing is a lateral flow immunoassay. The immune colloidal gold technique is used in the assay to detect N-protein of the antigen of COVID-19. The reagent binding pad is coated with anti-SARS-CoV-2 NP monoclonal antibodies and mouse IgG which are labeled with colloidal gold marker respectively. A nitrocellulose membrane in test area of a strip is coated with mouse anti-SARS-CoV-2 NP monoclonal antibodies. The quality control area within the nitrocellulose membrane is coated with goat anti-mouse IgG antibodies. When testing, the antibodies against COVID-19 form immuno-complexes with the antigen protein of the virus in the specimen to be tested. As a result of chromatography, immuno-complexes move along the membrane and will be captured by the anti-SARS-CoV-2 antibodies coated in the test area to form a visible line with red color (T line). The free colloidal gold marker or immune complexes continue to move forward and specifically bind to the goat anti-mouse antibody coated in the quality control area to form a visible line (C line). If the specimen does not contain the antigen of COVID-19, no test line will show, only quality control line(C line) will appear.



1.2.2. Components of the Product

Components	Specifications				
	A: **1 pc/box**	**B:** **2 pcs/box**	**C:** **5 pcs/box**	**D:** **7 pcs/box**	**E:** **25 pcs/box**
Test device: Sealed in an aluminum foil bag with a desiccant.	1 pc	2 pcs	5 pcs	7 pcs	25 pcs
Prepackaged extraction buffer: 350μL/tube	1 pc	2 pcs	5 pcs	7 pcs	25 pcs
Swab	1 pc	2 pcs	5 pcs	7 pcs	25 pcs
Package Insert	1 pc	1 pc	1 pc	1 pc	1 pc
Stand	/	/	1 pc	1 pc	1 pc
Pictures of Product					
Specification A 1 pc/box					
Specification B 2 pcs/box					
Specification C 5 pcs/box					

Specification D 7 pcs/box	
Specification E 25 pcs/box	

1.2.3. Detail description of Components

1.2.3.1. Test device

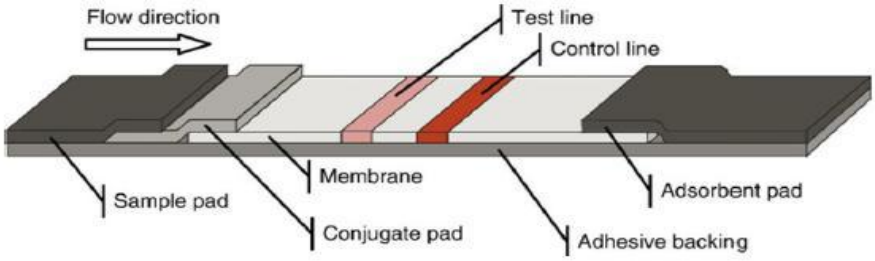
The test device is as the above picture. It is sealed in an aluminum foil bag with a desiccant. The cassette of the test device is made by high impact polystyrene(HIPS). On device must have “C” which is control line, “T” which is test line, “S” which is sample well. There is a test strip in the cassette. The structure of the test strip is as following.

Test Device consist of

(1) Chromatography membrane which is nitrocellulose pad is consist of anti-SARS-CoV-2 NP monoclonal antibodies which will be coated on the “T” (test zone) and goat anti-mouse IgG antibody produces which will be coated on the “C” (control zone)

(2) Conjugate pad producing from polyester is located between sample pad and chromatography membrane which is saturate by colloidal gold-conjugated-mouse anti-SARS-CoV-2 monoclonal antibody and mouse IgG.

(3) Sample pad made from glass fiber

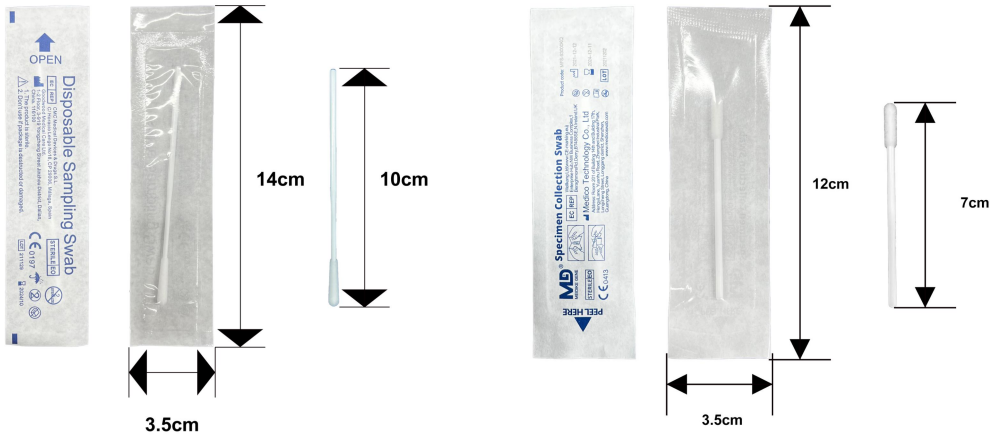


1.2.3.2. Specimen extraction buffer prepackaged in the tube

350μLof extraction buffer being pe-filled in a PE tube. Its ingredients are as follows:

Ingredients	Concentration
NaCl	0.9%
Na_2HPO_4	0.5%
NaH_2PO_4	0.5%
Tween-20	0.2%
H_2O	97.9%

1.2.3.3. Sterile nasal swab



Handle:PP plastic; Swab head:Nylon.

The swabs are supplied by the qualified supplier and all the swabs have been sterilized. The shelf-life of the swab is 3 years and it is longer than the shelf-life of the test device.

The suppliers of swab has been audited by Laihe and they have the certificate of CE& ISO13485.

1.2.4. Specimen collection

- Collection of Specimens

  1. **Nasal Swab:** Make sure the nasal cavity is moist, then Carefully insert the swab into one nostril of the patient. The swab tip should be inserted up to 2-4 cm until resistance is met. Roll the swab 5 times along the mucosa inside the nostril to ensure that both mucus and cells are collected. Using the same swab, repeat this process for the other nostril to ensure that an adequate sample is collected from both nasal cavities. Withdraw the swab.

  Treatment of Specimen: Tear off the buffer seal, insert the swab head into the extraction buffer after specimen collection, mix well, squeeze the swab 10-15 times by compressing the walls of the tube against the swab, and let it stand for 2 minutes to keep as many samples as possible in the specimen extraction buffer. Discard the swab.

  2. Handle all specimens as if they are capable of transmitting infectious agents.

  3. Swab specimens should be tested as soon as possible after collection. Use freshly collected specimens for best test performance.

  4. Do not use specimens that are obviously contaminate with blood, as it may interfere with the flow of sample with the interpretation of test results.

- Treatment of Specimens

  1. Dip the head of the cotton swab into the diluent after taking the sample from the nose.

  2. Squeeze the sample tube with a cotton swab 10-15 times to mix evenly so that the wall of the sample tube touches the cotton swab.

  3. Keep it upright for 1 minute to keep as much sample material as possible in the diluent. Discard the cotton swab. Place the dropper tip on the test tube and to be tested.

1.2.5. Instrumentation characteristics or dedicated instrumentation (if applicable)

Not applicable

1.3. Intended use

The LYHER® antigen test kit (Colloidal Gold) for the novel coronavirus (SARS-COV-2, which causes COVID-19) is a diagnostic test. The test is to be used as an aid in the rapid diagnosis of infection with SARS-CoV-2. The test is used for the direct and qualitative detection of viral protein (the antigen: N protein) of SARS-CoV-2 in nasal mucus. The rapid test uses highly sensitive antibodies to measure the N protein. With this self-diagnostic test, you can find out if you are infected with the virus caused COVID-19. To be used as a self-test from the age of 16. For children under the age of 16, a legal guardian will perform the test or the test will be done under their supervision.

A negative result of the LYHER COVID-19 antigen self-test does not exclude infection with COVID-19. If symptoms are suggestive of COVID-19, a negative result should be verified by laboratory test.

1.4. Instructions of Use

1.4.1. Preparing

- Bring the test kit to room temperature.
- Have watch, clock or stopwatch ready.
- Blow your nose and then wash your hands.
- Open the box and take out all the components. Make sure that you understand the different components of the test kit.
- Open the foil bag and place the test cassette on a clean and dry surface.
- Tear the seal off the tube pre-filled with diluent and gently place it on the surface. The diluent will not deplete the tube.

1.4.2. Specimen collection

- Scan the following QR code for a demonstration video
- the nasal cavity should be moist. Remove the cotton swab from the test kit. Do not touch the cotton wool on the end of the cotton swab!
- Insert the cotton swab into a nostril gently. Insert the tip of the cotton swab 2-4 cm (for children is 1-2 cm) until resistance is felt.
- Swirl the cotton swab along the nasal mucosa 5 times within 7-10 seconds to ensure that both mucus and cells are absorbed.Repeat the process with the same cotton swab in the other nostril to ensure that sufficient sample is taken from both nasal cavities. Pull the swab out of the nasal cavity gently.

1.4.3. Treatment of nasal swab samples

- Dip the head of the cotton swab into the diluent after taking the sample from the nose.
- Squeeze the sample tube with a cotton swab 10-15 times to mix evenly so that the wall of the sample tube touches the cotton swab.
- Keep it upright for 1 minute to keep as much sample material as possible in the diluent. Discard the cotton swab. Place the dropper on the test tube.

1.4.4. Test procedure.

- Nasal swabs should be tested as soon as possible after specimen collection. For optimal testing, fresh samples from the nose should be used.
- Do not use samples that are clearly contaminated with blood as this may interfere and affect the interpretation of the test results.
- Add the sample as follows. Place a clean dropper on the sample tube. Invert the sample tube so that it is perpendicular to the sample hole (S).
- Add 3 drops of the sample. Set the timer for 15 minutes.
- Read the result after 15 minutes. The nasal mucus sample can be read 15 minutes

after adding the sample to the test cassette

- Interpret the results according to the instructions on the IFU
- The used test cassette and all parts of the test can be disposed of with the household waste in a tightly closed bag.

1.5. Limitations

The test cannot confirm the reason of respiratory infection caused by viruses other than SARS-CoV-2. The COVID-19 antigen self-test can detect living and non-living SARS-CoV-2 viruses.

• The test is used for measuring SARS-CoV-2 antigen from a nasal swab. The test could NOT confirm the number of SARS-CoV-2 virus particles in a sample.

• The accuracy of the test depends on the quality of the nasal swab. False-negative results may result from improper collection of the nasal swab.

• Failure to follow the test procedure could adversely affect test performance and/or make the test result invalid.

• If the test result is negative and clinical symptoms persist, it is recommended to use other clinical methods for further testing. A negative result does not rule out the presence of SARS-CoV-2 virus particles in the nasal swab at any time, because the number of virus particles may be present below the minimum detection level of the test. The nasal swab may also have been taken in an improper manner.

• A negative result cannot rule out SARS-CoV-2 infection, especially in people who have been exposed to the virus. A follow-up research of molecular diagnosis should be considered to eliminate infections in these individuals.

• This test is not a substitute for medical consultation or the results of biological analysis in a medical research laboratory.

• A positive test result does not rule out simultaneous infection with other pathogens.

• The antigen detected by the test is the N protein. The different variants of the virus described so far in some countries (United Kingdom, South Africa, Brazil) concern mutations of another virus protein (the so-called Spike protein) and therefore do not affect the reliability of the test.

• Incorrect results may be obtained:

- if the test is not carried out according to the instructions in the user's manual;

- if the foil bag is broken, or if the test is not carried out immediately after the foil bag id is opened;

- if the test package has not been stored under the correct conditions or if the test is carried out after the expiry date on the foil bag.

• A positive result must be confirmed by laboratory analysis. Consult your physician and do not make any major medical decisions without the advice of your physician.

1.6. Warnings

Keep the self-test and components out of the reach of children - ingestion of the diluent can be dangerous.

- The test should only be used once for testing individual sample of nasal mucosa.
- The test kit or its components can no longer be used after the expiry date.
- Do not use the bag if it is open or damaged. Before opening each foil bag must be inspected. Do not use a test cassette with holes in the foil bag or where the foil bag is not fully sealed.
- Do not use the prefilled tube if it is discolored or cloudy.
- The used test cassette and all components of the test kit may be disposed of together with the household waste in a well-sealed bag.
- If samples and reagents are not at room temperature before they are used, test sensitivity may be reduced.
- If nasal mucus samples are collected, stored and transported improperly, false-negative test results may occur.
- Skin and eye contact with the buffer must be avoided. If the solution comes into contact with the skin or eyes, immediately wash with large amounts of water.
- If your skin contact with the buffer directly carelessly. Rinse the skin with large amounts of water please.