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

INSTRUCTIONS FOR USE
For self-testing with nasal swab specimens

Scan this QR Code to access a video of these instructions.

To access instructions printed in other languages and formats, please visit our website: www.2san.com/tga-ifu or call us on: 1800 630 750 (9 am to 7 pm AEST 7 days/week)

Please read the warnings and precautions for use before you start the test. You must carefully follow all instructions in the test procedure to achieve accurate results.

**TEST PROCEDURE**

**PREPARATION**

1. Bring the test kit to room temperature and have good lighting.
2. Have a watch, clock or stopwatch ready.
3. Blow your nose to remove excess mucus and then wash your hands to reduce the risk of contamination.
4. Open the box and remove the components. Ensure you can correctly identify them.
5. Open the foil pouch and place the test cassette on a clean and dry flat surface.
6. Tear the seal off the tube pre-filled with diluent and gently place it on a clean and dry flat surface.

**COLLECTING YOUR SAMPLE SPECIMEN**

01. Remove the nasal swab from the packet. Do not touch the cotton wool at the end of the swab. Insert the swab gently into your nostril. Insert the tip of the swab 2-4 cm (for children is 1-2 cm) until resistance is felt.

02. Roll the swab along the inside of one nostril 5 times within 7-10 seconds. Gently remove the swab. Repeat this step in your other nostril with the same swab.

**TESTING YOUR SAMPLE SPECIMEN**

03. Insert the tip of the swab containing your sample into the tube pre-filled with diluent.

04. Squeeze the sample tube with the swab inserted 10-15 times to mix evenly so that the wall of the sample tube touches the swab.

05. Use the sample tube holder provided to keep the tube upright with the swab inserted for 1 minute to expose as much of the sample to the diluent. Remove the swab from the sample tube and fit the dropper ensuring it’s well sealed.

06. Invert the sample tube perpendicular to the sample hole (S) on the test cassette.

07. Read the result after 15 MINUTES in good lighting.

Results observed after 20 MINUTES are considered invalid.

08. Interpret your results as directed below.

09. The used test cassette and all parts of the test should be disposed of with household (not recyclable) waste in a sealed bag.

**TREATING YOUR SAMPLE SPECIMEN**

04. Squeeze the sample tube with the swab inserted 10-15 times to mix evenly so that the wall of the sample tube touches the swab.

05. Use the sample tube holder provided to keep the tube upright with the swab inserted for 1 minute to expose as much of the sample to the diluent. Remove the swab from the sample tube and fit the dropper ensuring it’s well sealed.

06. Invert the sample tube perpendicular to the sample hole (S) on the test cassette.

Add 3 drops of sample to the sample hole (S). Set the timer for 15 MINUTES.

**INTERPRETING YOUR RESULTS**

Positive (+)

Two coloured lines appear on the test cassette. One coloured line appears in the control region (C) and the other line appears in the test region (T).

Any colour including a weak or faint line in the test region should be interpreted as a positive result.

What you need to do:

1. You must self-isolate to avoid spreading the virus to others.
2. Consult your state or territory health department or your healthcare professional as soon as possible to arrange a confirmatory laboratory PCR test.

Negative (-)

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

What you need to do:

It is possible for this test to give a negative result that is incorrect (false negative) in some people with COVID-19. The risk of a false negative result increases after the first seven days of symptom onset. This means that you could possibly still have COVID-19 even though the test result is negative.

1. You should repeat this test within 1-3 days if you have ongoing suspicion that you have COVID-19 or you are in a high risk setting or where there is an occupational risk or other requirement.
2. If your symptoms develop, persist or become more severe, you must seek immediate further testing by a laboratory PCR test.

Invalid

The line in the control region (C) does not appear. Even if a line appears in the test region (T), the test is still invalid.

What you need to do:

If your test is invalid, re-read the instructions and repeat the test with a new cassette or consult your healthcare professional. Until a new test is completed with a valid result you should self-isolate.

Why is my test result invalid?

The most likely reasons for the line not appearing in the control region (C) are due to incorrect procedural techniques including inadequate sample volume, improper sample collection or not reading the results within the specified time frame.
**RELIABILITY OF SELF-TESTED RESULTS**

What are the potential benefits and risks of the LYHER® COVID-19 Antigen Self-Test Kit?

**Potential benefits:**
- The test can determine if you have active COVID-19 infection.
- The results can help your healthcare provider make informed decisions about your treatment and taking appropriate social distancing measures.

**Possible risks:**
- Slight discomfort during the nasal sample collection.
- Refer to the section on Limitations Of The Test for other risks.

How accurate is the LYHER® COVID-19 Antigen Self-Test Kit?

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 (RT-PCR test) in two clinical studies one conducted in China with 411 samples and the other conducted in Spain with 273 subjects. The LYHER® COVID-19 Antigen Test Kit was shown to correctly identify 99.6% (250/251) of SARS-CoV-2 positive nasal samples for the study conducted in China and 100.0% (147/147) of negative samples for the study conducted in Spain. This is known as the sensitivity and specificity of the test. In the same studies, the test correctly identified 95.0% (152/160) of SARS-CoV-2 positive nasal samples for the study conducted in China and 94.4% (112/120) of negative samples for the study conducted in Spain. This is known as test sensitivity. The results from both studies demonstrated that the test is highly sensitive, by finding the first positive sample after the onset of symptoms. The limit of detection of this test is 135 TCID50/mL.

Is the accuracy of the LYHER® COVID-19 Antigen Self-Test Kit the same for known variants and mutations of SARS-CoV-2?

The accuracy (including sensitivity and specificity) of the LYHER® Novel Coronavirus (COVID-19) Antigen Test Kit has been shown to be similar of the alpha (B.1.1.7) and delta (B.1.617.1) variants. For these variants, the mutations are on the spike protein and not on the nucleoprotein region. Therefore, the test is not affected. The LYHER® COVID-19 Antigen Test Kit cannot detect SARS-CoV-2 mutations. This is because the test is designed to detect the nucleocapsid protein SARS-CoV-2 antigen in a sample. The test is not affected by the presence of an SARS-CoV-2 mutation. The test is designed to detect SARS-CoV-2 in a sample.

Which cross-reactivities can occur with the LYHER® COVID-19 Antigen Self-Test Kit?

Cross-reactivity with the following organisms and viruses have been studied and had no impact on the performance of the LYHER® Novel Coronavirus (COVID-19) Antigen Test Kit: Influenza A (H1N1, H1N2, H7N9), Rotavirus, Haemophilus influenzae, Influenza B (Yamagata, Victoria), Norovirus, Streptococcus pneumoniae, Rhinovirus (Group A, B, C), Enterovirus, Streptococcus pneumoniae, Adenovirus (Type 1, 2, 4, 7, 15, 34), Measles virus, Candida albicans, Enterovirus (Group A, B, C, D), Mumps virus, Bordetella pertussis, Respiratory syncytial virus, Legionella pneumoniae, Mumps virus, Varicella zoster virus, Coronavirus (HCoV-OC43, HCoV-NL63, 229E, NL43), Chlamydia psittaci, Herpes simplex virus Human Metapneumovirus (HMPV), Mycobacterium tuberculosis, Epstein-Barr virus, Parainfluenza virus, (Type 1, 2, 3, 4), Pneumocystis jiroveci (PJP)

Which interferences can occur with the LYHER® COVID-19 Antigen Self-Test Kit?

There are no known interferences with the LYHER® COVID-19 Antigen Self-Test Kit. In general, the test is not affected by the presence of other respiratory viruses, bacterial infections, or other conditions that may be artificially introduced into the respiratory tract have been studied and had no impact on the performance of the LYHER® Novel Coronavirus (COVID-19) Antigen Test Kit: interferon, cetuximab, hemoglobin, Zanamivir, Meropenem, White blood cells, Ribavirin, Tobramycin, Mucin, Paramivir, Phenylephrine, Mouthwash, Lopinavir, Oxymetazoline, Toothpaste, Ritonavir, Sodium chloride, Dexamethasone Acetate, Adhesive Tablets, Abido, Beclomethasone, Coasunshu Spray, Levofloxacin, Dexamethasone, Mirabolivan preaparatum, Azithromycin, Flunisolide, Golden Throat Lozenges

**CONFIRMATION OF TEST RESULTS**

**CONTACT INFORMATION FOR SELF-TESTING USERS**

If you have questions about your test kit, including how to use it or to make an enquiry or complaint, you can call 25AN on: 1800 630 750 (9 am to 7 pm AEST, 7 days/week).

Alternatively, you may wish to report poor performance or usability issues to the Therapeutic Goods Administration, please email info@tg.gov.au or call 1800 809 362.

Contact Details: Australian State and Territory Health Departments:
- Australian Capital: 02 6207 7244 | Coronavirus Helpline (8 am to 8 pm daily)
- Northern Territory: 1800 5269 | Coronavirus Helpline (8 am to 6 pm)
- Queensland: 1300 COVID (130 268) | Coronavirus Helpline (8 am to 6 pm)
- South Australia: 1800 253 787 | Coronavirus Helpline (9 am to 5 pm daily)
- Western Australia: 1800 COVID 19 (8 am to 6 pm, Mon to Fri) 1800 595 206 Website: https://www.health.wa.gov.au/