

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



www.lyherbio.com
 Please read this instruction carefully before Start. You also can find the instructed video in www.lyherbio.com/video/nasal
 This test is for no professional use authorized by GFMOH only.
 This test has not been CE marked for self-testing.
 This test has been authorized only for testing of nasal swabs for detection of antigen from SARS-CoV-2, not for any other viruses or pathogens.

What's included in the kit?



COVID-19 antigen test kit



Paper insert



Swabs

Prepacked extraction buffer

Product information leaflet also include.

When to use the kit?

As an aid in the diagnosis of **current COVID-19 infection**, and
 You have been exposed to COVID-19, and you are concerned

Do not use this kit, when

- Anyone under 2 years old
- You are prone to nosebleed
- You have had a facial or head injury / surgery in last 6 months

What are common symptoms of COVID-19?

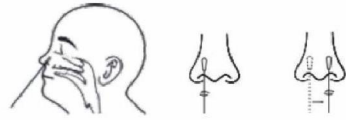
Symptoms may appear 2-14 days after exposure. Common symptoms may include fever, cough, shortness of breath, fatigue, muscle or body aches, headache, loss of sense of taste or smell, sore throat, congestion or a runny nose, nausea or vomiting and diarrhea. And sometimes, infected with no symptom at all.

Will this test hurt?

No, the nasal swab is not sharp and it will not hurt. Sometimes you may feel slightly uncomfortable when use the nasal swab collecting samples.

How do I know I have got a good sample?

Collecting a good sample requires rolling or rubbing the swab around the inside walls of both nostrils.
 Making sure you are touching the inside walls of the nostrils is very important.



Inserted the swab softly, until it touch the inside wall of the nostril.

Rotating the swab 5 times around the inside wall.

Inserted the swab softly into another nostril.
 Rotating the

What if the C-line did not display?

This means something with the test did not work properly. And the result is invalid. Please contact us at 0086-571-8665-8090 and we will assist you.

How accurate is this kit?

Lyher COVID-19) Antigen Test Kit is a rapid in vitro diagnostic test that has an analytical sensitivity, or ability to detect the SARS-CoV-2 virus, that is comparable to some of the best molecular tests performed in clinical settings and high complexity labs. In the Community Testing Studys, where the Lyher test was compared to a FDA authorized known high sensitivity SARS-CoV-2 test, Lyher test achieved a 95.0% sensitivity and a 99.6% Specificity.

Test Results of Lyher Kit	Clinical diagnosis(PCR results)		
	Positive(+)	Negative(-)	Total
Positive(+)	152	1	153
Negative(-)	8	250	258
Total	160	251	411

Clinical Sensitivity: 95.00% (90.39% , 97.82%)*
 Clinical Specificity: 99.60 (97.80% , 99.99%)*
 Total coincidence rate: 97.81% (95.88% ,

98.99%)*

*95% Confidence Interval

Indication

The Lyher COVID-19 Test Kit is a single-use test kit intended to detect the novel coronavirus SARS-CoV-2 that causes COVID-19.
 This test is authorized for prescription home use with self-collected nasal swab samples in individuals aged 14 and older who are suspected of COVID-19 by their healthcare provider. And in individuals aged 13 and under when the specimen is collected by his/her guardian.

This test utilizes a immune colloidal gold technique for the detection of SARS-CoV-2 antigens (N-protein) in individuals with known or suspected COVID-19.

Positive results are indicative of the presence of SARS-CoV-2. Individuals who test positive should self-isolate and seek additional care from their healthcare provider. Positive results do not rule out bacterial infection or co-infection with other viruses.

Negative results do not preclude SARS-CoV-2 infection. Individuals who test negative and continue to experience COVID-like symptoms should seek follow up care from their healthcare provider.

For use under the German Federal Ministry of Health's Authorization only.

Preparing the test

- Ensure your test is in room temperature (16-26°C)
- Ensure you have a horizontal table to do the test.
- Ensure you have a Clock, watch or mobile which can calculate the time.
- Ensure all packaging is intact.
- Only open the foil packaging when your are ready to do the test. Use it within 1 hour after opening.
- Wash your hands with soap and water, and



dry it before use.

- √Keep the swab clean.
- √Watch the operation video, if you are the first time to do the test. Please follow the video or this instruction step by step.

Do's during the test

- √Follow this instruction step by step carefully. Incorrect use may lead to a invalid result or incorrect result.
- √Children aged 2 to 13 must be tested by an adult (≥18 years old).
- √Children aged 2 to 13 must be swabbed with the child Adapter in place.
- √Keep out reach of children. To avoid putting it in their mouth and results to choking.
- √Only use the components provided. Do not replace the buffer by any other fluid.
- √Keep the swab clean.
- √Small children should be swabbed with the help of another adult.
- √After collecting the sample, immediately inserted it into the extraction buffer.
- √Keep the Cassette on a flat surface until the result is display.
- √Keep other substance away from the test during the testing.

Do not's during the test

- xDo not use the kit if the foil packaging is damaged.
- xDo not test second sample in the same Cassette after it had been used.
- xDo not test under direct sunlight, or put it under direct sunlight after open the foil packaging.
- xDo not use it on anyone under 2 years.
- xDo not dropped the Cassette after it had been taken out of the foil packaging.
- xDo not touch the tips of the swab, and ensure it does not touch any surface before use.
- xDo not touch the extraction buffer directly by any part of your body.
- xDo not take the test result as the only guide to manage your situation. Please consult

your doctor if your symptoms persist or become more severe.

Instructions - Start Here

Preparation

- ① Take the kit into room temperature (16-26°C)
- ② Make sure your test kit contain: 1×Cassette (foil packaging), 1×swab, 1×extraction buffer with tips, 1×Tube Stand, and 1×Instruction. And all of the packing are intact.
- ③ Get your flat surface and timer ready.
- ④ Wash and dry your hands.
- ⑤ Open the foil packaging of the Cassette, put it on the flat surface, and let the side with sampling hole faces up.
- ⑥ Fold up the Tube Stand, and put the extraction buffer tube into the hole.
- ⑦ Open the swab, Hold the end with the handle. Avoid touch the tip.

Collecting the sample

- ① Make sure the nasal cavity is moist.
- ② Carefully insert the swab into one nostril. The swab tip should be inserted up to 2-4 cm until it touch the inside wall of the nostril.



- ③ Roll the swab 5 times around the inside wall. Withdraw the swab.



- ④ Using the same swab, Carefully insert into another nostril. The swab tip should be inserted up to 2-4 cm until it touch the inside wall of the nostril.

- ⑤ Roll the swab 5 times around the inside wall. Withdraw the swab.



Pay particular attention to the instructions on how to swab your nose. Incorrect swabbing may lead to an inaccurate result. This is particularly important if you haven't any symptoms.

Treatment of Specimen

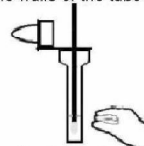
- ① Tear off the seal of the extraction buffer tube.

Please insert the image of "Tear off the seal" here.

- ② Insert the swab tip into the extraction buffer after specimen collection.



- ③ Squeeze the swab 10-15 times by compressing the walls of the tube against the swab.



- ④ let it stand for 1 minutes to keep as many samples as possible in the extraction buffer.



- ⑤ Discard the swab. Place the dropper tip on the tube

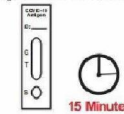


Testing

- ① Invert the tube so that it is perpendicular to the sample hole.
- ② Add 3 drops of the sample into the hole.



- ③ Record the time, waiting for 15 minutes, read the result.



Interpretation of Results



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

NEGATIVE: Only one colored line appears in the control region (C). No apparent colored line appears in the test region (T).

INVALID: Control line fails to appear. Please contact us at 0086-571-8665-8090 and we will assist you.



+ positive

A positive result indicates that you are likely have COVID-19 disease.

You need to:

1. Consult your doctor as soon as possible. Please tell them that you tested positive for COVID-19.
2. If you have no symptoms, particularly if you live in low COVID-19 infection area and have had no exposure to anyone diagnosed with COVID-19, additional molecular testing to confirm may be required.
3. you should self-isolate at home as recommendation to stop spreading the virus to others.

- negative

A negative result indicates that you are unlikely have COVID-19 disease currently.

1. Please note that negative cannot rule out infection of COVID-19.
2. If your symptoms persist or become more severe, please consult your doctor.
3. You may need additional molecular testing to confirm your test result.

Warnings and precautions

1. This product is only used for testing of individual Nasal specimens.
2. A negative result does not rule out the possibility of COVID-19 infection.
3. The test results of this product are for clinical reference only and shall not be taken as the only basis for clinical diagnosis and treatment.
4. The intensity of color in a positive line should not be evaluated as quantitative or semi-quantitative.
5. Failure to follow the TEST PROCEDURE may adversely affect test performance and / or invalidate the test result.
6. If the Cassette touching water before test, do not use it.
7. Do not use the kit in Humid environment, or directly under the sunlight.
8. Do not use the kit in the temperature under 15°C or above 30°C.
9. Do not use the kit on the child under 2 years old.
10. If the extraction buffer is leaked or spill out before the swab was handled, do not use.
11. Add sample less that 3 drops may lead to incorrect result.
12. Read the result after more that 20 minuets or less than 15 minuets will lead to incorrect result.

Catalogue No. 303036

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

Specimen: Nasal swab specimens

Format: Cassette



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 Amsterdam, Netherlands

Guide to Symbols

	Caution		Keep away from sunlight
	Manufacturer		Batch Code
	Consult instructions for use		Do not reuse
	Keep dry		Use-by date
	Catalogue number		In vitro diagnostic
	Do not use if package is damaged		Temperature Limitation (2-30°C)
	European Conformity		Authorized Representative
	Date when manufactured		For self-testing