LYHER®

SARS-Cov-2 Antigen Rapid Tests for self-testing

Novel Coronavirus (COVID-19) Antigen Test Kit (Colloidal Gold)

For self-testing CE 0197

INTRODUCTION

The novel coronaviruses belong to the β genus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection; asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifestations include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases.

INTENDED USE

The LYHER® antigen test kit 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-testing 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® Novel Coronavirus (COVID-19) Antigen Test Kit does not exclude infection with COVID-19. If symptoms are suggestive of COVID-19, a negative result should be verified by laboratory test.

PRINCIPLE

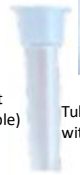
The immune colloidal gold technique is used in the assay to detect antigens of COVID-19. The sample pad is coated with colloidal gold bound antibodies. The quality control area is coated with goat anti-mouse IgG, and test area with anti-SARS-CoV-2 antibodies. When testing, if there are any SARS-CoV-2 antigen, the T line will become visiable red. The C line should be red after add sample.

COMPOSITION

Aluminum Foil Bag

Cassette

Desiccant (disposable)



Tube prefilled with diluent

Dropper

Cotton swab

Specifications: 1 test/box, 2 tests/box, 5 tests/box, 7 tests/box, 25 tests/box.

Manufacturer of Swab:

CE 0413 MDD 93/42/EEC

Medico Technology Co., Ltd.

Room 201 of Building 14th and Building 17th, Hengyi Lane, Yuanhu Road, Zhangbei Industrial Park, Longcheng Street, Longgang district, Shenzhen, Guangdong, China

ADVICES FOR SAMPLE COLLECTION

1. Before each test, hands should be washed to reduce the risk of hand contamination.

2. For accurate results, do not use samples that are too viscous or contain visible blood. Before the test blow nose to remove excess mucus before testing.

LIMITATIONS OF THE TEST

- The test cannot confirm the reason of respiratory infection caused by viruses other than SARS-CoV-2. The COVID-19 antigen self-test kit 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.
- The test results is recommended to be read at 15 minutes after adding sample. Do not read the test result at early than 10 minutes after adding sample because the test need sufficient time to reaction. The results after 20 minutes is invalid.
- The test results shall be read in sufficient lighting conditions.
- 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 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.

ACCURACY

The LYHER® Novel Coronavirus (COVID-19) Antigen Test Kit was examined with nasal mucus samples from individuals either infected or uninfected with SARS-CoV-2 and compared with a molecular test (RTPCR test), in order to determine sensitivity and specificity. The study was done in two countries, one in China and the other in Spain.

Clinical Study In China

COVID-19 Antigen Self-Test Compared to RT-PCR				Sensitivity: 95.0% Specificity: 99.6%
Test results from the Lyher kit	Clinical Diagnosis (PCR results)			
	Positive (+)	Negative (-)	Total	
Positive (+)	152	1	153	
Negative (-)	8	250	258	
Total	160	251	411	

Sensitivity for different CT values

CT value	PCR(+)	Lyher(+)	Sensitivity
≤25	93	93	100.0%
25<CT≤30	51	51	100.0%
33≥CT>30	16	8	50.0%
Total	160	152	95.0%

A feasibility study showed that 100.0% of participants understood how the results should be interpreted. Of the participants, 70.0% found the instructions for use very clear and 30.0% clear. Of the participants, 76.0% found the reading of the test result very clear and 23.0% clear. Of the participants, 67.0% found the test very easy and 33.0% easy.

97.8% of different test results were interpreted accurately. 84.7% of participants completed the test without help.

Clinical Study In Spain

COVID-19 Antigen Self-Test Compared to RT-PCR				Sensitivity: 94.4% Specificity: 100.0%
Test results from the Lyher kit	Clinical Diagnosis (PCR results)			
	Positive (+)	Negative (-)	Total	
Positive (+)	119	0	119	
Negative (-)	7	147	154	
Total	126	147	273	

Sensitivity for different CT values

CT value	PCR(+)	Lyher(+)	Sensitivity
<25	45	45	100.0%
25-30	58	54	93.1%
>30	23	20	87.0%
Total	126	119	94.4%

A feasibility study showed that 100.0% of participants understood the labels on the package and understood how to use the product. 99.3% of participants thought that the sample would be easy to take. 97.4% of participants understood how to interpret the results.

Detection of mutations of SARS-CoV-2

In the clinical studies of LYHER® Novel Coronavirus (COVID-19) Antigen Test Kit, the variants of SARS-CoV-2 have been tested. And LYHER® Novel Coronavirus (COVID-19) Antigen Test Kit can detect the variants of SARS-CoV-2 currently existing. And according to the information public by WHO and FDA, the mainly variants around the world are having spike protein mutation. While detection target of LYHER® Novel Coronavirus (COVID-19) Antigen Test Kit is N protein, so LYHER® kit may not be affected by these mutations.

STORAGE AND STABILITY

1. Store in a dry, protected and dark place between 2-30 ℃. Shelf-life: 18 months. The test kit should not be frozen.
2. The test cassette should be used generally within 30 minutes after opening the foil bag. If the temperature exceeds 30 ℃ or the humidity in the environment exceeds 70%, the test kit should be used as soon as possible after opening the foil bag.
3. The manufacturing date and expiry date are on the outside of the package.

WARNINGS

- Keep the product 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.

PREPARATION

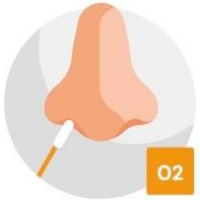
1. Bring the test kit to room temperature.
2. Have a watch, clock or stopwatch ready.
3. Blow your nose and then wash your hands.
4. Open the box and take out all the components. Make sure that you understand the different components of the test kit.
5. Open the foil bag and place the test cassette on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

NASAL MUCUS SAMPLING

Scan the following QR code for a demonstration video

Nasal swab: 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!

01. 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.



02. 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.

Treatment of nasal mucus samples

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

04. 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.

05. 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.

TEST PROCEDURE

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.

06. 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**.

07. Read the result after **15 MINUTES** in sufficient lighting condition.

The test result can be read at **15 MINUTES** after adding the sample to the test cassette.

The result after 20 minutes is invalid.

08. POSITIVE:
two colored lines appear in the test cassette
NEGATIVE:
only a single colored line appears in the control region (C).
INVALID:
The control line (C) does not appear in the test cassette.

09. The used test cassette and all parts of the test can be disposed of with the household waste in a tightly closed bag.

INTERPRETATION

Positive (+) **Negative (-)** **Invalid**

POSITIVE: Two colored lines appear on the membrane. One colored line appears in the control region (C) and the other line appears in the test region (T).

NEGATIVE: Only a single colored line appears in the control region (C). No visible colored line appears in the test region (T).

INVALID: The control line does not appear. The tests results which do not show a control line after the specified reading time should be discarded. The sample collection should be checked and repeated with a new test. Stop using the test kit immediately and contact your local dealer if the problem persists.

CAUTION

1. The color intensity in the test region (T) may vary depending on the concentration of virus proteins present in the nasal mucus sample. Therefore, any color in the test region should be considered positive. It should be noted that this is only a qualitative test and cannot determine the concentration of viral proteins in the nasal mucus sample.

2. Insufficient sample volume, improper procedure or expired tests are the most likely reasons why the control line does not appear.

QUALITY CONTROL

The LYHER® Novel Coronavirus (COVID-19) Antigen Test Kit has integrated (procedural) controls. Each test cassette has an internal quality control line to ensure proper sample flow. Before reading the result, the user must ensure that a dash can be seen in "C" region.

CROSS REACTIVITY & INTERFERENCE RESOURCES

No cross reactivity has been demonstrated for the following viruses and bacteria: *Influenza A & B, Rhinovirus, Adenovirus, Enterovirus, RSV, Varicella-zoster virus, Herpes simplex virus, Epstein-Barr virus, Rotavirus, Norovirus, Cytomegalovirus, Measles virus, Mumps virus, Legionella pneumophila, Coronavirus (HKU1, OC43, NL63, 229E, MERS, SARS), Human meta-pneumovirus, Parainfluenza virus, Haemophilus influenza, Streptococcus pneumoniae, Streptococcus pyogenes, Candida albicans, Bordetella pertussis, Mycoplasma pneumoniae, Chlamydia pneumoniae, Mycobacterium tuberculosis, Pneumocystis jirovecii.*

The following medicines and (body) substances do not affect ester rash: α-interferon, Zanamivir, Ribavirin, Paramivir, Lopinavir, Ritonavir, Abidol, Levofloxacin, Azithromycin, Ceftriaxone, Meropenem, Tobramycin, Phenylephrine, Oxymetazoline, Sodium chloride, Beclomethasone, examethasone, Flunisolide, hemoglobin, white blood cells, mucus, mouthwash, toothpaste, Dexamethasone acetate adhesive tablets and cough drops.

HOW TO ACT AFTER TEST

Questions? For more information please visit the official web sites or hotline of the CDC or related department in your country/area.

With this self-test, you can test whether you currently have a coronavirus infection. Below you can figure out what the results mean and what you should do with the results.

POSITIVE: You probably have a coronavirus infection. You shall go to the hospitals for a professional retest immediately. Why a retest?

A self-test is less reliable than the professional test at the hospitals. Therefore, there is a chance that your positive result is a false alarm. If the retest at the hospital is negative then you may be released from isolation.

NEGATIVE: A negative result gives the absence of SARS-CoV-2 antigens. A negative result from a self-test is not 100 % reliable. A negative result does not rule out a recent infection with SARS CoV-2. If you think you have contact with the virus (with infected person) in the last days before the test is carried out, we recommend that you take a Laboratory Test at the hospitals. Keep following the corona rules; keep your distance, wear mouth mask, wash your hands often and keep watching for complaints. If you have complaints or have had contact with infected person, have yourself tested at the hospital as soon as possible.

INVALID: The test is not valid, do a new test. Reread the procedure and repeat the test with a new cassette. The most likely reasons for the control line not appearing are inadequately sample volume or an overly viscous nasal mucus sample, improper procedural techniques (improper nasal mucus collection, temperature and humidity conditions for performing the test), or tests left open for more than one hour or even expired.

INFORMATION FOR SELF-TESTING USERS

Please note that in the following cases, do not take self-test but go to the hospital for a professional test:
- You have corona complaints
- You have been in contact with infected person
- You have returned from orange region in the last 10 days

INFORMATION

Catalog No.: 303036
Item: SARS-Cov-2 Antigen Rapid Tests for self-testing
Novel Coronavirus (COVID-19) Antigen Test Kit (Colloidal Gold) for self-testing
Specimen: Nasal swab
Format: Cassette

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Guide to Symbols

	Caution		Keep away from sunlight
	Manufacturer	LOT	Batch Code
	Consult instructions for use	2	Do not reuse
	Keep dry		Use-by date
REF	Catalogue number	IVD	In vitro diagnostic
	Do not use if package is damaged	2℃ 30℃	Temperature Limitation (2-30℃)
CE	European Conformity	EC REP	Authorized Representative
	Date when manufactured		

Vesrsion 2.0/EN
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