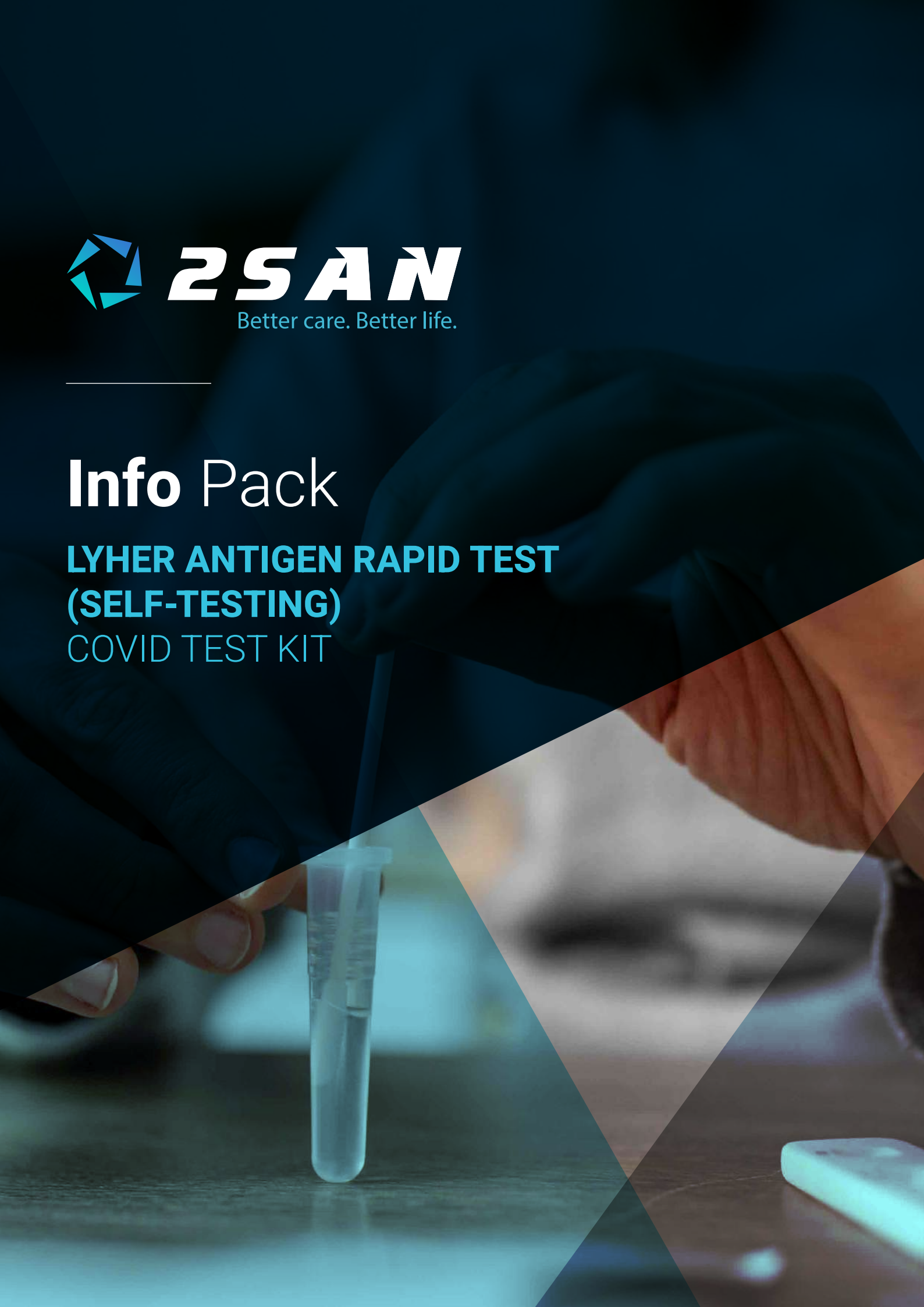
2SAN

Better care. Better life.

Info Pack

LYHER ANTIGEN RAPID TEST (SELF-TESTING)

COVID TEST KIT



COVID TEST KIT
RAPID ANTIGEN

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PACKAGE SIZE	Single pack, 5 pack
PACK INCLUDES	Test Cassettes Prefilled Extraction Tubes Dropper Cap Sterile Nasal Swab Workstation IFU
COLLECTION TYPE	Anterior nasal
RESULTS TIME	15 mins
ACCURACY (OVERALL)	97.8%
SENSITIVITY (ACCURACY IN DETECTING POSITIVE RESULTS)	95.0%
SPECIFICITY (ACCURACY IN DETECTING NEGATIVE RESULTS)	99.6%
STORAGE	2-30 degrees C
SHELF LIFE	18 months
APPROVED BY	41 countries
TRAINING	Training packaged and video
APP COMPATIBILITY	Yes

ACCREDITED BY:

Department of Health & Social Care
CIBG Ministerie van Volksgezondheid, Welzijn en Sport
Australian Government Department of Health Therapeutic Goods Administration
Bundesinstitut für Arzneimittel und Medizinprodukte
TÜVRheinland CERTIFIED
ansm Agence nationale de sécurité du médicament et des produits de santé
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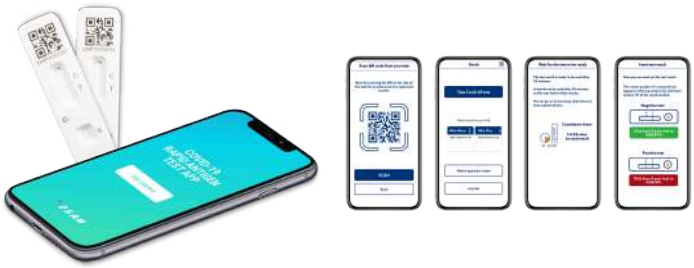
HOW IT WORKS?

Please refer to the below instructions video.

Video can be accessed via www.2san.com > COVID-19 Rapid Antigen Tests > How to self-test

2SAN TEST APP:
FULL VISIBILITY AND CONTROL

- Easy-to-use registration and reporting app
- Seamless interface that can be tailored to the country, region or corporation's requirements
- Gives the most cutting-edge solution to contain and control COVID-19 for today and tomorrow



REAL TIME DATA REPORTING
FOR HEALTHCARE AND SELF-TESTING PROGRAMMES

The detailed reporting interface allows full visibility and control for management.

INSTRUCTIONS FOR USE

Please refer to the below link for the instructions for use (IFU) document.
https://www.tga.gov.au/sites/default/files/covid-19-rapid-antigen-self-testsare-approved-australia-ifu-374507.pdf

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FAQs

Collection Type: Anterior nasal test meaning it is a shallow nasal swab. The swab is to be inserted 2-4 centimetres inside the end of each nostril. It is not a nasopharyngeal swab that goes right to the back of the nose.

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.

Results Time: The test will begin to show a result almost immediately however the result should be read between 15-20 minutes after completing the test to allow for any weak positive results to show.

Weak Positives: Sometimes a positive result can show where either the Control (C) line or the Test (T) line is fainter than the other. This must be regarded as a positive result.

Storage: The tests must be stored between 2 - 30 degrees C. Exposure to temperatures outside this range may effect the performance of the test and shorten the shelf-life.

Shelf-Life: The tests have an 18 month shelf life. The expiry date can be found on the side of the box or the back of the test cassette pouch.

Swab:
Can another type of swab be used instead of the one provided in the test? No, the sterile swab provided in the kit must be used to prevent any contamination of the test.

Is the swab sterilised by Ethylene Oxide (EO)? Yes, it is. Ethylene Oxide is a common gas used widely in sterilisation processes for medical and surgical equipment. During the sterilisation process there is no residue left on the swab. EO is only harmful if a person is exposed to it in large quantities for a long period of time.

Results:
Positive = two lines appear, one next to Control (C) and one next to Test (T). Action: isolate as per local government guidelines and seek medical attention in needed. Report positive result to state health department.

Negative = one line appears next to Test (T) only. Action: continue to go about in a safe way as per local-guidelines.

Invalid = control line doesn't show. Action: test must be retaken on another kit.

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FAQs

Why is my test 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.

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

COVID-19 Symptoms: 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.

COVID-19 Vaccination: A recent COVID-19 vaccination won't effect the result of your test.
Variants - Current and New: The 2San Lyher test is effective in detecting all current known variants. The test detects the nucleus protein of COVID-19 virus which remains mainly unchanged with all variants therefore to the best of our knowledge the test will be effective for future variants.

Age Limits: Tests must be performed under adult supervision if you are under the age of 16. You should not use this test on children 2 years or under.

Government Contact Details:
ACT: 02 6207 7244
NSW: 137 788
NT: 1800 020 080
QLD: 134 268
SA: 1800 253 787
TAS: 1800 671 738
VIC: 1800 675 398
WA: 1800 595 206

All Other Enquiries: Please refer to the instructions provided with the test for full instructions. Contact sales.au@2san.com for further details.

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Australian Government
Department of Health
Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate

Issued to

2San Pty Ltd

for approval to supply

Severe acute respiratory syndrome-associated coronavirus IVDs

ARTG Identifier	374507
ARTG Start Date	10/09/2021
Product Category	Medical Device Included - IVD Class 3
GMDN	CT772
GMDN Term	Severe acute respiratory syndrome-associated coronavirus IVDs
Intended Purpose	COVID-19 Antigen Rapid Test for the qualitative in vitro detection of the SARSCoV-2 antigen (Ag) in human nasal swab specimens. The test is intended to be used as an aid in the diagnosis of SARS-CoV-2 infection and is intended for use by medical professionals or clinical laboratory personnel or healthcare professionals trained in point of care settings.

Manufacturer Details	Address	Certificate number(s)
Hangzhou Laihe Biotech Co Ltd	Room 505-512 5th Floor No 2B Building B 688 Bin'an Road Changhe Street Binjiang District , Hangzhou , 310052 China	DV-2021-MC-15331-1

ARTG Standard Conditions

The above Medical Device Included - IVD Class 3 has been entered on the Register subject to the following conditions:

· - The inclusion of the kind of device in the ARTG is subject to compliance with all conditions placed or imposed on the ARTG entry. Refer Part 4-5, Division 2 (Conditions) of the Therapeutic Goods Act 1989 and Part 5, Division 5.2 (Conditions) of the Therapeutic Goods (Medical Devices) Regulations 2002 for relevant information.
- Breaching conditions of the inclusion related to the device of the kind may lead to suspension or cancellation of the ARTG entry; may be a criminal offence; and civil penalties may apply.

Products Covered by This Entry

1. Severe acute respiratory syndrome-associated coronavirus IVDs

This entry: does not contain System(s)/Procedure Pack(s)

IVD Information

Name	Category Description
LYHER Novel Coronavirus (Covid-19) Antigen Test Kit (Colloidal Gold)	Self Testing
LYHER Novel Coronavirus (Covid-19)	Point of care testing

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Name	Category Description
Antigen Test Kit (Colloidal Gold)	

Product Specific Conditions

No specific conditions have been recorded against this entry.

Therapeutic Goods Administration
PO Box 100, Woden ACT 2606 Australia
Phone: 1800 020 653
Email: info@tga.gov.au

ARTG Identifier: 374507
ARTG Start Date: 10/09/2021

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