

INSTRUCTIONS FOR USE

LYHER® Novel Coronavirus (COVID-19) Antigen Test Kit (Colloidal Gold) For self-testing with nasal swab specimens
Scan this QR Code to access a video of these instructions.

To access instructions, please visit our website:
<http://www.2san.com/ifu-australia> or call us on:

1800 630 750 (9am to 7pm 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

- Bring the test kit to room temperature and have good lighting.
- Have a watch, clock or stopwatch ready.
- Blow your nose** to remove excess mucus and then **wash your hands** to reduce the risk of contamination.
- Open the box and remove the components. Ensure you can correctly identify them.
- Open the foil pouch and place the test cassette on a clean and dry flat surface. **The test cassette must be used within 30 minutes after opening the foil pouch.**
- Tear the seal off the tube pre-filled with diluent and gently place it in the sample tube holder provided.

COLLECTING YOUR SAMPLE SPECIMEN



- 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 2-4cm (for children is 1-2cm) until resistance is felt.



- 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.

TREATING YOUR SAMPLE SPECIMEN



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



- 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.



- 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.

TESTING YOUR SAMPLE SPECIMEN



- 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**.



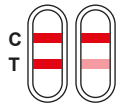
- Read the result after **15 MINUTES** in good lighting.
Results observed after **20 MINUTES** are considered **invalid**.



- Interpret your results as directed below.

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

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).

Positive

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

What you need to do: Consult the Department of Health website (<https://www.health.gov.au/topics/covid-19/testing-positive>) to check what you need to do if you get a positive result.

- If you test positive, you should not visit high-risk settings like hospitals and aged and disability care settings for at least 7 days or until symptoms have gone, unless seeking immediate medical care.
- To help protect those around you, we recommend to avoiding contact with people who are at higher risk of severe disease, wearing a mask outside the home, working from home where possible, avoiding going to school, public areas, or travel on public transport, in taxis or ride-share services, practicing good hygiene, and following your local health department's advice when leaving home.
- If you have any appointments you cannot miss (visit to a doctor, family violence service or police), let them know in advance that you have COVID-19.
- If you have a Covid-19 POSITIVE result, staying at home protects the people in your community and you should not visit high-risk settings like hospitals and aged and disability care settings.
- If you feel unwell or need COVID-19 advice for someone in your care, talk with your health provider, or speak to a nurse by calling the health direct helpline on 1800 022 222.
- If you develop symptoms such as severe shortness of breath or chest pain, call triple zero (000) immediately.** Tell the call handler and the paramedics on arrival if you have COVID-19.

- Most people with COVID-19 experience only mild symptoms, or no symptoms at all (asymptomatic). You can manage these symptoms with over-the-counter medication.
- Try to get plenty of rest, drink lots of water and eat well. You can still do moderate exercise if you feel well enough, within your home and/or garden if you have one. If you are eligible, your GP can prescribe COVID-19 oral treatments to reduce your chance of severe illness or hospitalisation. Seek urgent medical attention (call 000) if you develop severe symptoms, such as difficulty breathing, an oxygen level of less than 92% when tested with a pulse oximeter, blue lips or face, pain or pressure in the chest, cold and clammy, or pale and mottled, skin, fainting or collapsing, being confused, difficulty waking up, little or no urine output, and coughing up blood.
- Severe COVID-19 in children is rare. Most children will have no, or only mild symptoms. If you are worried about your child's symptoms, contact your GP as soon as possible. A GP or nurse will treat your child based on their age, symptoms and past medical history. If they are showing severe symptoms, call 000 immediately.
- Most people who test positive for COVID-19 recover completely, but some people may develop long COVID. COVID-19 vaccinations, including boosters, reduce your risk of re-infection and gives the best protection against severe illness from COVID-19. After testing positive, you should wait 6 months before making a booster dose appointment.



Negative

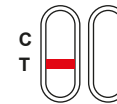
Negative (-)

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.**

- 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.
- Follow the guidance from your local State or Territory Health Department for guidance on confirmation testing if necessary, and if unwell seek medical assistance.



Invalid

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. Contact 2SAN using the details indicated on this IFU.

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.

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INTENDED USE

- The test kit is intended for self-testing purposes by untrained individuals outside of laboratory or clinical settings such as in your home.
- You can use this test if you have symptoms of COVID-19. It is recommended to use the test within the first 7 days following the start of symptoms; the test is less reliable in the later phases of infection and in asymptomatic individuals.

If you have a **Covid-19 POSITIVE** result, staying at home protects the people in your community and you should not visit high-risk settings like hospitals and aged and disability care settings.

If you feel unwell or need COVID-19 advice for someone in your care, talk with your health provider, or call the health direct helpline on 1800 022 222.

If you develop symptoms such as severe shortness of breath or chest pain, call triple zero (000) immediately. Tell the call handler and the paramedics on arrival if you have COVID-19.

WARNINGS & PRECAUTIONS FOR USE

- Do not use the test kit after the expiry date indicated on the carton or if any components appear to be damaged or tampered with.
- If you are below 16 years old, you must ask an adult to do the test, or you must perform the test under adult supervision.
- You should not use this test in children aged 2 years and under.
- Keep the test kit including all components, out of the reach of children- ingestion of the diluent can be dangerous.
- If the diluent solution comes into contact with your skin or eyes, immediately wash with large amounts of water.
- You should not use this test if you are likely to experience difficulties taking the sample specimen or interpreting the results unless you have someone to help you.
- You should not use this test if you are prone to nosebleeds.

HOW DOES THE LYHER® ANTIGEN SELFTEST KIT WORK?

The LYHER® Novel Coronavirus COVID-19 Antigen Self-Test Kit is a single use, *in vitro* (outside the body) test to aid in the diagnosis of SARS-CoV-2 infection in individuals with symptoms of COVID-19. The test uses specimens collected from your nasal cavity using a nasal swab to detect the presence of the nucleocapsid protein SARS-CoV-2 antigen (Ag). An immunoassay technique is used to detect antigens of Covid-19. The sample pad is coated with goat anti-mouse Immunoglobulin G (IgG), and test area with anti-SARS-CoV-2 antibodies. If SARS-CoV-2 antigen is detected in specimen, the T line will become visibly coloured. The C line should always be coloured, or the test is not valid.

KIT CONTENTS

Included:

- Aluminium Foil Pouch containing test cassette and desiccant (disposable)
- Tube pre-filled with diluent
- Sample tube holder: perforated area indicated on carton for packs containing 1 test, separate cardboard tube holder for packs containing 5, 7 and 25 tests
- Cotton nasal swab
- Dropper

Required but not included: Timer

HOW DO I STORE THE LYHER® ANTIGEN SELF-TEST KIT?

- Store the test kit in a dry, protected, and dark place, out of direct sunlight and between 2-30°C.
- Do not freeze the test kit or any of its components.

LIMITATIONS OF THE TEST

- Positive or negative results observed using this test kit should not be the sole basis for diagnosis or be considered a substitute for biological analysis in a laboratory.
- The results from this test provide only a presumptive initial screening test result.
- A positive result cannot determine whether a person is infectious.
- Positive test results do not rule out simultaneous infection with other pathogens.
- The risk of a false negative result is higher in the later phase of infection and in asymptomatic individuals. It is recommended to use the test within the first 7 days of symptom onset (false negative results may occur if testing is not performed within the first 7 days of symptom onset).
- A negative result does not rule out infection with another type of respiratory virus.
- Negative test results do not rule out COVID-19 infection. If the concentration of SARS-CoV-2 antigen in a sample is less than the detection limit of the test, the likelihood of a false-negative result increases.

- The likelihood of a false-negative result or an invalid test result increases if these instructions are not followed carefully, including improper collection of the nasal swab.
- The test is a qualitative test only and cannot determine the concentration of nucleocapsid protein SARS-CoV-2 antigen in a sample.
- Each test can only be used once. Only samples collected from the nasal mucosa in accordance with the test procedure must be used; other samples such as saliva must not be used.
- 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.
- If samples and reagents are not at room temperature before they are used, test sensitivity may be reduced.

FREQUENTLY ASKED QUESTIONS

What are the potential risks of The LYHER® Novel Coronavirus COVID-19 Antigen Self-Test Kit?

- Slight discomfort during the nasal sample collection.
- Refer to the section on Limitations of The Test for other risks.

How accurate is The LYHER® Novel Coronavirus 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 subjects and the other in Spain with 273 subjects. The LYHER® Novel Coronavirus (COVID-19) Antigen Test Kit was shown to correctly identify 99.6% (250/251) of SARS-CoV-2 negative 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 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% (119/126) of positive samples for the study conducted in Spain. This is known as test sensitivity. The results from both studies demonstrated that the test is at its highest sensitivity following the first up to the seventh day following onset of symptoms. The limit of detection of this test is 135 TCID₅₀/mL.

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

The clinical and analytical sensitivity of the LYHER® Novel Coronavirus (COVID-19) Antigen Test Kit has been confirmed for the Alpha, Delta and Omicron variants. Whilst no difference in the test's sensitivity or specificity for the beta and gamma variants is expected, it cannot be ruled out. The manufacturer is monitoring the evolution of further mutations, and variants. The manufacturer will assess the risk of potential mutations to the SARS-CoV-2 nucleocapsid (N) protein and its impact on the test kit's performance and will revise these instructions accordingly.

Which cross-reactivities can occur with The LYHER® Novel Coronavirus COVID-19 Antigen Self-Test Kit

Cross reactivity with the following organisms and viruses tabled have been studied and had no impact on the performance of the LYHER® Novel Coronavirus (COVID-19) Antigen Test Kit: Influenza A (H1N1, H3N2, H5N1, H7N9), Rotavirus, Haemophilus influenzae, Influenza B (Yamagata, Victoria), Norovirus, Streptococcus pneumoniae, Rhinovirus (Group A,B,C), Cytomegalovirus, Streptococcus pyogenes, Adenovirus (Type 1,2,3,4,5,7,55), Measles virus, Candida albicans, Enterovirus (Group A,B,C,D), Mumps virus, Bordetella pertussis, Respiratory syncytial virus, Legionella pneumonia, Mycoplasma pneumoniae, Varicella zoster virus, Coronavirus (HKU1, OC43, NL63, 229E, MERS, SARS), Chlamydia pneumoniae, Herpes simplex virus, Human Metapneumovirus (hMPV), Mycobacterium tuberculosis, Epstein-Barr virus, Parainfluenza virus (Type 1, 2, 3, 4) and Pneumocystis jirovecii (PJP).

Which interferences can occur with The LYHER® Novel Coronavirus COVID-19 Antigen Self-Test Kit?

The following substances, naturally present in respiratory specimens or 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: a-interferon, Ceftriaxone, Hemoglobin, Zanamivir, Meropenem, White blood cells, Ribavirin, Tobramycin, Mucin, Paramivir, Phenylephrine, Mouthwash, Lopinavir, Oxymetazoline, Toothpaste, Ritonavir, Sodium chloride, Dexamethasone Acetate, Adhesive Tablets, Abidol, Beclomethasone, Caoshanhu Spray, Levofloxacin, Dexamethasone, Mirabilium praeparatum, Azithromycin, Flunisolide, Golden Throat Lozenges.

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 2SAN on: 1800 630 750 (9am to 7pm AEST, 7 days/week)

MEDICAL DEVICE INCIDENT REPORTING

You can contact the Therapeutic Goods Administration (TGA) to report poor performance or usability issues via the Medical Device Incident Reporting (MDIR). Email iris@health.gov.au or call 1800 809 361 (8:30am to 5:00pm Monday to Friday).

INFORMATION

Item: LYHER® Novel Coronavirus COVID-19 Antigen Self-Test Kit
Novel Coronavirus (COVID-19) Antigen Test Kit (Colloidal Gold) for self-testing
Specimen: Nasal swab
Format: Cassette
Pack Sizes and Number of components per pack

Pack Size	Test Cassette	Tube with pre-filled Diluent	Sample Tube Holder	Cotton Nasal Swab	Package Insert
1 test	1	1	Incorporated in test kit carton	1	1
5 tests	5	5	1	5	1
7 tests	7	7	1	7	2
25 tests	25	25	1	25	5

GLOSSARY OF 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		Date when manufactured



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