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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 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. **The test cassette must be used within 30 minutes after opening the foil pouch**.
6. Tear the seal off the tube pre-filled with diluent and gently place it in the sample tube holder provided.

COLLECTING YOUR SAMPLE SPECIMEN

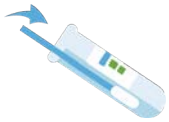
01. Remove the nasal swab from the packet. Do not touch the cotton wool at the end of the swab. Insert the swab gently into your nostril. Insert the tip of the swab 2-4 cm (for children is 1-2 cm) until resistance is felt.

02. Roll the swab along the inside of one nostril **5 times** within 7-10 seconds. Gently remove the swab.

03. Repeat this step in your other nostril with the same swab.

TREATING YOUR SAMPLE SPECIMEN

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



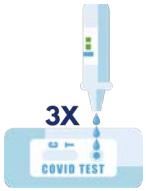
04. Squeeze the sample tube with the swab inserted **10-15 times** to mix evenly so that the wall of the sample tube touches the swab.

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.

TESTING YOUR SAMPLE SPECIMEN

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**.



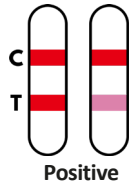
07. Read the result after **15 MINUTES** in good lighting.

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.

INTERPRETING YOUR RESULTS



Positive

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:
Consult your state or territory health department websites to check what you need to do if you get a positive result.

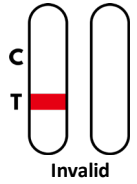
Negative

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.**

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. 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 Pty Ltd using the details indicated on the start of 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.

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.

WARNINGS & PRECAUTIONS FOR USE

- Do not use the test kit after the expiry date on the carton or if any components appear to be damaged or tampered with.
- You must ask an adult to do the test, or you must do it under adult supervision If you are under the age of 16.
- 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 SELF-TEST KIT WORK?

The LYHER® antigen test 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 colloidal gold bound antibodies. The quality control area 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)
- Cotton nasal swab
- Tube pre-filled with diluent
- Dropper
- 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

Required but not included: Timing device

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

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

LIMITATIONS OF THE TEST

- 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 test results may occur if testing is not performed within the first 7 days of symptom onset. A positive result cannot determine whether a person is infectious.
- Positive test results do not rule out simultaneous infection with other pathogens.
- 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® 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® 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 $TCID_{50}$/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 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® 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® 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: α-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, Mirabilitum praeparatum, Azithromycin, Flunisolide, Golden Throat Lozenge.

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 (9 am to 7 pm AEST, 7 days/week)
Additionally, should you wish to report poor performance or usability issues to the Therapeutic Goods Administration, please email iris@tga.gov.au or call 1800 809 361.
Contact Details: Australian State and Territory Health Departments:

Australian Capital Territory	02 6207 7244 | Coronavirus Helpline (8 am to 8 pm daily) Website: https://health.act.gov.au/
New South Wales	137 788 | Coronavirus Helpline (Service NSW 24/7) Website: https://www.health.nsw.gov.au/
Northern Territory	1800 020 080 | (National Coronavirus Helpline) Website: https://health.nt.gov.au/
Queensland	134COVID (134 268) | Coronavirus Helpline Website: https://www.health.qld.gov.au/
South Australia	1800 253 787 | Coronavirus Helpline (9 am to 5 pmdaily) Website: https://www.sahealth.sa.gov.au/
Tasmania	1800 671 738 | Public Health Hotline (Coronavirus) Website: https://www.health.tas.gov.au/
Victoria	1800 675 398 | Coronavirus Hotline (24/7) Website: https://www.dhhs.vic.gov.au/
Western Australia	13COVID | Coronavirus Hotline (8 am to 6 pm, Mon to Fri) 1800 595 206 Website : https://www.healthywa.wa.gov.au/

INFORMATION

Catalogue 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
Pack Sizes and Number of components per pack

Pack Size	Test Cassette	Tube pre-filled with 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

	Test Kit Manufacturer: Hangzhou Laihe Biotech Co., Ltd. Room 401-406, F1-3, Building 1, No.425 Miaohouwang Road, Xixing Street, Binjiang District, Hangzhou, 310051 Zhejiang P.R. China Tel.: +86 571 8765 3090 Fax: +86 571 8665 8000 www.lyherbio.com
Australian Sponsor:	2SAN Pty Ltd | Level 35, Tower One Barangaroo, 100 Barangaroo Avenue, Sydney, NSW 2000 | www.2san.com

GUIDE TO SYMBOLS

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

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